

# Regulatory Analysis Form

(Completed by Promulgating Agency)



# IRRC

## 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**

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INDEPENDENT REGULATORY  
REVIEW COMMISSION

(3) Short Title:

**Perfusionists**

(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: **Thomas A. Blackburn, Regulatory unit counsel, Department of State;**  
**(717)783-7200; P.O. Box 2649, Harrisburg, PA 17105-2649; (717)787-0251; tblackburn@state.pa.us**

Secondary Contact: **Joyce McKeever, Deputy Chief Counsel, Department of State**  
**(717)783-7200; P.O. Box 2649, Harrisburg, PA 17105-2649; (717)787-0251; jmckeever@state.pa.us**

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

**(717)783-1400; P.O. Box 2649, Harrisburg, PA 17105-2649; (717)787-7769; st-medicine@state.pa.us**

(All Comments will appear on IRRC'S website)

(7) 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

## 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 receive public comments:                               | 30 days after publ.     |
| B. The date or dates on which public meetings or hearings will be held:                     | N/A                     |
| C. The expected date of promulgation of the proposed regulation as a final-form regulation: | within 2 years of publ. |
| D. The expected effective date of the final-form regulation:                                | final promulgation      |
| E. The date by which compliance with the final-form regulation will be required:            | effective date          |
| F. The date by which required permits, licenses or other approvals must be obtained:        | effective date          |

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

**The Board continually reviews the efficacy of its regulations, as part of its annual review process under Executive Order 1996-1. The Board reviews its regulatory proposals at regularly scheduled public meetings, generally the fourth Tuesday of each month. More information can be found on the Board's website ([www.dos.state.pa.us/med](http://www.dos.state.pa.us/med)).**

## **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 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?

**Persons currently practicing perfusion in this Commonwealth will be adversely affected by the rulemaking by being required to become licensed, as required by the Act 19 amendments to the act. The Board does not foresee any other groups being adversely affected by the rulemaking.**

(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.**

## Regulatory Analysis Form

### **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 \$23,125 [ $\$50 \times (500 - 50 + \frac{1}{4} 50)$ ] in fiscal year 2010-11, \$1250 [ $\$50 \times \frac{1}{2} 50$ ] in 2012-13, \$23,750 [ $\$50 \times (500 - 50 + \frac{1}{2} 50)$ ] in fiscal year 2013-14 and repeating in two-year cycles. Reactivation application fees of \$625 [ $\$50 \times \frac{1}{4} 50$ ] in fiscal year 2010-11, and \$1250 [ $\$50 \times \frac{1}{2} 50$ ] 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.

There are no other costs or savings to the regulated community associated with compliance with the rulemaking.

## Regulatory Analysis Form

(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.**

(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.

	<b>Current FY Year</b>	<b>FY +1 Year</b>	<b>FY +2 Year</b>	<b>FY +3 Year</b>	<b>FY +4 Year</b>	<b>FY +5 Year</b>
<b>SAVINGS:</b>	<b>2008-09</b>	<b>2009-10</b>	<b>2010-11</b>	<b>2011-12</b>	<b>2012-13</b>	<b>2013-14</b>
Regulated Community						
Local Government						
State Government						
<b>Total Savings</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>
<b>COSTS:</b>						
Regulated Community	N/A	N/A	\$38,000	\$16,750	\$39,250	\$16,750
Local Government	N/A	N/A	N/A	N/A	N/A	N/A
State Government	N/A	N/A	N/A	N/A	N/A	N/A
<b>Total Costs</b>	<b>N/A</b>	<b>N/A</b>	<b>\$38,000</b>	<b>\$16,750</b>	<b>\$39,250</b>	<b>\$16,750</b>
<b>REVENUE LOSSES:</b>						
Regulated Community						

## Regulatory Analysis Form

Local Government						
State Government						
Total Revenue Losses	N/A	N/A	N/A	N/A	N/A	N/A

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

Program	FY -3 (FY 06-07) actual	FY -2 (FY 07-08) projected	FY -1 (FY 08-09) budgeted	Current FY (FY 09-10) budgeted
Pa. State Board of Medicine	\$6,332,084	\$5,834,202	\$8,409,000	\$9,717,000

(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.**

(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.**

(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.**

## Regulatory Analysis Form

(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.**

## FEE REPORT FORM

**Agency:** State - BPOA

**Date:** May 4, 2009

**Contact:** Basil Merenda  
Commissioner, Bureau of Professional & Occupational Affairs

**Phone No.** 783-7192

**Fee Title, Rate and Estimated Collections:** **\$50.00**

**Application Fee - Perfusionist:**

Estimated Initial Application Revenue: \$25,000.00 (500 applications x \$50.00)

**Fee Description:**

The fee will be charged to each applicant as a Perfusionist.

