SENATE AMENDED

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL No. 48 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 CORMAN, APPROPRIATIONS, IN SENATE, RE-REPORTED AS AMENDED, JUNE 27, 2012

AN ACT

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

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

1	~ ~ ~ + ~ ~ +	~] ~ ~ ~]		
\perp	context	crearry	Indicates	otherwise:

	-
2	* * *
3	"Accommodative." Designed with a primary goal of conforming
4	<u>to an individual's anatomy.</u>
5	* * *
6	"Custom-fabricated device." A prosthesis, orthosis or
7	pedorthic device that is fabricated to original COMPREHENSIVE
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	or pedorthic device TO ACCOMMODATE THE PATIENT'S MEASUREMENT
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	<u>its successor.</u>
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

- 2 -

1 <u>OR DEFORMITY.</u>

2	"Orthotic fitter." An individual who is licensed under this
3	act to practice orthotics PROPERLY FIT, DISPENSE AND ADJUST
4	PREFABRICATED ORTHOTIC DEVICES pursuant to a written
5	prescription of a physician, podiatrist, certified registered
6	nurse practitioner or physician assistant or pursuant to a work
7	<u>order.</u>
8	"Orthotics." Evaluating THE PRACTICE OF EVALUATING,
9	measuring, designing, fabricating, assembling, fitting,
10	adjusting or servicing an orthosis for the correction or
11	alleviation of neuromuscular or musculoskeletal dysfunction,
12	disease, 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	fitter licensed under this act to practice orthotics pursuant to
16	a written prescription of a physician, podiatrist, certified
17	registered nurse practitioner or physician assistant or pursuant
18	<u>to a work order.</u>
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	supports, corsets, generic arch supports and elastic hose.
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	adjusting or servicing necessary to accomplish the application
5	of a pedorthic device for the prevention or amelioration of
6	painful or disabling conditions related to the lower
7	<u>extremities.</u>
8	"Pedorthist." An individual licensed under this act to
9	practice pedorthics pursuant to a written prescription of a
10	physician, podiatrist, certified registered nurse practitioner
11	or physician assistant or pursuant to a work order.
12	* * *
13	"Podiatrist." An individual licensed under the act of March
14	2, 1956 (1955 P.L.1206, No.375), known as the Podiatry Practice
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	counter items by a drug store, department store, corset shop or
24	surgical supply facility.
25	"Prosthesis." A custom-designed, custom-fabricated, custom-
26	fitted or custom-modified device to replace an absent external
27	limb for purposes of restoring physiological function or
28	cosmesis THAT IS NOT SURGICALLY IMPLANTED. The term does not
29	include artificial eyes, ears, fingers or toes, dental
30	appliances, cosmetic devices, such as artificial breasts,

- 4 -

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	<u>or physician assistant or pursuant to a work order.</u>	←
11	* * *	
12	"Therapeutic devices." Devices that address a medical	←
13	condition.	
14	* * *	
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 qualificationsTo 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	<u>a bachelor's degree with a major in prosthetics or </u>	
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	care services. Patient logs must be kept and available
2	for audit purposes.
3	(ii) For orthotists, at least four years of
4	education, training and/or work experience, consisting of
5	<u>a bachelor's degree with a major in orthotics or </u>
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	<u>audit purposes.</u>
13	(I) FOR PROSTHETISTS, AT LEAST FOUR YEARS OF
14	EDUCATION, TRAINING AND/OR WORK EXPERIENCE, CONSISTING
15	<u>OF:</u>
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	<u>OF:</u>
23	(A) A BACHELOR'S DEGREE WITH A MAJOR IN
24	ORTHOTICS OR ORTHOTICS 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.

←

- 6 -

1	(iv) For orthotic fitters, a successfully completed
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	$\frac{(6)}{(7)}$ Not be addicted to alcohol, narcotics or other \leftarrow
19	habit-forming drugs.
20	$\frac{(7)}{(8)}$ Not been convicted of a felony under the act of \leftarrow
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	gualifications required under this act.
8	(b) Term of licenseA 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 requirementsPrior 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 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) Keep RETAIN a copy of the prescription or work order

- 8 -

1	and the results of the medical diagnostic examination in the
2	patient's file.
3	<u>(d) Exceptions</u>
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	practice of a prosthetist, orthotist, pedorthist or orthotic
20	fitter while in the discharge of the employee's official
21	<u>duties.</u>
22	$\frac{(3)}{(4)}$ (4) Nothing in this section shall prohibit the sale \leftarrow
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 A MEDICAL device
27	manufacturer registered with the United States Food and Drug
28	Administration from measuring, fitting and adjusting orthoses +
29	AN ORTHOSIS A MEDICAL DEVICE when the representative PURSUANT
30	TO A WRITTEN AGREEMENT is supervised by a THE physician or

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

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

←

←

1	date of this section.
2	(2) THIS SUBSECTION SHALL EXPIRE 730 DAYS FROM THE
3	EFFECTIVE DATE OF THIS SUBSECTION.
4	(g) Biennial license renewalFor biennial renewal of a
5	license:
6	(1) A prosthetist and orthotist must provide
7	certification of successful completion of a minimum of 24
8	hours of continuing education as approved by the board.
9	(2) An orthotic fitter and a pedorthist must provide
10	certification of successful completion of a minimum of 13
11	hours of continuing education as approved by the board.
12	(3) Certification of continuing education credit hours
13	submitted by the prosthetist, orthotist, pedorthist or
14	orthotic fitter shall be verified as being correct and true
15	by the applicant.
16	(4) A licensee must file a completed board-approved
17	renewal application.
18	(5) A licensee must pay any fees established by
19	regulation by the board.
20	(6) No credit for continuing education may be given for
21	courses in office management or practice building.
22	(7) The board may waive all or part of the continuing
23	education requirements to a licensee who shows to the
24	satisfaction of the board that the licensee was unable to
25	complete the requirement due to illness, emergency or
26	hardship.
27	(h) Orthotic fitter scope of practiceThe scope of
28	practice of an orthotic fitter is limited to measuring, fitting,
29	dispensing and adjusting prefabricated devices not requiring
30	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	<u>(i) Trusses.</u>
11	<u>(ii) Flexible supports.</u>
12	<u>(iii) Maternity supports.</u>
13	(10) Compression devices:
14	(i) Lymphedema garments.
15	<u>(ii) Compression garments.</u>
16	<u>(iii) Burn garments.</u>
17	(11) Breast prosthesis and ancillary supplies.
18	(i) Liability insurance coverageAn individual licensed to
19	practice prosthetics, orthotics, pedorthics or orthotic fitting
20	in this Commonwealth shall maintain a level of professional
21	<u>liability insurance coverage in the minimum amount of \$1,000,000</u>
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 <u>coverage acceptable to the board.</u>

2 (j) Practice by unregistered persons. -- Any person who is not 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 any business card, letterhead or sign or otherwise assume the 6 title "Prosthetist," "Orthotist," "Pedorthist" or "Orthotic 7 Fitter" nor any other title, abbreviation, name or description 8 9 implying or calculated to lead to the belief that he is qualified to practice prosthetics, orthotics, pedorthics or 10 11 orthotic fitting. 12 Section 3. The board shall promulgate regulations to 13 implement the amendment or addition of sections 2 and $\frac{13.4}{13.5}$ 14 of the act within 18 months of the effective date of this section. The amendment or addition of sections 2 and 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 18 section or 24 months following the effective date of this 19 section, whichever occurs first.

4

20 Section 4. This act shall take effect immediately.

- 14 -