

**INDEPENDENT REGULATORY
REVIEW COMMISSION**

2012 JUN 12 AM 10:54

RECEIVED
IRRC

Regulatory Analysis Form

(Completed by Promulgating Agency)

(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: **16A-4935**

IRRC Number: **2951**

(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: **Louis Lawrence Boyle, Assistant Regulatory Counsel, State Board of Medicine, Department of State, 2601 North Third Street, Harrisburg, PA 17105; Phone Number: (717) 783-7200; Fax Number: (717) 787-0251; E-mail address: llboyle@pa.gov.**

Secondary Contact: **Cynthia Montgomery, Regulatory Counsel, Department of State, P.O. Box 2649, Harrisburg, PA 17105-2649 (phone 717-783-7200) (fax 787-0251) 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) 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 rulemaking implements licensing of perfusionists under Act 19.

(8) 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).

(9) 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 (10). The rulemaking is not mandated by any other federal or state law or court order or federal regulation.

(10) 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 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.

(11) 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.

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

(12) Describe who and how many people 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.

(13) 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. Currently, as of December 22, 2011, there are 320 perfusionists licensed in the Commonwealth of Pennsylvania.

(14) 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. Although the Board initially anticipated a licensee population of 500, currently, as of December 22, 2011, there are 320 perfusionists licensed in the Commonwealth of Pennsylvania. In Pennsylvania, perfusionists may register with either the State Board of Medicine or with the State Board of Osteopathic Medicine and may renew their license with either board. Because the licensee makes this selection, neither board can predict with absolute certainty how many perfusionists will be licensed with one of these boards in the future, so the Board has based its current estimates on the total number of 320 licensed perfusionists for both boards.

Based on the total number of 320 licensed perfusionists, the Board estimates that during each biennial renewal period, new licensees will be approximately 5 percent of the current licensee population of 320 persons (or 16 persons), who will apply for licensure to practice as perfusionists. The Board estimates that during each renewal cycle, it will receive applications of approximately 5 percent of the current licensee population (or 16 persons) who will apply for a temporary graduate license, and it will receive approximately 2.5 percent (or 8 persons) of the current licensee population who will apply for a temporary provisional license. The next biennial renewal cycle ends on December 31, 2012. Additionally, the Board estimates that during each renewal cycle beginning January 1, 2013, approximately 95 percent of those licensed (or 304 persons) will timely renew their licenses. The remaining 5 percent of those licensed (or 16 persons) will not renew their licenses in timely fashion, and will apply to reactivate an expired license. The Board estimates that the number of new licensees will replace the number of licensees who choose not to renew their licenses, so the total number of licensees will probably remain fairly constant. The amount of these fees to be paid to the Board is identified in the response to question 17.

For the current fiscal year (July 1, 2011 – June 30, 2012), there will be no renewal license application fees because the renewal cycle does not end until December 31, 2012. For the current fiscal year, as well as each subsequent fiscal year, the Board estimates 16 new applications of \$800 [$\$50 \times 5\% \times 320$]. The Board estimates 16 temporary graduate license application fees of \$800 per fiscal year [$\$50 \times 5\% \times 320$] and 8 temporary provisional license application fees of \$320 [$\$40 \times 2.5\% \times 320$], for a total of \$1,920 in each fiscal year beginning 2011-12.

In 2012 – 13, the Board estimates 304 renewal application fees of \$15,200 [$\$50 \times 95\% \times 320$]; 16 new application license fees of \$800 [$\$50 \times 5\% \times 320$]; 16 temporary graduate license application fees of \$800; 8 temporary provisional license application fees of \$320; and 8 reactivation fees of \$400 because there will only be half the time or 6 months for reactivation from January through June of 2013 [$\$50 \times 16 \times \frac{1}{2}$]; for a total of \$17,520.

For 2013 – 14, the Board estimates \$1,920 for new applications, temporary graduate license applications and temporary provisional license applications [$\$800 + \$800 + \$320$]; renewals of \$800 [$\$50 \times 5\% \times 320$]; and reactivations for the full fiscal year of \$800 [$\$50 \times 5\% \times 320$] for a total of \$3,520.

