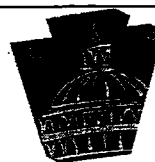


Regulatory Analysis Form

(Completed by Promulgating Agency)



IRRC

Independent Regulatory Review Commission

SECTION I: PROFILE

(1) Agency:

Department of State, Bureau of Professional and Occupational Affairs, State Board of Medicine

(2) Agency Number: 16A

Identification Number: 4931

IRRC Number:

2848

2011 SEP 12 AM 10:59

RECEIVED
IRRC

(3) Short Title:

Perfusionist

(4) PA Code Cite:

49 Pa. Code §§ 16.11, 16.13, 18.531 – 18.541

(5) Agency Contacts (List Telephone Number, Address, Fax Number and Email Address):

Primary Contact: David Green, Regulatory Unit Counsel, Department of State, 2601 North Third Street, Harrisburg, PA 17105; Phone Number: (717) 783-7200; Fax Number: (717) 787-0251; E-mail address: davgreen@state.pa.us

Secondary Contact: Cynthia Montgomery, Regulatory Counsel, Department of State, 2601 North Third Street, Harrisburg, PA 17105; Phone Number: (717) 783-7200; Fax Number: (717) 787-0251; E-mail address: cymontgome@state.pa.us

(6) Primary Contact for Public Comments (List Telephone Number, Address, Fax Number and Email Address) – Complete if different from #5:

(All Comments will appear on IRRC'S website)

(7) Type of Rulemaking (check applicable box):

X Final Regulation

Regulatory Analysis Form

(8) Briefly explain the regulation in clear and nontechnical language. (100 words or less)_____

The act of June 11, 2008 (P.L. 194, No. 19) (Act 19) amended the Medical Practice Act of 1985 (the act) (63 P.S. §§ 422.1 et seq.) to provide for licensure of perfusionists. This proposed rulemaking would implement licensing of perfusionists under Act 19.

(9) Include a schedule for review of the regulation including:

- A. The date by which the agency must have received public comments: **June 21, 2010**
- B. The date or dates on which public meetings or hearings were held: **September 23, 2008, November 25, 2008, February 24, 2009, April 28, 2009, August 24, 2010.**
- C. The expected date of promulgation of the proposed regulation as a final-form regulation: **Anticipated Fall 2010**
- D. The expected effective date of the final-form regulation **Upon publication as final-form rulemaking.**
- E. The date by which compliance with the final-form regulation will be required: **Upon publication as final-form rulemaking – Anticipated Fall of 2010.**
- F. The date by which required permits, licenses or other approvals must be obtained. **Not applicable.**

(10) Provide the schedule for continual review of the regulation.

The Board continuously reviews its regulations at its scheduled meetings.

SECTION II STATEMENT OF NEED

(11) State the statutory authority for the regulation. Include specific statutory citation.

This rulemaking is authorized by sections 8 and 13.3 of the Medical Practice Act of 1985 (act) (63 P.S. §§ 422.8 and 422.13c).

Regulatory Analysis Form

(12) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.

Yes, as explained in the response to question (8). The rulemaking is not mandated by any other federal or state law or court order or federal regulation.

(13) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

The proposed rulemaking is required to implement licensure of perfusionists as mandated by the Act 19 amendments to the act. The General Assembly recognized the benefits of perfusionist licensure in amending the act.

(14) If scientific data, studies, references are used to justify this regulation, please submit material with the regulatory package. Please provide full citation and/or links to internet source.

This rulemaking is not based upon any scientific data, studies, or references.

(15) Describe who and how many will be adversely affected by the regulation. How are they affected?

There are no perceived people or groups of people who would be adversely affected by this regulation.

(16) List the persons, groups or entities that will be required to comply with the regulation. Approximate the number of people who will be required to comply.

All persons practicing perfusion in this Commonwealth will be required to comply with the rulemaking. The Board estimates that up to 500 perfusionists will seek to become licensed during each biennial renewal cycle.

SECTION III: COST AND IMPACT ANALYSIS

(17) Provide a specific estimate of the costs and/or savings to the **regulated community** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

Persons currently practicing perfusion will experience an increase in costs due to the requirement to become licensed. The Board estimates that during each biennial renewal period 500 persons will apply for licensure to practice as perfusionist. The Board estimates that during each renewal cycle approximately 50 persons will apply for a temporary graduate license, and 25 persons will apply for a temporary provisional license. Additionally, the Board estimates that during each renewal cycle beginning January 1, 2011, approximately 500 licensees will renew their licenses and 50 persons will apply to reactivate an expired license. The amount of these fees to be paid to the Board are identified in the response to question 19. Persons seeking to practice will first apply for licensure in the first half of fiscal year 2010-11, which is the last quarter of the 2010-11 biennial renewal period, and they will be required to renew for the 2012-13 biennial renewal period. The Board also assumes an equal distribution of applications throughout each time period other than the initial startup, except that all persons who renew without having to reactivate the license will do so at the beginning of the period.

Based upon these assumptions and estimates and the fees discussed below, the Board anticipates licensure costs to licensees as shown in the table in response to question 20.

Initial license application fees of \$12,500 [$\$50 \times (\frac{1}{2} 500)$] in each fiscal year beginning 2010-11. Temporary graduate license application fees of \$1250 [$\$50 \times \frac{1}{2} 50$] in each fiscal year beginning 2010-11; and temporary provisional license application fees of \$500 [$\$40 \times \frac{1}{2} 25$] in each fiscal year beginning 2010-11. Renewal application fees of \$25,000 [$\50×500] in fiscal year 2012-13 and \$50,000 [$\$50 \times 1,000$] in fiscal year 2014-15. Reactivation application fees of \$1,250 [$\$50 \times \frac{1}{2} 50$] in in fiscal year 2013-2014 and in each subsequent fiscal year.

The Act 19 amendments to the act require the Board to implement licensure of perfusionists. The Board has drafted the proposed rulemaking to minimize the costs of licensure. Other than application fees to be charged by the Board, the Board cannot estimate the legal, accounting, consulting procedures or other costs associated with licensure.

(18) Provide a specific estimate of the costs and/or savings to **local governments** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

There are no costs or savings to local governments associated with compliance with the rulemaking.

Regulatory Analysis Form

(19) Provide a specific estimate of the costs and/or savings to **state government** associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.

The Board will charge a fee of \$50 to review an initial application for licensure and a fee of \$50 to reactivate an inactive license. The Board will also charge a fee of \$50 to review an application for a temporary graduate license and a fee of \$40 to review an application for a temporary provisional license. These fees have been calculated to recover the cost of the providing the service. Additionally, the Board will charge a renewal fee of \$50, which has been calculated to recover the proportionate cost of operating the Board. Because these fees will recover the cost of Board operations, there should be no net cost or savings to the Board associated with the implementation of the proposed rulemaking. There are no other costs or savings to state government associated with compliance with the rulemaking.

(20) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY 2010-11	FY +1 2011-12	FY +2 2012-13	FY +3 2013-14	FY +4 2014-15	FY +5 2015-16
SAVINGS:	\$	\$	\$	\$	\$	\$
Regulated Community						
Local Government						
State Government						
Total Savings						
COSTS:						
Regulated Community	\$14,250	\$14,250	\$39,250	\$15,500	\$65,500	\$15,500
Local Government						
State Government						
Total Costs	\$14,250	\$14,250	\$39,250	\$15,500	\$65,500	\$15,500
REVENUE LOSSES:						
Regulated Community						
Local Government						
State Government						
Total Revenue Losses						

Regulatory Analysis Form

(20a) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY -3 2007-2008	FY -2 2008-2009	FY -1 2009-2010	Current FY 2010-2011 (Budget)
State Board of Medicine	\$5,836,998.79	\$5,800,654.85	\$4,834,369.34	\$6,349,000.00

(21) Explain how the benefits of the regulation outweigh any cost and adverse effects.

The General Assembly concluded that the benefits of licensure would outweigh the anticipated costs. The Board drafted the proposed rulemaking to minimize the costs of required licensure. No adverse effects or costs other than necessary application fees have been associated with compliance with the rulemaking. Therefore, the above-identified benefits outweigh any costs.

(22) Describe the communications with and input from the public and any advisory council/group in the development and drafting of the regulation. List the specific persons and/or groups who were involved.

The Board provided an initial draft and discussed this proposed rulemaking at various public meetings of its health-related professions committee before approving a revised proposed rulemaking at a public meeting of the Board. Representatives of the perfusionist community participated in those committee meetings.

After publication of the proposed rulemaking, the Board received comments from the following: Tracy Sabella-Mineard; Raffaele Mirarchi, Chief Perfusionist of St. Christopher's Hospital (Mirarchi); and Michael Homishak, Department of Perfusion of St. Luke's Hospital (Homishak). In addition, the Board received comments from the Independent Regulatory Review Commission (IRRC) and the House Professional Licensure Committee (HPLC) in response to their review of the regulations under the Regulatory Review Act. Subsequently the Board corresponded and conferenced with representatives of the perfusionist community, including in-person at a meeting on August 24, 2010.

(23) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

No alternative regulatory schemes were considered.

Regulatory Analysis Form

(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulations.

This proposed rulemaking would not be more stringent and would not overlap or conflict with any federal requirements.

(25) How does this regulation compare with those of other states? How will this affect Pennsylvania's ability to compete with other states?

Perfusionists are not licensed in Delaware, Maryland, New York, Ohio or West Virginia. New Jersey licenses perfusionists on substantially the same standards as in the proposed rulemaking.

This proposed rulemaking would not put Pennsylvania at a competitive disadvantage.

(26) Will the regulation affect any other regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

This proposed rulemaking would not affect other regulations of the Board or other state agencies.

(27) Submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

Because this proposed rulemaking implements licensure for perfusionists, persons practicing perfusion will be required to obtain licensure by submitting appropriate applications. This proposed rulemaking would not require any legal, accounting or consulting procedures or any additional recordkeeping or other paperwork.

(28) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

The Board has determined that there are no special needs of any subset of its applicants or licensees for whom special accommodations should be made.

Regulatory Analysis Form

SUPPLEMENTAL PAGE VALID FOR USE THROUGH 11/1/2011

(Completed by Promulgating Agency)

RECEIVED
INDEPENDENT REGULATORY
REVIEW COMMISSION
201 SEP 12 A 10:59

(All Comments submitted on this regulation will appear on IRRC's website)

(1) Agency: **Department of State, Bureau of Professional and Occupational Affairs, State Board of Medicine**

(2) Agency Number: **16A**
Identification Number: **4931**

IRRC Number:

2848

(3) PA Code Cite: **49 Pa. Code §§ 16.11, 16.13, 18.531 – 18.541**

(4) Short Title: **Perfusionist**

(5) Agency Contacts (List Telephone Number and Email Address):

Primary Contact: **David Green, Regulatory Unit Counsel, Department of State, 2601 North Third Street, Harrisburg, PA 17104; Phone Number (717) 783-7200; Fax Number (717) 787-0251; E-mail address: davgreen@pa.gov**

Secondary Contact: **Cynthia Montgomery, Regulatory Counsel, Department of State, 2601 North Third Street, Harrisburg, PA 17104; Phone Number (717) 783-7200; Fax Number (717) 787-0251; E-mail address: cymontgome@pa.gov**

(6) Type of Rulemaking (check applicable box):

☐ Proposed Regulation

☒ Final Regulation

☐ Final Omitted Regulation

☐ Emergency Certification Regulation;

☐ Certification by the Governor

☐ Certification by the Attorney General

(7) If data is the basis for this regulation, please provide a description of the data, explain in detail how the data was obtained, and how it meets the acceptability standard for empirical, replicable and testable data that is supported by documentation, statistics, reports, studies or research. Please submit data or supporting materials with the regulatory package. If the material exceeds 50 pages, please provide it in a searchable electronic format or provide a list of citations and internet links that, where possible, can be accessed in a searchable format in lieu of the actual material. If other data was considered but not used, please explain why that data was determined not to be acceptable.

No data formed the basis for this regulation.

**FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU**

(Pursuant to Commonwealth Documents Law)

RECEIVED
IRRC

2011 SEP 12 A 10:59

DO NOT WRITE IN THIS SPACE

Copy below is hereby approved as to
form and legality. Attorney General

BY: _____
(DEPUTY ATTORNEY GENERAL)

Copy below is hereby certified to be a true and correct
copy of a document issued, prescribed or promulgated by:

STATE BOARD OF MEDICINE
(AGENCY)

DOCUMENT/FISCAL NOTE NO. 16A-4931

DATE OF ADOPTION: _____

BY: _____

Carol E. Rose, M.D.

