

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 48 Session of 2011

INTRODUCED BY SCAVELLO, BAKER, BOYD, CALTAGIRONE, DeLUCA, GEORGE, HARHART, HELM, HENNESSEY, HORNAMAN, KILLION, KIRKLAND, KORTZ, KOTIK, MILLARD, MILLER, MILNE, MOUL, O'NEILL, PASHINSKI, PEIFER, PICKETT, READSHAW, REICHLEY, VULAKOVICH, WAGNER, WATSON, YOUNGBLOOD, KNOWLES, JOSEPHS AND GIBBONS, JANUARY 19, 2011

REFERRED TO COMMITTEE ON PROFESSIONAL LICENSURE, JANUARY 19, 2011

AN ACT

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

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

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

17 Section 2. Definitions.

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

1 \* \* \*

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

4 \* \* \*

5 "Custom-fabricated device." A prosthesis, orthosis or  
6 pedorthic device that is fabricated to original measurements or  
7 a mold for use by a patient in accordance with a prescription or  
8 work order and which requires substantial clinical and technical  
9 judgment in its design and fitting.

10 "Custom-fitted device." A prefabricated prosthesis, orthosis  
11 or pedorthic device that is sized or modified for use by the  
12 patient in accordance with a prescription or work order and  
13 which requires substantial clinical judgment and substantive  
14 alteration for appropriate use.

15 \* \* \*

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

19 \* \* \*

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

22 "Nontherapeutic devices." Devices that do not address a  
23 medical condition.

24 "Orthotic fitter." An individual who is licensed under this  
25 act to practice orthotics pursuant to a written prescription of  
26 a physician, podiatrist, certified registered nurse practitioner  
27 or physician assistant or pursuant to a work order.

28 "Orthotics." Evaluating, measuring, designing, fabricating,  
29 assembling, fitting, adjusting or servicing an orthosis for the  
30 correction or alleviation of neuromuscular or musculoskeletal

1 dysfunction, disease, injury or deformity, as provided in this  
2 act.

3 "Orthotist." An individual other than an orthotic fitter  
4 licensed under this act to practice orthotics pursuant to a  
5 written prescription of a physician, podiatrist, certified  
6 registered nurse practitioner or physician assistant or pursuant  
7 to a work order.

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

13 "Pedorthic device." Includes therapeutic shoes, shoe  
14 modifications made for therapeutic purposes, partial foot  
15 prostheses, foot orthoses and below-the-knee pedorthic  
16 modalities. The term does not include nontherapeutic,  
17 accommodative inlays and nontherapeutic accommodative footwear,  
18 regardless of method of manufacture; unmodified, nontherapeutic  
19 over-the-counter shoes; or prefabricated unmodified or  
20 unmodifiable foot care and footwear products.

21 "Pedorthics." Evaluating, measuring, designing, fabricating,  
22 assembling, fitting, adjusting or servicing necessary to  
23 accomplish the application of a pedorthic device for the  
24 prevention or amelioration of painful or disabling conditions  
25 related to the lower extremities.

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

30 \* \* \*

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

4 "Prefabricated orthosis." A brace or support designed to  
5 provide for alignment, correction or prevention of neuromuscular  
6 or musculoskeletal dysfunction, disease, injury or deformity.  
7 The term does not include fabric or elastic support, corsets,  
8 arch supports, low-temperature plastic splints, trusses, elastic  
9 hose, canes, crutches, soft cervical collars, dental appliances  
10 or other similar devices carried in stock and sold as over-the-  
11 counter items by a drug store, department store, corset shop or  
12 surgical supply facility.

13 "Prosthesis." A custom-designed, custom-fabricated, custom-  
14 fitted or custom-modified device to replace an absent external  
15 limb for purposes of restoring physiological function or  
16 cosmesis. The term does not include artificial eyes, ears,  
17 fingers or toes, dental appliances, cosmetic devices, such as  
18 artificial breasts, eyelashes or wigs, or other devices that do  
19 not have a significant impact on the musculoskeletal functions  
20 of the body.

21 "Prosthetics." Evaluating, measuring, designing,  
22 fabricating, assembling, fitting, adjusting or servicing a  
23 prosthesis.

24 "Prosthetist." An individual licensed under this act to  
25 practice prosthetics pursuant to a written prescription of a  
26 physician, podiatrist, certified registered nurse practitioner  
27 or physician assistant or pursuant to a work order.

28 \* \* \*

29 "Therapeutic devices." Devices that address a medical  
30 condition.

1 \* \* \*

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

3 Section 13.4. Prosthetists, orthotists, pedorthists and  
4 orthotic fitters.

5 (a) Licensure qualifications.--To qualify for licensure to  
6 practice prosthetics, orthotics, pedorthics or orthotic fitting,  
7 an applicant shall:

8 (1) Be of good moral character.

9 (2) Possess the following education:

10 (i) For prosthetists, at least four years of  
11 education, training and/or work experience, consisting of  
12 a bachelor's degree with a major in prosthetics or  
13 orthotics and prosthetics, an associate degree in  
14 prosthetics or orthotics and prosthetics or two or more  
15 years of education, training and/or work experience in  
16 the field of prosthetics; and a minimum of two years  
17 (3,800 hours) of experience in providing direct patient  
18 care services. Patient logs must be kept and available  
19 for audit purposes.

