

No. 2008-19

AN ACT

HB 500

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 its composition, powers and duties; providing for the issuance of licenses and certificates and the suspension and revocation of licenses and certificates; providing penalties; and making repeals," further providing for definitions; providing for perfusionist licensing, qualifications, supervision and scope of practice, regulations and exemptions.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Section 2 of the act of December 20, 1985 (P.L.457, No.112), known as the Medical Practice Act of 1985, is amended by adding definitions to read:

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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"Extracorporeal circulation." *The diversion of a patient's blood through a heart-lung machine or similar device that assumes the functions of the patient's heart, lungs, kidneys, liver or other organs.*

* * *

"Perfusion." *The functions necessary for the support, treatment, measurement or supplementation of the cardiovascular system or other organs, or a combination of those functions, and for ensuring the safe management of physiologic functions by monitoring and analyzing the parameters of the systems under the supervision of a physician licensed under this act or the act of October 5, 1978 (P.L.1109, No.261), known as the Osteopathic Medical Practice Act.*

"Perfusionist." *An individual who is licensed to practice perfusion by the State Board of Medicine or the State Board of Osteopathic Medicine.*

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"Ventricular assist device." *A mechanical device used to partially or completely replace the function of a failing heart through connections to the heart and great vessels that may be located intracorporeally or extracorporeally. The term includes a device that is placed intravascularly or extravascularly and provides support through direct means or via counterpulsation.*

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Section 2. Section 3(a) and (b) of the act, amended July 2, 1993 (P.L.424, No.60) and December 10, 2001 (P.L.859, No.92), are amended to read:

Section 3. State Board of Medicine.

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

(b) Terms of office.—The term of each professional and public member of the board shall be four years or until his or her successor has been appointed and qualified, but not longer than six months beyond the four-year period. In the event that any of said members shall die or resign or otherwise become disqualified during his or her term, a successor shall be appointed in the same way and with the same qualifications and shall hold office for the unexpired term. No member shall be eligible for appointment to serve more than two consecutive terms. The Governor shall assure that nurse midwives, physician assistants, certified registered nurse practitioners, *perfusionists* and respiratory care practitioners are appointed to four-year terms on a rotating basis so that, of every four appointments to a four-year term, one is a nurse midwife, one is a physician assistant, one is a certified registered nurse practitioner and one is a respiratory care practitioner.

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Section 3. The act is amended by adding a section to read:

Section 13.3. Perfusionist.

(a) *License required.*—*Two years after the effective date of this section, it shall be unlawful for any person to hold himself out to the public as a perfusionist or to practice or offer to practice perfusion unless the person holds a valid, current license issued by the board or the State Board of Osteopathic Medicine.*

(b) *Use of title.*—*A perfusionist who holds a valid, current license issued by either board may use the title perfusionist or licensed perfusionist or an appropriate abbreviation of the title, such as “LP.”*

(c) *Regulations.*—*The board is authorized to promulgate regulations to implement this section.*

(d) *Supervision and scope of practice.*—*A perfusionist may perform perfusion on an individual being treated by a physician licensed under this act or the act of October 5, 1978 (P.L.1109, No.261), known as the*

Osteopathic Medical Practice Act under medical supervision and approval consistent with standing orders or protocols of a hospital that are promulgated and approved by the physician designated as the medical director of the cardiovascular surgery program. These services shall include:

(1) *The use of extracorporeal circulation, long-term cardiopulmonary support techniques, including extracorporeal carbon dioxide removal, extracorporeal membrane oxygenation and associated therapeutic and diagnostic techniques.*

(2) *Counterpulsation, ventricular assistance, autotransfusion, blood and blood component conservation techniques, myocardial and organ preservation, extracorporeal life support and isolated limb perfusion.*

(3) *Blood and blood component management techniques, advanced life support and other related functions.*

(4) *In the performance of the acts described in paragraphs (1), (2) and (3):*

(i) *The administration of:*

(A) *Pharmacological and therapeutic agents.*

(B) *Blood products or anesthetic agents through the extracorporeal circuit or through an intravenous line in conjunction with extracorporeal support, under the supervision of the treating physician.*