**Fee Objective:**

The fee should (1) offset the identifiable costs incurred by the State Board of Medicine to review and process an application as a Perfusionist and (2) defray a portion of the Board's administrative overhead.

**Fee-Related Activities and Costs:**

Staff time (CT3) - review and process examination application (.50 hr)	\$16.23
Administrative Overhead:	\$30.05
Total Estimated Cost:	\$46.28
Proposed Fee:	\$50.00

**Analysis, Comment, and Recommendation:**

It is recommended that a fee of \$50.00 be established to evaluate the application as a Perfusionist.

**Perfusionist Application Fee:**

Board Staff: Reviews application for completeness, verifies that supporting documents are attached, contacts candidate to request any missing information. Issues approval through computer or prepares letter of rejection.



## **FEE REPORT FORM**

**Agency:** State - BPOA

**Date:** May 4, 2009

**Contact:** Basil Merenda  
Commissioner, Bureau of Professional & Occupational Affairs

**Phone No.** 783-7192

**Fee Title, Rate and Estimated Collections:** **\$50.00**

Biennial Renewal Fee – Perfusionist – Medical Board

Estimated Biennial Revenue: \$25,000.00 (500 applications x \$50.00)

**Fee Description:**

The fee will be charged biennially to every Perfusionist applicant for license renewal.

**Fee Objective:**

The fee should defray a portion of the State Board of Medicine's administrative overhead.

**Analysis, Comment, and Recommendation:**

It is recommended that a renewal fee of \$50.00 be established for Perfusionist licensees, thereby causing those licensees to contribute to the operational costs of the State Board of Medicine.

## FEE REPORT FORM

Agency: State - BPOA Date: 5/4/2009  
Contact: Basil Merenda  
Commissioner, Bureau of Professional & Occupational Affairs  
Phone No. 783-7192

### Fee Title, Rate and Estimated Collections:

License Reactivation Fee: Perfusionist \$50.00  
Estimated Biennial Revenue: \$ 2,500.00 (50 applications x \$50.00)

### Fee Description:

The fee will be charged to each applicant who requests reactivation of an expired license. **This fee is charged in addition to the appropriate biennial renewal fee.**

### Fee Objective:

The fee should (1) offset the identifiable costs incurred by the State Board of Medicine to review and process an application for reactivation of an inactive license and (2) defray a portion of the Board's administrative overhead.

### Fee-Related Activities and Costs:

Board Staff (CT3) - review and process application:	(.50/hr)	16.23
Administrative Overhead:		30.05
Total Estimated Cost:		\$46.28
Proposed Fee:		\$50.00

### Analysis, Comment, and Recommendation:

It is recommended that a fee of \$50.00 be established to process an application for reactivation of an inactive license. **This fee is charged in addition to the appropriate biennial renewal fee**

Staff receives application, reviews for completeness, contacts applicant to request any missing information, researches computer and/or microfilm files to retrieve pertinent information and verifies period of non-practice to ensure compliance with the Act and Regulations, issues registration for current cycle through computer.

## FEE REPORT FORM

**Agency:** State - BPOA

**Date:** May 4, 2009

**Contact:** Basil Merenda  
Commissioner, Bureau of Professional & Occupational Affairs

**Phone No.** 783-7192

### Fee Title, Rate and Estimated Collections:

**Application Fee - Temporary Graduate Perfusionist:** **\$50.00**  
Estimated Initial Application Revenue: \$2,500.00 (50 applications x \$50.00)

### Fee Description:

The fee will be charged to each applicant applying for Temporary Graduate Perfusionist license.

### Fee Objective:

The fee should (1) offset the identifiable costs incurred by the State Board of Medicine to review and process an application for Temporary Graduate Perfusionist and (2) defray a portion of the Board's administrative overhead.

### Fee-Related Activities and Costs:

Staff time (CT3) - review and process examination application (.50 hr)	\$16.23
Administrative Overhead:	\$30.05
Total Estimated Cost:	\$46.28
Proposed Fee:	\$50.00

### Analysis, Comment, and Recommendation:

It is recommended that a fee of \$50.00 be established to evaluate the application for Temporary Graduate Perfusionist.