For 2014 – 15, the Board estimates renewal application fees of \$15,200; \$1,920 for new applications, temporary graduate license applications and temporary provisional license applications; and reactivations for the full fiscal year of \$800 [$\$50 \times 5\% \times 320$] for a total of \$17,920.

For 2015 – 2016, the Board again estimates \$1,920 for new applications, temporary graduate license applications and temporary provisional license applications [$\$800 + \$800 + \$320$]; renewals of \$800 [$\$50 \times 5\% \times 320$]; and reactivations for the full fiscal year of \$800 [$\$50 \times 5\% \times 320$] for a total of \$3,520.

For 2016 – 2017, the Board again estimates renewal application fees of \$15,200; \$1,920 for new applications, temporary graduate license applications and temporary provisional license applications; and reactivations for the full fiscal year of \$800 [$\$50 \times 5\% \times 320$] for a total of \$17,920.

The Act 19 amendments to the act require the Board to implement licensure of perfusionists. 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.

(15) 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.

(16) 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 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.

--

(17) 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 Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS:	\$	\$	\$	\$	\$	\$
Regulated Community						
Local Government						
State Government						
Total Savings	NA	NA	NA	NA	NA	NA
COSTS:						
Regulated Community	\$1,920	\$17,520	\$3,520	\$17,920	\$3,520	\$17,920
Local Government	NA	NA	NA	NA	NA	NA
State Government	NA	NA	NA	NA	NA	NA
Total Costs	\$1,920	\$17,520	\$3,520	\$17,920	\$3,520	\$17,920
REVENUE LOSSES:						
Regulated Community						
Local Government						
State Government						
Total Revenue Losses	NA	NA	NA	NA	NA	NA

(17a) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY -3	FY -2	FY -1	Current FY
State Board of Medicine	\$5,836,998.79	\$5,800,654.85	\$4,834,369.34	\$6,349,000.00

(18) 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.

(19) 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 has withdrawn the previous regulation on this subject (16A-4931) and resubmits this regulation as proposed. On January 24, 2012, the Board reviewed this regulatory package at its public meeting and approved the new proposed rulemaking. Because this regulation is now being submitted as proposed, there has been no public input yet on this regulation.

Regarding the previous regulation (16A-4931), the Board has been discussing that regulation intermittently at its monthly public meetings since the passage of Act 19. For the previous regulation, after publication of the proposed rulemaking, the Board received comments from Michael Homishak, Department of Perfusion of St. Luke's Hospital in Bethlehem, Pennsylvania (Homishak); Ralph Mirarchi, Chief Perfusionist at St. Christopher's Hospital for Children in Philadelphia; and Tracy Sabella-Mineard, CCP. 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. Again, on November 10, 2011, representatives of the perfusionist community were invited and met with representatives of the Board to develop further amendments to the regulations, specifically regarding continuing education.

(20) 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.

(21) 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 rulemaking would not be more stringent and would not overlap or conflict with any federal requirements.

(22) 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 rulemaking would not put Pennsylvania at a competitive disadvantage.

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

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

(24) 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 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.

(25) 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.

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

- A. The date by which the agency must have received public comments: **Thirty days after publication in the *Pennsylvania Bulletin*.**
- B. The date or dates on which public meetings or hearings were held: **The Board met and discussed the current regulation at its public meeting on January 24, 2012. On the previous regulation on perfusionists (16A-4931), which was withdrawn, the Board met in public meetings on September 23, 2008, November 25, 2008, February 24, 2009, April 28, 2009, August 24, 2010, November 22, 2011, and December 27, 2011.**
- C. The expected date of promulgation of the proposed regulation as a final-form regulation: **2012.**
- 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.**

F. The date by which required permits, licenses or other approvals must be obtained: **December 31, 2012.**

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

The Board continuously reviews its regulations at its scheduled meetings. The Board meets monthly on the fourth Tuesday of each month.

FEE REPORT FORM

Agency: State - BPOA

Date: January 11, 2012

Contact: Katie True
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: January 11, 2012

Contact: Katie True
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: January 11, 2012

Contact: Katie True
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: January 11, 2012

Contact: Katie True
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: January 11, 2012

Contact: Katie True
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 (.50 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.

