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2 "Extracorporeal circulation." The diversion of a patient's
3 blood through a heart-lung machine or similar device that
4 assumes the functions of the patient's heart, lung, kidney,
5 liver or other organs.

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7 "Perfusion." The functions necessary for the support,
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 supervision of a licensed physician.

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

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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 3(a) of the act, amended December 10,
25 2001 (P.L.859, No.92), is amended to read:

26 Section 3. State Board of Medicine.

27 (a) Establishment.--The State Board of Medicine shall
28 consist of the commissioner or his designee, the Secretary of
29 Health or his designee, two members appointed by the Governor
30 who shall be persons representing the public at large and seven

1 members appointed by the Governor, six of whom shall be medical
2 doctors with unrestricted licenses to practice medicine and
3 surgery in this Commonwealth for five years immediately
4 preceding their appointment and one who shall be a nurse
5 midwife, physician assistant, certified registered nurse
6 practitioner, respiratory care practitioner [or], certified
7 athletic trainer or perfusionist licensed or certified under the
8 laws of this Commonwealth. All professional and public members
9 of the board shall be appointed by the Governor, with the advice
10 and consent of a majority of the members elected to the Senate.

11 * * *

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

13 Section 13.3. Perfusionist.

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

20 (b) Use of title.--A perfusionist who holds a valid, current
21 license issued by either board may use the title perfusionist or
22 licensed perfusionist, or an appropriate abbreviation of the
23 title, such as "LP."

24 (c) Regulations.--The board is authorized to promulgate
25 regulations to implement this section.

26 (d) Supervision and scope of practice.--A perfusionist may
27 perform perfusion ~~to~~ ON an individual being treated by a ←
28 licensed physician under medical supervision and approval
29 consistent with standing orders or protocols of a hospital that
30 are promulgated and approved by the physician designated as the

1 medical director of the cardiovascular surgery program. These
2 services shall include:

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

7 (2) Counterpulsion, ventricular assistance,
8 autotransfusion, blood and blood component conservation
9 techniques, myocardial and organ preservation, extracorporeal
10 life support and isolated limb perfusion.

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

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

15 (i) The administration of:

16 (A) Pharmacological and therapeutic agents.

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

21 (ii) The performance and use of:

22 (A) Anticoagulation monitoring and analysis.

23 (B) Physiologic monitoring and analysis.

24 (C) Blood gas and chemistry monitoring and
25 analysis.

26 (D) Hematologic monitoring and analysis.

27 (E) Hypothermia.

28 (F) Hyperthermia.

29 (G) Normothermia.

30 (H) Hemoconcentration and hemodilution.

1 (I) Hemodialysis in conjunction with perfusion
2 service.

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

9 (e) Exemptions.--The following persons may perform
10 perfusion, as indicated:

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

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

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

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

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

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

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

29 (4) A legally qualified person employed by the Federal
30 Government to practice perfusion while in the discharge of

1 the person's official duties.

2 (5) FOR A VENTRICULAR ASSIST DEVICE UNDER INVESTIGATIVE ←
3 TRIALS BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION OR
4 APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION
5 SOLELY AS A VENTRICULAR ASSIST DEVICE, A PERSON WHO:

6 (I) HAS SATISFACTORILY COMPLETED SPECIFIC
7 VENTRICULAR ASSIST DEVICE TRAINING IN A COURSE PROVIDED
8 BY THE VENTRICULAR ASSIST DEVICE MANUFACTURER; AND

9 (II) PROVIDES CARE RELATED TO THE VENTRICULAR ASSIST
10 DEVICE UNDER THE SUPERVISION OF A LICENSED PHYSICIAN.

11 (6) A PERSON WHO PERFORMS AUTOTRANSFUSION OR BLOOD
12 CONSERVATION TECHNIQUES UNDER THE SUPERVISION OF A LICENSED
13 PHYSICIAN.

14 (7) A PERSON WHO:

15 (I) IS TRAINED ACCORDING TO THE EXTRACORPOREAL
16 MEMBRANE OXYGENATION SPECIALIST GUIDELINES OF THE
17 EXTRACORPOREAL LIFE SUPPORT ORGANIZATION; AND

18 (II) OPERATES AN EXTRACORPOREAL MEMBRANE OXYGENATION
19 CIRCUIT UNDER THE SUPERVISION OF A LICENSED PHYSICIAN.

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

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

25 (2) The person is of good moral character.

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

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

1 examination approved by the board.

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

4 (g) Certain certified persons not graduates of accredited
5 programs.--Within two years of the effective date of this
6 section, an applicant who was not a graduate of an accredited
7 program prior to 1981, but met the then-current eligibility
8 requirements for certification as a certified clinical
9 perfusionist and subsequently was certified, shall be licensed
10 as a perfusionist if the applicant otherwise complies with the
11 provisions of this act.

12 (h) Temporary graduate license to practice perfusion.--

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

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

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

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

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

27 (i) Temporary provisional license to practice perfusion.--

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

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

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

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

10 (j) Temporary emergency exemption.--

11 (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) Professional liability.--

24 (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 Fund. IN THE MINIMUM AMOUNT OF \$1,000,000 PER
 2 OCCURRENCE OR CLAIMS MADE. FAILURE TO MAINTAIN INSURANCE
 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:

- 7 (I) SELF-INSURANCE;
- 8 (II) PERSONALLY PURCHASED LIABILITY INSURANCE; OR
- 9 (III) PROFESSIONAL LIABILITY INSURANCE COVERAGE
 10 PROVIDED BY THE PERFUSIONIST'S EMPLOYER OR SIMILAR
 11 INSURANCE COVERAGE ACCEPTABLE TO THE BOARD.

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

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

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

1 (n) Continuing education.--

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

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

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

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

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

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

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

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

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