TITLE: Chairperson
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

Copy below is approved as
to form and legality.
Executive or Independent
Agencies.

BY: _____

Andrew C. Clark

JUL 29 2011

DATE OF APPROVAL

Deputy General Counsel,
~~Chief Counsel,~~
Independent Agency
(Strike inapplicable title)

- [] Check if applicable
Copy not approved.
Objections attached.
[] Check if applicable.
No Attorney General approval
or objection within 30 day
after submission.

FINAL RULEMAKING

**COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF MEDICINE
49 PA. CODE, CHAPTERS 16 AND 18**

**GENERAL LICENSE, CERTIFICATION AND REGISTRATION PROVISIONS; PRACTITIONERS
OTHER THAN MEDICAL DOCTORS**

PERFUSIONISTS

The State Board of Medicine (Board) hereby amends §§ 16.11 and 16.13 (relating to licenses, certificates and registrations; and licensure, certification, examination and registration fees) adds §§ 18.531-18.541 (relating to perfusionists), to read as set forth in Annex A.

Effective date

The amendments are effective upon publication of the final-form rulemaking in the *Pennsylvania Bulletin*.

Statutory Authority

The amendments are authorized under sections 8 and 13.3 of the Medical Practice Act of 1985 (act) (63 P.S. §§ 422.8 and 422.13.3).

Background and Purpose

The act of June 11, 2008 (P.L. 154, No. 19) (Act 19) amended the Medical Practice Act of 1985 (act) to provide for licensure of perfusionists. Section 2 of the act defines the term “perfusion” as “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.” This rulemaking is intended to implement licensure of perfusionists under the act as amended by Act 19. Practice of perfusion in this Commonwealth without a license from the Board is prohibited after August 10, 2010. This rulemaking is also designed to provide to prospective licensees adequate notice of the requirements for licensure as a perfusionist.

Summary of Comments and Responses to Proposed Rulemaking

Notice of the proposed rulemaking was published at 40 Pa.B. 2652 (May 22, 2010). The Board received comments from the following: Tracy Sabella-Mineard; Raffaele Mirarchi, Chief Perfusionist of St. Christopher’s Hospital (Mirarchi); and Michael Homishak, Department of Perfusion of St. Luke’s Hospital (Homishak). In addition, the Board received comments from the Independent Regulatory Review Commission (IRRC) and the House Professional Licensure Committee (HPLC) in response to their review of the regulations under the Regulatory Review Act. Responses to the comments have been grouped under general categories, as follows:

General Comments.

Commentator Homishak correctly pointed the version of the preamble published in the *Pennsylvania Bulletin* in one instance read “profusion,” which has been corrected in the final rulemaking.

Commentator Mirarchi expressed concern with the number of perfusionists that are to be available per case. This commentator also expressed concern that the regulations, as he read them,

seem to provide that an individual other than a perfusionist may operate a ventricular assist device, or heart-lung machine to provide extracorporeal circulation services. These matters, however, are not specifically covered by the regulations, having been already set forth in detail in section 13.3(d) and (e) of the act (63 P.S. §§ 422.13c (d) and (e), pertaining to supervision and scope of practice; and exemptions.

HPLC and IRRC inquired about the publication of the proposed rulemaking in the May 22, 2010 *Pennsylvania Bulletin*, given that Act 19 provided that the Board “shall promulgate regulations to carry out the provisions of this act within 18 months of the effective date of this section.” HPLC and IRRC noted that the effective date of the act (Act 19 of 2008) was August 11, 2008, with the 18 months ending on February 11, 2010.

Act 19 (amending the Medical Practice Act) became law on the same date as Act 20 of 2008 (amending the Osteopathic Medical Practice Act relating to perfusionists). Both acts set forth the 18-month timetable for promulgation of regulations. The efforts at coordinating concurrent review of the regulations by the two separate Boards (one of which delegated initial review and comment to its health-related professions committee) of the various drafts, and review and approval of the resultant revisions itself took place over 14 months. Internal departmental and general counsel and attorney general reviews for publication followed. Following publication of the two sets of proposed regulations on May 22, 2010, the Boards have been engaged in a concerted effort to facilitate licensure of the perfusionists in compliance with the timeframe anticipated by section 13.3(a) of Act 19.

Section 13.3(a) of the act provides that “[t]wo 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.” HPLC and IRRC inquired as to how the Board could enforce this section in the event that final rulemaking did not occur before August 11, 2010 (2 years from the effective date of Act 19). The Board did not propose any rulemaking to incorporate the “grandfather” provision of section 13.3(g) of the act (63 P.S. § 422.13c(g)). That section provided that, during the first 2 years after the effective date of Act 19, a person who was not a graduate of an accredited program prior to 1981, but who met the then-current eligibility requirements for certification as a certified clinical perfusionist and subsequently was certified, could become licensed if the person otherwise complies with the requirements for licensure. This statutory provision is self-executing on this particular issue, and the qualifications for licensure set forth in the statute are clear and unambiguous.

In anticipation of the concerns of HPLC and IRRC, and mindful of the effective date, the Board developed an application for licensure, which was placed on the Board’s (and the Osteopathic Board’s) websites. With the cooperation of stakeholders, including the Pennsylvania State Perfusion Society and the American Society of ExtraCorporeal Technology (AMSECT), the Board notified the perfusionist community of the availability of the application process and the statutory deadline, as well as the availability of the application forms electronically and by mail. The Board has worked to facilitate and expedite the access and transmittal of documentation of certification, education and insurance coverage. The Board also agreed on this occasion to consider the date of filing of the

application as the controlling date, even if supporting documentation remained in transit. The application and license issuance procedure concluded with every applicant who was eligible under the “grandfather” provision, and was otherwise qualified for licensure, receiving a license.

Definitions.

During discussions concerning the implementation of the “grandfather” provision of the act, the Pennsylvania State Perfusion Society and the American Society of ExtraCorporeal Technology (AMSECT) pointed out that the Commission on Accreditation of Allied Health Education Programs (CAAHEP), as opposed to the American Board of Cardiovascular Perfusion (ABCP), is the agency that accredits perfusionist education programs nationally. The Board has added CAAHEP to its definitions and has identified CAAHEP within the definition of “Nationally-recognized accrediting agency approved by the Board” in § 18.532 (relating to definitions).

In addition, notwithstanding the statutory definition of the term “extracorporeal circulation,” these regulations are not to be interpreted as applicable to hemodialysis technicians acting within the scope of their profession.

Supervision.

IRRC suggested that § 18.534(a) (relating to application for temporary graduate perfusionist license) be amended to specify that the temporary graduate perfusionist may practice only under the supervision of a perfusionist licensed under the act. In implementing the suggestion, the Board has placed the statutory language of section 13.3(h)(1)(ii) of the act (63 P.S. § 422.13c(h)(1)(ii)) at the forefront of the regulation, which brings it greater clarity.

Application for temporary graduate perfusionist license.

HPLC and IRRC inquired as to how the Board will receive notice under § 18.534(e) that a temporary graduate perfusionist licensee has failed a certifying examination given by a Nationally-recognized certifying agency. The Board’s experience with another licensing group may be instructive. A temporary permit to practice as a respiratory care practitioner is valid for 12 months and expires if the holder fails the CRTT (Certification Examination for Entry Level Respiratory Therapy Practitioners). See §§ 18.302 and 18.306(b) (relating to definitions; and temporary permits). The Board routinely receives reports of test results directly from the NBRC (National Board for Respiratory Care), which is the credentialing body of respiratory care practitioners. The Board anticipates entering into an arrangement for receipt of the perfusionist test results directly from the Nationally-recognized certifying agency. If direct receipt of these results cannot be arranged with the certifying agency, the Board intends to include within the application an acknowledgement by the applicant that he or she authorizes the testing entity to release the results to the Board.

IRRC questioned the cross-reference to section 13.3(h)(1)(i) of the act as it appeared in § 18.534(b)(1). In its comment, IRRC correctly pointed out that the cross-reference was not broad enough. The Board intends to require the applicant for a temporary graduate perfusionist license to satisfy the several requirements included in section 13.3(h)(1) of the act in addition to the specific

requirements set forth in the regulation at § 18.534(b). Accordingly, the Board has made the requisite amendments to further clarify its intention. Because § 18.534 enumerates several of the general statutory requirements for licensure set forth in section 13.3(f) of the act, the Board also has added § 18.534(b)(iv) to incorporate the requirement that the applicant complete the application form made available by the board and pay the appropriate fee.

Application for temporary provisional perfusionist license.

IRRC noted in § 18.535(a) (relating to application for temporary provisional perfusionist license) that the phrase “temporary graduate perfusionist license” should be changed to “temporary provisional perfusionist license,” and the Board has made the corresponding change. HPLC pointed out that, in § 18.535(c), the word “certification” should be replaced with “licensure,” and the Board has made the corresponding change.

Temporary emergency perfusionist service.

IRRC expressed a concern that the Board’s use within § 18.536 (relating to registration of temporary emergency perfusionist service) of the statutory phrase “out-of-State perfusionist” might be misinterpreted to allow licensees from other countries to register to provide temporary emergency service. IRRC recommended replacing “out-of-State” with the phrase “another state, the District of Columbia or a territory of the United States,” which appears in the language of section 13.3(j)(1) of the act, and yields to “out of state” throughout the remainder of section 13.3(j)(1)(i) and (ii), (2) and (3). Neither “out-of-State” nor “out-of-State perfusionist” are defined in the act. To foreclose the misinterpretation of which IRRC is concerned, the Board has added a definition of “out-of-State perfusionist” to § 18.532 (relating to definitions) as “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 certification by a certifying agency approved by a Nationally-recognized accrediting agency.” Having defined this term at the outset of the regulations, the Board’s repeated use of the term “out-of-State perfusionist” throughout § 18.536 need not be replaced.

IRRC also suggested inclusion of the statutory provision that the application to provide temporary emergency perfusion service be submitted by “electronic means,” and that the regulation include its interpretation of how that submission would take place. In response, the Board looked to the analogous provisions in the State Board of Pharmacy’s regulations for electronic submissions at § 27.201 (relating to electronically submitted prescriptions). To that end, § 18.536(b) is amended to add submission “by electronic means, to include computer-to-computer, computer-to-facsimile machine, or e-mail transmission.” The act does not specify the means, electronic or otherwise, by which the Board will accept or reject those submissions. Given the emergency nature of the submission, and the possibility that the Board office may not be open for business during the time of the application or emergency procedure, a response from the Board might not occur prior to the provision of the perfusionist services.

IRRC also questioned the Board’s interpretation, in § 18.536(c) of the statutory provision of “a one-time emergency perfusionist service.” Section 13.3(j) of the act (63 P.S. § 422.13c(j))

provides an exemption to the general prohibition against unlicensed practice for one-time emergency perfusionist services by an out-of-state licensed perfusionist, subject to certain requirements and restrictions. The term “one-time emergency perfusionist services” is not defined in the act. Rather than defining that term in its regulations, the Board implements this provision by providing in § 18.536(c) that, “[a]lthough not limited to a single procedure or single patient or group of related patients, an out-of-state perfusionist may provide temporary emergency perfusionist services in this Commonwealth for not longer than a period of 72 hours.” The Board chose this method because it provides a bright-line rule and would be more applicable to the situations for which emergency services would be needed.

As to its selection of the 72-hour time limit, the Board believes that surgeons and health care facilities plan for groups of patients with procedures requiring perfusionist services, not necessarily a single patient with a single procedure. Should the planned perfusionist suddenly become unavailable, this would affect multiple patients and procedures, not just a single patient for a single procedure. An upper limit of 72 hours provides adequate time to perform those procedures that cannot wait and also to make alternative arrangements with one or more perfusionists licensed in this Commonwealth. The Board acknowledges that section 13.3(j)(1)(ii) of the act requires the healthcare facility to certify that “the emergency perfusionist services were provided for a patient of the health care facility,” and that 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.” The Board interprets this awkward language to limit perfusionist services to those that are emergencies as otherwise required in section 13.3(j) of the act, even if not for only a single patient.

Biennial Registration.

