2778, 3217

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 501

Session of 2007

INTRODUCED BY SANTONI, BARRAR, BOYD, CALTAGIRONE, CURRY, FABRIZIO, GERGELY, HENNESSEY, KILLION, KOTIK, MARKOSEK, PALLONE, REICHLEY, WALKO, YOUNGBLOOD, SIPTROTH, JAMES, MURT AND SOLOBAY, FEBRUARY 26, 2007

AS AMENDED ON THIRD CONSIDERATION, IN SENATE, APRIL 29, 2008

AN ACT

- Amending the act of October 5, 1978 (P.L.1109, No.261), entitled "An act requiring the licensing of practitioners of 2 osteopathic medicine and surgery; regulating their practice; 3 providing for certain funds and penalties for violations and 4 5 repeals, "FURTHER PROVIDING FOR DEFINITIONS; AND providing for perfusionist licensing, qualifications, supervision and 6 7 scope of practice, regulations and exemptions.
- 8 The General Assembly of the Commonwealth of Pennsylvania
- hereby enacts as follows:
- 10 Section 1. Section 2 of the act of October 5, 1978
- (P.L.1109, No.261), known as the Osteopathic Medical Practice 11
- Act, is amended by adding definitions to read:
- 13 Section 2. Definitions.
- 14 The following words and phrases when used in this act shall
- 15 have, unless the context clearly indicates otherwise, the
- 16 meanings given to them in this section:
- 17
- "Extracorporeal circulation." The diversion of a patient's 18

- 1 blood through a heart-lung machine or similar device that
- 2 assumes the functions of the patient's heart, lung, kidney,
- 3 <u>liver or other organs</u>.
- 4 * * *
- 5 <u>"Perfusion."</u> The functions necessary for the support,
- 6 treatment, measurement or supplementation of the cardiovascular
- 7 systems or other organs, or a combination of those functions,
- 8 and for ensuring the safe management of physiologic functions by
- 9 monitoring and analyzing the parameters of the systems under the
- 10 <u>supervision of a physician licensed under this act or the act of</u>
- 11 December 20, 1985 (P.L.457, No.112), known as the "Medical
- 12 Practice Act of 1985."
- 13 <u>"Perfusionist." An individual who is licensed to practice</u>
- 14 perfusion by the State Board of Osteopathic Medicine or the
- 15 State Board of Medicine.
- 16 * * *
- 17 <u>"VENTRICULAR ASSIST DEVICE." A MECHANICAL DEVICE USED TO</u>
- 18 PARTIALLY OR COMPLETELY REPLACE THE FUNCTION OF A FAILING HEART

<----

- 19 THROUGH CONNECTIONS TO THE HEART AND GREAT VESSELS THAT MAY BE
- 20 LOCATED INTRACORPOREALLY OR EXTRACORPOREALLY. THE TERM INCLUDES
- 21 A DEVICE THAT IS PLACED INTRAVASCULARLY OR EXTRAVASCULARLY AND
- 22 PROVIDES SUPPORT THROUGH DIRECT MEANS OR VIA COUNTERPULSATION.
- 23 * * *
- Section 2. Section 2.1(a) of the act, amended December 10,
- 25 2001 (P.L.863, No.93), is amended to read:
- 26 Section 2.1. State Board of Osteopathic Medicine.
- 27 (a) The State Board of Osteopathic Medicine shall consist of
- 28 the Commissioner of Professional and Occupational Affairs or his
- 29 designee; the Secretary of Health or his designee; two members
- 30 appointed by the Governor who shall be persons representing the

- 1 public at large; one member appointed by the Governor who shall
- 2 be a respiratory care practitioner, a perfusionist, a physician
- 3 assistant or a certified athletic trainer; and six members
- 4 appointed by the Governor who shall be graduates of a legally
- 5 incorporated and reputable college of [osteopathy] <u>osteopathic</u>
- 6 <u>medicine</u> and shall have been licensed to practice osteopathic
- 7 medicine under the laws of this Commonwealth and shall have been
- 8 engaged in the practice of osteopathy in this Commonwealth for a
- 9 period of at least five years. All professional and public
- 10 members of the board shall be appointed by the Governor with the
- 11 advice and consent of a majority of the members elected to the
- 12 Senate. The Governor shall assure that respiratory care
- 13 practitioners, <u>PERFUSIONISTS</u>, physician assistants and certified <-
- 14 athletic trainers are appointed to four-year terms on a rotating
- 15 basis.
- 16 * * *
- 17 Section 3. The act is amended by adding a section to read:
- 18 Section 13.3. Perfusionist.
- 19 (a) Two years after the effective date of this section, it
- 20 shall be unlawful for any person to hold himself out to the
- 21 <u>public as a perfusionist or to practice or offer to practice</u>
- 22 perfusion unless the person holds a valid, current license
- 23 issued by the board or the State Board of Medicine.
- 24 (b) A perfusionist who holds a valid, current license issued
- 25 by either board may use the title perfusionist or licensed
- 26 perfusionist, or an appropriate abbreviation of the title, such
- 27 as "LP."
- 28 (c) The board is authorized to promulgate regulations to
- 29 <u>implement this section</u>.
- 30 (d) A perfusionist <u>may perform perfusion to ON an individual</u>