2012 JUN 12 AM 10: 54

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

DO NOT WRITE IN THIS SPACE

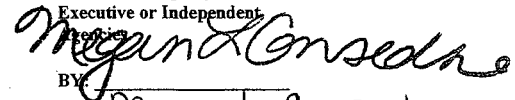
Copy below is hereby approved as to form and legality. Attorney General

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

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


BY: _____
(DEPUTY ATTORNEY GENERAL)

State Board of Medicine
(AGENCY)


BY: _____
Megan L. Consedine

MAY 24 2012

DOCUMENT/FISCAL NOTE NO. 16A-4935

MAY 02 2012

DATE OF APPROVAL

DATE OF ADOPTION: _____

DATE OF APPROVAL

BY: 
Carol E. Rose, M.D.

~~(Executive Deputy General Counsel~~
Strike inapplicable title)

TITLE: Chairperson
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

- Check if applicable. Copy not approved. Objections attached.
- 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, §§ 16.1, 16.11, 16.13, 18.531-18.541

PERFUSIONIST

The State Board of Medicine (Board) proposes to amend §§ 16.1, 16.11 and 16.13 (relating to definitions; 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 proposed rulemaking will be effective upon publication of the final-form rulemaking in the *Pennsylvania Bulletin*.

Statutory Authority

The proposed rulemaking is authorized under sections 8 and 13.3(c) of the Medical Practice Act of 1985 (act) (63 P.S. §§ 422.8 and 422.13.3(c)).

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

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.” 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.

Practice of perfusion in this Commonwealth without a license from the Board was prohibited after August 10, 2010. In June of 2010, the Board, in conjunction with the State Board of Osteopathic Medicine (Osteopathic 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 and the Osteopathic 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.

Description of the Proposed Rulemaking

The proposed rulemaking would first amend § 16.1 (relating to definitions) to add perfusionist to the list of other Board-regulated practitioners. 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 of the act (63 P.S. § 422.13c). 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 administers the exam and certifies perfusionists. The CAAHEP is the Commission on Accreditation of Allied Health Education Programs, which accredits perfusion education programs. 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 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. The Board would also 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. The Board also 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. Finally, the Board defines

“out-of-state perfusionist” 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. The Board determined that it is necessary to define the term “out-of-state perfusionist” because section 13.3(j)(1) of the act contains the phrase “in another state, the District of Columbia or a territory of the United States” and uses the phrase “out-of-state perfusionist” throughout the remainder of subsections 13.3(j)(1)(i) and (ii), (2) and (3). Therefore, the Board defined “out-of-state perfusionist” as including these geographic entities and used the phrase “out-of-state perfusionist” in § 18.536 (relating to registration of temporary emergency perfusionist service).

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, be certified by a certifying agency approved by a Nationally-recognized accrediting agency approved by the Board, and complete an application form and pay the appropriate fee. Accordingly, proposed § 18.533(b)(1), in conjunction with § 18.533(a), 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)(4) 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).

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. Because section 13.3(h)(1)(ii) of the act (63 P.S. § 422.13c(h)(1)(ii)) requires that an individual’s authorization to practice perfusion is granted only under the supervision and direction of a perfusionist licensed under the act, the Board would place this requirement at the beginning of proposed § 18.534(b). Section 13.3(h)(1) of the act provides that an individual who has graduated from an educational program in compliance with the education requirements may receive a temporary graduate license. This requirement, along with good moral character and being at least 18 years of age, as required by subsections 13.3(f)(1) – (2) of the act, and the requirement at section 13.3(h)(1)(i) of the act that the individual has applied for and is eligible to take the examination would be set forth in proposed § 18.534(b)(1) – (3) 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)(4) would require that an applicant provide proof of liability insurance. As discussed below, because the Board is also setting forth in this proposed rulemaking grounds for disciplinary action, proposed § 18.534(c) would provide 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. Due to the fact that 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. The Board receives perfusionist test results directly from the ABCP, the organization that administers the two-part examination. (For example, during 2011, the Board received the results of the March exam in April and the results of the October exam in December. As of December 22, 2011, there were only 2 licensed temporary graduate perfusionists in the Commonwealth.) If the Board were to receive a report that an individual has failed one of the two parts of the examination, the Board staff would determine if the individual holds a temporary graduate perfusionist license and if so, would take appropriate steps to inform the license holder that the license was null and void and request return of the license. Furthermore, the Board would clarify in the last sentence of proposed § 18.534(e) that a perfusionist who fails the examination must immediately cease practice and return the temporary graduate perfusionist license to the Board.