### Temporary Graduate Perfusionist Application Fee:

Board Staff: Reviews application for completeness, verifies that supporting documents are attached, contacts candidate to request any missing information. Issues approval through computer or prepares letter of rejection.

## FEE REPORT FORM

**Agency:** State - BPOA

**Date:** May 7, 2009

**Contact:** Basil Merenda  
Commissioner, Bureau of Professional & Occupational Affairs

**Phone No.** 783-7192

### Fee Title, Rate and Estimated Collections:

**Application Fee - Temporary Provisional Perfusionist: \$40.00**

Estimated Initial Application Revenue: \$1,000.00 (25 applications x \$40.00)

### Fee Description:

The fee will be charged to each applicant applying for Temporary Provisional Perfusionist license.

### Fee Objective:

The fee should (1) offset the identifiable costs incurred by the State Board of Medicine to review and process an application for Temporary Provisional Perfusionist and (2) defray a portion of the Board's administrative overhead.

### Fee-Related Activities and Costs:

Staff time (CT3) - review and process examination application (.25 hr)	\$ 8.12
Administrative Overhead:	\$30.05
Total Estimated Cost:	\$38.17
Proposed Fee:	\$40.00

### Analysis, Comment, and Recommendation:

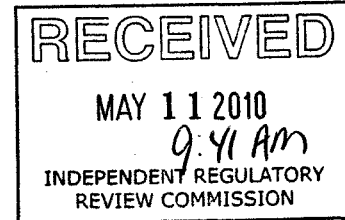
It is recommended that a fee of \$40.00 be established to evaluate the application for Temporary Provisional Perfusionist.

### Temporary Graduate Perfusionist Application Fee:

Board Staff: Reviews application for completeness, verifies that supporting documents are attached, contacts candidate to request any missing information. Issues approval through computer or prepares letter of rejection.

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

(Pursuant to Commonwealth Documents Law)



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



BY: \_\_\_\_\_  
(DEPUTY ATTORNEY GENERAL)

**APR 29 2010**

DATE OF APPROVAL

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:

  
Ollice Bates, Jr., MD

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Executive or Independent  
Agencies.



BY:

**MAR -9 2010**

DATE OF APPROVAL

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

[ ] Check if applicable  
Copy not approved.  
Objections attached.

TITLE: Chairman  
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

[ ] Check if applicable.  
No Attorney General approval  
or objection within 30 day  
after submission.

**PROPOSED RULEMAKING**

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

49 Pa. Code §§ 16.11, 16.13, 18.531-18.541  
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 §§ 18.531-18.541 (relating to perfusionists), to read as set forth in Annex A.

#### Effective date

The amendments will be 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 Need for the Amendment

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 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 rulemaking is also designed to provide to prospective licensees adequate notice of the requirements for licensure as a perfusionist.

#### Description of the Proposed Amendments

The Board’s current regulation at § 16.11(b) identifies those licenses that the Board issues. The proposed rulemaking would add licensure as a perfusionist. Similarly, § 16.11(c) identifies those registrations that the Board issues, and the proposed rulemaking would add biennial registration of perfusionist licenses. The proposed rulemaking would also amend § 16.13 to add a new subsection (k) setting forth the fees associated with perfusionist licensure to be charged by the Board, as authorized by section 13.3(l) of the act (63 P.S. § 422.13c(l)). In order 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. In order 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 would also amend Chapter 18 to add a new Subchapter J (relating to perfusionists). Proposed § 18.531 (relating to purpose) would identify the purpose of the subchapter as providing for licensure of perfusionists. Proposed § 18.532 (relating to definitions) would provide 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 would define “ABCP” as the American Board of Cardiovascular Perfusion, 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 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; and would define “Nationally- recognized certifying agency approved by the Board” as 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. 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 ABCP for recertification.

Proposed § 18.533 (relating to application for perfusionist license) would address the application for licensure as perfusionist. Under proposed § 18.533(a), an applicant must submit a completed application form, including any necessary supporting documents, and pay the required application fee. Section 13.3(f) of the act (63 P.S. § 422.13c(f)) 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) would provide 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 (63 P.S. § 422.13c(k)) requires a perfusionist to carry a minimum level of professional liability insurance, proposed § 18.533(b)(2) would require that an applicant provide proof of liability insurance. Because, as discussed below, 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 set forth in § 18.539 (relating to disciplinary action for licensed perfusionist).

