## 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 SECOND CONSIDERATION, IN SENATE, FEBRUARY 11, 2008

## AN ACT

1 2 3 4 5 6 7	Amending the act of October 5, 1978 (P.L.1109, No.261), entitled "An act requiring the licensing of practitioners of osteopathic medicine and surgery; regulating their practice; providing for certain funds and penalties for violations and repeals," providing for perfusionist licensing, qualifications, supervision and scope of practice, regulations and exemptions.
8	The General Assembly of the Commonwealth of Pennsylvania
9	hereby enacts as follows:
10	Section 1. Section 2 of the act of October 5, 1978
11	(P.L.1109, No.261), known as the Osteopathic Medical Practice
12	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	* * *
18	"Extracorporeal circulation." The diversion of a patient's

1	blood through a heart-lung machine or similar device that
2	assumes the functions of the patient's heart, lung, kidney,
3	liver or other organs.
4	* * *
5	"Perfusion." 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	supervision of a physician licensed under this act or the act of
11	December 20, 1985 (P.L.457, No.112), known as the "Medical
12	Practice Act of 1985."
13	"Perfusionist." An individual who is licensed to practice
14	perfusion by the State Board of Osteopathic Medicine or the
15	State Board of Medicine.
16	* * *
17	"VENTRICULAR ASSIST DEVICE." A MECHANICAL DEVICE USED TO
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	* * *
24	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
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public at large; one member appointed by the Governor who shall 1 be a respiratory care practitioner, <u>a perfusionist</u>, a physician 2 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] osteopathic medicine and shall have been licensed to practice osteopathic 6 medicine under the laws of this Commonwealth and shall have been 7 engaged in the practice of osteopathy in this Commonwealth for a 8 period of at least five years. All professional and public 9 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 Senate. The Governor shall assure that respiratory care 12 13 practitioners, physician assistants and certified athletic 14 trainers are appointed to four-year terms on a rotating basis. \* \* \* 15 16 Section 3. The act is amended by adding a section to read: Section 13.3. Perfusionist. 17 18 (a) Two years after the effective date of this section, it

20 public as a perfusionist or to practice or offer to practice

shall be unlawful for any person to hold himself out to the

21 perfusion unless the person holds a valid, current license

22 issued by the board or the State Board of Medicine.

23 (b) A perfusionist who holds a valid, current license issued
24 by either board may use the title perfusionist or licensed

25 perfusionist, or an appropriate abbreviation of the title, such 26 as "LP."

27 (c) The board is authorized to promulgate regulations to
28 implement this section.

29 (d) A perfusionist may perform perfusion to ON an individual
30 being treated by a physician licensed under this act or the act