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) – (3) 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)(4) would require that an applicant provide proof of liability insurance. As discussed below, because 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. Sections 13.3(j)(1)(i) – (ii) require 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 by electronic means 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. To provide clarity, the Board would state in § 18.532(b) what is meant by electronic means, as including "computer-to-computer, computer-to-facsimile machine or e-mail transmission." 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. 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 sections 13.3(j)(1)(ii)(A) & (D) of the act require 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 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. 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 licenses issued by the Board must be registered biennially as a condition of continued practice in accordance with section 25(b) of the act (63 P.S. § 422.25(b)) and § 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, and disclose the following on the application itself: any license to practice as a perfusionist in any other jurisdiction, any disciplinary action pending before or taken by the appropriate healthcare licensing authority in another jurisdiction, any pending

criminal charges and any convictions. A licensed perfusionist must also verify on the application that the licensee has complied with the continuing education requirements, and finally verify on the application 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.

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 a 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 subsection (d), 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. 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. Therefore, the Board proposes to amend the definition of "board-regulated practitioner" in § 16.1 (relating to definitions) to add perfusionists. Further, 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 (relating to unprofessional and immoral conduct for physicians) and § 18.181 (relating to 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, 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, drugs, physical disability or mental instability, and revealing personally identifiable facts obtained as the result of the practitioner-patient relationship. 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)(8) 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. 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.

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 during each biennial registration period at least 30 hours of continuing education – including at least 10 hours in category I continuing education - applicable to the practice of perfusion. 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. In keeping with the statutory requirement for completing the continuing education requirement during each 2-year license period at section 13.3(n)(2) of the act, a licensee would not be permitted to carry over continuing education credit into a subsequent renewal period at proposed § 18.540(a)(2). The Board views the statutorily-mandated number of hours of continuing education for biennial license renewal as a minimum to maintain competence during each biennial period and encourages its licensees to take as much continuing education as each licensee believes assists in maintaining excellence in practice. Consistent with this view, the Board's continuing education regulations for medical doctors, respiratory care practitioners and athletic trainers, as well as the continuing education regulations for other health care practitioners, such as nurses, do not provide for the carryover of continuing education credits taken over the minimum required for license renewal.

As a practical consideration, this regulation 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. 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)(3) would permit a licensee to request a waiver under these circumstances and would require that the request for a

waiver 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 subsection 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(a)(4) would provide that a licensee would be subject to disciplinary action if the licensee submits false information to the Board regarding completion of the continuing education credit hour requirements or if a licensee fails to complete the required continuing education and practices as a perfusionist after the end of the biennial period.

Proposed § 18.540(b) would set forth the standards for documentation of continuing education that will be required for licensees to prove compliance with the continuing education requirements. In determining these requirements, representatives of the Board met with representatives of the Pennsylvania State Perfusion Society on November 10, 2011, and included detailed information in the regulatory provisions based on the documentation required by the American Board of Cardiovascular Perfusion (ABCP). Under proposed § 18.540(b)(1), a licensee must receive a certified record of completion from the continuing education provider for attendance at an ABCP-approved perfusion meeting, 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 subsections 18.540(b)(2) – (11) would set forth the documentation that a licensee must retain for any of the following types of continuing education: publication of a book, chapter or paper in a perfusion-related publication; a presentation at an ABCP-approved or international perfusion meeting; participation in an ABCP knowledge base survey; reading or viewing medical journals, audio-visual or other educational materials; participation in a perfusion-related self-study module or electronic forum; participation in a perfusion-related journal club; completion of an academic course; presentation of a perfusion topic at a meeting that is not approved by the ABCP; participation as a clinical or didactic instructor in an accredited program; and participation in a site visitors' workshop or as an official site visit. Proposed § 18.540(b)(12) would require the licensee to retain the required documentation 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 the Board will conduct post-renewal audits of licensees to verify compliance with the continuing education requirements, proposed § 18.540(b)(13) would require the licensee to submit proof of continuing education activities upon request by the Board.