(ii) *The performance and use of:*

(A) *Anticoagulation monitoring and analysis.*

(B) *Physiologic monitoring and analysis.*

(C) *Blood gas and chemistry monitoring and analysis.*

(D) *Hematologic monitoring and analysis.*

(E) *Hypothermia.*

(F) *Hyperthermia.*

(G) *Normothermia.*

(H) *Hemoconcentration and hemodilution.*

(I) *Hemodialysis in conjunction with perfusion service.*

(iii) *The observation of signs and symptoms related to perfusion services, the determination of whether the signs and symptoms exhibit abnormal characteristics and the implementation of appropriate reporting, perfusion protocols or changes in or the initiation of emergency procedures.*

(e) *Exemptions.—The following persons may perform perfusion, as indicated:*

(1) *A person licensed under any other section of this act or any other law of this Commonwealth while engaging in the practice for which the person is licensed.*

(2) *A student enrolled in an accredited perfusion education program if perfusion performed by the student:*

(i) *is an integral part of the student's course of study; and*

(ii) is performed under the direct supervision of a perfusionist who is assigned to supervise the student and who is on duty and immediately available in the assigned patient care area.

(3) A graduate of an accredited perfusion education program if perfusion services:

(i) are necessary to fulfill the eligibility requirements for a certification examination; and

(ii) are performed under the supervision and responsibility of a perfusionist who is on duty and assigned to supervise the graduate.

(4) A legally qualified person employed by the Federal Government to practice perfusion while in the discharge of the person's official duties.

(5) For a ventricular assist device under investigative trials by the United States Food and Drug Administration or approved by the United States Food and Drug Administration solely as a ventricular assist device, a person who:

(i) has satisfactorily completed specific ventricular assist device training in a course provided by the ventricular assist device manufacturer; and

(ii) provides care related to the ventricular assist device under the supervision of a licensed physician.

(6) A person who performs autotransfusion or blood conservation techniques under the supervision of a licensed physician.

(7) A person who:

(i) is trained according to the extracorporeal membrane oxygenation specialist guidelines of the Extracorporeal Life Support Organization; and

(ii) operates an extracorporeal membrane oxygenation circuit under the supervision of a licensed physician.

(f) **Qualifications.**—An applicant shall be licensed to practice perfusion under this act if the applicant meets all of the following qualifications and has otherwise complied with the provisions of this act:

(1) The person is at least 18 years of age.

(2) The person is of good moral character.

(3) The person has graduated from an accredited perfusion program approved by the board.

(4) The person is certified by a certifying agency approved by a nationally recognized accrediting agency approved by the board. The certification shall include an examination approved by the board.

(5) The person has completed an application form provided by the board and paid the appropriate fee.

(g) **Certain certified persons not graduates of accredited programs.**—Within two years of the effective date of this section, an applicant who was not a graduate of an accredited program prior to 1981, but met the then-current eligibility requirements for certification as a

certified clinical perfusionist and subsequently was certified, shall be licensed as a perfusionist if the applicant otherwise complies with the provisions of this act.

(h) Temporary graduate license to practice perfusion.—

(1) The board may issue a temporary graduate license to practice perfusion to an individual who has graduated from an educational program that complies with the education requirements of this act. All of the following shall apply:

(i) The individual has applied for the examination and is eligible to take the required examination.

(ii) The individual's authorization to practice perfusion is granted only under the supervision and direction of a perfusionist licensed under this act.

(iii) The license shall be issued for a period of two years and shall be nonrenewable.

(iv) The license shall expire immediately upon notice that the individual has failed the required examination under this act.

(2) (Reserved).

(i) Temporary provisional license to practice perfusion.—

(1) The board may issue a temporary provisional license to practice perfusion if all the following requirements are met:

(i) The individual holds a current license which is in good standing under the laws of another state, the District of Columbia or a territory of the United States, which includes certification by a certifying agency approved by a nationally recognized accrediting agency.

(ii) The individual meets the requirements as set forth in subsection (f)(1), (2) and (3).

(2) The license shall be issued for a period of one year and shall be nonrenewable.

