## THE GENERAL ASSEMBLY OF PENNSYLVANIA

## **HOUSE BILL**

Session of 2011

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

SENATOR TOMLINSON, CONSUMER PROTECTION AND PROFESSIONAL LICENSURE, IN SENATE, AS AMENDED, APRIL 3, 2012

## AN ACT

- 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 5 its composition, powers and duties; providing for the issuance of licenses and certificates and the suspension and 7 revocation of licenses and certificates; providing penalties; and making repeals," adding definitions; and providing for 9 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
- amended by adding definitions to read: 16
- Section 2. Definitions. 17
- 18 The following words and phrases when used in this act shall
- have the meanings given to them in this section unless the

- 1 context clearly indicates otherwise:
- 2 \* \* \*
- 3 "Accommodative." Designed with a primary goal of conforming
- 4 to an individual's anatomy.
- 5 \* \* \*
- 6 <u>"Custom-fabricated device."</u> A prosthesis, orthosis or
- 7 pedorthic device that is fabricated to original COMPREHENSIVE

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- 8 measurements or a mold for use by a patient in accordance with a
- 9 prescription or work order and which requires substantial
- 10 clinical and technical judgment in its design FABRICATION and
- 11 <u>fitting.</u>
- 12 "Custom-fitted device." A prefabricated prosthesis, orthosis
- 13 <u>or pedorthic device TO ACCOMMODATE THE PATIENT'S MEASUREMENT</u>
- 14 that is sized or modified for use by the patient in accordance
- 15 with a prescription or work order and which requires substantial +
- 16 clinical judgment and substantive alteration IN ITS DESIGN for
- 17 appropriate use.
- 18 \* \* \*
- 19 "ICE." The Institute for Credentialing Excellence,
- 20 previously known as the National Organization for Competency
- 21 Assurance (NOCA).
- 22 \* \* \*
- 23 "NCCA." The National Commission for Certifying Agencies or
- 24 its successor.
- 25 "Nontherapeutic devices." Devices that do not address a
- 26 medical condition.
- 27 "ORTHOSIS." A CUSTOM-FABRICATED OR CUSTOM-FITTED DEVICE
- 28 DESIGNED TO EXTERNALLY PROVIDE SUPPORT, ALIGNMENT OR PREVENTION
- 29 TO THE BODY OR A LIMB FOR THE PURPOSES OF CORRECTING OR
- 30 ALLEVIATING A NEUROMUSCULAR OR MUSCULOSKELETAL DISEASE, INJURY

- 1 OR DEFORMITY.
- 2 "Orthotic fitter." An individual who is licensed under this
- 3 act to <del>practice orthotics</del> PROPERLY FIT, DISPENSE AND ADJUST
- **←**

- 4 PREFABRICATED ORTHOTIC DEVICES pursuant to a written
- 5 prescription of a physician, podiatrist, certified registered
- 6 <u>nurse practitioner or physician assistant <del>or pursuant to a work</del></u>
- 7 <del>order</del>.
- 8 "Orthotics." Evaluating THE PRACTICE OF EVALUATING,
- 9 measuring, designing, fabricating, assembling, fitting,
- 10 adjusting or servicing an orthosis for the correction or
- 11 <u>alleviation of neuromuscular or musculoskeletal dysfunction</u>,
- 12 <u>disease</u>, injury or deformity, as provided in this act.
- 13 "Orthotist." An individual other than A LICENSED PHYSICAL
- 14 THERAPIST, A LICENSED OCCUPATIONAL THERAPIST OR an orthotic
- 15 <u>fitter licensed under this act to practice orthotics pursuant to</u>
- 16 <u>a written prescription of a physician, podiatrist, certified</u>
- 17 registered nurse practitioner or physician assistant or pursuant
- 18 to a work order.
- 19 "Over-the-counter prostheses, orthoses and pedorthic
- 20 devices." Prefabricated, mass-produced items that are
- 21 prepackaged and require no professional advice or judgment in
- 22 either size selection or use, including fabric or elastic
- 23 <u>supports</u>, <u>corsets</u>, <u>generic arch supports and elastic hose</u>.
- 24 "Pedorthic device." Includes therapeutic shoes, shoe
- 25 modifications made for therapeutic purposes, partial foot
- 26 prostheses, foot orthoses and below-the-knee pedorthic
- 27 modalities. The term does not include nontherapeutic,
- 28 accommodative inlays and nontherapeutic accommodative footwear,
- 29 regardless of method of manufacture; unmodified, nontherapeutic
- 30 over-the-counter shoes; or prefabricated unmodified or