Commentator Sabell-Mineard commented that she opposes renewal on a biennial basis, as set forth in § 18.537 (relating to biennial registration of perfusionist license) because it does not coincide with the ABCP renewal and continuing education cycle. As indicated in the regulations, ABCP is American Board of Cardiovascular Perfusion, which is a Nationally-recognized certifying agency approved by the Board. Every profession regulated by the Department of State operates on a biennial renewal cycle. Every category of license issued by the Board is renewable on the same biennial cycle, ending December 31 of each even-numbered year. Given the relative ease of obtaining documentation of continuing education credits, and the 5-year record retention requirement of § 18.540(b)(2) (relating to continuing education for licensed perfusionists), the Board does not view the concerns raised by the commentator as an impediment to biennial compliance by the licensees. Further, in response to an inquiry by this commentator, § 18.540 (a)(1) provides that a licensee is not required to complete continuing education during the biennium in which the licensee was first licensed.

Disciplinary action

HPLC and IRRC suggested that the language in § 18.539(c)(2) (relating to discipline for licensed perfusionists) be amended in its reference to jurisdictional entities wherein a licensee may have been convicted of a crime, to include those of another country, the District of Columbia or a

territory of the United States. The Board has amended the regulation's language accordingly.

Continuing education.

HPLC and IRRC requested an explanation as to how continuing education other than category I credit hours are quantified. Section 13.3(n) of the act (63 P.S. § 422.13c(n)) requires a licensed perfusionist to complete 30 hours of mandatory continuing education during each biennial renewal period. As provided in proposed § 18.540(c) (relating to continuing education for licensed perfusionists), continuing education may be earned by, among other things, attendance or presentation at certain meetings, publication of appropriate articles or books, participation in certain workshops or forums, teaching, or certain self-directed study. The regulations at § 18.540(b)(1) have been amended to set forth the particular methods of acceptable proof for each category of continuing education.

HPLC and IRRC also asked whether “working as a clinical or didactic instructor in an accredited school of perfusion” should earn continuing education credit, and how many hours can be earned in this fashion. Section 18.540(c)(2)(vi) provides that category II continuing education credits may be earned by teaching, since it involves preparation work similar to the other types of category II continuing education activities. Instructors still will need to fulfill 10 hours of category I as provided in § 18.540(c)(1). The Board has implemented the suggested substitution of “earned” for “earning” in § 18.540(c)(2) to enhance the regulation's clarity. Also, the Board has identified ABCP as the approving entity for continuing education perfusionist programs, as opposed to CAAHEP, which is the nationally recognized accrediting agency for perfusionist degree programs.

HPLC and IRRC questioned why the regulations contain no provision for the carry-over of surplus continuing education credits into the next biennial registration period. No such provision is among the Board's continuing education regulations for medical doctors, respiratory care practitioners or athletic trainers. In addition, section 13.3(n)(2) of the act provides that “licensees shall be required to attend and complete 30 hours of mandatory continuing education during each 2-year licensure period.”

Professional liability insurance coverage.

Section 18.533(b)(2) states that an applicant for a license to practice as a perfusionist must provide proof that the applicant has obtained professional liability insurance as required by section 13.3(k) of the act. This same requirement applies to applicants for a temporary graduate perfusionist license under § 18.534(b)(2) and applicants for a temporary provisional perfusionist license under § 18.535(b)(2).

Commentator Homishak expressed concern over the requirement in § 13.3(k)(2) of the act that an applicant provide proof that he has obtained liability insurance. Perfusionist liability insurance is generally provided as part of employment with a hospital. Homishak commented that a perfusionist who separates from employment with a hospital would no longer hold current individual perfusionist liability insurance, thereby jeopardizing licensure. Homshak expressed concern that a

perfusionist would need to obtain individual liability coverage at significant expense in order to obtain or maintain licensure. Similar concerns were articulated by others who submitted comments after the close of the public comment period. In addition, the Pennsylvania State Perfusion Society and the American Society of ExtraCorporeal Technology (AMSECT) raised this issue during discussions with the Board concerning the implementation of the “grandfather” provision of the act.

Section 13.3(k) of the act (63 P.S. § 422.13c(k)) requires professional liability insurance for perfusionists, and § 18.541(a) requires a licensed perfusionist to maintain a level of professional liability insurance as required by section 13.3(k) of the act. Conversely, § 18.541(d) prohibits a perfusionist who does not have the required amount of liability insurance from practicing as a perfusionist in this Commonwealth. Section 13.3(k)(2) of the act requires an applicant to provide proof that the applicant has obtained the liability insurance. Section 18.541(b) sets forth the general requirement that proof of liability insurance consists of a certificate of insurance or a copy of the declarations page from the insurance policy setting forth the effective and expiration dates and the dollar amounts of coverage.

Section 13.3(k)(2) permits an applicant to file with the application a letter from an insurance carrier stating that the applicant will be covered in the required amounts effective upon issuance of the license, but the applicant must then submit the certificate of insurance or copy of the declaration page within 30 days after issuance of the license. In order to effectuate this provision, § 18.541(c) provides that a license issued in reliance upon the insurance carrier’s letter will become inactive as a matter of law 30 days after the license is issued if the licensee has not submitted proof of insurance. The license will be inactivated and not suspended, because it is not a disciplinary action, as insurance is required only if practicing as a perfusionist in this Commonwealth.

Section 13.3(k)(1) of the act sets forth the types of insurance that are acceptable. These include self-insurance, personally purchased liability insurance, or coverage provided by the perfusionist’s employer “or similar insurance coverage acceptable to the board.” As a practical matter, most if not all practicing perfusionists at any given moment are hospital employees, and therefore will be covered by the employer’s professional liability insurance. To the extent that compliance with the regulation might require a perfusionist applicant or licensee to self-insure or personally pay for insurance, the Board is bound by the statutory language.

Fiscal Impact and Paperwork Requirements

The amendments will have no adverse fiscal impact on the Commonwealth or its political subdivisions. Perfusionists who wish to become licensed to practice in this Commonwealth will bear the fiscal impact of the rulemaking in the form of required fees and costs associated with obtaining the required continuing education. The Board will be required to develop forms required to implement the proposed rulemaking. The amendments will impose no additional paperwork requirements upon the Commonwealth, political subdivisions or the private sector.

Sunset Date

The Board continuously monitors the effectiveness of its regulations. Therefore, no sunset

date has been assigned.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on May 11, 2010, the Board submitted a copy of the proposed rulemaking, published at 40 Pa.B. 2652 and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC), and the Chairpersons of the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) and the House Professional Licensure Committee (HPLC) for review and comment.

Under section 5(c) of the Regulatory Review Act (71 P.S. § 745.5(c)), IRRC, the SCP/PLC and the HPLC were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing for the final-form rulemaking, the Board has considered all comments from the IRRC, the HPLC and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P.S. § 745.5a(j.2)), on _____, _____, the final-form rulemaking was approved by the HPLC. On _____, _____, the final-form rulemaking was deemed approved by SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on _____ and approved the final-form rulemaking.

Contact Person

Interested persons may obtain information regarding the final-form rulemaking by writing to Steven Dade or David Green, Board Counsel, State Board of Medicine, P.O. Box 2649, Harrisburg, PA 17105-2649, or by e-mail at sdade@state.pa.us or davgreen@state.pa.us.

Findings

The Board finds that:

- (1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§1201 and 1202) and the regulations promulgated thereunder, 1 Pa. Code §§7.1 and 7.2 (relating to notice of proposed rulemaking required; and adoption of regulations).
- (2) A public comment period was provided as required by law and all comments were considered.
- (3) The amendments to the final-form rulemaking do not enlarge the purpose of the proposed rulemaking published at 40 Pa. B. 2652.
- (4) This final-form rulemaking is necessary and appropriate for administration and enforcement of the authorizing acts identified in this Preamble.

Order

The Board orders that:

- (a) The Regulations of the Board at 49 Pa. Code Chapters 16 and 18 are amended by amending §§ 16.11 and 16.13 and by adding §§ 18.531-18.541 (relating to perfusionists) to read as set forth in Annex A.
- (b) The Board shall submit this order and Annex A to the Office of General Counsel and to the Office of Attorney General as required by law.
- (c) The Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.
- (d) This order shall take effect on publication in the Pennsylvania Bulletin.

Carol E. Rose, MD
Chairperson

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 16. STATE BOARD OF MEDICINE—

GENERAL PROVISIONS

* * * * *

**Subchapter B. GENERAL LICENSE, CERTIFICATION AND
REGISTRATION PROVISIONS**

§ 16.11. Licenses, certificates and registrations.

* * * * *

(b) The following nonmedical doctor licenses and certificates are issued by the Board:

* * * * *

(6) Perfusionist license.

(c) The following registrations are issued by the Board:

* * * * *

(10) Biennial registration of a perfusionist license.

* * * * *

§ 16.13. Licensure, certification, examination and registration fees.

* * * * *

(k) Perfusionist license.

Application for perfusionist license\$ 50

<u>Biennial renewal of perfusionist license</u>	<u>\$ 50</u>
<u>Application for reactivation of perfusionist license</u>	<u>\$ 50</u>
<u>Application for temporary graduate perfusionist license</u>	<u>\$ 50</u>
<u>Application for temporary provisional perfusionist license</u>	<u>\$ 40</u>

* * * * *

CHAPTER 18. STATE BOARD OF MEDICINE—PRACTITIONERS

OTHER THAN MEDICAL DOCTORS

* * * * *

Subchapter J. PERFUSIONISTS

§ 18.531. Purpose.

This subchapter implements section 13.3 of the act (63 P.S. § 422.13c) pertaining to perfusionists, which was added by the act of June 11, 2008 (P.L. 154, No. 19), effective August 10, 2008.

§ 18.532. Definitions.

The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise:

ABCP – American Board of Cardiovascular Perfusion.

Accredited perfusion program approved by the Board – A perfusion program accredited by a Nationally-recognized accrediting agency approved by the Board.

Board – The State Board of Medicine.

CAAHEP – COMMISSION ON ACCREDITATION OF ALLIED HEALTH EDUCATION PROGRAMS.

Extracorporeal circulation – As defined in section 2 of the act (63 P.S. § 422.2), 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.

Hour of continuing education – At least 50 minutes of instruction (including relevant question and answer sessions) in an approved course of continuing education or an equivalent time that an on-line or correspondence course would be presented live.

Nationally-recognized accrediting agency approved by the Board – ABCP, CAAHEP, or any other organization for which the Board publishes notice that the organization is approved by the Board as an accrediting agency for perfusionist programs.

Nationally-recognized certifying agency approved by the Board – ABCP, or any other organization for which the Board publishes notice that the organization is approved by the Board as a certifying agency for perfusionists.

OUT-OF-STATE PERFUSIONIST – 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 CERTIFICATION BY A CERTIFYING AGENCY APPROVED BY A NATIONALLY-RECOGNIZED ACCREDITING AGENCY.

Perfusion – As defined in section 2 of the act, 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 the act or the Osteopathic Medical Practice Act (63 P.S. §§ 271.1 – 271.18).

Perfusionist – As defined in section 2 of the act, an individual who is licensed to practice perfusion by the Board or the State Board of Osteopathic Medicine.

Ventricular assist device –

(i) As defined in section 2 of the act, 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.

(ii) The term includes a device that is placed intravascularly or extravascularly and provides support through direct means or via counterpulsation.

§ 18.533. Application for perfusionist license.

(a) An applicant for a license to practice as a perfusionist shall submit, on forms ~~supplied~~ MADE AVAILABLE by the Board, a completed application, including all necessary supporting documents, for license to practice as a perfusionist and pay the fee set forth in § 16.13(k) (relating to licensure, certification, examination and registration fees) for application for perfusionist license.

(b) Except as otherwise provided in subsection (c), the Board will license to practice as a perfusionist an applicant who:

(1) Demonstrates that the applicant satisfies the requirements of section 13.3(f) of the act (63 P.S. § 422.13c(f)) for licensure to practice as a perfusionist, including the following:

(i) The applicant holds a current certification by a certifying agency approved by a Nationally-recognized accrediting agency approved by the Board.

(ii) The applicant has graduated from an accredited perfusion program approved by the Board.

(iii) The applicant is at least 18 years of age and of good moral character.

(2) Provides proof as set forth in § 18.541 (relating to professional liability insurance coverage for licensed perfusionist) that the applicant has obtained professional liability insurance as required under section 13.3(k) of the act.

(3) Otherwise complies with this subchapter.

(c) The Board may deny an application for licensure as a perfusionist upon the grounds for disciplinary action set forth in § 18.539 (relating to disciplinary action for licensed perfusionist).

§ 18.534. Application for temporary graduate perfusionist license.

