

# Regulatory Analysis Form

(Completed by Promulgating Agency)

INDEPENDENT REGULATORY  
REVIEW COMMISSION

(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

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(3) PA Code Cite:

**49 Pa. Code §§ 16.11, 16.13, 18.601 – 18.611**

(4) Short Title: **Perfusionists**

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

**Primary Contact: Teresa Lazo, Board Counsel, State Board of Medicine, Department of State, P.O. Box 2649, Harrisburg, PA 17105-2649 (phone 717-783-7200) (fax 787-0251); [tlazo@pa.gov](mailto:tlazo@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](mailto: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?

**In enacting Act 19, the General Assembly determined that the benefits of licensure outweigh any adverse effects on licensees. If licensing requirements can be considered an adverse effect, as of September 5, 2012, the Board and the Board of Osteopathic Medicine have licensed a total of 329 perfusionists under the act (303 are licensed by the Board of Medicine and 26 are licensed by the Board of Osteopathic Medicine). Perfusionists may obtain a license from either Board.**

**All licensed perfusionists are impacted by the regulation, in that they must pay application fees and biennial renewal fees.**

**Perfusionists must also complete continuing education for licensure renewal; however, perfusionists already completed continuing education to renew their National certification and the Board has drafted this regulation so that the continuing education completed for certification will satisfy the statutory requirement of continuing education for licensure renewal.**

**Licensees will also be required to retain certificates of attendance that demonstrate that the licensees completed the mandated biennial continuing education.**

(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 individuals providing perfusion services within the Commonwealth (currently 303 individuals are licensed by the Board of Medicine) will be required to comply with the amendments to the Medical Practice Act and these regulations. The regulations do not impose any requirements on groups or other entities.**

(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.

**The financial impact of the regulation on individuals is as follows:**

**Initial application for licensure.....\$50 (one time cost)  
Biennial renewal fee.....\$50 (every other year)  
30 hours biennial continuing education.....\$100 – 300 (cost per year)  
Continuing education may be earned less expensively through on-line sources.**

**The estimated cost per year for a perfusionist to comply with the statutory requirement for continuing education was calculated by considering the cost of local and National perfusion conferences, specifically, the PA State Perfusion Society fall meeting, which in November 2012 will offer 15.3 hours of continuing education credits and has a registration fee of \$150 and the American Society of Extracorporeal Technology National Conference which provides 40.8 hours of continuing education and has a registration fee of \$350 for members and \$575 for non-members.**

**Perfusionists will enjoy a positive social impact from licensure, as evidenced by the state perfusion society lobbying for the law that required licensure for perfusionists. Perfusionists may also enjoy a positive financial impact from licensure, which may have influenced the state society to lobby for the licensure requirement.**

**Act 19 required the Board to implement licensure of perfusionists. Other than application fees, biennial renewal fees and the cost of completing statutorily mandated continuing education, the Board does not foresee any additional legal, accounting or consulting procedures or other costs associated with licensure.**

(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 fees have been calculated to recover the cost of providing the services. The Board will charge a fee of \$50 to review and process an initial application for licensure, including issuing a wall certificate and wallet card to each licensee. The Board will charge a fee of \$50 to review and process an application to reactivate an inactive license, which will also necessitate issuing a wall certificate and wallet card. The Board will charge a fee of \$50 to review and process an application for a temporary graduate license and issue a wall certificate and wallet card. The Board will charge a fee of \$40 to review and process an application for a temporary provisional license, including issuing a wall certificate and wallet card. The Board will not charge a fee for registration of an out-of-State perfusionist to perform an emergency temporary perfusion service. Additionally, the Board will charge a biennial 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 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
<b>SAVINGS:</b>	\$	\$	\$	\$	\$	\$
Regulated Community						
Local Government						
State Government						
<b>Total Savings</b>						
<b>COSTS:</b>						
Regulated Community	\$750	\$750	\$150,600	\$750	\$164,100	\$750
Local Government						
State Government						
<b>Total Costs</b>	\$750	\$750	\$150,600	\$750	\$164,100	\$750
<b>REVENUE LOSSES:</b>						
Regulated Community						
Local Government						
State Government						
<b>Total Revenue Losses</b>						

**Current FY (2012-2013), FY + 1 (2013-2014)**

15 new applicants x \$50 application fee = \$750

**FY + 2 (2014-2015)**

15 new applicants x \$50 application fee = \$750

303 current licensees + 30 new apps (over 2 yrs) = 333 x \$50 biennial renewal fee = \$16,650