Proposed § 18.540(c) would set forth the types of activities for which continuing education credit may be earned detailing how these continuing education activities will be quantified and the number of continuing education credits that a licensee may earn for completing each of the enumerated types of continuing education. In determining these requirements, representatives of the Board met with representatives of the Pennsylvania State Perfusion Society and included in the regulatory provisions the quantification of continuing education used by the American Board of Cardiovascular Perfusion (ABCP). In some instances, the Board's provisions are not identical to those of the ABCP because the ABCP requires continuing education on a triennial, rather than biennial, basis, thereby making an identical match difficult. However, the specific quantification of the credits would provide licensees with notice of how continuing education activities will be quantified for license renewal. Under

proposed § 18.540(c)(1), specific hours of category I continuing education (which must provide at least 10 of the required 30 hours) could be earned by attendance at ABCP-approved perfusion meetings, publication of a perfusion-related book, chapter or paper in a professional publication, presentation at an ABCP-approved or international perfusion meeting, or completion of an ABCP-knowledge base survey. Under proposed § 18.540(c)(2), other continuing education specific hours to reach the required total could be earned by reading or viewing medical journals, audio-visual or other educational materials, participating in perfusion-related self-study modules, electronic forums or journal clubs, completion of a science or healthcare-related academic course at a regionally accredited college or university, presentation of a perfusion topic at a meeting that is not approved by the ABCP, working as a clinical or didactic instructor in an accredited school of perfusion, or participating in a site visitors' workshop or as an official site visitor for perfusion program accreditation. However, as required by section 13.3(n)(6) of the act, proposed § 18.540(c)(3) would prohibit continuing education credit for a course in office management.

Because section 13.3(k) of the act (63 P.S. § 422.13c(k)) provides for required professional liability insurance for perfusionists, proposed § 18.541(a) (relating to professional liability insurance coverage for licensed perfusionist) would require a licensed perfusionist to maintain professional liability insurance. 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. Subsection 13.3(k)(1) of the act requires evidence of insurance in the form of self-insurance, personally purchased liability insurance or professional liability insurance coverage provided by the perfusionist's employer or similar insurance coverage acceptable to the Board. Accordingly, proposed § 18.541(b) would set forth the two possible options that proof of liability insurance may include. Proposed § 18.541(b)(1) would require either 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. Proposed § 18.541(b)(2) would allow for evidence of a plan of self-insurance as approved by the Insurance Commissioner of the Commonwealth under regulations of the Insurance Department at 31 Pa. Code §§ 243.1 – 243.11 (relating to medical malpractice and health-related self-insurance plans). 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, 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 has developed

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 June 12, 2012, 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@pa.gov, within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*. Please reference No. 16A-4935 (perfusionist), when submitting comments.

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**

§ 16.1. Definitions.

The following words and terms, when used in this chapter and Chapters 17 and 18 (relating to State Board of Medicine—medical doctors; and State Board of Medicine—practitioners other than medical doctors), have the following meanings, unless the context clearly indicates otherwise:

* * * * *

Board-regulated practitioner—A medical doctor, midwife, physician assistant, drugless therapist, athletic trainer, acupuncturist, practitioner of Oriental medicine, perfusionist or an applicant for a license or certificate that the Board may issue.

* * * * *

§ 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.

<u>Application for perfusionist license</u>	<u>\$ 50</u>
<u>Biennial registration 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 – 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 – 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 – 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 – An individual who is licensed to practice perfusion by the Board or the State Board of Osteopathic Medicine.

Ventricular assist device –

(i) 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 made available by the Board, a completed application, including all necessary supporting documents, for a 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) The Board may issue a license to practice as a perfusionist to an applicant who:

(1) Demonstrates that the applicant holds a current certification by a certifying agency approved by a Nationally-recognized accrediting agency approved by the Board.

(2) Demonstrates that the applicant has graduated from an accredited perfusion program approved by the Board.