- 1 being treated by a physician licensed under this act or the act
- 2 of act of December 20, 1985 (P.L.457, No.112), known as the
- 3 "Medical Practice Act of 1985," under medical supervision and
- 4 approval consistent with standing orders or protocols of a
- 5 <u>hospital that are promulgated and approved by the physician</u>
- 6 <u>designated</u> as the medical director of the cardiovascular surgery
- 7 program. These services shall include:
- 8 (1) The use of extracorporeal circulation, long-term
- 9 <u>cardiopulmonary support techniques, including extracorporeal</u>
- 10 <u>carbon dioxide removal, extracorporeal membrane oxygenation</u>
- and associated therapeutic and diagnostic techniques.
- 12 (2) Counterpulsion, ventricular assistance,
- 13 <u>autotransfusion</u>, blood and blood component conservation
- 14 <u>techniques</u>, myocardial and organ preservation, extracorporeal
- 15 <u>life support and isolated limb perfusion.</u>
- 16 (3) Blood and blood component management techniques,
- 17 advanced life support and other related functions.
- 18 <u>(4) In the performance of the acts described in</u>
- 19 paragraphs (1) through (3):
- 20 (i) The administration of:
- 21 (A) Pharmacological and therapeutic agents.
- 22 (B) Blood products or anesthetic agents through
- 23 the extracorporeal circuit or through an intravenous
- line in conjunction with extracorporeal support,
- 25 under the supervision of the treating physician.
- 26 <u>(ii) The performance and use of:</u>
- 27 (A) Anticoagulation monitoring and analysis.
- 28 (B) Physiologic monitoring and analysis.
- 29 (C) Blood gas and chemistry monitoring and
- analysis.

1	(D) Hematologic monitoring and analysis.
2	(E) Hypothermia.
3	(F) Hyperthermia.
4	(G) Normothermia.
5	(H) Hemoconcentration and hemodilution.
6	(I) Hemodialysis in conjunction with perfusion
7	service.
8	(iii) The observation of signs and symptoms related
9	to perfusion services, the determination of whether the
10	signs and symptoms exhibit abnormal characteristics and
11	the implementation of appropriate reporting, perfusion
12	protocols or changes in or the initiation of emergency
13	procedures.
14	(e) The following persons may perform perfusion, as
15	<u>indicated:</u>
16	(1) A person licensed under any other section of this
17	act or any other law of this Commonwealth, while engaging in
18	the practice for which the person is licensed.
19	(2) A student enrolled in an accredited perfusion
20	education program if perfusion performed by the student:
21	(i) is an integral part of the student's course of
22	study; and
23	(ii) is performed under the direct supervision of a
24	perfusionist who is assigned to supervise the student and
25	who is on duty and immediately available in the assigned
26	patient care area.
27	(3) A graduate of an accredited perfusion education
28	<pre>program, if perfusion services:</pre>
29	(i) are necessary to fulfill the eligibility
30	requirements for a certification examination; and