(a) An applicant for a temporary graduate perfusionist license TO PRACTICE PERFUSION ONLY UNDER THE SUPERVISION OF A PERFUSIONIST LICENSED UNDER THE ACT shall submit, on forms supplied MADE AVAILABLE by the Board, a completed application, including all necessary supporting documents, and pay the fee in § 16.13(k) (relating to licensure, certification, examination and registration fees) for application for temporary graduate perfusionist license.

(b) Except as otherwise provided in subsection (c), the Board will grant a temporary graduate perfusionist license to an applicant who:

(1) Demonstrates that the applicant satisfies the requirements of section 13.3(h)(1)(i) of the act (63 P.S. § 422.13c(h)(1)(i)) for temporary graduate licensure to practice as a perfusionist, including IN ADDITION TO all of the following:

(i) The applicant is qualified and has applied to sit for the examination of a certifying agency approved by a Nationally-recognized accrediting agency

approved by the Board.

(ii) The applicant has graduated from an accredited perfusion program approved by the Board.

(iii) The applicant is at least 18 years of age and of good moral character.

(2) Provides proof as set forth in § 18.541 (relating to professional liability insurance coverage for licensed perfusionist) that the applicant has obtained professional liability insurance as required by section 13.3(k) of the act (63 P.S. § 422.13c(k)).

(3) Otherwise complies with this subchapter.

(c) The Board may deny an application for temporary graduate perfusionist license upon the grounds for disciplinary action set forth in § 18.539 (relating to disciplinary action for licensed perfusionist).

(d) A temporary graduate perfusionist license will expire 2 years after the date of issuance and may not be renewed.

(e) A temporary graduate perfusionist license will expire upon notice to the Board that the holder has failed the Nationally-recognized certifying agency's certification examination.

§ 18.535. Application for temporary provisional perfusionist license.

(a) An applicant for a temporary provisional perfusionist license shall submit, on forms supplied MADE AVAILABLE by the Board, a completed application, including all necessary supporting documents, and pay the fee set forth in § 16.13(k) (relating to licensure, certification, examination and registration fees) for application for temporary ~~graduate~~ PROVISIONAL perfusionist license.

(b) Except as otherwise provided in subsection (c), the Board will grant a temporary provisional perfusionist license to an applicant who:

(1) Demonstrates that the applicant satisfies the requirements of section 13.3(i) of the act (63 P.S. § 422.13c(i)) for temporary provisional licensure to practice as a perfusionist, including the following:

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

(ii) The applicant has graduated from an accredited perfusion program approved by the Board.

(iii) The applicant is at least 18 years of age and of good moral character.

(2) Provides proof as set forth in § 18.541 (relating to professional liability insurance coverage for licensed perfusionist) that the applicant has obtained professional liability insurance as required by section 13.3(k) of the act.

(3) Otherwise complies with this subchapter.

(c) The Board may deny an application for ~~certification~~ LICENSURE as a perfusionist upon the grounds for disciplinary action set forth in § 18.539 (relating to disciplinary action for licensed perfusionist).

(d) A temporary provisional perfusionist license will expire 1 year after the date of issuance and may not be renewed.

§ 18.536. Registration of temporary emergency perfusionist service.

(a) An out-of-State perfusionist shall register with the Board in accordance with this section prior to providing temporary emergency perfusionist service in this Commonwealth in accordance with section 13.3(j) of the act (63 P.S. § 422.13c(j)).

(b) The out-of-State perfusionist or another person acting on behalf of the out-of-State perfusionist shall submit, BY ELECTRONIC MEANS, TO INCLUDE COMPUTER-TO-COMPUTER, COMPUTER-TO-FACSIMILE MACHINE OR E-MAIL TRANSMISSION, AND on forms supplied MADE AVAILABLE by the Board, a completed registration form, fully answering all questions.

(c) Although not limited to a single procedure or single patient or group of related patients, an out-of-State perfusionist may provide temporary emergency perfusionist services in this Commonwealth for not longer than a period of 72 hours.

(d) An out-of-State perfusionist may not provide temporary emergency perfusionist service in this Commonwealth more than once without being licensed in accordance with §§ 18.533, 18534 or 18535 (relating to application for perfusionist license; application for temporary graduate perfusionist license; and application for temporary provisional perfusionist license).

§ 18.537. Biennial registration of perfusionist license.

(a) A licensed perfusionist shall register biennially by December 31 of each even-numbered year, in accordance with § 16.15 (relating to biennial registration; inactive status and unregistered status).

(b) A licensee applying for biennial registration of a perfusionist license shall submit a completed application, including payment of the biennial registration fee set forth in § 16.13(k)

(relating to licensure, certification, examination and registration fees) for application for biennial registration of perfusionist license. On the biennial registration application, the licensed perfusionist shall:

(1) Disclose any license to practice as a perfusionist in another state, territory, possession, or country.

(2) Disclose any disciplinary action pending before or taken by the appropriate healthcare licensing authority in any other jurisdiction since the most recent application for biennial registration, whether or not licensed to practice in that other jurisdiction.

(3) Disclose any pending criminal charges and any finding or verdict of guilt, admission of guilt, plea of *nolo contendere*, probation without verdict, disposition in lieu of ~~trial~~ TRIAL or accelerated rehabilitative disposition in any criminal matter since the most recent application for biennial registration.

(4) Verify that the licensed perfusionist has complied with the continuing education requirements mandated by section 13.3(n) of the act (63 P.S. § 422.13c(n)) during the biennial period immediately preceding the period for which registration is sought in accordance with § 18.540 (relating to continuing education for licensed perfusionists).

(5) Verify that, if practicing as a perfusionist in this Commonwealth, the licensee maintains professional liability insurance coverage in accordance with section 13 3(k) of the act.

§ 18.538. Inactive status of perfusionist license; reactivation of inactive license.

(a) A perfusionist license will become inactive upon either of the following:

(1) The licensee requests in writing THAT the Board to place the license on inactive status. Written confirmation of inactive status will be forwarded to the licensee.

(2) The licensee fails to register the license by the expiration of the biennial registration period, that is, by December 31 of each even-numbered year.

(b) A perfusionist whose license has expired or been placed on inactive status may not practice as a perfusionist in this Commonwealth until the license has been reactivated.

(c) To reactivate an inactive license, the licensee shall apply on forms supplied MADE AVAILABLE by the Board, answering all questions fully. The licensee shall:

(1) Include the documentation required under § 18.540(b) (relating to continuing education for licensed perfusionist) for the immediately preceding biennium, which may be completed during the current biennium. Unless waived by the Board under section 13.3(n)(4) of the act (63 P.S. § 422.13c(n)(4)), the Board will not reactivate any license until the required continuing education for the preceding biennium has been successfully completed.

(2) Pay the current biennial registration fee and the reactivation application fee specified in § 16.13(k) (relating to licensure, certification, examination and registration fees).

(3) Except as provided in subsection (d), verify that the licensee did not practice as a perfusionist in this Commonwealth while the license was inactive.

(d) A licensee who has practiced with an inactive license, and who cannot make the verification required by subsection (c)(3) shall also pay the fees required by this subsection. Payment of a late fee does not preclude the Board from taking disciplinary action for practicing as a perfusionist without a currently registered license.

(1) A licensee whose license was active at the end of the immediately preceding biennial registration period and who practiced after the license became inactive shall pay a late fee of \$5 for each month or part of a month from the beginning of the current biennium until the date the reactivation application is filed.

(2) A licensee whose license has been inactive since before the beginning of the current biennium shall pay the biennial registration fee for each biennial registration period during which the licensee practiced and shall pay a late fee of \$5 for each month or part of a month from the first date the licensee practiced as a perfusionist in this Commonwealth after the license became inactive until the date the reactivation application is filed.

§ 18.539. Disciplinary action for licensed perfusionists.

(a) A licensed perfusionist, including a perfusionist holding a temporary graduate license or a temporary provisional license, is subject to disciplinary action under the grounds of section 41 of the act (63 P.S. § 422.41). Following a final determination subject to the right of notice, hearing and adjudication and the right of appeal therefrom in accordance with 2 Pa.C.S. (relating to administrative law and procedure), the Board may impose any of the corrective actions of section 42 of the act (63 P.S. § 422.42).

(b) Unprofessional conduct includes:

(1) Engaging in any conduct prohibited under § 16.110 (relating to sexual misconduct).

(2) Performing acts in a healthcare profession in a fraudulent, incompetent or negligent manner.

(3) Performing acts in the practice of a healthcare profession in violation of a

statute or regulation in this Commonwealth, ~~another state of the~~ United States, OR ANOTHER STATE, THE DISTRICT OF COLUMBIA, A TERRITORY OF THE UNITED STATES, or another country.

(4) Violating a provision of the act or this chapter setting a standard of professional conduct.

(5) Engaging in healthcare practice beyond the licensee's authority to practice.

(6) Representing oneself to be a physician, physician assistant, certified registered nurse practitioner or other healthcare practitioner whose profession the perfusionist is not licensed to practice.

(7) Practicing while the licensee's ability to do so is impaired by alcohol, drugs, physical disability or mental instability.

(8) Revealing personally identifiable facts obtained as the result of a practitioner-patient relationship without the prior consent of the patient, except as authorized or required by statute or regulation.

(9) Failing to provide supervision as required by section 13.3(e)(2) of the act (63 P.S. § 422.13c(e)(2)) of a perfusion student or failing to provide supervision as required by section 13.3(e)(3) of the act of a perfusion graduate who is not otherwise licensed by the Board to perform perfusion in this Commonwealth.

(c) Immoral conduct includes:

(1) Misrepresenting or concealing a material fact in obtaining a license issued by the Board or renewal, reactivation or reinstatement thereof.

(2) Being convicted of a crime involving moral turpitude, dishonesty or

corruption in the courts of this Commonwealth, the United States, or another state, territory or county THE DISTRICT OF COLUMBIA, A TERRITORY OF THE UNITED STATES, OR ANOTHER COUNTRY.

(3) Committing an act involving moral turpitude, dishonesty or corruption.

§ 18.540. Continuing education for licensed perfusionists.

(a) Credit hour requirements. A licensed perfusionist shall satisfy the following continuing education credit hour requirements.

(1) During each biennial registration period, a licensee shall complete 30 hours of continuing education applicable to the practice of perfusion, including at least 10 hours of category I continuing education. A licensee is not required to complete continuing education during the biennium in which the licensee was first licensed.

(2) Except as permitted in § 18.538(c)(1) (relating to inactive status of perfusionist license; reactivation of inactive license), paragraph (4), or as directed by the Board, continuing education may satisfy the requirement of paragraph (1) only for the biennium during which it was completed. No hour of continuing education may be used to satisfy the requirement of paragraph (1) for more than one biennium.

(3) Unless otherwise excused by the act or this subchapter, failure to complete the minimum required amount of continuing education during the applicable biennial registration period as required by section 13.3(n) of the act (63 P.S. § 422.13c(n)) and this section will subject the licensee to discipline under section 41(6) of the act (63 P.S. § 422.41(6)).

(4) A licensee seeking waiver of the continuing education requirements under section 13.3(n)(4) of the act (63 P.S. § 422.13c(n)(4)) shall submit the request with all

supporting documentation to the Board at least 90 days prior to end of the biennial registration period for which waiver is sought. Waiver may include extending the deadline by which the required continuing education must be completed.

(b) Documentation of continuing education. Continuing education shall be documented in the following manner.

(1) Proof of completion of continuing education COURSES OR PROGRAMS OR ATTENDANCE AT AN ABCP-APPROVED PERFUSION MEETING must consist of a certified record issued by the provider, including:

- (i) The name of the participant.
- (ii) The name of the provider.
- (iii) The date or dates of the course.
- (iv) The name of the course.
- (v) The number of hours of continuing education credit.

(2) PROOF OF PROFESSIONAL WRITING MUST CONSIST OF A COMPLETE REFERENCE TO THE BOOK OR ARTICLE, INCLUDING AUTHORS, TITLE, JOURNAL AND DATE/VOLUME OF JOURNAL.

(3) PROOF OF PARTICIPATION IN THE PRESENTATION OF A PROGRAM AT AN INTERNATIONAL, NATIONAL, REGIONAL OR STATE ABCP-APPROVED PERFUSION MEETING MUST CONSIST OF A COPY OF THE PROGRAM AGENDA.

(4) PROOF OF COMPLETION OF A SELF-DIRECTED CONTINUING EDUCATION PROGRAM MUST CONSIST OF AN OFFICIAL DOCUMENT FROM THE SPONSOR DOCUMENTING SUCCESSFUL COMPLETION OF THE POST-

TEST ON ABCP-APPROVED MATERIAL AND THE NUMBER OF CONTINUING EDUCATION HOURS AWARDED.