333 licensees x \$400 (cost of CE) = \$133,200

Total cost to regulated community in FY + 2: \$150,600

**FY + 3 (2015-2016)**

15 new applicants x \$50 application fee = \$750

**FY + 4 (2016-2017)**

15 new applicants x \$50 application fee = \$750

333 current licensees + 30 new apps(over 2 yrs) = 363 x \$50 biennial renewal fee = \$18,150

363 licensees x \$400 (cost of CE) = \$145,200

Total cost to regulated community in FY + 3: \$164,100

**FY + 5 (2017-2018)**

15 new applicants x \$50 application fee = \$750

(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 determined the fees for applications and biennial renewal based on the fee report forms generated by the Division Chief of the Revenue Division of the Department of State.**

**The Board made every effort to minimize the costs to perfusionists, particularly the costs of completing mandatory continuing education. The Board, through its regulation, has approved a wide array of continuing education activities that are already required to be completed by perfusionists annually in order to maintain National certification. Accordingly, the regulation minimizes the impact of compliance with the continuing education provisions of the law and regulations by recognizing for licensure renewal the continuing education courses that perfusionists routinely take for renewal of their National certification. Eliminating duplication of continuing education saves costs to licensees, and, if a small business covers the cost of continuing education, to small businesses.**

**Licensees will benefit from the statute and regulations by being recognized in the public eye and for insurance purposes as licenses of the Board.**

(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 withdrew a previous rulemaking on this subject (16A-4931) and resubmitted this regulation.**

**Regarding the previous rulemaking, the Board discussed the rulemaking intermittently at its monthly public meetings since the passage of Act 19. The Board also discussed the prior version of the rulemaking and this current version with interested parties, members and representatives of the perfusionist community and IRRC analysts.**

**In responding to the comments submitted by the HPLC and IRRC and preparing this final rulemaking, the Board met either by teleconference or in person with representatives of the perfusionist community and IRRC analysts.**

(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.

**The prior version of the proposed rulemaking was withdrawn after IRRC raised concerns about some of its provisions, particularly provisions related to continuing education.**

**Before submitting the current form of the rulemaking, Board counsel conducted several meetings with representatives from the perfusion society to further discuss the rulemaking, with special focus on amending the regulatory sections related to continuing education to make them parallel the existing requirements that perfusionists must meet for their National certification. The Board chose to align these requirements because it is the least burdensome alternative to protect the public by ensuring the ongoing competence of licensees while placing the minimum burden on individual licensees.**

(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.

**There are no Federal standards. There are no provisions that are more stringent than Federal standards.**

(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 with substantially the same standards as in this rulemaking.**

**This rulemaking should not put Pennsylvania at a competitive disadvantage because licensure-related fees are minimal.**

(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.

**Copies of the application forms for licensure as a perfusionist, including emergency temporary registration, are attached to this Regulatory Analysis Form. Perfusionists will be required to maintain evidence of completed continuing education for 5 years.**

(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 not identified any affected groups with particular needs that would be impacted by the regulation.**

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

- |   |                                   |
|---|-----------------------------------|
| A. The date by which the agency must receive public comments:                               | NA                                |
| B. The date or dates on which public meetings or hearings will be held:                     | NA                                |
| C. The expected date of promulgation of the proposed regulation as a final-form regulation: | Spring 2013                       |
| D. The expected effective date of the final-form regulation:                                | Spring 2013                       |
| E. The date by which compliance with the final-form regulation will be required:            | upon publication                  |
| F. The date by which required permits, licenses or other approvals must be obtained:        | Licenses have already been issued |

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

**The Board continuously monitors the effectiveness of its regulations. The Board meets every 4 to 6 weeks throughout the year.**

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

**(Pursuant to Commonwealth Documents Law)**

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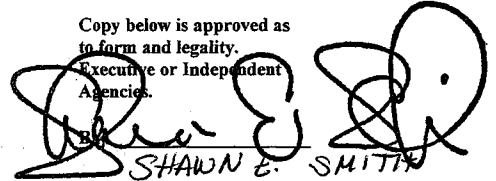
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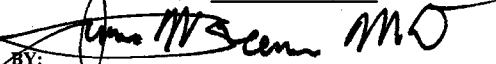
BY: \_\_\_\_\_  
(DEPUTY ATTORNEY GENERAL)

State Board of Medicine  
(AGENCY)

  
SHAWN E. SMITH

DOCUMENT/FISCAL NOTE NO. 16A-4935

DATE OF APPROVAL

DATE OF ADOPTION: \_\_\_\_\_  


MAY 02 2013  
DATE OF APPROVAL

BY: \_\_\_\_\_  
James W. Freeman, 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.

