2007

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL No. 500 Session of

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, MAY 6, 2008

AN ACT

1 2 3 4 5	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
6	its composition, powers and duties; providing for the
7	issuance of licenses and certificates and the suspension and
8 9	revocation of licenses and certificates; providing penalties;
و L0	and making repeals, FURTHER PROVIDING FOR DEFINITIONS; providing for perfusionist licensing, qualifications,
11	supervision and scope of practice, regulations and
L2	exemptions.
L3	The General Assembly of the Commonwealth of Pennsylvania
L 4	hereby enacts as follows:
L5	Section 1. Section 2 of the act of December 20, 1985
L6	(P.L.457, No.112), known as the Medical Practice Act of 1985, is
L7	amended by adding definitions to read:
L8	Section 2. Definitions.

The following words and phrases when used in this act shall

have the meanings given to them in this section unless the

context clearly indicates otherwise:

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- 1 * * *
- 2 <u>"Extracorporeal circulation." The diversion of a patient's</u>
- 3 <u>blood through a heart-lung machine or similar device that</u>
- 4 assumes the functions of the patient's heart, lung, kidney,
- 5 <u>liver or other organs</u>.
- 6 * * *
- 7 <u>"Perfusion." The functions necessary for the support,</u>
- 8 treatment, measurement or supplementation of the cardiovascular
- 9 systems or other organs, or a combination of those functions,
- 10 and for ensuring the safe management of physiologic functions by
- 11 monitoring and analyzing the parameters of the systems under the
- 12 <u>supervision of a licensed physician PHYSICIAN LICENSED UNDER</u>
- 13 THIS ACT OR THE ACT OF OCTOBER 5, 1978 (P.L.1109, NO.261), KNOWN
- 14 AS THE OSTEOPATHIC MEDICAL PRACTICE ACT.
- 15 <u>"Perfusionist." An individual who is licensed to practice</u>
- 16 perfusion by the State Board of Medicine or the State Board of
- 17 Osteopathic Medicine.
- 18 * * *
- 19 "VENTRICULAR ASSIST DEVICE." A MECHANICAL DEVICE USED TO
- 20 PARTIALLY OR COMPLETELY REPLACE THE FUNCTION OF A FAILING HEART
- 21 THROUGH CONNECTIONS TO THE HEART AND GREAT VESSELS THAT MAY BE
- 22 LOCATED INTRACORPOREALLY OR EXTRACORPOREALLY. THE TERM INCLUDES
- 23 A DEVICE THAT IS PLACED INTRAVASCULARLY OR EXTRAVASCULARLY AND
- 24 PROVIDES SUPPORT THROUGH DIRECT MEANS OR VIA COUNTERPULSATION.
- 25 * * *
- 26 Section 2. Section 3(a) of the act, amended December 10,
- 27 2001 (P.L.859, No.92), is amended to read:
- 28 SECTION 2. SECTION 3(A) AND (B) OF THE ACT, AMENDED JULY 2, <-

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- 29 1993 (P.L.424, NO.60) AND DECEMBER 10, 2001 (P.L.859, NO.92),
- 30 ARE AMENDED TO READ:

- 1 Section 3. State Board of Medicine.
- 2 (a) Establishment. -- The State Board of Medicine shall
- 3 consist of the commissioner or his designee, the Secretary of
- 4 Health or his designee, two members appointed by the Governor
- 5 who shall be persons representing the public at large and seven
- 6 members appointed by the Governor, six of whom shall be medical
- 7 doctors with unrestricted licenses to practice medicine and
- 8 surgery in this Commonwealth for five years immediately
- 9 preceding their appointment and one who shall be a nurse
- 10 midwife, physician assistant, certified registered nurse
- 11 practitioner, respiratory care practitioner [or], certified
- 12 athletic trainer or perfusionist licensed or certified under the
- 13 laws of this Commonwealth. All professional and public members
- 14 of the board shall be appointed by the Governor, with the advice
- 15 and consent of a majority of the members elected to the Senate.