(5) PROOF OF COMPLETION OF SELF-STUDY ACTIVITIES NOT APPROVED FOR CATEGORY I CREDIT MUST CONSIST OF AN OFFICIAL RECORD OF COMPLETION OR WRITTEN SUMMARY OF THE ACTIVITY.

(6) PROOF OF PARTICIPATION AS A CLINICAL OR DIDACTIC INSTRUCTOR IN AN ACCREDITED PROGRAM SHALL CONSIST OF A LETTER OF CONFIRMATION OF THE INSTRUCTOR'S STATUS FROM THE PROGRAM DIRECTOR AND, FOR DIDACTIC INSTRUCTORS, DOCUMENTATION OF THE DIDACTIC INSTRUCTOR'S COURSE TITLE AND CONTACT HOURS.

(7) A licensee shall retain proof of completion of continuing education for 5 years after completion of the continuing education or after the completion of the biennial registration period for which the continuing education was required, whichever is later.

~~(3)~~ (8) The Board will audit licensees to verify compliance with continuing education requirements.

~~(c)~~ Continuing education activities. Credit for continuing education may be earned in the following activities.

(1) Category I continuing education may be earned by:

(i) Attendance at an international, national, regional or state perfusion meeting.

(ii) Publication of a perfusion-related book, chapter or paper in a professional journal.

(iii) Presentation at an international, national, regional, state or local

perfusion meeting.

(iv) Participation in a site visitors workshop or as a site visitor for perfusion program accreditation.

(v) Completion of ABCP-approved self-directed continuing education for which the licensee scored at least 80% on an examination.

(2) In addition to category I, continuing education may also be ~~earning~~

EARNED by:

(i) Reading or viewing medical journals, audio-visual, or other educational materials.

(ii) Participation in electronic forums.

(iii) Participation in a journal club.

(iv) Participation in degree-oriented, professionally-related course work.

(v) Presentation of A perfusion topic at a non-perfusion meeting.

(vi) Working as a clinical or didactic instructor in an accredited school of perfusion.

(3) Continuing education credit may not be earned in any course in office management.

§ 18.541. Professional liability insurance coverage for licensed perfusionist.

(a) A licensed perfusionist shall maintain a level of professional liability insurance coverage as required by section 13.3(k) of the act (63 P.S. § 422.13c(k)).

(b) Proof of professional liability insurance coverage shall consist of a certificate of insurance or copy of the declaration page from the insurance policy setting forth the effective

date, expiration date, and dollar amounts of coverage.

(c) A license that was issued in reliance upon a letter from the applicant's insurance carrier indicating that the applicant will be covered against professional liability effective upon the issuance of the applicant's license as permitted under section 13.3(k)(2) of the act will become inactive as a matter of law 30 days after the date of issuance on the license if the licensee has not provided proof of professional liability insurance coverage and will remain inactive until the licensee provides proof of insurance coverage.

(d) A licensee who does not have professional liability insurance coverage as required by section 13.3(k) of the act may not practice as a perfusionist in this Commonwealth.

Agent state—A state in which an individual files a claim for benefits from another state.

Benefits—Compensation payable to an individual with respect to the individual's unemployment, under the unemployment insurance law of a state.

Interstate Benefit Payment Plan—The plan approved by the National Association of State Workforce Agencies, under which benefits are payable to unemployed individuals absent from the state in which benefit credits have been accumulated.

Interstate claimant—

(i) An individual who claims benefits under the unemployment insurance law of one or more liable states through the facilities of an agent state.

(ii) The term does not include an individual who customarily commutes from a residence in an agent state to work in a liable state unless the Department finds that this exclusion would create undue hardship on the claimants in specified areas.

Liable state—A state against which an individual files, through another state, a claim for benefits.

State—The term includes Puerto Rico, the Virgin Islands and the District of Columbia.

Week of unemployment—Any week of unemployment as defined in the law of the liable state from which benefits with respect to the week are claimed.

Subchapter H. ALLOWANCES FOR DEPENDENTS

§ 65.156. Reserve accounts of employers.

(a) [Allowances for dependents are not chargeable to the reserve accounts of employers.

(b)] If a reserve account for an employer subject to this act is not authorized or not required to be maintained under criteria established in the law, allowances for dependents shall be subject to a reimbursement as follows:

* * * * *

(2) The Unemployment Compensation Fund [will] shall be reimbursed for dependent's allowance paid as a result of service in the employ of a reimbursable nonprofit organization as defined under section 1101 of the law (43 P.S. § 901). Charges will be made to the employer's account in accordance with section 1108 of the law (43 P.S. § 908). Reimbursement will be made in accordance with section 1106 of the law (43 P.S. § 906).

(3) The Unemployment Compensation Fund shall be reimbursed for dependent's allowance paid as a result of service in the employ of a reimbursable instrumentality or political subdivision of this Commonwealth as defined under section 1201 of the law (43 P.S. § 911). Charges will be made to the employer's account in accordance with section 1203 of the law (43 P.S. § 913). Reimbursement shall be made in accordance with section 1202.4 of the law (43 P.S. § 912.4).

(4) The Unemployment Compensation Fund [will] shall be reimbursed based upon the percent of charge for dependent's allowance paid on a combined wage claim. The transferring state's reimbursement shall be in accordance with arrangements entered into under section 312 of the law (43 P.S. § 792).

[Pa.B. Doc. No. 10-937 Filed for public inspection May 21, 2010, 9:00 a.m.]

STATE BOARD OF MEDICINE

[49 PA. CODE CHS. 16 AND 18-]

Perfusionist

The State Board of Medicine (Board) proposes to amend §§ 16.11 and 16.13 (relating to licenses, certificates and registrations; and licensure, certification, examination and registration fees) and to add Subchapter J (relating to perfusionists) to read as set forth in Annex A.

Effective Date

The proposed rulemaking will be effective upon final-form publication in the *Pennsylvania Bulletin*.

Statutory Authority

The proposed rulemaking is authorized under sections 8 and 13.3 of the Medical Practice Act of 1985 (act) (63 P.S. §§ 422.8 and 422.13c).

Background and Need for the Proposed Rulemaking

The act of June 11, 2008 (P.L. 154, No. 19) (Act 19) amended the act to provide for licensure of perfusionists. Section 2 of the act (63 P.S. § 422.2) now defines the term "perfusion" as "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. . . ." This proposed rulemaking is intended to implement licensure of perfusionists under the act as amended by Act 19. Practice of perfusion in this Commonwealth without a license from the Board will be prohibited after August 10, 2010. This proposed rulemaking is also designed to provide to prospective licensees adequate notice of the requirements for licensure as a perfusionist.

Description of the Proposed Rulemaking

The Board's current regulation in § 16.11(b) identifies licenses that the Board issues. The proposed rulemaking adds licensure as a perfusionist. Similarly, § 16.11(c) identifies registrations that the Board issues and the proposed rulemaking adds biennial registration of perfusionist licenses. The proposed rulemaking also adds § 16.13(k) setting forth the fees associated with perfusionist licensure to be charged by the Board, as authorized under section 13.3(l) of the act. To recover the costs of providing those services, the fee for applications for perfusionist license, reactivation of perfusionist license and temporary graduate perfusionist license would each be \$50 and the fee for application for temporary provisional perfusionist license would be \$40. Because the Board believes that the cost to provide the service would be minimal and does not want to delay application, the Board has not set any fee for notification of emergency

practice as a perfusionist. To provide for an appropriate share of the general costs of operating the Board, the biennial renewal fee for a perfusionist would be \$50.

The proposed rulemaking amends Chapter 18 by adding Subchapter J. Proposed § 18.531 (relating to purpose) identifies the purpose of the subchapter as providing for licensure of perfusionists. Proposed § 18.532 (relating to definitions) provides necessary definitions. These include the statutory definitions of "extracorporeal circulation," "perfusion," "perfusionist" and "ventricular assist device" as are used in the subchapter. Additionally, the Board defines "ABCP" as the American Board of Cardiovascular Perfusion (ABCP), the National body that both accredits perfusion education programs and certifies perfusionists. The Board proposes to define "accredited perfusion program approved by the Board" as a perfusion program accredited by a Nationally-recognized accrediting agency approved by the Board. The Board would further define "Nationally-recognized accrediting agency approved by the Board" as the ABCP or another organization for which the Board publishes notice that the organization is approved by the Board as an accrediting agency for perfusionist programs. The Board also defines "Nationally-recognized certifying agency approved by the Board" as the ABCP or another organization for which the Board publishes notice that the organization is approved by the Board as a certifying agency for perfusionists. Finally, the Board proposes to define an "hour of continuing education" to consist of at least 50 minutes of instruction (including question and answer sessions) in an approved course of continuing education or an equivalent time that an on-line or correspondence course would be presented live. This time is consistent with the standards for continuing education that is required by the ABCP for recertification.

Under proposed § 18.533(a) (relating to application for perfusionist license), an applicant shall submit a completed application form, including necessary supporting documents, and pay the required application fee. Section 13.3(f) of the act sets five criteria for licensure as a perfusionist: The applicant must be at least 18 years of age, be of good moral character, have graduated from an accredited perfusion program approved by the Board and be certified by a certifying agency approved by a Nationally-recognized accrediting agency approved by the Board. Accordingly, proposed § 18.533(b)(1) provides that the Board will license as a perfusionist an applicant who demonstrates that the applicant satisfies the requirements of section 13.3(f) of the act for licensure as a perfusionist. Because section 13.3(k) of the act requires a perfusionist to carry a minimum level of professional liability insurance, proposed § 18.533(b)(2) requires that an applicant provide proof of liability insurance. Because, as discussed as follows, the Board is also setting forth in this proposed rulemaking grounds for disciplinary action, proposed § 18.533(c) would provide that the Board may, in its discretion, deny an application for perfusionist licensure upon those grounds for disciplinary action in § 18.539 (relating to disciplinary action for licensed perfusionists).

The Board has not proposed a rulemaking to incorporate the grandfather provision of section 13.3(g) of the act, which, during the first 2 years after the effective date of Act 20, permits a person who was not a graduate of an accredited program prior to 1981, but who met the then-current eligibility requirements for certification as a certified clinical perfusionist and subsequently was certified, to become licensed if the person otherwise complies with the requirements for licensure. Not only is this

statutory provision self-executing, but the opportunity to take advantage of it will expire August 10, 2010, not long after final promulgation of the rulemaking.

Proposed § 18.534 (relating to application for temporary graduate perfusionist license) addresses the application for temporary graduate perfusionist license, as provided in section 13.3(h) of the act. Under proposed § 18.534(a), an applicant shall submit a completed application form, including necessary supporting documents, and pay the required application fee. Section 13.3(h)(1)(i) of the act provides that an individual who has graduated from an educational program in compliance with the education requirements and is eligible for and has applied for the examination may receive a temporary graduate license. These criteria, along with good moral character and being at least 18 years of age, would be in proposed § 18.534(b)(1) as the basic requirements for a temporary graduate license. Because section 13.3(k) of the act requires a perfusionist to carry a minimum level of professional liability insurance, proposed § 18.534(b)(2) requires that an applicant provide proof of liability insurance. Because, as discussed as follows, the Board is also setting forth in this proposed rulemaking grounds for disciplinary action, proposed § 18.534(c) provides that the Board may, in its discretion, deny an application for temporary graduate perfusionist license upon those grounds for disciplinary action in § 18.539. Because section 13.3(h)(1)(iii) of the act provides that a temporary graduate license is to be issued for 2 years but not be renewable, proposed § 18.534(d) provides that a temporary graduate perfusionist license will expire 2 years after the date of issuance and may not be renewed. Because section 13.3(h)(1)(iv) of the act provides that a temporary graduate license is to expire upon notice of failing the required examination, proposed § 18.534(e) provides that a temporary graduate perfusionist license will expire upon notice to the Board that the holder failed the Nationally-recognized certifying agency's certification examination.