**FINAL 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, 18.601-18.611**

**PERFUSIONISTS**



The State Board of Medicine (Board) hereby amends § 16.1, 16.11 and 16.13 (relating to basic definitions; general license provisions; and fees) and adopts §§ 18.601 – 18.611 (relating to perfusionists) to read as set forth in Annex A.

### **Effective Date**

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

### **Statutory Authority**

The amendments are authorized under sections 8 and 13.3(c) of the Medical Practice Act of 1985 (act) (63 P.S. §§ 422.8 and 422.13(c)). The act of June 11, 2008 (P.L. 154, No. 19) amended the act to provide for licensure of perfusionists. This final-form rulemaking effectuates those amendments.

### **Summary of Comments to Proposed Rulemaking and the Board's Response**

The Board published notice of proposed rulemaking in the *Pennsylvania Bulletin* on June 23, 2012, at 42 Pa. B. 3597, and requested public comments. The Board did not receive any comments from the public.

The House Professional Licensure Committee (HPLC) reviewed the proposed regulation and submitted comments to the Board on July 27, 2012. The Senate Consumer Protection and Professional Licensure Committee submitted no comments. The Independent Regulatory Review Commission (IRRC) submitted comments to the Board on August 22, 2012. The Board reviewed the comments and proposed amendments to the Annex at its meeting on September 11, 2012, and voted to promulgate final-form rulemaking.

HPLC noted that the proposed rulemaking was published approximately 18 months after the effective date of Act 19 of 2008. The Board had published proposed rulemaking on May 22, 2010, and the final-form rulemaking was submitted to the Committees and IRRC on September 12, 2011. On October 20, 2011, IRRC disapproved the final-form rulemaking for lack of clarity. On January 6, 2012, the Board withdrew the rulemaking in order to address IRRC's concerns. As noted above, the new version of the proposed rulemaking was published on June 23, 2012. The Board acknowledges that the regulatory process has been lengthy, but suggests that much of the delay was beyond the Board's control.

HPLC recommended that corrections be made to the references to § 16.13(k) (relating to fees) by replacing them with references to § 16.13(l). The corrections have been made.

HPLC next raised an issue with the language in § 18.606 (relating to registration of temporary emergency perfusionist service). HPLC noted that the act requires that an out-of-State perfusionist submit a notification of emergency practice with an acknowledgement that the out-

of-State perfusionist is subject to the jurisdiction of the Board. This acknowledgement is part of the registration form that an applicant for temporary emergency practice must submit. To address this concern, the Board clarified at § 18.606(b) that an out-of-State perfusionist must verify by personal or electronic signature the completed registration form. HPLC also noted that the statute specifies that the health care facility must certify certain information to the Board. The certifications that the act requires be made by the health care facility are part of the registration form that must be submitted by the health care facility. Therefore, the Board added a new subsection (e) to clarify that the application for temporary emergency registration of the out-of-State perfusionist will not be complete unless the health care facility licensed by the Department of Health has submitted to the Board the certification required by the act. HPLC also questioned whether there is a fee for an out-of-State emergency service perfusion registration. There is no fee for the registration; therefore, no fee is listed in § 16.13(l).

HPLC asked for clarification of whether an out-of-State emergency service perfusionist needs individual professional liability insurance or is covered by a facility policy and suggested the Board require proof of insurance prior to the perfusionist performing any services. The registration form both notifies the individual applicant that insurance is required and mandates that the health care facility in which the individual will provide perfusion services ensure that the perfusionist has professional liability coverage for at least the minimum amount required by the act. Liability insurance for a perfusionist performing temporary emergency perfusion services may come from inclusion on a certificate of insurance issued to the institution where the services will be performed, individual purchase of a short term insurance policy or an extension of coverage/endorsement by the insurance carrier who covers the perfusionist in the perfusionist's home state. The Board chose to require the facility to ensure liability coverage because obtaining documentation of private coverage or providing facility-based coverage is already part of the credentialing process every institution undertakes prior to permitting a perfusionist to provide perfusion services within the facility.

