

THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 630 Session of 2009

INTRODUCED BY PICCOLA, RAFFERTY, FERLO, ALLOWAY, ROBBINS AND  
COSTA, SEPTEMBER 17, 2009

REFERRED TO CONSUMER PROTECTION AND PROFESSIONAL LICENSURE,  
SEPTEMBER 17, 2009

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:

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

1       \* \* \*

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

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

12       \* \* \*

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

15       "NOCA." The National Organization for Competency Assurance  
16 or its successor.

17       "Nontherapeutic devices." Devices that do not address a  
18 medical condition.

19       "Orthotic fitter." An individual who is licensed under this  
20 act to practice orthotics pursuant to a written prescription of  
21 a physician, podiatrist, certified registered nurse practitioner  
22 or physician assistant or pursuant to a work order.

23       "Orthotics." Evaluating, measuring, designing, fabricating,  
24 assembling, fitting, adjusting or servicing an orthosis for the  
25 correction or alleviation of neuromuscular or musculoskeletal  
26 dysfunction, disease, injury or deformity, as provided in this  
27 act.

28       "Orthotist." An individual other than an orthotic fitter  
29 licensed under this act to practice orthotics pursuant to a  
30 written prescription of a physician, podiatrist, certified

registered nurse practitioner or physician assistant or pursuant to a work order.

"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." 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 or pursuant to a work order.

\* \* \*

"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

1 or musculoskeletal dysfunction, disease, injury or deformity.  
2 The term does not include fabric or elastic support, corsets,  
3 arch supports, low-temperature plastic splints, trusses, elastic  
4 hose, canes, crutches, soft cervical collars, dental appliances  
5 or other similar devices carried in stock and sold as over-the-  
6 counter items by a drug store, department store, corset shop or  
7 surgical supply facility.

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

16 "Prosthetics." Evaluating, measuring, designing,  
17 fabricating, assembling, fitting, adjusting or servicing a  
18 prosthesis.

19 "Prosthetist." An individual licensed under this act to  
20 practice prosthetics pursuant to a written prescription of a  
21 physician, podiatrist, certified registered nurse practitioner  
22 or physician assistant or pursuant to a work order.

23 \* \* \*

24 "Therapeutic devices." Devices that address a medical  
25 condition.

26 \* \* \*

27 Section 2. The act is amended by adding a section to read:  
28 Section 13.4. Prosthetists, orthotists, pedorthists and  
29 orthotic fitters.

30 (a) Licensure qualifications.--To qualify for licensure to

1 practice prosthetics, orthotics, pedorthics or orthotic fitting,  
2 an applicant shall:

3 (1) Be of good moral character.

4 (2) Possess a high school diploma or its equivalent.

5 (3) Have fulfilled all educational and training required  
6 for certification by a prosthetic, orthotic, pedorthic and  
7 orthotic fitting credentialing organization recognized by  
8 NOCA and accredited by NCCA and any additional requirements  
9 as required by the board.

10 (4) Pass all examinations that are required for  
11 certification by a prosthetic, orthotic, pedorthic or  
12 orthotic fitting credentialing organization recognized by  
13 NOCA and accredited by NCCA.

14 (5) Submit an application and fee as prescribed by the  
15 board by regulation.

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

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

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

27 (ii) The applicant satisfactorily demonstrates to  
28 the board that the applicant has made significant  
29 progress in personal rehabilitation since the conviction  
30 and the licensure of the applicant is not expected to

1 create a substantial risk of harm to the health and  
2 safety of the applicant's clients or the public or a  
3 substantial risk of further criminal violations.

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

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

9 (c) Treatment requirements.--Prior to administering the  
10 first treatment, a prosthetist, orthotist, pedorthist or  
11 orthotics fitter shall do all of the following:

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

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

24 (3) Keep a copy of the prescription or work order and,  
25 if provided, the results of the medical diagnostic  
26 examination in the patient's file.

27 (d) Exceptions.--

28 (1) Nothing in this section shall prohibit students  
29 enrolled in a prosthetics, orthotics, pedorthics or orthotics  
30 fitter educational program from performing prosthetics,

1 orthotics, pedorthics or orthotic fitting in the course of  
2 their instruction, provided that a physician or podiatrist is  
3 readily available for consultations and that a prosthetist,  
4 orthotist, pedorthist or orthotic fitter, respectively, is on  
5 site and responsible for the direct supervision of students.

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

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

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

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

29 (f) License without examination.--Within two years after the  
30 effective date of this section, an individual may be granted a

prosthetic, orthotic, pedorthotic or orthotic fitting license by  
the board if the individual:

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

(2) Complies with one of the following:

(i) Holds a national certification as a prosthetist,  
orthotist, pedorthist or orthotic fitter.

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

(g) License renewal.--To renew a license, a licensee must:

(1) File a renewal application with the board.

(2) Pay a fee established by regulation by the board.

(3) Complete continuing education as required by the  
board. The following apply:

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

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

(iii) 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       (1) Cervical soft foam collars.

2       (2) Thoraco-lumbo-sacral orthoses.

3       (3) Lumbo-sacral orthoses.

4       (4) Knee orthoses.

5       (5) Ankle foot orthoses.

6       (6) Foot orthoses.

7       (7) Elbow orthoses.

8       (8) Shoulder orthoses.

9       (9) Abdominal and pelvic:

10       (i) Trusses.

11       (ii) Flexible supports.

12       (iii) Maternity supports.

13       (10) Compression devices:

14       (i) Lymphedema garments.

15       (ii) Compression garments.

16       (iii) Burn garments.

17       (11) Breast prosthesis and ancillary supplies.

18       (i) Liability insurance coverage.--An individual licensed to  
19 practice prosthetics, orthotics, pedorthics or orthotic fitting  
20 in this Commonwealth shall maintain a level of professional  
21 liability insurance coverage in the minimum amount of \$1,000,000  
22 per occurrence or claims made and shall verify to the board the  
23 required coverage. Failure to maintain insurance coverage as  
24 required shall subject the licensee to disciplinary proceedings.  
25 The licensee must provide proof of coverage to the board upon  
26 request. The board shall accept from a licensee as satisfactory  
27 evidence of insurance coverage any of the following:

28       (1) Personally purchased liability insurance.

29       (2) Professional liability insurance coverage provided  
30 by the individual licensee's employer or similar insurance

1 coverage acceptable to the board.

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

12 Section 3. The board shall promulgate regulations to  
13 implement the amendment or addition of sections 2 and 13.4 of  
14 the act within 18 months of the effective date of this section.  
15 The amendment or addition of sections 2 and 13.4 of the act  
16 shall not be enforceable by the State Board of Medicine until  
17 the publication of final regulations under this section or 24  
18 months following the effective date of this section, whichever  
19 occurs first.

20 Section 4. This act shall take effect immediately.