Proposed § 18.535 (relating to application for temporary provisional perfusionist license) would address the application for temporary provisional perfusionist license, as provided under section 13.3(i) of the act. Under proposed § 18.535(a), an applicant must submit a completed application form, including necessary supporting documents, and pay the required application fee. Section 13.3(i)(1) of the act provides that an individual who holds a current license in good standing under the laws of another state, which includes certification by a certifying agency approved by a Nationally-recognized accrediting agency, may receive a temporary provisional license if the applicant meets the requirements of section 13.3(f) of the act that the applicant is at least 18 years of age and of good moral character and has graduated from an accredited perfusion program approved by the Board. These criteria are in proposed § 18.535(b)(1) as the basic requirements for a temporary provisional license. Because section 13.3(k) of the act requires a perfusionist to carry a minimum level of professional liability insurance, proposed § 18.535(b)(2) would require that an applicant provide proof of liability insurance. Because, as discussed as follows, the Board is also setting forth in this proposed rulemaking grounds for disciplinary action, proposed § 18.535(c) provides that the Board may, in its discretion, deny an application for perfusionist temporary provisional license upon those grounds for disciplinary action in § 18.539. Because section 13.3(i)(2) of the act provides that a temporary provisional license is to be issued for 1 year but not be renewable, proposed § 18.535(d) provides

that a temporary provisional perfusionist license will expire 1 year after the date of issuance and may not be renewed thereafter.

Section 13.3(j) of the act provides an exemption to the general prohibition against unlicensed practice for one-time temporary emergency services by an out-of-State licensed perfusionist when the licensed perfusionist that would normally have provided the services is unavailable or incapable of providing services and no other licensed perfusionist is available or capable of providing services. Section 13.3(j) of the act requires the out-of-State perfusionist to provide to the Board electronic notice of the emergency and acknowledgment that the out-of-State perfusionist is subject to jurisdiction of the Board as if licensed by the Board and requires the healthcare facility to provide to the Board electronic notice that services were provided and the grounds for the exemption. Proposed § 18.536(a) (relating to registration of temporary emergency perfusionist service) requires the out-of-State perfusionist to register with the Board in accordance with section 13.3(j) of the act prior to providing emergency services. Under proposed § 18.536(b), the out-of-State perfusionist or other person acting on behalf of the out-of-State perfusionist (such as healthcare facility staff) shall submit a completed registration on forms provided by the Board. It is anticipated that this registration will be done almost exclusively from the Board's web site. Because "one-time emergency perfusionist service" is not defined in section 13.3(j) of the act, proposed § 18.536(c) provides that although the services are not limited to a single procedure or patient or group of related patients, the out-of-State perfusionist may not provide emergency services for a period longer than 72 hours. However, section 13.3(j)(3) of the act prohibits the out-of-State perfusionist from providing services other than emergency services. Consistent with section 13.3(j)(2) of the act, proposed § 18.536(d) provides that the out-of-State perfusionist may not provide further perfusionist service in this Commonwealth without being licensed as a perfusionist or holding a temporary graduate license or temporary provisional license.

Because licenses issued by the Board must be registered biennially as a condition of continued practice in accordance with § 16.15 (relating to biennial registration; inactive status and unregistered status), proposed § 18.537 (relating to biennial registration of perfusionist licenses) addresses biennial registration of perfusionist licenses. Proposed § 18.537(a) provides that licensed perfusionists shall register biennially by December 31 of each even-numbered year. Under proposed § 18.537(b), a licensed perfusionist is required to complete and submit an application for biennial registration, including the required fee, disclose a license to practice as a perfusionist in another jurisdiction, disclose a disciplinary action pending before or taken by the appropriate healthcare licensing authority in another state, disclose pending criminal charges and convictions, verify that the licensee has complied with the continuing education requirements, and verify that, if practicing as a perfusionist in this Commonwealth, the licensed perfusionist maintains professional liability insurance coverage as required under section 13.3(k) of the act. Because the ABCP requires a perfusionist to complete a minimum number of procedures each year to maintain certification, the Board has chosen not to require continued National certification as a condition of renewal.

Proposed § 18.538 (relating to inactive status of perfusionist license; reactivation of inactive license) addresses inactive status of perfusionist licenses. Proposed

§ 18.538(a) provides that the license may become inactive either by the licensee's request or by expiration at the end of the biennial registration period. To minimize the opportunity or consequence of a license being incorrectly placed on inactive status at what appears to be the request of the licensee, proposed § 18.538(a)(1) provides that the Board will forward written confirmation of inactive status to the licensee. Proposed § 18.538(b) provides that a perfusionist whose license is inactive may not practice as a perfusionist in this Commonwealth until the license has been reactivated. Proposed § 18.538(c) provides the general requirement for reactivation of an inactive perfusionist license that the licensee shall apply on forms supplied by the Board, answer questions fully, provide documentation of completion of the required amount of continuing education for the preceding biennium, as required under section 13.3(n)(5) of the act, pay the current biennial registration fee and the reactivation fee specified in § 16.13(k) and verify that the licensee did not practice as a perfusionist in this Commonwealth while the license was inactive. If the licensee cannot verify that the licensee did not practice during the period of lapse, the license may be reactivated under proposed § 18.538(d). Under that proposed section, in addition to the requirements of subsection (c), the licensee shall pay the biennial registration fee for past registration periods and a late fee of \$5 per month. This late fee is the standard late fee of section 225 of the Bureau of Professional and Occupational Affairs Fee Act (63 P. S. § 1401-225). However, as provided in proposed § 18.538(d), payment of late fees will not preclude the Board from taking disciplinary action for practicing while the license was inactive.

Proposed § 18.539 next addresses disciplinary action. Although section 13.3 of the act does not specifically authorize the Board to take disciplinary action against a licensed perfusionist, section 13.3(m) of the act provides that disciplinary action taken by the Board against a perfusionist shall be enforceable by the State Board of Osteopathic Medicine if the perfusionist seeks licensure by that board. Section 41 of the act (63 P. S. § 422.41) authorizes the Board "to impose disciplinary or corrective measures on a board-regulated practitioner" for a variety of grounds. Accordingly, proposed § 18.539(a) provides that a licensed perfusionist, including one holding a temporary graduate license or temporary provisional license, is subject to disciplinary action under the grounds of section 41 of the act and that the Board may impose a corrective action in section 42 of the act (63 P. S. § 422.42). Because section 41(8) of the act authorizes the Board to take disciplinary action for immoral or unprofessional conduct, proposed § 18.539(b) defines unprofessional conduct and proposed § 18.539(c) defines immoral conduct. Modeled upon §§ 16.61 and 18.181 (relating to unprofessional and immoral conduct, and disciplinary and corrective measures), unprofessional conduct includes the following: performing acts in a healthcare profession in a fraudulent or incompetent or negligent manner; performing acts in the practice of a healthcare profession in violation of statute or regulation in this Commonwealth or another state; violating a provision of the act or regulation of the Board setting a standard of professional conduct; engaging in healthcare practice beyond the licensee's authority to practice; representing oneself to be a licensed physician or other healthcare provider; practicing while the licensee's ability to do so is impaired by alcohol or drugs or disability; and revealing personally identifiable facts obtained as the result of the practitioner-patient relationship. Immoral conduct includes the following: misrepresenting or concealing a

material fact in obtaining a license or reactivating or renewing the biennial registration of the license; being convicted of a crime involving moral turpitude; or committing an act involving moral turpitude or dishonesty or corruption. Additionally, unprofessional conduct includes engaging in conduct prohibited under § 16.110 (relating to sexual misconduct). Section 13.3(e)(2) of the act exempts from the general prohibition against practicing perfusion without a license a perfusion student who, among other requirements, is performing under the direct supervision of a perfusionist who is assigned to supervise the student. Section 13.3(e)(3) of the act exempts a perfusion graduate who, among other requirements, is performing under the supervision and responsibility of a perfusionist. Accordingly, proposed § 18.539(b)(9) includes as unprofessional conduct failing to provide supervision as required under section 13.3(e)(2) of the act of a perfusion student or failing to provide supervision as required under section 13.3(e)(3) of the act of a perfusion graduate who is not otherwise licensed by the Board to practice perfusion.

Section 13.3(n) of the act provides for required continuing education and proposed § 18.540 (relating to continuing education for licensed perfusionists) addresses that topic. Proposed § 18.540(a) sets forth the general credit hour requirements. As required under section 13.3(n)(2) of the act, proposed § 18.540(a)(1) requires each licensed perfusionist to complete at least 30 hours of continuing education—including at least 10 hours in category I continuing education—applicable to the practice of perfusion during each biennial registration period. Consistent with section 13.3(n)(3) of the act, a licensee would not be required to complete continuing education during the biennial registration period in which the licensee was first licensed. Although a licensee would not be permitted to carry over continuing education credit into a subsequent renewal period, proposed § 18.540(a)(2) recognizes that a licensee may need to make up deficient continuing education credit to reactivate an inactive license or if otherwise ordered by the Board. However, a particular hour of continuing education taken in a given biennial registration period may not be used to satisfy the requirement both for that period and to make up a deficiency for a prior period. Proposed § 18.540(a)(3) identifies that a licensee who failed to complete the required continuing education is subject to disciplinary action. Section 13.3(n)(4) of the act permits a licensee to submit a written request for waiver of the continuing education requirement due to serious illness, military service or other demonstrated hardship. Proposed § 18.540(a)(4) requires that the request be submitted at least 90 days before the end of the biennial registration period so that the Board could address the request and, if it is denied, give the licensee adequate opportunity to complete the required continuing education before the end of the period. Additionally, this proposed section explicitly notes that waiver may include extending the deadline, rather than simply relieving the licensee of the obligation to take continuing education. Proposed § 18.540(b) sets forth the standards for documentation of continuing education. Under proposed § 18.540(b)(1), a licensee shall receive a record of completion from the continuing education provider, setting forth the participant's name, the provider's name, the date of the course, the name of the course and the number of hours of continuing education. Proposed § 18.540(b)(2) requires the licensee to retain the record for at least 5 years after completion of the continuing education course or biennial registration period for which the continuing education was required, whichever is later. Because records of continuing education will not be sent

to the Board and the Board will not track licensees' completion of required continuing education, the Board will conduct postrenewal audits of licensees to verify compliance. Proposed § 18.540(c) sets forth the types of activities for which continuing education credit may be earned. To better facilitate compliance with the requirements, these standards are modeled upon those of the ABCP. Under proposed § 18.540(c)(1), category I continuing education (which must provide at least 10 of the required 30 hours) could be earned by attendance at perfusion meetings, publication of a perfusion-related book, chapter or paper in a professional journal, presentation at a perfusion meeting, participation in a site visitor workshop or as a site visitor for perfusion program accreditation or completion of an ABCP-approved self-directed continuing education course for which the licensee scores at least 80% on an examination. Under proposed § 18.540(c)(2), other continuing education to reach the required total could be earned by reading journals or other educational materials, participating in electronic forums or journal clubs, participation in degree-oriented professional-related course work, presentation of perfusion topics at a nonperfusion meeting or working as a clinical or didactic instructor in an accredited school of perfusion. However, as noted in section 13.3(n)(6) of the act, proposed § 18.540(c)(3) prohibits continuing education credit for a course in office management.

Section 13.3(k) of the act provides for required professional liability insurance for perfusionists and proposed § 18.541(a) (relating to professional liability insurance coverage for licensed perfusionist) requires a licensed perfusionist to maintain a level of professional liability insurance as required under section 13.3(k) of the act. Conversely, proposed § 18.541(d) prohibits a perfusionist who does not have the required amount of liability insurance from practicing as a perfusionist in this Commonwealth. Section 13.3(k)(2) of the act requires an applicant to provide proof that the applicant has obtained the liability insurance. Proposed § 18.541(b) sets forth the general requirement that proof of liability insurance consists of a certificate of insurance or a copy of the declarations page from the insurance policy setting forth the effective and expiration dates and the dollar amounts of coverage. However, section 13.3(k)(2) of the act permits an applicant to file with the application a letter from an insurance carrier stating that the applicant will be covered in the required amounts effective upon issuance of the license, but the applicant must then submit the certificate of insurance or copy of the declaration page within 30 days after issuance of the license. To effectuate this provision, proposed § 18.541(c) provides that a license issued in reliance upon the insurance carrier's letter will become inactive as a matter of law 30 days after the license is issued if the licensee has not submitted proof of insurance. The license will be inactivated and not suspended, because it is not a disciplinary action, as insurance is required only if practicing as a perfusionist in this Commonwealth.

Fiscal Impact and Paperwork Requirements

The proposed rulemaking will not have adverse fiscal impact on the Commonwealth or its political subdivisions. Perfusionists who wish to become licensed to practice in this Commonwealth will bear the fiscal impact of the proposed rulemaking in the form of required fees and costs associated with obtaining the required continuing education. The Board will be required to develop forms required to implement the proposed rulemaking. The

proposed rulemaking will impose no additional paperwork requirements upon the Commonwealth, political subdivisions or the private sector.