The Board has not proposed any rulemaking to incorporate the grandfather provision of section 13.3(g) of the act (63 P.S. § 422.13c(g)), which, during the first two 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 regulation.

Proposed § 18.534 (relating to application for temporary graduate perfusionist license) would address the application for temporary graduate perfusionist license, as provided in section 13.3(h) of the act (63 P.S. § 422.13c(h)). Under proposed § 18.534(a), an applicant must submit a completed application form, including any necessary supporting documents, and pay the required application fee. Section 13.3(h)(1)(i) of the act (63 P.S. § 422.13c(h)(1)(i)) 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 set forth 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) would require that an applicant provide proof of liability insurance. Because, as discussed below, 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 set forth in § 18.539. Because section 13.3(h)(1)(iii) of the act (63 P.S. § 422.13c(h)(1)(iii)) provides that a temporary graduate license is to be issued for 2 years but not be renewable, proposed § 18.534(d) would provide 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 (63 P.S. § 422.13c(h)(1)(iv)) provides that a temporary graduate license is to expire upon notice of failing the required examination, proposed § 18.534(e) would provide 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 in section 13.3(i) of the act (63 P.S. § 422.13c(i)). Under proposed § 18.535(a), an applicant must submit a completed application form, including any 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 set forth 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 below, the Board is also setting forth in this proposed rulemaking grounds for disciplinary action, proposed § 18.535(c) would provide that the Board may, in its discretion, deny an application for perfusionist temporary provisional license upon those grounds for disciplinary action set forth 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) would provide 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 (63 P.S. § 422.13c(j)) provides an exemption to the general prohibition against unlicensed practice for one-time temporary emergency services by an out-of-state licensed perfusionist where 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) 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) would require 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) must 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 website. Because "one-time emergency perfusionist service" is not defined in section 13.3(j), proposed § 18.536(c) would provide 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) would provide 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 all 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 license) would address biennial registration of perfusionist licenses. Proposed § 18.537(a) would provide that all 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 any license to practice as a perfusionist in any other jurisdiction, disclose any disciplinary action pending before or taken by the appropriate healthcare licensing authority in another state, disclose any pending criminal charges and any 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 by section 13.3(k) of the act. Because ABCP requires a perfusionist to complete a minimum number of procedures each year in order 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) would address inactive status of perfusionist licenses. Proposed § 18.538(a) would provide that license may become inactive either by the licensee's request or by expiration at the end of the biennial registration period. In order 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) would provide that the Board will forward written confirmation of inactive status to the licensee. Proposed § 18.538(b) would provide 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) would provide the general requirement for reactivation of an inactive perfusionist license that the licensee must apply on forms supplied by the Board, answer all questions fully, provide documentation of completion of the required amount of continuing education for the preceding biennium, as required by section 13.3(n)(5) of the act (63 P.S. § 422.13c(n)(5)), pay the current biennial registration fee and the reactivation fee specified in § 16.13(k) (relating to licensure, certification, examination and registration fees), 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 must 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 (relating to disciplinary action for licensed perfusionists) 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 (63 P.S. § 422.13c(m)) 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) would provide 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 any of the corrective actions of 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) would define unprofessional conduct and proposed § 18.539(c) would define immoral conduct. Modeled upon § 16.61 (unprofessional and immoral conduct for physicians) and § 18.181 (disciplinary and corrective measures for physician assistants), unprofessional conduct would include: 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 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 would include: 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 would include engaging in any conduct prohibited by § 16.110 (relating to sexual misconduct). Section 13.3(e)(2) of the act (63 P.S. § 422.13c(e)(2)) 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 (63 P.S. § 422.13c(e)(3)) exempts a perfusion graduate who, among other requirements, is performing under the supervision and responsibility of a perfusionist. Accordingly, proposed § 18.539(b)(9) would include as unprofessional conduct failing to provide supervision as required by section 13.3(e)(2) of the act 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 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) would address that topic. Proposed §

18.540(a) would set forth the general credit hour requirements. As required by section 13.3(n)(2) of the act, proposed § 18.540(a)(1) would require 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) would recognize that a licensee may need to make up deficient continuing education credit in order 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) would identify 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) would require 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 would explicitly note that waiver may include extending the deadline, rather than simply relieving the licensee of the obligation to take continuing education. Proposed § 18.540(b) would set forth the standards for documentation of continuing education. Under proposed § 18.540(b)(1), a licensee must 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) would require 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 post-renewal audits of licensees to verify compliance. Proposed § 18.540(c) would set forth the types of activities for which continuing education credit may be earned. In order to better facilitate compliance with the requirements, these standards are modeled upon those of 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 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 non-perfusion 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) would prohibit continuing education credit for a course in office management.