1	(ii) are performed under the supervision and	
2	responsibility of a perfusionist who is on duty and	
3	assigned to supervise the graduate.	
4	(4) A legally qualified person employed by the Federal	
5	Government to practice perfusion while in the discharge of	
6	the person's official duties.	
7	(5) FOR A VENTRICULAR ASSIST DEVICE UNDER INVESTIGATIVE	<
8	TRIALS BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION OR	
9	APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION	
10	SOLELY AS A VENTRICULAR ASSIST DEVICE, A PERSON WHO:	
11	(I) HAS SATISFACTORILY COMPLETED SPECIFIC	
12	VENTRICULAR ASSIST DEVICE TRAINING IN A COURSE PROVIDED	
13	BY THE VENTRICULAR ASSIST DEVICE MANUFACTURER; AND	
14	(II) PROVIDES CARE RELATED TO THE VENTRICULAR ASSIST	
15	DEVICE UNDER THE SUPERVISION OF A LICENSED PHYSICIAN.	
16	(6) A PERSON WHO PERFORMS AUTOTRANSFUSION OR BLOOD	
17	CONSERVATION TECHNIQUES UNDER THE SUPERVISION OF A LICENSED	
18	PHYSICIAN.	
19	(7) A PERSON WHO:	
20	(I) IS TRAINED ACCORDING TO THE EXTRACORPOREAL	
21	MEMBRANE OXYGENATION SPECIALIST GUIDELINES OF THE	
22	EXTRACORPOREAL LIFE SUPPORT ORGANIZATION; AND	
23	(II) OPERATES AN EXTRACORPOREAL MEMBRANE OXYGENATION	
24	CIRCUIT UNDER THE SUPERVISION OF A LICENSED PHYSICIAN.	
25	(f) An applicant shall be licensed to practice perfusion	
26	under this act if the applicant meets all of the following	
27	qualifications and has otherwise complied with the provisions of	
28	this act:	
29	(1) The person is at least 18 years of age.	
30	(2) The person is of good moral character.	

1	(3) The person has graduated from an accredited	
2	perfusion program approved by the board.	
3	(4) The person is certified by a certifying agency	
4	approved by a nationally recognized accrediting agency	
5	approved by the board. The certification shall include an	
6	examination approved by the board.	
7	(5) The person has completed an application form	
8	provided by the board and paid the appropriate fee.	
9	(g) Within two years of the effective date of this section,	
10	an applicant who was not a graduate of an accredited program	
11	prior to 1981, but met the then-current eligibility requirements	
12	for certification as a certified clinical perfusionist and	
13	subsequently was certified, shall be licensed as a perfusionist	
14	if the applicant otherwise complies with the provisions of this	
15	act.	
16	(h) The board may issue a temporary graduate license to	
17	practice perfusion to an individual who has graduated from an	
18	educational program that complies with the education	
19	requirements of this act. The ALL OF THE following shall apply:	<
20	(1) The individual has applied for the examination and	
21	is eligible to take the required examination.	
22	(2) The individual's authorization to practice perfusion	
23	is granted only under the supervision and direction of a	
24	perfusionist licensed under this act.	
25	(3) The license shall be issued for a period of two	
26	years and shall be nonrenewable.	
27	(4) The license shall expire immediately upon notice	
28	that the individual has failed the required examination under	
29	this act.	
30	(i) (1) The board may issue a temporary provisional license	

- 7 -

20070Н0501В3638

1	to practice perfusion if all the following requirements are
2	met:
3	(i) The individual holds a current license which is
4	in good standing under the laws of another state,
5	District of Columbia or territory of the United States
6	which includes certification by a certifying agency
7	approved by a nationally recognized accrediting agency.
8	(ii) The individual meets the requirements as set
9	forth in subsection (f)(1), (2) and (3).
10	(2) The license shall be issued for a period of one year
11	and shall be nonrenewable.
12	(j) (1) An individual who holds a current license as a
13	perfusionist in another state, the District of Columbia or a
14	territory of the United States or has obtained national
15	certification may provide a one-time emergency perfusionist
16	service in this Commonwealth without first obtaining a
17	license from the board if:
18	(i) Prior to the out-of-State perfusionist
19	performing the emergency perfusionist services in this
20	Commonwealth, the out-of-State perfusionist submits by
21	electronic means and on forms approved by the board,
22	notification of emergency practice which shall include an
23	acknowledgment that the out-of-State perfusionist is
24	subject to the jurisdiction of the board in the same
25	manner as if the out-of-State perfusionist were licensed
26	by the board.
27	(ii) The health care facility licensed by the
28	Department of Health certifies to the board, by
29	electronic means and on forms approved by the board,
30	prior to the out-of-State perfusionist performing the