(j) Temporary emergency exemption.—

(1) An individual who holds a current license as a perfusionist in another state, the District of Columbia or a territory of the United States or has obtained national certification may provide a one-time emergency perfusionist service in this Commonwealth without first obtaining a license from the board if:

(i) Prior to the out-of-State perfusionist performing the emergency perfusionist services in this Commonwealth, the out-of-State perfusionist submits by electronic means and on forms approved by the board, notification of emergency practice which shall include an acknowledgment that the out-of-State perfusionist is subject to the jurisdiction of the board in the same manner as if the out-of-State perfusionist were licensed by the board.

(ii) The health care facility licensed by the Department of Health certifies to the board, by electronic means and on forms approved by

the board, prior to the out-of-State perfusionist performing the emergency perfusionist services in this Commonwealth that all of the following apply:

(A) The emergency perfusionist services were provided for a patient of the health care facility.

(B) The perfusionist licensed by the board and retained by the health care facility that would normally perform the emergency perfusionist services was not available or incapable of providing the perfusionist services.

(C) No other perfusionist licensed by the board was available to provide or capable of providing the emergency perfusion service.

(D) The out-of-State perfusionist provided only the emergency perfusionist services for the patient of the health care facility and no other perfusionist services at the health care facility.

(2) The out-of-State perfusionist shall obtain a license from the board if a health care facility licensed by the Department of Health retains the perfusionist or if the perfusionist provides any future perfusionist services.

(3) The out-of-State perfusionist shall not perform any other perfusionist services other than the emergency perfusionist services.

(k) Professional liability.—

(1) A licensed perfusionist practicing in this Commonwealth shall maintain a level of professional liability insurance coverage in the minimum amount of \$1,000,000 per occurrence or claims made. Failure to maintain insurance coverage as required shall subject the licensee to disciplinary proceedings. The board shall accept from perfusionists as satisfactory evidence of insurance coverage any of the following:

(i) self-insurance;

(ii) personally purchased liability insurance; or

(iii) professional liability insurance coverage provided by the perfusionist's employer or similar insurance coverage acceptable to the board.

(2) A license applicant shall provide proof that the applicant has obtained professional liability insurance in accordance with paragraph (1). It is sufficient if the applicant files with the application a copy of a letter from the applicant's professional liability insurance carrier indicating that the applicant will be covered against professional liability in the required amounts effective upon the issuance of the applicant's license to practice perfusion in this Commonwealth. Upon issuance of the license, the licensee has 30 days to submit to the board the certificate of insurance or a copy of the policy declaration page.

(l) Licensure fees.—All application and licensure fees shall be set by the board by regulation.

(m) Reciprocal disciplinary action.—Disciplinary action taken by the State Board of Medicine against a perfusionist licensed by it shall be enforceable by the State Board of Osteopathic Medicine against that same individual if the individual holds or seeks a license to practice as a perfusionist with the State Board of Osteopathic Medicine.

(n) Continuing education.—

(1) The board shall adopt, promulgate and enforce rules and regulations consistent with the provisions of this act establishing requirements of continuing education to be met by individuals licensed as perfusionists under this act as a condition for renewal of their licenses. The regulations shall include any fees necessary for the board to carry out its responsibilities under this section.

(2) Beginning with the license period designated by regulation, licensees shall be required to attend and complete 30 hours of mandatory continuing education during each two-year license period. Nationally certified education courses shall be considered as creditable, in addition to any other courses the board deems creditable toward meeting the requirements for continuing education.

(3) An individual applying for the first time for licensure in this Commonwealth shall be exempted from the continuing education requirements for the biennial renewal period following initial licensure.

(4) (i) The board may waive all or a portion of the continuing education requirement for biennial renewal for a licensee who shows to the satisfaction of the board that the licensee was unable to complete the requirements due to serious illness, military service or other demonstrated hardship.

(ii) The request shall be made in writing with appropriate documentation and shall include a description of circumstances sufficient to show why the licensee is unable to comply with the continuing education requirement.

(5) A licensee seeking to reinstate an inactive or lapsed license shall show proof of compliance with the continuing education requirement for the preceding biennium.

(6) All courses, locations, instructors and providers shall be approved by the board. No credit shall be given for any course in office management.

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

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

APPROVED—The 11th day of June, A.D. 2008.

EDWARD G. RENDELL