- 1 unmodifiable foot care and footwear products.
- 2 "Pedorthics." Evaluating THE PRACTICE OF EVALUATING,
- 3 measuring, designing, fabricating, assembling, fitting,
- 4 <u>adjusting or servicing necessary to accomplish the application</u>
- 5 of a pedorthic device for the prevention or amelioration of
- 6 painful or disabling conditions related to the lower
- 7 extremities.
- 8 <u>"Pedorthist." An individual licensed under this act to</u>
- 9 <u>practice pedorthics pursuant to a written prescription of a</u>
- 10 physician, podiatrist, certified registered nurse practitioner
- 11 <u>or physician assistant <del>or pursuant to a work order</del>.</u>
- 12 \* \* \*
- 13 <u>"Podiatrist." An individual licensed under the act of March</u>
- 14 <u>2, 1956 (1955 P.L.1206, No.375), known as the Podiatry Practice</u>
- 15 Act, to practice podiatry.
- 16 "Prefabricated orthosis." A brace or support designed to
- 17 provide for alignment, correction or prevention of neuromuscular
- 18 or musculoskeletal dysfunction, disease, injury or deformity.
- 19 The term does not include fabric or elastic support, corsets,
- 20 arch supports, low-temperature plastic splints, trusses, elastic
- 21 hose, canes, crutches, soft cervical collars, dental appliances
- 22 or other similar devices carried in stock and sold as over-the-
- 23 <u>counter items by a drug store, department store, corset shop or</u>
- 24 <u>surgical supply facility.</u>
- 25 "Prosthesis." A custom-designed, custom-fabricated, custom-
- 26 fitted or custom-modified device to replace an absent external
- 27 <u>limb for purposes of restoring physiological function or</u>
- 28 cosmesis THAT IS NOT SURGICALLY IMPLANTED. The term does not
- 29 <u>include artificial eyes, ears, fingers or toes, dental</u>
- 30 appliances, cosmetic devices, such as artificial breasts,

1	eyelashes or wigs, or other devices that do not have a
2	significant impact on the musculoskeletal functions of the body.
3	"Prosthetics." Evaluating THE PRACTICE OF EVALUATING,
4	measuring, designing, fabricating, assembling, fitting,
5	adjusting or servicing a prosthesis.
6	"Prosthetist." An individual, OTHER THAN A LICENSED PHYSICAL
7	THERAPIST OR OCCUPATIONAL THERAPIST, licensed under this act to
8	practice prosthetics pursuant to a written prescription of a
9	physician, podiatrist, certified registered nurse practitioner
10	or physician assistant or pursuant to a work order.
11	* * *
12	"Therapeutic devices." Devices that address a medical
13	condition.
14	<del>* * *</del>
15	Section 2. The act is amended by adding a section to read:
16	Section 13.4 13.5. Prosthetists, orthotists, pedorthists and
17	orthotic fitters.
18	(a) Licensure qualifications To qualify for licensure to
19	practice prosthetics, orthotics, pedorthics or orthotic fitting,
20	an applicant shall:
21	(1) Be of good moral character.
22	(2) Possess the following education:
23	(i) For prosthetists, at least four years of
24	education, training and/or work experience, consisting of
25	a bachelor's degree with a major in prosthetics or
26	orthotics and prosthetics, an associate degree in
27	prosthetics or orthotics and prosthetics or two or more
28	years of education, training and/or work experience in
29	the field of prosthetics; and a minimum of two years
30	(3.800 hours) of experience in providing direct patient