Sunset Date

The Board continuously monitors the effectiveness of its regulations. Therefore, no sunset date has been assigned.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on May 11, 2010, the Board submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Senate Consumer Protection and Professional Licensure Committee and the House Professional Licensure Committee. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey comments, recommendations or objections to the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections must specify the regulatory review criteria which have not been met. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the rulemaking, by the Board, the General Assembly and the Governor of comments, recommendations or objections raised.

Public Comment

Interested persons are invited to submit written comments, suggestions or objections regarding this proposed rulemaking to the Regulatory Unit Counsel, Department of State, P. O. Box 2649, Harrisburg, PA 17105-2649, st-medicine@state.pa.us within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*. Reference No. 16A-4931 (perfusionist) when submitting comments

CAROL E. ROSE, M.D.,
Chairperson

Fiscal Note: 16A-4931. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 16. STATE BOARD OF MEDICINE—GENERAL PROVISIONS

Subchapter B. GENERAL LICENSE, CERTIFICATION AND REGISTRATION PROVISIONS

§ 16.11. Licenses, certificates and registrations.

* * * * *

(b) The following nonmedical doctor licenses and certificates are issued by the Board:

* * * * *

(6) Perfusionist license.

(c) The following registrations are issued by the Board:

* * * * *

(10) Biennial registration of a perfusionist license.

§ 16.13. Licensure, certification, examination and registration fees.

* * * * *

(k) Perfusionist license.

Application for perfusionist license \$50

Biennial renewal of perfusionist license \$50

Application for reactivation of perfusionist license \$50

Application for temporary graduate perfusionist license \$50

Application for temporary provisional perfusionist license \$40

CHAPTER 18. STATE BOARD OF MEDICINE—PRACTITIONERS OTHER THAN MEDICAL DOCTORS

(Editor's Note: The following subchapter is new and printed in regular type to enhance readability.)

Subchapter J. PERFUSIONISTS

Sec.	Purpose.
18.531.	Purpose.
18.532.	Definitions.
18.533.	Application for perfusionist license.
18.534.	Application for temporary graduate perfusionist license.
18.535.	Application for temporary provisional perfusionist license.
18.536.	Registration of temporary emergency perfusionist service.
18.537.	Biennial registration of perfusionist license.
18.538.	Inactive status of perfusionist license; reactivation of inactive license.
18.539.	Disciplinary action for licensed perfusionists.
18.540.	Continuing education for licensed perfusionists.
18.541.	Professional liability insurance coverage for licensed perfusionist.

§ 18.531. Purpose.

This subchapter implements section 13.3 of the act (63 P. S. § 422.13c) pertaining to perfusionists, which was added by the act of June 11, 2008 (P. L. 154, No. 19), effective August 10, 2008.

§ 18.532. Definitions.

The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise:

ABCP—American Board of Cardiovascular Perfusion.

Board—The State Board of Medicine.

Accredited perfusion program approved by the Board—A perfusion program accredited by a Nationally-recognized accrediting agency approved by the Board.

Extracorporeal circulation—As defined in section 2 of the act (63 P. S. § 422.2), 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.

Hour of continuing education—At least 50 minutes of instruction (including relevant question and answer sessions) in an approved course of continuing education or an equivalent time that an on-line or correspondence course would be presented live.

Nationally-recognized accrediting agency approved by the Board—ABCP, or any other organization for which the Board publishes notice that the organization is approved by the Board as an accrediting agency for perfusionist programs.

Nationally-recognized certifying agency approved by the Board—ABCP, or any other organization for which the

Board publishes notice that the organization is approved by the Board as a certifying agency for perfusionists.

Perfusion—As defined in section 2 of the act, 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 the act or the Osteopathic Medical Practice Act (63 P.S. §§ 271.1—271.18).

Perfusionist—As defined in section 2 of the act, an individual who is licensed to practice perfusion by the Board or the State Board of Osteopathic Medicine.

Ventricular assist device—

(i) As defined in section 2 of the act, 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.

(ii) The term includes a device that is placed intravascularly or extravascularly and provides support through direct means or via counterpulsation.

§ 18.533. Application for perfusionist license.

(a) An applicant for a license to practice as a perfusionist shall submit, on forms supplied by the Board, a completed application, including all necessary supporting documents, for license to practice as a perfusionist and pay the fee set forth in § 16.13(k) (relating to licensure, certification, examination and registration fees) for application for a perfusionist license.

(b) Except as otherwise provided in subsection (c), the Board will license to practice as a perfusionist an applicant who:

(1) Demonstrates that the applicant satisfies the requirements of section 13.3(f) of the act (63 P.S. § 422.13c(f)) for licensure to practice as a perfusionist, including the following:

(i) The applicant holds a current certification by a certifying agency approved by a Nationally-recognized accrediting agency approved by the Board.

(ii) The applicant has graduated from an accredited perfusion program approved by the Board.

(iii) The applicant is at least 18 years of age and of good moral character.

(2) Provides proof as set forth in § 18.541 (relating to professional liability insurance coverage for licensed perfusionist) that the applicant has obtained professional liability insurance as required under section 13.3(k) of the act.

(3) Otherwise complies with this subchapter.

(c) The Board may deny an application for licensure as a perfusionist upon the grounds for disciplinary action set forth in § 18.539 (relating to disciplinary action for licensed perfusionists).

§ 18.534. Application for temporary graduate perfusionist license.

(a) An applicant for a temporary graduate perfusionist license shall submit, on forms supplied by the Board, a completed application, including all necessary supporting documents, and pay the fee in § 16.13(k) (relating to

licensure, certification, examination and registration fees) for application for a temporary graduate perfusionist license.

(b) Except as otherwise provided in subsection (c), the Board will grant a temporary graduate perfusionist license to an applicant who:

(1) Demonstrates that the applicant satisfies the requirements of section 13.3(h)(1)(i) of the act (63 P.S. § 422.13c(h)(1)(i)) for temporary graduate licensure to practice as a perfusionist, including all of the following:

(i) The applicant is qualified and has applied to sit for the examination of a certifying agency approved by a Nationally-recognized accrediting agency approved by the Board.

(ii) The applicant has graduated from an accredited perfusion program approved by the Board.

(iii) The applicant is at least 18 years of age and of good moral character.

(2) Provides proof as set forth in § 18.541 (relating to professional liability insurance coverage for licensed perfusionist) that the applicant has obtained professional liability insurance as required under section 13.3(k) of the act.

(3) Otherwise complies with this subchapter.

(c) The Board may deny an application for a temporary graduate perfusionist license upon the grounds for disciplinary action set forth in § 18.539 (relating to disciplinary action for licensed perfusionists).

(d) A temporary graduate perfusionist license will expire 2 years after the date of issuance and may not be renewed.

(e) A temporary graduate perfusionist license will expire upon notice to the Board that the holder has failed the Nationally-recognized certifying agency's certification examination.

§ 18.535. Application for temporary provisional perfusionist license.

(a) An applicant for a temporary provisional perfusionist license shall submit, on forms supplied by the Board, a completed application, including all necessary supporting documents, and pay the fee in § 16.13(k) (relating to licensure, certification, examination and registration fees) for application for a temporary graduate perfusionist license.

(b) Except as otherwise provided in subsection (c), the Board will grant a temporary provisional perfusionist license to an applicant who:

(1) Demonstrates that the applicant satisfies the requirements of section 13.3(i) of the act (63 P.S. § 422.13c(i)) for temporary provisional licensure to practice as a perfusionist, including the following:

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

(ii) The applicant has graduated from an accredited perfusion program approved by the Board.

(iii) The applicant is at least 18 years of age and of good moral character.

(2) Provides proof as set forth in § 18.541 (relating to professional liability insurance coverage for licensed

perfusionist) that the applicant has obtained professional liability insurance as required under section 13.3(k) of the act.

(3) Otherwise complies with this subchapter.

(c) The Board may deny an application for certification as a perfusionist upon the grounds for disciplinary action set forth in § 18.539 (relating to disciplinary action for licensed perfusionists).

(d) A temporary provisional perfusionist license will expire 1 year after the date of issuance and may not be renewed.

§ 18.536. Registration of temporary emergency perfusionist service.

(a) An out-of-State perfusionist shall register with the Board in accordance with this section prior to providing temporary emergency perfusionist service in this Commonwealth in accordance with section 13.3(j) of the act (63 P. S. § 422.13c(j)).

(b) The out-of-State perfusionist or another person acting on behalf of the out-of-State perfusionist shall submit, on forms supplied by the Board, a completed registration form, fully answering all questions.

(c) Although not limited to a single procedure or single patient or group of related patients, an out-of-State perfusionist may provide temporary emergency perfusionist services in this Commonwealth for not longer than a period of 72 hours.

(d) An out-of-State perfusionist may not provide temporary emergency perfusionist service in this Commonwealth more than once without being licensed in accordance with § 18.533, § 18.534 or § 18.535 (relating to application for perfusionist license; application for temporary graduate perfusionist license; and application for temporary provisional perfusionist license).

§ 18.537. Biennial registration of perfusionist license.

(a) A licensed perfusionist shall register biennially by December 31 of each even-numbered year, in accordance with § 16.15 (relating to biennial registration; inactive status and unregistered status).

(b) A licensee applying for biennial registration of a perfusionist license shall submit a completed application, including payment of the biennial registration fee set forth in § 16.13(k) (relating to licensure, certification, examination and registration fees) for application for biennial registration of perfusionist license. On the biennial registration application, the licensed perfusionist shall:

(1) Disclose any license to practice as a perfusionist in another state, territory, possession, or country.

(2) Disclose any disciplinary action pending before or taken by the appropriate healthcare licensing authority in any other jurisdiction since the most recent application for biennial registration, whether or not licensed to practice in that other jurisdiction.

(3) Disclose any pending criminal charges and any finding or verdict of guilt, admission of guilt, plea of *nolo contendere*, probation without verdict, disposition in lieu of trial or accelerated rehabilitative disposition in any criminal matter since the most recent application for biennial registration.

(4) Verify that the licensed perfusionist has complied with the continuing education requirements mandated under section 13.3(n) of the act (63 P. S. § 422.13c(n))

during the biennial period immediately preceding the period for which registration is sought in accordance with § 18.540 (relating to continuing education for licensed perfusionists).

(5) Verify that, if practicing as a perfusionist in this Commonwealth, the licensee maintains professional liability insurance coverage in accordance with section 13.3(k) of the act.

§ 18.538. Inactive status of perfusionist license; reactivation of inactive license.

(a) A perfusionist license will become inactive upon either of the following:

(1) The licensee requests in writing the Board to place the license on inactive status. Written confirmation of inactive status will be forwarded to the licensee.

(2) The licensee fails to register the license by the expiration of the biennial registration period, that is, by December 31 of each even-numbered year.

(b) A perfusionist whose license has expired or been placed on inactive status may not practice as a perfusionist in this Commonwealth until the license has been reactivated.

(c) To reactivate an inactive license, the licensee shall apply on forms supplied by the Board, answering all questions fully. The licensee shall:

(1) Include the documentation required under § 18.540(b) (relating to continuing education for licensed perfusionists) for the immediately preceding biennium, which may be completed during the current biennium. Unless waived by the Board under section 13.3(n)(4) of the act (63 P. S. § 422.13c(n)(4)), the Board will not reactivate any license until the required continuing education for the preceding biennium has been successfully completed.

(2) Pay the current biennial registration fee and the reactivation application fee specified in § 16.13(k) (relating to licensure, certification, examination and registration fees).

(3) Except as provided in subsection (d), verify that the licensee did not practice as a perfusionist in this Commonwealth while the license was inactive.

(d) A licensee who has practiced with an inactive license, and who cannot make the verification required by subsection (c)(3) shall also pay the fees required by this subsection. Payment of a late fee does not preclude the Board from taking disciplinary action for practicing as a perfusionist without a currently registered license.

(1) A licensee whose license was active at the end of the immediately preceding biennial registration period and who practiced after the license became inactive shall pay a late fee of \$5 for each month or part of a month from the beginning of the current biennium until the date the reactivation application is filed.

(2) A licensee whose license has been inactive since before the beginning of the current biennium shall pay the biennial registration fee for each biennial registration period during which the licensee practiced and shall pay a late fee of \$5 for each month or part of a month from the first date the licensee practiced as a perfusionist in this Commonwealth after the license became inactive until the date the reactivation application is filed.

§ 18.539. Disciplinary action for licensed perfusionists.