(3) Demonstrates that the applicant is at least 18 years of age and of good moral character.

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

(5) 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 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 an application for a temporary graduate perfusionist license.

(b) The Board may grant a temporary graduate perfusionist license, which authorizes the license holder to practice only under the supervision and direction of a perfusionist licensed under this act, to an applicant, who:

(1) Demonstrates that the applicant is eligible for and has applied to sit for the examination of a certifying agency approved by a Nationally-recognized accrediting agency approved by the Board.

(2) Demonstrates that the applicant has graduated from an accredited perfusion program approved by the Board.

(3) Demonstrates that the applicant is at least 18 years of age and of good moral character.

(4) Demonstrates that the applicant has obtained professional liability insurance as required by section 13.3(k) of the act (63 P.S. § 422.13c(k)).

(5) 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. The holder of a temporary graduate perfusionist license who fails the examination shall immediately cease practicing and return the license to the board.

§ 18.535. Application for temporary provisional perfusionist license.

(a) An applicant for a temporary provisional perfusionist license shall submit, on forms 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 a temporary provisional perfusionist license.

(b) The Board may grant a temporary provisional perfusionist license to an applicant who:

(1) Demonstrates that 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.

(2) Demonstrates that the applicant has graduated from an accredited perfusion program approved by the Board.

(3) Demonstrates that the applicant is at least 18 years of age and of good moral character.

(4) Demonstrates that the applicant has obtained professional liability insurance as required by section 13.3(k) of the act.

(5) Otherwise complies with this subchapter.

(c) The Board may deny an application for temporary provisional perfusionist licensure 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, by electronic means, to include computer-to-computer, computer-to-facsimile machine or e-mail transmission, and on forms 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, 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) The license of a perfusionist will expire biennially on December 31 of each even-numbered year, in accordance with § 16.15 (relating to biennial registration; inactive status and unregistered status). A perfusionist may not practice after December 31 of an even-numbered year unless the perfusionist has completed the biennial registration process and the Board has issued a renewed registration.

(b) As a condition of biennial registration, a perfusionist shall:

(1) 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.

(2) Disclose on the application any license to practice as a perfusionist in another state, territory, possession, or country.

(3) Disclose on the application 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.

(4) Disclose on the application 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.

(5) Verify on the application 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).

(6) Verify on the application 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 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 become inactive 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 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 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 the administrative agency law, 2 Pa.C.S. §§ 101-754, 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 an act in a healthcare profession in a fraudulent, incompetent or negligent manner.

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

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

(5) 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.

(6) Practicing while the licensee's ability to do so is impaired by alcohol.

drugs, physical disability or mental instability.

(7) 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.

(8) 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 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 this Commonwealth, the United States, or another state, 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) As a condition for biennial registration, a licensee shall complete at least 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 when reactivating an inactive license, when the Board has granted

a waiver, or when ordered by the Board, continuing education credits may be used to satisfy the continuing education credit hour requirements only for the biennial period in which the credits were earned. No hour of continuing education may be used to satisfy the requirement of paragraph (1) for more than one biennium.

(3) A licensee may request a waiver of the continuing education credit hour requirements because of serious illness, military service or other demonstrated hardship by submitting a request for waiver with all supporting documentation to the Board at least 90 days prior to the end of the biennial registration period for which the waiver is sought. The Board may grant the waiver request in whole or in part and may extend the deadline by which the credit hour requirements must be met.

(4) A licensee may be subject to disciplinary sanction as provided in section 41 of the act (63 p.s. § 422.41), including the suspension or revocation of the license, imposition of a civil penalty or other corrective measure as determined by the Board if the licensee either submits false information to the Board regarding completion of the continuing education credit hour requirements in order to complete biennial registration or fails to complete the continuing education hour requirements and practices as a perfusionist after the end of the biennial period.