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- 16 (B) TERMS OF OFFICE. -- THE TERM OF EACH PROFESSIONAL AND
- 17 PUBLIC MEMBER OF THE BOARD SHALL BE FOUR YEARS OR UNTIL HIS OR
- 18 HER SUCCESSOR HAS BEEN APPOINTED AND QUALIFIED, BUT NOT LONGER
- 19 THAN SIX MONTHS BEYOND THE FOUR-YEAR PERIOD. IN THE EVENT THAT
- 20 ANY OF SAID MEMBERS SHALL DIE OR RESIGN OR OTHERWISE BECOME
- 21 DISQUALIFIED DURING HIS OR HER TERM, A SUCCESSOR SHALL BE
- 22 APPOINTED IN THE SAME WAY AND WITH THE SAME QUALIFICATIONS AND
- 23 SHALL HOLD OFFICE FOR THE UNEXPIRED TERM. NO MEMBER SHALL BE
- 24 ELIGIBLE FOR APPOINTMENT TO SERVE MORE THAN TWO CONSECUTIVE
- 25 TERMS. THE GOVERNOR SHALL ASSURE THAT NURSE MIDWIVES, PHYSICIAN
- 26 ASSISTANTS, CERTIFIED REGISTERED NURSE PRACTITIONERS,
- 27 PERFUSIONISTS AND RESPIRATORY CARE PRACTITIONERS ARE APPOINTED
- 28 TO FOUR-YEAR TERMS ON A ROTATING BASIS SO THAT, OF EVERY FOUR
- 29 APPOINTMENTS TO A FOUR-YEAR TERM, ONE IS A NURSE MIDWIFE, ONE IS
- 30 A PHYSICIAN ASSISTANT, ONE IS A CERTIFIED REGISTERED NURSE

- 1 PRACTITIONER AND ONE IS A RESPIRATORY CARE PRACTITIONER.
- 2 * * *
- 3 Section 3. The act is amended by adding a section to read:
- 4 <u>Section 13.3. Perfusionist.</u>
- 5 (a) License required. -- Two years after the effective date of
- 6 this section, it shall be unlawful for any person to hold
- 7 <u>himself out to the public as a perfusionist or to practice or</u>
- 8 offer to practice perfusion unless the person holds a valid,
- 9 current license issued by the board or the State Board of
- 10 Osteopathic Medicine.
- 11 (b) Use of title.--A perfusionist who holds a valid, current
- 12 <u>license issued by either board may use the title perfusionist or</u>
- 13 <u>licensed perfusionist</u>, or an appropriate abbreviation of the
- 14 title, such as "LP."
- (c) Regulations.--The board is authorized to promulgate
- 16 <u>regulations to implement this section.</u>
- 17 (d) Supervision and scope of practice. -- A perfusionist may
- 18 perform perfusion to ON an individual being treated by a
- 19 licensed physician PHYSICIAN LICENSED UNDER THIS ACT OR THE ACT

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- 20 OF OCTOBER 5, 1978 (P.L.1109, NO.261), KNOWN AS THE OSTEOPATHIC
- 21 MEDICAL PRACTICE ACT under medical supervision and approval
- 22 consistent with standing orders or protocols of a hospital that
- 23 are promulgated and approved by the physician designated as the
- 24 medical director of the cardiovascular surgery program. These
- 25 services shall include:
- 26 (1) The use of extracorporeal circulation, long-term
- 27 cardiopulmonary support techniques, including extracorporeal
- 28 <u>carbon dioxide removal, extracorporeal membrane oxygenation</u>
- 29 <u>and associated therapeutic and diagnostic techniques.</u>
- 30 <u>(2) Counterpulsion, ventricular assistance,</u>

1	autotransfusion, blood and blood component conservation
2	techniques, myocardial and organ preservation, extracorporeal
3	life support and isolated limb perfusion.
4	(3) Blood and blood component management techniques,
5	advanced life support and other related functions.
6	(4) In the performance of the acts described in
7	paragraphs (1), (2) and (3):
8	(i) The administration of:
9	(A) Pharmacological and therapeutic agents.
10	(B) Blood products or anesthetic agents through
11	the extracorporeal circuit or through an intravenous
12	line in conjunction with extracorporeal support,
13	under the supervision of the treating physician.
14	(ii) The performance and use of:
15	(A) Anticoagulation monitoring and analysis.
16	(B) Physiologic monitoring and analysis.
17	(C) Blood gas and chemistry monitoring and
18	analysis.
19	(D) Hematologic monitoring and analysis.
20	(E) Hypothermia.
21	(F) Hyperthermia.
22	(G) Normothermia.
23	(H) Hemoconcentration and hemodilution.
24	(I) Hemodialysis in conjunction with perfusion
25	service.
26	(iii) The observation of signs and symptoms related
27	to perfusion services, the determination of whether the
28	signs and symptoms exhibit abnormal characteristics and
29	the implementation of appropriate reporting, perfusion
30	protocols or changes in or the initiation of emergency