20 (ii) For orthotists, at least four years of  
21 education, training and/or work experience, consisting of  
22 a bachelor's degree with a major in orthotics or  
23 orthotics and prosthetics, an associate degree in  
24 orthotics or orthotics and prosthetics or two or more  
25 years of education, training and/or work experience in  
26 the field of orthotics; and a minimum of two years (3,800  
27 hours) of experience in providing direct patient care  
28 services. Patient logs must be kept and available for  
29 audit purposes.

30 (iii) For pedorthists, a successfully completed

1 board-approved entry-level pedorthic education program  
2 and a minimum of 1,000 hours of supervised patient  
3 fitting experience.

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

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

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

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

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

20 (7) Not been convicted of a felony under the act of  
21 April 14, 1972 (P.L.233, No.64), known as The Controlled  
22 Substance, Drug, Device and Cosmetic Act, or of an offense  
23 under the laws of another jurisdiction which, if committed in  
24 this Commonwealth, would be a felony under The Controlled  
25 Substance, Drug, Device and Cosmetic Act, unless the  
26 following apply:

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

29 (ii) The applicant satisfactorily demonstrates to  
30 the board that the applicant has made significant

1 progress in personal rehabilitation since the conviction  
2 and the licensure of the applicant is not expected to  
3 create a substantial risk of harm to the health and  
4 safety of the applicant's clients or the public or a  
5 substantial risk of further criminal violations.

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

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

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

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

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

29 (3) Keep a copy of the prescription or work order and  
30 the results of the medical diagnostic examination in the

1 patient's file.

2 (d) Exceptions.--

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

11 (2) Nothing in this section shall prohibit an individual  
12 from engaging in the practice for which that individual is  
13 licensed or certified to practice or to act within the scope  
14 of that license or certification held in this Commonwealth.  
15 Nothing in this act shall prohibit an individual who is  
16 employed by the Federal Government from engaging in the  
17 practice of a prosthetist, orthotist, pedorthist or orthotic  
18 fitter while in the discharge of the employee's official  
19 duties.

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

22 (4) Nothing in this section shall prohibit a  
23 representative of a medical device manufacturer registered  
24 with the United States Food and Drug Administration from  
25 measuring, fitting and adjusting orthoses when the  
26 representative is supervised by a physician or other licensed  
27 health care professional.

28 (e) License requirement effective.--Commencing two years  
29 after the effective date of this section, individuals shall not  
30 practice or hold themselves out as being able to practice

1 prosthetics, orthotics, pedorthics or orthotic fitting in this  
2 Commonwealth unless the individuals are licensed in accordance  
3 with this section.

4 (f) License without examination.--Within two years after the  
5 effective date of this section, an individual may be granted a  
6 prosthetic, orthotic, pedorthotic or orthotic fitting license by  
7 the board if the individual:

8 (1) Complies with subsection (a) (1), (2), (5), (6) and  
9 (7); and

10 (2) Complies with the following:

11 (i) holds a valid national certification as a  
12 prosthetist, orthotist, pedorthist or orthotic fitter;  
13 and

14 (ii) has been in active, continuous practice for the  
15 three years immediately preceding the effective date of  
16 this section.

17 (g) Biennial license renewal.--For biennial renewal of a  
18 license:

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

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

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

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

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

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

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

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

14           (1) Cervical soft foam collars.

15           (2) Thoraco-lumbo-sacral orthoses.

16           (3) Lumbo-sacral orthoses.

17           (4) Knee orthoses.

18           (5) Ankle foot orthoses.

19           (6) Foot orthoses.

20           (7) Elbow orthoses.

21           (8) Shoulder orthoses.

22           (9) Abdominal and pelvic:

23            (i) Trusses.

24            (ii) Flexible supports.

25            (iii) Maternity supports.

26           (10) Compression devices:

27            (i) Lymphedema garments.

28            (ii) Compression garments.

29            (iii) Burn garments.

30           (11) Breast prosthesis and ancillary supplies.

1 (i) Liability insurance coverage.--An individual licensed to  
2 practice prosthetics, orthotics, pedorthics or orthotic fitting  
3 in this Commonwealth shall maintain a level of professional  
4 liability insurance coverage in the minimum amount of \$1,000,000  
5 per occurrence or claims made and shall verify to the board the  
6 required coverage. Failure to maintain insurance coverage as  
7 required shall subject the licensee to disciplinary proceedings.  
8 The licensee must provide proof of coverage to the board upon  
9 request. The board shall accept from a licensee as satisfactory  
10 evidence of insurance coverage any of the following:

11 (1) Personally purchased liability insurance.

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

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

25 Section 3. The board shall promulgate regulations to  
26 implement the amendment or addition of sections 2 and 13.4 of  
27 the act within 18 months of the effective date of this section.  
28 The amendment or addition of sections 2 and 13.4 of the act  
29 shall not be enforceable by the State Board of Medicine until  
30 the publication of final regulations under this section or 24

1 months following the effective date of this section, whichever  
2 occurs first.

3 Section 4. This act shall take effect immediately.