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

(1) Proof of 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 a perfusion-related publication must consist of the complete citation reference to the book, chapter or paper in a professional publication.
- (3) Proof of presentation at an ABCP-approved or international perfusion meeting must consist of a copy of the program agenda.
- (4) Proof of participation in an ABCP knowledge base survey must consist of a letter from ABCP.
- (5) Proof of reading or viewing medical journals, audio-visual or other educational materials must consist of a list of the complete citation reference for the materials read or reviewed.
- (6) Proof of participation in a perfusion-related self-study module or electronic forum must consist of a copy of the printed completion document supplied by the sponsor.
- (7) Proof of participation in a perfusion-related journal club must consist of the meeting agenda with topic and date.
- (8) Proof of completion of an academic course must consist of a copy of the official college or university transcript.
- (9) Proof of presentation of a perfusion topic at a meeting that is not approved by the ABCP must consist of a copy of the meeting agenda.

(10) 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.

(11) Proof of participation in a site visitors' workshop or as an official site visit shall consist of a letter from the ABCP.

(12) 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.

(13) The Board will audit licensees to verify compliance with continuing education requirements. A licensee shall submit proof of continuing education activities upon request by the board.

(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 ABCP-approved perfusion meeting, for which one continuing education credit may be earned for each hour of continuing education.

(ii) Publication of a perfusion-related book, chapter or paper in a professional publication, for which five continuing education credits may be earned for each publication.

(iii) Presentation at an ABCP-approved or international, perfusion meeting, for which five continuing education credits may be earned for each presentation; however, only two credits may be earned for each poster

presentation or exhibit.

(iv) Completion of an ABCP-knowledge base survey, for which five continuing education hours may be earned for completing the continuing education activity. The activity may only be counted for credit once in any biennial period.

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

(i) Reading or viewing medical journals, audio-visual, or other educational materials, for which one continuing education credit may be earned for each medical journal, audio- visual or other educational material read or viewed, with a maximum of ten credits biennially.

(ii) Participation in perfusion-related self-study modules or electronic forums, for which one continuing education credit may be earned for each 50 to 60 minute period of the activity, with a maximum of ten credits biennially.

(iii) Participation in a perfusion-related journal club, for which one continuing education credit may be earned for each 50 to 60 minute period of the activity, with a maximum of ten credits biennially.

(iv) Completion of a science or healthcare-related academic course at a regionally accredited college or university, for which one continuing education credit may be earned biennially.

(v) Presentation of a perfusion topic at a meeting that is not approved by the ABCP, for which one continuing education credit may be earned biennially.

(vi) Working as a clinical or didactic instructor in an accredited school of perfusion, for which two continuing education credits may be earned with a maximum of four credits biennially.

(vii) Participation in a site visitors' workshop or as an official site visitor for perfusion program accreditation, for which five continuing education credits may be earned. The activity may only be counted for credit once in any biennial period.

(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 may include:

(1) 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.

(2) Evidence of a plan of self-insurance approved by the Insurance Commissioner of the Commonwealth under regulations of the Department of Insurance at 31 Pa. Code §§ 243.1 – 243.11 (relating to medical malpractice and health-related self-insurance plans).

(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

June 12, 2012

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

Re: Proposed Regulation
State Board of Medicine
16A-4935: Perfusionist

Dear Chairman Lutkewitte:

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,

A handwritten signature in black ink, appearing to read "James W. Freeman MD".

James W. Freeman, Chair
State Board of Medicine

CKM/LLB:jsg

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
Louis Lawrence Boyle, Counsel
State Board of Medicine
State Board of Medicine

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

I.D. NUMBER: 16A-4935
SUBJECT: PERFUSIONIST
AGENCY: DEPARTMENT OF STATE (STATE BOARD OF MEDICINE)
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

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

2012 JUN 12 AM 10:54

RECEIVED
IRRC

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
6/12/12	<i>A. Kelly</i>	HOUSE COMMITTEE ON PROFESSIONAL LICENSURE MAJORITY CHAIR <u>Julie Harhart</u>
6/12/12	<i>Mary Walmer</i>	SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE MAJORITY CHAIR <u>Robert M. Tomlinson</u>
6/12/12	<i>K. Cooper</i>	INDEPENDENT REGULATORY REVIEW COMMISSION ATTORNEY GENERAL (for Final Omitted only)
6/12/12	<i>Samela Hasen</i>	LEGISLATIVE REFERENCE BUREAU (for Proposed only)