1	procedures.
2	(e) Exemptions The following persons may perform
3	perfusion, as indicated:
4	(1) A person licensed under any other section of this
5	act or any other law of this Commonwealth, while engaging in
6	the practice for which the person is licensed.
7	(2) A student enrolled in an accredited perfusion
8	education program if perfusion performed by the student:
9	(i) is an integral part of the student's course of
10	study; and
11	(ii) is performed under the direct supervision of a
12	perfusionist who is assigned to supervise the student and
13	who is on duty and immediately available in the assigned
14	patient care area.
15	(3) A graduate of an accredited perfusion education
16	<pre>program, if perfusion services:</pre>
17	(i) are necessary to fulfill the eligibility
18	requirements for a certification examination; and
19	(ii) are performed under the supervision and
20	responsibility of a perfusionist who is on duty and
21	assigned to supervise the graduate.
22	(4) A legally qualified person employed by the Federal
23	Government to practice perfusion while in the discharge of
24	the person's official duties.
25	(5) FOR A VENTRICULAR ASSIST DEVICE UNDER INVESTIGATIVE <
26	TRIALS BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION OR
27	APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION
28	SOLELY AS A VENTRICULAR ASSIST DEVICE, A PERSON WHO:
29	(I) HAS SATISFACTORILY COMPLETED SPECIFIC
30	VENTRICULAR ASSIST DEVICE TRAINING IN A COURSE PROVIDED

1	BY THE VENTRICULAR ASSIST DEVICE MANUFACTURER; AND
2	(II) PROVIDES CARE RELATED TO THE VENTRICULAR ASSIST
3	DEVICE UNDER THE SUPERVISION OF A LICENSED PHYSICIAN.
4	(6) A PERSON WHO PERFORMS AUTOTRANSFUSION OR BLOOD
5	CONSERVATION TECHNIQUES UNDER THE SUPERVISION OF A LICENSED
6	PHYSICIAN.
7	(7) A PERSON WHO:
8	(I) IS TRAINED ACCORDING TO THE EXTRACORPOREAL
9	MEMBRANE OXYGENATION SPECIALIST GUIDELINES OF THE
10	EXTRACORPOREAL LIFE SUPPORT ORGANIZATION; AND
11	(II) OPERATES AN EXTRACORPOREAL MEMBRANE OXYGENATION
12	CIRCUIT UNDER THE SUPERVISION OF A LICENSED PHYSICIAN.
13	(f) Qualifications An applicant shall be licensed to
14	practice perfusion under this act if the applicant meets all of
15	the following qualifications and has otherwise complied with the
16	<pre>provisions of this act:</pre>
17	(1) The person is at least 18 years of age.
18	(2) The person is of good moral character.
19	(3) The person has graduated from an accredited
20	perfusion program approved by the board.
21	(4) The person is certified by a certifying agency
22	approved by a nationally recognized accrediting agency
23	approved by the board. The certification shall include an
24	examination approved by the board.
25	(5) The person has completed an application form
26	provided by the board and paid the appropriate fee.
27	(g) Certain certified persons not graduates of accredited
28	programs Within two years of the effective date of this
29	section, an applicant who was not a graduate of an accredited
30	program prior to 1981, but met the then-current eligibility

1	requirements for certification as a certified clinical	
2	perfusionist and subsequently was certified, shall be licensed	
3	as a perfusionist if the applicant otherwise complies with the	
4	provisions of this act.	
5	(h) Temporary graduate license to practice perfusion	
6	(1) The board may issue a temporary graduate license to	
7	practice perfusion to an individual who has graduated from an	
8	educational program that complies with the education	
9	requirements of this act. The ALL OF THE following shall	<
10	apply:	
11	(i) The individual has applied for the examination	
12	and is eligible to take the required examination.	
13	(ii) The individual's authorization to practice	
14	perfusion is granted only under the supervision and	
15	direction of a perfusionist licensed under this act.	
16	(iii) The license shall be issued for a period of	
17	two years and shall be nonrenewable.	
18	(iv) The license shall expire immediately upon	
19	notice that the individual has failed the required	
20	examination under this act.	
21	(2) (RESERVED).	<
22	(i) Temporary provisional license to practice perfusion	
23	(1) The board may issue a temporary provisional license	
24	to practice perfusion if all the following requirements are	
25	met:	
26	(i) The individual holds a current license which is	
27	in good standing under the laws of another state,	
28	District of Columbia or territory of the United States	
29	which includes certification by a certifying agency	
30	approved by a nationally recognized accrediting agency.	