(a) A licensed perfusionist, including—a—perfusionist holding a temporary graduate license or a temporary

provisional license, is subject to disciplinary action under the grounds of section 41 of the act (63 P.S. § 422.41). Following a final determination subject to the right of notice, hearing and adjudication and the right of appeal therefrom in accordance with 2 Pa.C.S. (relating to administrative law and procedure), the Board may impose any of the corrective actions of section 42 of the act (63 P.S. § 422.42).

(b) Unprofessional conduct includes:

(1) Engaging in any conduct prohibited under § 16.110 (relating to sexual misconduct).

(2) Performing acts in a healthcare profession in a fraudulent, incompetent or negligent manner.

(3) Performing acts in the practice of a healthcare profession in violation of a statute or regulation of the Commonwealth, another state of the United States, or another country.

(4) Violating a provision of the act or this chapter setting a standard of professional conduct.

(5) Engaging in healthcare practice beyond the licensee's authority to practice.

(6) Representing oneself to be a physician, physician assistant, certified registered nurse practitioner or other healthcare practitioner whose profession the perfusionist is not licensed to practice.

(7) Practicing while the licensee's ability to do so is impaired by alcohol, drugs, physical disability or mental instability.

(8) Revealing personally identifiable facts obtained as the result of a practitioner-patient relationship without the prior consent of the patient, except as authorized or required by statute or regulation.

(9) Failing to provide supervision as required under section 13.3(e)(2) of the act (63 P.S. § 422.13(e)(2)) of a perfusion student or failing to provide supervision as required under section 13.3(e)(3) of the act of a perfusion graduate who is not otherwise licensed by the Board to perform perfusion in this Commonwealth.

(c) Immoral conduct includes:

(1) Misrepresenting or concealing a material fact in obtaining a license issued by the Board or renewal, reactivation or reinstatement thereof.

(2) Being convicted of a crime involving moral turpitude, dishonesty or corruption in the courts of the Commonwealth, the United States, or another state, territory or county.

(3) Committing an act involving moral turpitude, dishonesty or corruption.

§ 18.540. Continuing education for licensed perfusionists.

(a) *Credit hour requirements.* A licensed perfusionist shall satisfy the following continuing education credit hour requirements.

(1) During each biennial registration period, a licensee shall complete 30 hours of continuing education applicable to the practice of perfusion, including at least 10 hours of category I continuing education. A licensee is not required to complete continuing education during the biennium in which the licensee was first licensed.

(2) Except as permitted in § 18.538(c)(1) (relating to inactive status of perfusionist license; reactivation of inactive license), paragraph (4), or as directed by the

Board, continuing education may satisfy the requirement of paragraph (1) only for the biennium during which it was completed. No hour of continuing education may be used to satisfy the requirement of paragraph (1) for more than one biennium.

(3) Unless otherwise excused by the act or this subchapter, failure to complete the minimum required amount of continuing education during the applicable biennial registration period as required under section 13.3(n) of the act (63 P.S. § 422.13(n)) and this section will subject the licensee to discipline under section 41(6) of the act (63 P.S. § 422.41(6)).

(4) A licensee seeking waiver of the continuing education requirements under section 13.3(n)(4) of the act shall submit the request with all supporting documentation to the Board at least 90 days prior to the end of the biennial registration period for which waiver is sought. Waiver may include extending the deadline by which the required continuing education must be completed.

(b) *Documentation of continuing education.* Continuing education shall be documented in the following manner.

(1) Proof of completion of continuing education must consist of a certified record issued by the provider, including:

(i) The name of the participant.

(ii) The name of the provider.

(iii) The date or dates of the course.

(iv) The name of the course.

(v) The number of hours of continuing education credit.

(2) A licensee shall retain proof of completion of continuing education for 5 years after completion of the continuing education or after the completion of the biennial registration period for which the continuing education was required, whichever is later.

(3) The Board will audit licensees to verify compliance with continuing education requirements.

(c) *Continuing education activities.* Credit for continuing education may be earned in the following activities.

(1) Category I continuing education may be earned by:

(i) Attendance at an international, National, regional or state perfusion meeting.

(ii) Publication of a perfusion-related book, chapter or paper in a professional journal.

(iii) Presentation at an international, National, regional, state or local perfusion meeting.

(iv) Participation in a site visitors workshop or as a site visitor for perfusion program accreditation.

(v) Completion of ABCP-approved self-directed continuing education for which the licensee scored at least 80% on an examination.

(2) In addition to category I, continuing education may also be earning by:

(i) Reading or viewing medical journals, audio-visual, or other educational materials.

(ii) Participation in electronic forums.

(iii) Participation in a journal club.

(iv) Participation in degree-oriented, professionally-related course work.

(v) Presentation of perfusion topic at a nonperfusion meeting.

(vi) Working as a clinical or didactic instructor in an accredited school of perfusion.

(3) Continuing education credit may not be earned in any course in office management.

§ 18.541. Professional liability insurance coverage for licensed perfusionist.

(a) A licensed perfusionist shall maintain a level of professional liability insurance coverage as required under section 13.3(k) of the act (63 P. S. § 422.13c(k)).

(b) Proof of professional liability insurance coverage shall consist of a certificate of insurance or copy of the declaration page from the insurance policy setting forth the effective date, expiration date, and dollar amounts of coverage.

(c) A license that was issued in reliance upon a letter from the applicant's insurance carrier indicating that the applicant will be covered against professional liability effective upon the issuance of the applicant's license as permitted under section 13.3(k)(2) of the act will become inactive as a matter of law 30 days after the date of issuance on the license if the licensee has not provided proof of professional liability insurance coverage and will remain inactive until the licensee provides proof of insurance coverage.

(d) A licensee who does not have professional liability insurance coverage as required under section 13.3(k) of the act may not practice as a perfusionist in this Commonwealth.

[Pa.B. Doc. No. 10-988 Filed for public inspection May 21, 2010, 9 00 a.m.]

STATE BOARD OF OSTEOPATHIC MEDICINE

[49 PA. CODE CH. 25]

Perfusionist

The State Board of Osteopathic Medicine (Board) proposes to amend § 25.231 (relating to schedule of fees) and to add Subchapter N (relating to perfusionists) to read as set forth in Annex A.

Effective Date

The proposed rulemaking will be effective upon final-form publication in the *Pennsylvania Bulletin*.

Statutory Authority

The proposed rulemaking is authorized under sections 13.3 and 16 of the Osteopathic Medical Practice Act (act) (63 P. S. §§ 271.13c and 271.16).

Background and Need for the Proposed Rulemaking

The act of June 11, 2008 (P. L. 161, No. 20) (Act 20) amended the act to provide for licensure of perfusionists. Section 2 of the act (63 P. S. § 271.2) now defines the term "perfusion" as "the functions necessary for the support, treatment, measurement or supplementation of the cardiovascular systems or other organs, or a combination of those functions . . . by monitoring and analyzing the parameters of the systems under the supervision of a physician. . . ." This proposed rulemaking amends the Board's regulations to implement licensure of perfusionists under the act as amended by Act 20. Practice of

perfusion in this Commonwealth without a license from the Board will be prohibited after August 10, 2010. This proposed rulemaking is also designed to provide to prospective licensees adequate notice of the requirements for licensure as a perfusionist.

Description of the Proposed Rulemaking

The proposed rulemaking adds licensure as a perfusionist. The proposed rulemaking amends § 25.231 to set the fees associated with perfusionist licensure to be charged by the Board, as authorized by section 13.3(l) of the act. To recover the costs of providing those services, the fee for applications for perfusionist license, reactivation of perfusionist license and temporary graduate perfusionist license would each be \$50 and the fee for application for temporary provisional perfusionist license would be \$40. Because the Board believes that the cost to provide the service would be minimal and does not want to delay application, the Board has not set fees for notification of emergency practice as a perfusionist. To provide for an appropriate share of the general costs of operating the Board, the biennial renewal fee for a perfusionist would be \$50.

The proposed rulemaking adds Subchapter N. Proposed § 25.811 (relating to purpose) identifies the purpose of the subchapter as providing for licensure of perfusionists. Proposed § 25.812 (relating to definitions) provides necessary definitions. These include the statutory definitions of "extracorporeal circulation," "perfusion," "perfusionist" and "ventricular assist device" as are used in the subchapter. Additionally, the Board defines "ABCP" as the American Board of Cardiovascular Perfusion (ABCP), the National body that both accredits perfusion education programs and certifies perfusionists. The Board defines "accredited perfusion program approved by the Board" as a perfusion program accredited by a Nationally-recognized accrediting agency approved by the Board. The Board further defines "Nationally-recognized accrediting agency approved by the Board" as the ABCP or another organization for which the Board publishes notice that the organization is approved by the Board as an accrediting agency for perfusionist programs. Finally, the Board defines an "hour of continuing education" as "at least 50 minutes of instruction (including question and answer sessions) in an approved course of continuing education or an equivalent time that an on-line or correspondence course would be presented live." This time is consistent with the standards for continuing education that is required by the ABCP for recertification.

Under § 25.813(a) (relating to application for perfusionist license), an applicant shall submit a completed application form, including necessary supporting documents, and pay the required application fee. Section 13.3(f) of the act sets five criteria for licensure as a perfusionist as follows: at least 18 years of age; good moral character; graduation from an accredited perfusion program approved by the Board; and certification by a certifying agency approved by a Nationally-recognized accrediting agency approved by the Board. Accordingly, proposed § 25.813(b)(1) provides that the Board will license as a perfusionist an applicant who demonstrates that the applicant satisfies the requirements of section 13.3(f) of the act for licensure as a perfusionist. Because, as discussed regarding proposed § 25.821 (relating to professional liability insurance coverage for licensed perfusionist), section 13.3(k) of the act requires a perfusionist to carry a minimum level of professional liability insurance, proposed § 25.813(b)(2) requires that an applicant provide proof of liability insurance. Because, as discussed as

16A-4931 Perfusionists
List of Public Commentators

Raffaele Mirarchi, MAOM, MBA, CCP, LP
St. Christopher's Pediatric Associates
Section of Cardiothoracic Surgery
Erie Avenue at Front Street
Philadelphia, PA 19134-1095
RalphMirarchi@cs.com

Michael Homishak
Department of Perfusion
St. Luke's Hospital
801 Ostrum Street
Bethlehem, PA 18015

Tracy Sabella-Mineard, CCP
Tsabella1981@yahoo.com



**COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF MEDICINE**

Post Office Box 2649
Harrisburg, Pennsylvania 17105-2649
(717) 783-1400

September 12, 2011

The Honorable Silvan B. Lutkewitte, III, Chairman
INDEPENDENT REGULATORY REVIEW COMMISSION
14th Floor, Harristown 2, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Final Regulation
State Board of Medicine
16A-4931: PERFUSIONIST

Dear Chairman Lutkewitte:

Enclosed is a copy of a final rulemaking package of the State Board of Medicine pertaining to perfusionists.

The Board will be pleased to provide whatever information the Commission may require during the course of its review of the rulemaking.

Sincerely,

A handwritten signature in cursive script that reads "Carol E. Rose".

Carol E. Rose, MD, Chairperson
State Board of Medicine

CER/DMG:klh

Enclosure

cc: Katie True, Commissioner
Bureau of Professional and Occupational Affairs
Rebecca Oyler, Director of Policy
Department of State
Steven V. Turner, Chief Counsel
Department of State
Cynthia Montgomery, Regulatory Counsel
Department of State
David M. Green, Counsel
State Board of Medicine
State Board of Medicine

**TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE
REGULATORY REVIEW ACT**

I.D. NUMBER: 16A-4931

SUBJECT: GENERAL LICENSE, CERTIFICATION AND REGISTRATION PROVISIONS;
PRACTITIONERS OTHER THAN MEDICAL DOCTORS - PERFUSIONISTS

AGENCY: DEPARTMENT OF STATE
STATE BOARD OF MEDICINE

TYPE OF REGULATION

Proposed Regulation

X Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

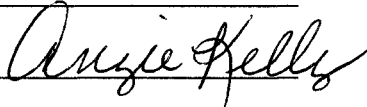
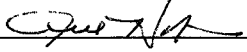

120-day Emergency Certification of the Governor

Delivery of Tolled Regulation

a. With Revisions b. Without Revisions

RECEIVED
IRRC
2011 SEP 12 A 10:39

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
		HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
9/12/11		MAJORITY CHAIRMAN <u>Julie Harhart</u>
9/12/11		SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
		MAJORITY CHAIRMAN <u>Robert Tomlinson</u>
9/12/11		INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
		LEGISLATIVE REFERENCE BUREAU (for Proposed only)