1	<u>care services. Patient logs must be kept and available</u>
2	for audit purposes.
3	(ii) For orthotists, at least four years of
4	education, training and/or work experience, consisting of
5	a bachelor's degree with a major in orthotics or
6	orthotics and prosthetics, an associate degree in
7	orthotics or orthotics and prosthetics or two or more
8	years of education, training and/or work experience in
9	the field of orthotics; and a minimum of two years (3,800
10	hours) of experience in providing direct patient care
11	services. Patient logs must be kept and available for
12	audit purposes.
13	(I) FOR PROSTHETISTS, AT LEAST FOUR YEARS OF
14	EDUCATION, TRAINING AND/OR WORK EXPERIENCE, CONSISTING
15	OF:
16	(A) A BACHELOR'S DEGREE WITH A MAJOR IN
17	PROSTHETICS OR ORTHOTICS AND PROSTHETICS; AND
18	(B) A MINIMUM OF TWO YEARS (3,800 HOURS) OF
19	EXPERIENCE IN PROVIDING DIRECT PATIENT CARE SERVICES.
20	(II) FOR ORTHOTISTS, AT LEAST FOUR YEARS OF
21	EDUCATION, TRAINING AND/OR WORK EXPERIENCE, CONSISTING
22	OF:
23	(A) A BACHELOR'S DEGREE WITH A MAJOR IN
24	ORTHOTICS OR OTHOTICS AND PROSTHETICS; AND
25	(B) A MINIMUM OF TWO YEARS (3,800 HOURS) OF
26	EXPERIENCE IN PROVIDING DIRECT PATIENT CARE SERVICES.
27	(iii) For pedorthists, a successfully completed
28	board-approved entry-level pedorthic education program
29	and a minimum of 1,000 hours of supervised patient
30	fitting experience.

1	<u>(iv) For orthotic fitters, a successfully completed</u>
2	board-approved entry-level education program specific to
3	orthotic fitting and a minimum of 1,000 hours of
4	documented patient care.
5	(3) Have fulfilled all educational and training required
6	for certification AND RECEIVED CERTIFICATION by a prosthetic,
7	orthotic, pedorthic and orthotic fitting credentialing
8	organization recognized by ICE, accredited by NCCA and
9	approved 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	ICE, accredited by NCCA and approved by the board.
14	(5) Submit a board-approved application and any fees as
15	prescribed by the board by regulation.
16	(6) KEEP AND MAKE AVAILABLE ALL PATIENT LOGS FOR AUDIT
17	PURPOSES OF THE EXPERIENCE REQUIREMENT.
18	(6) (7) Not be addicted to alcohol, narcotics or other
19	habit-forming drugs.
20	(7) (8) 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	<pre>following apply:</pre>
27	(i) Ten years have elapsed from the date of
28	conviction.
29	(ii) The applicant satisfactorily demonstrates to
3.0	the hoard 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	<pre>prosthetic, orthotic, pedorthic or orthotic fitting treatment, a</pre>
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 BY THE ←
18	PRESCRIBING AUTHORITY using prosthetics, orthotics,
19	pedorthics or orthotic fitting from a physician, podiatrist,
20	certified registered nurse practitioner or physician
21	assistant. A prescription or work order under this paragraph
22	shall place conditions and restrictions BY THE PRESCRIBING +
23	AUTHORITY on the course of treatment if required as a matter
24	of sound medical practice.
25	(2) Ensure the patient has undergone a medical
26	diagnostic examination or has had the results of a recently
27	performed medical diagnostic examination reviewed by a
28	physician, podiatrist, certified registered nurse
29	practitioner or physician assistant.
30	(3) <del>Keep</del> RETAIN a copy of the prescription <del>or work order</del>

1	and the results of the medical diagnostic examination in the
2	<pre>patient's file.</pre>
3	(d) Exceptions
4	(1) Nothing in this section shall prohibit students
5	enrolled in a prosthetics, orthotics, pedorthics or orthotics
6	fitter educational program from performing prosthetics,
7	orthotics, pedorthics or orthotic fitting in the course of
8	their instruction, provided that a physician or podiatrist is
9	readily available for consultations and that a prosthetist,
10	orthotist, pedorthist or orthotic fitter, respectively, is on
11	site and responsible for the direct supervision of students.
12	(2) Nothing in this section shall prohibit an individual
13	from engaging in the practice for which that individual is
14	licensed or certified to practice or to act within the scope
15	of that license or certification held in this Commonwealth.
16	Nothing in this act shall prohibit an individual who is
17	(3) NOTHING IN THIS ACT SHALL PROHIBIT AN INDIVIDUAL WHO
18	IS employed by the Federal Government from engaging in the
19	<pre>practice of a prosthetist, orthotist, pedorthist or orthotic</pre>
20	fitter while in the discharge of the employee's official
21	<u>duties.</u>
22	(3) (4) Nothing in this section shall prohibit the sale
23	of over-the-counter prostheses, orthoses or pedorthic
24	devices.
25	(4) (5) Nothing in this section shall prohibit a
26	representative of a medical AN ORTHOSIS device manufacturer
27	registered with the United States Food and Drug
28	Administration from measuring, fitting and adjusting orthoses
29	AN ORTHOSIS when the representative is supervised by a THE
30	physician or other licensed health care professional