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

1	normally perform the emergency perfusionist services	
2	was not available or incapable of providing the	
3	perfusionist services.	
4	(C) No other perfusionist licensed by the board	
5	was available to provide or capable of providing the	
6	emergency perfusion service.	
7	(D) The out-of-State perfusionist provided only	
8	the emergency perfusionist services for the patient	
9	of the health care facility and no other perfusionist	
10	services at the health care facility.	
11	(2) The out-of-State perfusionist shall obtain a license	
12	from the board if a health care facility licensed by the	
13	Department of Health retains the perfusionist or if the	
14	perfusionist provides any future perfusionist services.	
15	(3) The out-of-State perfusionist shall not perform any	
16	other perfusionist services other than the emergency	
17	perfusionist services.	
18	(k) Professional liability	
19	(1) A licensed perfusionist practicing in this	
20	Commonwealth shall maintain a level of professional liability	
21	insurance coverage as required for a nonparticipating health	<
22	care provider under the act of March 20, 2002 (P.L.154,	
23	No.13), known as the Medical Care Availability and Reduction	
24	of Error (Mcare) Act, but shall not be eligible to	
25	participate in the Medical Care Availability and Reduction of	
26	Error Fund. IN THE MINIMUM AMOUNT OF \$1,000,000 PER	<
27	OCCURRENCE OR CLAIMS MADE. FAILURE TO MAINTAIN INSURANCE	
28	COVERAGE AS REQUIRED SHALL SUBJECT THE LICENSEE TO	
29	DISCIPLINARY PROCEEDINGS. THE BOARD SHALL ACCEPT FROM	
30	PERFUSIONISTS AS SATISFACTORY EVIDENCE OF INSURANCE COVERAGE	

1	ANY OF THE FOLLOWING:
2	(I) SELF-INSURANCE;
3	(II) PERSONALLY PURCHASED LIABILITY INSURANCE; OR
4	(III) PROFESSIONAL LIABILITY INSURANCE COVERAGE
5	PROVIDED BY THE PERFUSIONIST'S EMPLOYER OR SIMILAR
6	INSURANCE COVERAGE ACCEPTABLE TO THE BOARD.
7	(2) A license applicant shall provide proof that the
8	applicant has obtained professional liability insurance in
9	accordance with paragraph (1). It is sufficient if the
10	applicant files with the application a copy of a letter from
11	the applicant's professional liability insurance carrier
12	indicating that the applicant will be covered against
13	professional liability in the required amounts effective upon
14	the issuance of the applicant's license to practice perfusion
15	in this Commonwealth. Upon issuance of the license, the
16	licensee has 30 days to submit to the board the certificate
17	of insurance or a copy of the policy declaration page.
18	(1) Licensure feesAll application and licensure fees
19	shall be set by the board by regulation.
20	(m) Reciprocal disciplinary action Disciplinary action
21	taken by the State Board of Medicine against a perfusionist
22	licensed by it shall be enforceable by the State Board of
23	Osteopathic Medicine against that same individual if the
24	individual holds or seeks a license to practice as a
25	perfusionist with the State Board of Osteopathic Medicine.
26	(n) Continuing education
27	(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
30	by individuals licensed as perfusionists under this act as a

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. (2) Beginning with the license period designated by 4 5 regulation, licensees shall be required to attend and complete 30 hours of mandatory continuing education during 6 7 each two-year license period. Nationally certified education courses shall be considered as creditable, in addition to any 8 9 other courses the board deems creditable toward meeting the requirements for continuing education. 10 (3) An individual applying for the first time for 11 12 licensure in this Commonwealth shall be exempted from the 13 continuing education requirements for the biennial renewal period following initial licensure. 14 15 (4) (i) The board may waive all or a portion of the continuing education requirement for biennial renewal for 16 a licensee who shows to the satisfaction of the board 17 18 that the licensee was unable to complete the requirements due to serious illness, military service or other 19 20 demonstrated hardship. (ii) The request shall be made in writing with 21 22 appropriate documentation and shall include a description 23 of circumstances sufficient to show why the licensee is 2.4 unable to comply with the continuing education 25 requirement. (5) A licensee seeking to reinstate an inactive or 26 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

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shall be approved by the board. No credit shall be given for

- any course in office management. 1
- 2 Section 4. The State Board of Medicine shall promulgate
- 3 regulations to carry out the provisions of this act within 18
- 4 months of the effective date of this section.
- 5 Section 5. This act shall take effect in 60 days.