1	<u>emergency perfusionist services in this Commonwealth that</u>
2	all of the following apply:
3	(A) The emergency perfusionist services were
4	provided for a patient of the health care facility.
5	(B) The perfusionist licensed by the board and
6	retained by the health care facility that would
7	normally perform the emergency perfusionist services
8	was not available or incapable of providing the
9	perfusionist services.
10	(C) No other perfusionist licensed by the board
11	was available to provide or capable of providing the
12	emergency perfusion service.
13	(D) The out-of-State perfusionist provided only
14	the emergency perfusionist services for the patient
15	of the health care facility and no other perfusionist
16	services at the health care facility.
17	(2) The out-of-State perfusionist shall obtain a license
18	from the board if a health care facility licensed by the
19	Department of Health retains the perfusionist or if the
20	perfusionist provides any future perfusionist services.
21	(3) The out-of-State perfusionist shall not perform any
22	other perfusionist services other than the emergency
23	perfusionist services.
24	(k) (1) A licensed perfusionist practicing in this
25	Commonwealth shall maintain a level of professional liability
26	insurance coverage as required for a nonparticipating health <-
27	care provider under the act of March 20, 2002 (P.L.154,
28	No.13), known as the Medical Care Availability and Reduction
29	of Error (Mcare) Act, but shall not be eligible to
30	participate in the Medical Care Availability and Reduction of

- 1 Error (Mcare) Fund. IN THE MINIMUM AMOUNT OF \$1,000,000 PER
- 2 <u>OCCURRENCE OR CLAIMS MADE. FAILURE TO MAINTAIN INSURANCE</u>
- 3 COVERAGE AS REQUIRED SHALL SUBJECT THE LICENSEE TO
- 4 DISCIPLINARY PROCEEDINGS. THE BOARD SHALL ACCEPT FROM
- 5 PERFUSIONISTS AS SATISFACTORY EVIDENCE OF INSURANCE COVERAGE
- 6 ANY OF THE FOLLOWING: SELF-INSURANCE, PERSONALLY PURCHASED
- 7 LIABILITY INSURANCE, PROFESSIONAL LIABILITY INSURANCE
- 8 COVERAGE PROVIDED BY THE PERFUSIONIST'S EMPLOYER OR SIMILAR
- 9 <u>INSURANCE COVERAGE ACCEPTABLE TO THE BOARD.</u>
- 10 (2) A license applicant shall provide proof that the
- 11 applicant has obtained professional liability insurance in
- 12 <u>accordance with paragraph (1). It is sufficient if the</u>
- applicant files with the application a copy of a letter from
- 14 the applicant's professional liability insurance carrier
- indicating that the applicant will be covered against
- 16 <u>professional liability in the required amounts effective upon</u>
- 17 the issuance of the applicant's license to practice perfusion
- 18 in this Commonwealth. Upon issuance of the license, the
- 19 <u>licensee has 30 days to submit to the board the certificate</u>
- 20 <u>of insurance or a copy of the policy declaration page.</u>
- 21 (1) All application and licensure fees shall be set by the
- 22 board by regulation.
- 23 (m) Disciplinary actions taken by the State Board of
- 24 Osteopathic Medicine against a perfusionist licensed by it shall
- 25 be enforceable by the State Board of Medicine against the same
- 26 individual if such individual holds or seeks a license to
- 27 practice as a perfusionist with the State Board of Medicine.
- 28 (n) (1) The board shall adopt, promulgate and enforce rules
- 29 <u>and regulations consistent with the provisions of this act</u>
- 30 establishing requirements of continuing education to be met

1	by individuals licensed as perfusionists under this act as a
2	condition for renewal of their licenses. The regulations
3	shall include any fees necessary for the board to carry out
4	its responsibilities under this section.
5	(2) Beginning with the license period designated by
6	regulation, licensees shall be required to attend and
7	complete 30 hours of mandatory continuing education during
8	each two-year license period. Nationally certified education
9	courses shall be considered as creditable, in addition to any
10	other courses the board deems creditable toward meeting the
11	requirements for continuing education.
12	(3) An individual applying for the first time for
13	licensure in this Commonwealth shall be exempted from the
14	continuing education requirement for the biennial renewal
15	period following initial licensure.
16	(4) (i) The board may waive all or a portion of the
17	continuing education requirement for biennial renewal for
18	a licensee who shows to the satisfaction of the board
19	that the licensee was unable to complete the requirements
20	due to serious illness, military service or other
21	demonstrated hardship.
22	(ii) The request shall be made in writing with
23	appropriate documentation and shall include a description
24	of circumstances sufficient to show why the licensee is
25	unable to comply with the continuing education
26	requirement.
27	(5) A licensee seeking to reinstate an inactive or
28	lapsed license shall show proof of compliance with the
29	continuing education requirement for the preceding biennium.
30	(6) All courses, locations, instructors and providers

- 1 shall be approved by the board. No credit shall be given for
- any course in office management. 2
- Section 4. The State Board of Osteopathic Medicine shall 3
- initiate the promulgation of regulations to carry out the
- 5 provisions of this act within 18 months of the effective date of
- 6 this section.
- Section 5. This act shall take effect in 60 days. 7