1	PERFORMING THE PROCEDURE PURSUANT TO A WRITTEN AGREEMENT.
2	(e) License requirement effective Commencing two years
3	after the effective date of this section, individuals shall not
4	practice or hold themselves out as being able to practice
5	prosthetics, orthotics, pedorthics or orthotic fitting in this
6	Commonwealth unless the individuals are licensed in accordance
7	with this section.
8	(f) License without examination. Within two years after the
9	(F) LICENSE WITHOUT EXAMINATION
10	(1) WITHIN TWO YEARS AFTER THE effective date of this
11	section, an individual may be granted a prosthetic, orthotic,
12	pedorthotic or orthotic fitting license by the board if the
13	individual DOES ALL OF THE FOLLOWING:
14	(1) Complies with subsection (a) (1), (2), (5), (6) and
15	<del>(7); and</del>
16	(2) Complies with the following:
17	(i) holds a valid national certification as a
18	(I) COMPLIES WITH SUBSECTION (A) (1), (5), (6) AND
19	<u>(7).</u>
20	(II) MEETS THE FOLLOWING:
21	(A) FOR PROSTHETISTS, A COMBINATION OF AT LEAST
22	FOUR YEARS OF EDUCATION, TRAINING AND/OR WORK
23	EXPERIENCE, CONSISTING OF:
24	(I) A BACHELOR'S DEGREE WITH A MAJOR IN
25	PROSTHETICS OR ORTHOTICS AND PROSTHETICS;
26	(II) AN ASSOCIATE'S DEGREE IN PROSTHETICS OR
27	ORTHOTICS AND PROSTHETICS OR TWO OR MORE YEARS OF
28	EDUCATION, TRAINING AND/OR WORK EXPERIENCE IN THE
29	FIELD OF PROSTHETICS; AND
30	(III) A MINIMUM OF TWO YEARS OR 3,800 HOURS

1	OF EXPERIENCE IN PROVIDING DIRECT PATIENT CARE
2	SERVICES.
3	(B) FOR ORTHOTISTS, A COMBINATION OF AT LEAST
4	FOUR YEARS OF EDUCATION, TRAINING AND/OR WORK
5	EXPERIENCE, CONSISTING OF:
6	(I) A BACHELOR'S DEGREE WITH A MAJOR IN
7	ORTHOTICS OR ORTHOTICS AND PROSTHETICS;
8	(II) AN ASSOCIATE'S DEGREE IN ORTHOTICS OR
9	ORTHOTICS AND PROSTHETICS OR TWO OR MORE YEARS OF
10	EDUCATION, TRAINING AND/OR WORK EXPERIENCE IN THE
11	FIELD OF ORTHOTICS; AND
12	(III) A MINIMUM OF TWO YEARS OR 3,800 HOURS
13	OF EXPERIENCE IN PROVIDING DIRECT PATIENT CARE
14	SERVICES.
15	(C) FOR PEDORTHISTS, A SUCCESSFULLY COMPLETED
16	BOARD-APPROVED ENTRY-LEVEL PEDORTHIC EDUCATION
17	PROGRAM AND A MINIMUM OF 1,000 HOURS OF SUPERVISED
18	PATIENT FITTING EXPERIENCE.
19	(D) FOR ORTHOTIC FITTERS, A SUCCESSFULLY
20	COMPLETED BOARD-APPROVED ENTRY-LEVEL EDUCATION
21	PROGRAM SPECIFIC TO ORTHOTIC FITTING AND A MINIMUM OF
22	1,000 HOURS OF DOCUMENTED PATIENT CARE.
23	(III) COMPLIES WITH THE FOLLOWING:
24	(A) HOLDS A VALID NATIONAL CERTIFICATION FROM AN
25	ORGANIZATION APPROVED BY THE BOARD AS A prosthetist,
26	orthotist, pedorthist or orthotic fitter; and
27	(ii) has been in active, continuous practice for the
28	(B) HAS BEEN IN ACTIVE, CONTINUOUS PRACTICE FOR
29	THE three years immediately preceding the effective
30	date of this section.