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1	of act of December 20, 1985 (P.L.457, No.112), known as the
2	"Medical Practice Act of 1985," under medical supervision and
3	approval consistent with standing orders or protocols of a
4	hospital that are promulgated and approved by the physician
5	designated as the medical director of the cardiovascular surgery
6	program. These services shall include:
7	(1) The use of extracorporeal circulation, long-term
8	cardiopulmonary support techniques, including extracorporeal
9	carbon dioxide removal, extracorporeal membrane oxygenation
10	and associated therapeutic and diagnostic techniques.
11	(2) Counterpulsion, ventricular assistance,
12	autotransfusion, blood and blood component conservation
13	techniques, myocardial and organ preservation, extracorporeal
14	life support and isolated limb perfusion.
15	(3) Blood and blood component management techniques,
16	advanced life support and other related functions.
17	(4) In the performance of the acts described in
18	paragraphs (1) through (3):
19	(i) The administration of:
20	(A) Pharmacological and therapeutic agents.
21	(B) Blood products or anesthetic agents through
22	the extracorporeal circuit or through an intravenous
23	line in conjunction with extracorporeal support,
24	under the supervision of the treating physician.
25	(ii) The performance and use of:
26	(A) Anticoagulation monitoring and analysis.
27	(B) Physiologic monitoring and analysis.
28	(C) Blood gas and chemistry monitoring and
29	analysis.
30	(D) Hematologic monitoring and analysis.
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1	<u>(E) Hypothermia.</u>
2	(F) Hyperthermia.
3	(G) Normothermia.
4	(H) Hemoconcentration and hemodilution.
5	(I) Hemodialysis in conjunction with perfusion
б	service.
7	(iii) The observation of signs and symptoms related
8	to perfusion services, the determination of whether the
9	signs and symptoms exhibit abnormal characteristics and
10	the implementation of appropriate reporting, perfusion
11	protocols or changes in or the initiation of emergency
12	procedures.
13	(e) The following persons may perform perfusion, as
14	indicated:
15	(1) A person licensed under any other section of this
16	act or any other law of this Commonwealth, while engaging in
17	the practice for which the person is licensed.
18	(2) A student enrolled in an accredited perfusion
19	education program if perfusion performed by the student:
20	(i) is an integral part of the student's course of
21	study; and
22	(ii) is performed under the direct supervision of a
23	perfusionist who is assigned to supervise the student and
24	who is on duty and immediately available in the assigned
25	<u>patient care area.</u>
26	(3) A graduate of an accredited perfusion education
27	program, if perfusion services:
28	(i) are necessary to fulfill the eligibility
29	requirements for a certification examination; and
30	(ii) are performed under the supervision and
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1	responsibility of a perfusionist who is on duty and	
2	assigned to supervise the graduate.	
3	(4) A legally qualified person employed by the Federal	
4	Government to practice perfusion while in the discharge of	
5	the person's official duties.	
6	(5) FOR A VENTRICULAR ASSIST DEVICE UNDER INVESTIGATIVE	<
7	TRIALS BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION OR	
8	APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION	
9	SOLELY AS A VENTRICULAR ASSIST DEVICE, A PERSON WHO:	
10	(I) HAS SATISFACTORILY COMPLETED SPECIFIC	
11	VENTRICULAR ASSIST DEVICE TRAINING IN A COURSE PROVIDED	
12	BY THE VENTRICULAR ASSIST DEVICE MANUFACTURER; AND	
13	(II) PROVIDES CARE RELATED TO THE VENTRICULAR ASSIST	
14	DEVICE UNDER THE SUPERVISION OF A LICENSED PHYSICIAN.	
15	(6) A PERSON WHO PERFORMS AUTOTRANSFUSION OR BLOOD	
16	CONSERVATION TECHNIQUES UNDER THE SUPERVISION OF A LICENSED	
17	PHYSICIAN.	
18	(7) A PERSON WHO:	
19	(I) IS TRAINED ACCORDING TO THE EXTRACORPOREAL	
20	MEMBRANE OXYGENATION SPECIALIST GUIDELINES OF THE	
21	EXTRACORPOREAL LIFE SUPPORT ORGANIZATION; AND	
22	(II) OPERATES AN EXTRACORPOREAL MEMBRANE OXYGENATION	
23	CIRCUIT UNDER THE SUPERVISION OF A LICENSED PHYSICIAN.	
24	(f) An applicant shall be licensed to practice perfusion	
25	under this act if the applicant meets all of the following	
26	qualifications and has otherwise complied with the provisions of	
27	this act:	
28	(1) The person is at least 18 years of age.	
29	(2) The person is of good moral character.	
30	(3) The person has graduated from an accredited	

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

<ul> <li>(i) The individual holds a current license which is</li> <li>in good standing under the laws of another state,</li> <li>District of Columbia or territory of the United States</li> <li>which includes certification by a certifying agency</li> <li>approved by a nationally recognized accrediting agency.</li> <li>(ii) The individual meets the requirements as set</li> <li>forth in subsection (f)(1), (2) and (3).</li> <li>(2) The license shall be issued for a period of one year</li> </ul>
<ul> <li>District of Columbia or territory of the United States</li> <li>which includes certification by a certifying agency</li> <li>approved by a nationally recognized accrediting agency.</li> <li>(ii) The individual meets the requirements as set</li> <li>forth in subsection (f)(1), (2) and (3).</li> </ul>
<ul> <li>which includes certification by a certifying agency</li> <li>approved by a nationally recognized accrediting agency.</li> <li>(ii) The individual meets the requirements as set</li> <li>forth in subsection (f)(1), (2) and (3).</li> </ul>
<ul> <li>approved by a nationally recognized accrediting agency.</li> <li>(ii) The individual meets the requirements as set</li> <li>forth in subsection (f)(1), (2) and (3).</li> </ul>
<ul> <li>7 (ii) The individual meets the requirements as set</li> <li>8 forth in subsection (f)(1), (2) and (3).</li> </ul>
8 forth in subsection $(f)(1)$ , $(2)$ and $(3)$ .
9 (2) The license shall be issued for a period of one year
10 <u>and shall be nonrenewable.</u>
11 <u>(j) (1) An individual who holds a current license as a</u>
12 perfusionist in another state, the District of Columbia or a
13 <u>territory of the United States or has obtained national</u>
14 certification may provide a one-time emergency perfusionist
15 service in this Commonwealth without first obtaining a
16 license from the board if:
17 (i) Prior to the out-of-State perfusionist
18 performing the emergency perfusionist services in this
19 <u>Commonwealth, the out-of-State perfusionist submits by</u>
20 <u>electronic means and on forms approved by the board</u> ,
21 <u>notification of emergency practice which shall include an</u>
22 <u>acknowledgment that the out-of-State perfusionist is</u>
23 <u>subject to the jurisdiction of the board in the same</u>
24 <u>manner as if the out-of-State perfusionist were licensed</u>
25 by the board.
26 (ii) The health care facility licensed by the
27 Department of Health certifies to the board, by
27Department of Health certifies to the board, by28electronic means and on forms approved by the board,
28 <u>electronic means and on forms approved by the board</u> ,