Section 13.3(k) of the act (63 P.S. § 422.13c(k)) provides for required professional liability insurance for perfusionists, and proposed § 18.541(a) would require a licensed perfusionist to

maintain a level of professional liability insurance as required by section 13.3(k) of the act. Conversely, proposed § 18.541(d) would prohibit 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) would set 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) 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 provide submit the certificate of insurance of copy of the declaration page within 30 days after issuance of the license. In order to effectuate this provision, proposed § 18.541(c) would provide 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 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 this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of 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 shall 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 Regulatory Unit Counsel, Department of State, by mail at P.O. Box 2649, Harrisburg, PA 17105-2649, or by email at [st-medicine@state.pa.us](mailto:st-medicine@state.pa.us), within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*. Please reference No. 16A-4931 (perfusionist), when submitting comments.

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:

\* \* \* \* \*

(4) 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>

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## **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.

*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 (63 P.S. § 422.2), 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 (63 P.S. § 271.2), an individual who is licensed to practice perfusion by the Board or the State Board of Osteopathic Medicine.

Ventricular assist device – As defined in section 2 of the act (63 P.S. § 422.2), a mechanical device used to partially or completely replace the function of a failing heart through connections to the heart and great vessels that may be located intracorporeally or extracorporeally. The term includes a device that is placed intravascularly or extravascularly and provides support through direct means or via counterpulsation.

**§ 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 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 by section 13.3(k) of the act (63 P.S. § 422.13c(k)).

(3) Otherwise complies with this subchapter.

(c) In its discretion, 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 shall submit, on forms supplied by the Board, a completed application, including all necessary supporting documents, and pay the fee set forth in § 16.13(k) 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 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) In its discretion, 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 by the Board, a completed application, including all necessary supporting documents, and pay the fee set forth in § 16.13(k) for application for 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 by section 13.3(k) of the act (63 P.S. § 422.13c(k)).

(3) Otherwise complies with this subchapter.

(c) In its discretion, 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 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, 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 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 perfusionist).

(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 (63 P.S. § 422.13c(k)).

**§ 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) In order 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 by § 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) must 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 Title 2 of the Pennsylvania Consolidated Statutes (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 by § 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 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 (63 P.S. § 422.13c(e)(3)) 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.

(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 shall 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 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.



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

May 11, 2010

The Honorable Arthur Coccodrilli, Chairman  
INDEPENDENT REGULATORY REVIEW COMMISSION  
14<sup>th</sup> Floor, Harristown 2, 333 Market Street  
Harrisburg, Pennsylvania 17101

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

Dear Chairman Coccodrilli:

Enclosed is a copy of a proposed rulemaking package of the State Board of Medicine pertaining to Perfusionist.

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

Sincerely,

*Carol E. Rose*

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

CER/TAB:rs

Enclosure

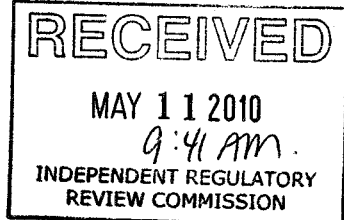
cc: Basil L. Merenda, Commissioner  
Bureau of Professional and Occupational Affairs  
Steven V. Turner, Chief Counsel  
Department of State  
Joyce McKeever, Deputy Chief Counsel  
Department of State  
Cynthia Montgomery, Regulatory Counsel & Senior Counsel in Charge  
Department of State  
Thomas A. Blackburn, 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: PERFUSIONIST  
AGENCY: DEPARTMENT OF STATE  
STATE BOARD OF MEDICINE

**TYPE OF REGULATION**

- X Proposed Regulation  
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



**FILING OF REGULATION**

DATE	SIGNATURE	DESIGNATION
5/11/10	<i>Clairine Nichols</i>	HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
		MAJORITY CHAIRMAN <u>Michael P. McGeehan</u>
5/11/10	<i>Mary Walmer</i>	SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
		MAJORITY CHAIRMAN <u>Robert M. Tomlinson</u>
5/11/10	<i>K. Cooper</i>	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
5/11/10	<i>Marya Garas</i>	LEGISLATIVE REFERENCE BUREAU (for Proposed only)

May 3, 2010