1	(2) THIS SUBSECTION SHALL EXPIRE 730 DAYS FROM THE
2	EFFECTIVE DATE OF THIS SUBSECTION.
3	(g) Biennial license renewal For biennial renewal of a
4	<u>license:</u>
5	(1) A prosthetist and orthotist must provide
6	certification of successful completion of a minimum of 24
7	hours of continuing education as approved by the board.
8	(2) An orthotic fitter and a pedorthist must provide
9	certification of successful completion of a minimum of 13
10	hours of continuing education as approved by the board.
11	(3) Certification of continuing education credit hours
12	submitted by the prosthetist, orthotist, pedorthist or
13	orthotic fitter shall be verified as being correct and true
14	by the applicant.
15	(4) A licensee must file a completed board-approved
16	renewal application.
17	(5) A licensee must pay any fees established by
18	regulation by the board.
19	(6) No credit for continuing education may be given for
20	courses in office management or practice building.
21	(7) The board may waive all or part of the continuing
22	education requirements to a licensee who shows to the
23	satisfaction of the board that the licensee was unable to
24	complete the requirement due to illness, emergency or
25	hardship.
26	(h) Orthotic fitter scope of practice The scope of
27	practice of an orthotic fitter is limited to measuring, fitting,
28	dispensing and adjusting prefabricated devices not requiring
29	more than minor modification of:

30

(1) Cervical soft foam collars.

1 (2) Thoraco-lumbo-sacral orthoses. 2 (3) Lumbo-sacral orthoses. 3 (4) Knee orthoses. (5) Ankle foot orthoses. 4 5 (6) Foot orthoses. 6 (7) Elbow orthoses. 7 (8) Shoulder orthoses. 8 (9) Abdominal and pelvic: 9 (i) Trusses. 10 (ii) Flexible supports. 11 (iii) Maternity supports. 12 (10) Compression devices: 13 (i) Lymphedema garments. 14 (ii) Compression garments. 15 (iii) Burn garments. (11) Breast prosthesis and ancillary supplies. 16 (i) Liability insurance coverage. -- An individual licensed to 17 practice prosthetics, orthotics, pedorthics or orthotic fitting 18 19 in this Commonwealth shall maintain a level of professional 20 liability insurance coverage in the minimum amount of \$1,000,000 21 per occurrence or claims made and shall verify to the board the required coverage. Failure to maintain insurance coverage as 22 23 required shall subject the licensee to disciplinary proceedings. 24 The licensee must provide proof of coverage to the board upon 25 request. The board shall accept from a licensee as satisfactory 26 evidence of insurance coverage any of the following: 27 (1) Personally purchased liability insurance. (2) Professional liability insurance coverage provided 28 29 by the individual licensee's employer or similar insurance coverage acceptable to the board. 30

- 1 (j) Practice by unregistered persons. -- Any person who is not\_
- 2 licensed as a prosthetist, orthotist, pedorthist or orthotic
- 3 fitter shall not practice prosthetics, orthotics, pedorthics or
- 4 orthotic fitting nor in any written or printed circular or in
- 5 <u>any business card, letterhead or sign or otherwise assume the</u>
- 6 <u>title "Prosthetist," "Orthotist," "Pedorthist" or "Orthotic</u>
- 7 Fitter" nor any other title, abbreviation, name or description
- 8 <u>implying or calculated to lead to the belief that he is</u>
- 9 qualified to practice prosthetics, orthotics, pedorthics or
- 10 orthotic fitting.
- 11 Section 3. The board shall promulgate regulations to
- 12 implement the amendment or addition of sections 2 and  $\frac{13.4}{13.5}$
- 13 of the act within 18 months of the effective date of this
- 14 section. The amendment or addition of sections 2 and  $\frac{13.4}{13.5}$
- 15 of the act shall not be enforceable by the State Board of
- 16 Medicine until the publication of final regulations under this
- 17 section or 24 months following the effective date of this
- 18 section, whichever occurs first.
- 19 Section 4. This act shall take effect immediately.