

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

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] osteopathic
6 medicine 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, 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:

17 Section 13.3. Perfusionist.

18 (a) Two years after the effective date of this section, it
19 shall be unlawful for any person to hold himself out to the
20 public as a perfusionist or to practice or offer to practice
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

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.

- 1 (E) Hypothermia.
- 2 (F) Hyperthermia.
- 3 (G) Normothermia.
- 4 (H) Hemoconcentration and hemodilution.
- 5 (I) Hemodialysis in conjunction with perfusion
- 6 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 patient care area.

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

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

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 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

1 met:

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

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

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

11 (j) (1) An individual who holds a current license as a
12 perfusionist in another state, the District of Columbia or a
13 territory of the United States or has obtained national
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 Commonwealth, the out-of-State perfusionist submits by
20 electronic means and on forms approved by the board,
21 notification of emergency practice which shall include an
22 acknowledgment that the out-of-State perfusionist is
23 subject to the jurisdiction of the board in the same
24 manner as if the out-of-State perfusionist were licensed
25 by the board.

26 (ii) The health care facility licensed by the
27 Department of Health certifies to the board, by
28 electronic means and on forms approved by the board,
29 prior to the out-of-State perfusionist performing the
30 emergency perfusionist services in this Commonwealth that

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
6 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 of Error (Mcare) Act, but shall not be eligible to
29 participate in the Medical Care Availability and Reduction of
30 Error (Mcare) Fund. IN THE MINIMUM AMOUNT OF \$1,000,000 PER <—

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
6 LIABILITY INSURANCE, PROFESSIONAL LIABILITY INSURANCE
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
10 applicant has obtained professional liability insurance in
11 accordance with paragraph (1). It is sufficient if the
12 applicant files with the application a copy of a letter from
13 the applicant's professional liability insurance carrier
14 indicating that the applicant will be covered against
15 professional liability in the required amounts effective upon
16 the issuance of the applicant's license to practice perfusion
17 in this Commonwealth. Upon issuance of the license, the
18 licensee has 30 days to submit to the board the certificate
19 of insurance or a copy of the policy declaration page.

20 (1) All application and licensure fees shall be set by the
21 board by regulation.

22 (m) Disciplinary actions taken by the State Board of
23 Osteopathic Medicine against a perfusionist licensed by it shall
24 be enforceable by the State Board of Medicine against the same
25 individual if such individual holds or seeks a license to
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
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.

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

1 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
4 provisions of this act within 18 months of the effective date of
5 this section.

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