1	all of the following apply:	
2	(A) The emergency perfusionist services were	
3	provided for a patient of the health care facility.	
4	(B) The perfusionist licensed by the board and	
5	retained by the health care facility that would	
б	normally perform the emergency perfusionist services	
7	was not available or incapable of providing the	
8	perfusionist services.	
9	(C) No other perfusionist licensed by the board	
10	was available to provide or capable of providing the	
11	emergency perfusion service.	
12	(D) The out-of-State perfusionist provided only	
13	the emergency perfusionist services for the patient	
14	of the health care facility and no other perfusionist	
15	services at the health care facility.	
16	(2) The out-of-State perfusionist shall obtain a license	
17	from the board if a health care facility licensed by the	
18	Department of Health retains the perfusionist or if the	
19	perfusionist provides any future perfusionist services.	
20	(3) The out-of-State perfusionist shall not perform any	
21	other perfusionist services other than the emergency	
22	perfusionist services.	
23	(k) (1) A licensed perfusionist practicing in this	
24	Commonwealth shall maintain a level of professional liability	
25	insurance coverage as required for a nonparticipating health	<
26	care provider under the act of March 20, 2002 (P.L.154,	
27	No.13), known as the Medical Care Availability and Reduction	
28	<u>of Error (Mcare) Act, but shall not be eligible to</u>	
29	participate in the Medical Care Availability and Reduction of	
30	Error (Mcare) Fund. IN THE MINIMUM AMOUNT OF \$1,000,000 PER	<

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1 OCCURRENCE OR CLAIMS MADE. FAILURE TO MAINTAIN INSURANCE 2 COVERAGE AS REQUIRED SHALL SUBJECT THE LICENSEE TO 3 DISCIPLINARY PROCEEDINGS. THE BOARD SHALL ACCEPT FROM 4 PERFUSIONISTS AS SATISFACTORY EVIDENCE OF INSURANCE COVERAGE 5 ANY OF THE FOLLOWING: SELF-INSURANCE, PERSONALLY PURCHASED LIABILITY INSURANCE, PROFESSIONAL LIABILITY INSURANCE 6 7 COVERAGE PROVIDED BY THE PERFUSIONIST'S EMPLOYER OR SIMILAR 8 INSURANCE COVERAGE ACCEPTABLE TO THE BOARD. 9 (2) A license applicant shall provide proof that the applicant has obtained professional liability insurance in 10 accordance with paragraph (1). It is sufficient if the 11 12 applicant files with the application a copy of a letter from 13 the applicant's professional liability insurance carrier indicating that the applicant will be covered against 14 15 professional liability in the required amounts effective upon 16 the issuance of the applicant's license to practice perfusion in this Commonwealth. Upon issuance of the license, the 17 18 licensee has 30 days to submit to the board the certificate of insurance or a copy of the policy declaration page. 19 (1) All application and licensure fees shall be set by the 20 21 board by regulation. 22 (m) Disciplinary actions taken by the State Board of 23 Osteopathic Medicine against a perfusionist licensed by it shall be enforceable by the State Board of Medicine against the same 24 individual if such individual holds or seeks a license to 25 26 practice as a perfusionist with the State Board of Medicine. 27 (n) (1) The board shall adopt, promulgate and enforce rules 28 and regulations consistent with the provisions of this act 29 establishing requirements of continuing education to be met by individuals licensed as perfusionists under this act as a 30

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1	condition for renewal of their licenses. The regulations
2	shall include any fees necessary for the board to carry out
3	its responsibilities under this section.
4	(2) Beginning with the license period designated by
5	regulation, licensees shall be required to attend and
6	complete 30 hours of mandatory continuing education during
7	each two-year license period. Nationally certified education
8	courses shall be considered as creditable, in addition to any
9	other courses the board deems creditable toward meeting the
10	requirements for continuing education.
11	(3) An individual applying for the first time for
12	licensure in this Commonwealth shall be exempted from the
13	continuing education requirement for the biennial renewal
14	period following initial licensure.
15	(4) (i) The board may waive all or a portion of the
16	continuing education requirement for biennial renewal for
17	a licensee who shows to the satisfaction of the board
18	that the licensee was unable to complete the requirements
19	due to serious illness, military service or other
20	demonstrated hardship.
21	(ii) The request shall be made in writing with
22	appropriate documentation and shall include a description
23	of circumstances sufficient to show why the licensee is
24	unable to comply with the continuing education
25	requirement.
26	(5) A licensee seeking to reinstate an inactive or
27	lapsed license shall show proof of compliance with the
28	continuing education requirement for the preceding biennium.
29	(6) All courses, locations, instructors and providers
30	shall be approved by the board. No credit shall be given for

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## 1 <u>any course in office management.</u>

Section 4. The State Board of Osteopathic Medicine shall initiate the promulgation of regulations to carry out the provisions of this act within 18 months of the effective date of this section.

6 Section 5. This act shall take effect in 60 days.