HPLC asked whether the District of Columbia should be named on the list of other states and jurisdictions in § 18.607 (relating to biennial registration of perfusionist license). The Board notes that section 1991 of the Statutory Construction Act (1 Pa.C.S.A. § 1991) provides that "[w]hen used in reference to the different parts of the United States, [the term "state"] includes the District of Columbia and the several territories of the United States." Therefore, the use of the term "state" in section 37 of the act (63 P.S. § 422.37) relating to reporting of multiple licensure, which is the statutory basis for the requirement, includes the District of Columbia. However, for added clarity, the Board has added "district" to the listed jurisdictions in § 18.607(b)(2).

HPLC recommended a typographical correction in § 18.610(b)(5) (relating to continuing education for licensed perfusionist), which has been made. HPLC questioned whether a reference to a continuing education "sponsor" in § 18.610(b)(6) referred to a continuing education provider discussed elsewhere in the section. It does, and the Board has changed the word "sponsor" to "provider" in § 18.610(b)(6) for clarity. HPLC recommended correcting the word "visit" in § 18.610(b)(11) to "visitor." The Board has made the correction.

HPLC suggested that § 18.610(b)(12) be written to read: “Proof of completion of continuing education shall be retained by a licensee for 5 years after completion of the continuing education or after the completion of the biennial registration period for which the continuing education as required, whichever is later.” Upon review of § 18.610, the Board realized that neither paragraph (12) nor paragraph (13) should be subparts of subsection (b). Accordingly, rather than rewrite paragraph (12), the Board will renumber paragraphs (12) and (13) as subsections (c) and (d), and has renumbered proposed subsection (c) as subsection (e) in the final rulemaking.

HPLC asked whether there are any sanctions for a licensee who fails to submit proof of meeting continuing education requirements upon the Board’s request pursuant to § 18.610(b)(13). A licensee who cannot submit proof of meeting the CE requirements is subject to discipline under section 41(1) or (6) of the act (63 P.S. §422.41(1) and (6)), which authorize the Board to discipline a licensee for failing to demonstrate the qualifications for registration and for violating a lawful regulation promulgated by the Board. Currently, individuals who have failed to meet the CE requirement are most frequently disciplined via a consent agreement, where the individual pays a fine and agrees to make up the deficiency in addition to completing the CE required for the current biennial period.

Finally, HPLC pointed out a typographical error in § 18.611(c) (relating to professional liability insurance coverage for licensed perfusionists), which has been corrected.

IRRC questioned the proposed application and biennial renewal fees for perfusionists, which are higher than the fees for other licensees. Application fees are determined by the Department of State’s Division Chief for the Revenue Office at the time the application is developed and are based on the estimated amount of time to review the application and the level of the individual who performs the reviewing functions. Biennial renewal fees are based on the Board’s overall budget and are intended to cover the expenses of functions performed by the Board. Fee report forms are developed by the Division Chief and presented to the Board for approval. Some of the Board’s fees have not been reevaluated in many years; therefore, the fees are not necessarily comparable.

IRRC suggested that the Board use the term “may” instead of “will” in § 18.610(b)(13) (renumbered in the final rulemaking as § 18.610(c)), pertaining to the biennial audit performed for continuing education compliance. The Board has made the suggested amendment.

IRRC also commented that the limitation on counting continuing education credits for teaching was not clear in § 18.610(c)(2)(vi) (renumbered in the final rulemaking as § 18.610(e)). The Board has amended the section to clarify that two CE credits may be earned for teaching a single course, with a maximum of four credits earned biennially under the subsection.

Finally, IRRC suggested that the language in § 18.610(c)(2)(vii), related to counting credits for site visits, was unclear as to whether all site visits counted for five credits or whether five was the maximum number of credits. A site visit is an extensive, multi-day evaluation and the Board intended that participation in a site visit would be credited with five credits. The

Board also intended that an individual not be permitted to earn these five credits more than once in a biennial period. The Board has clarified the language of the subsection.

### **Description of Amendments to the Final-Form Rulemaking**

The Board has amended incorrect references to § 16.13(k) by changing the reference to § 16.13(l) in §§ 18.603(a), 18.604(a), 18.605(a), 18.607(b)(1) and 18.608(c)(2).

In § 18.606(b), the Board has added a requirement for registration of temporary emergency perfusionist service that the out-of-State perfusionist verify the completed registration form by personal or electronic signature. The application form requires that the out-of-State perfusionist verify that the registrant is subject to the authority of the Pennsylvania Board. In § 18.606(e), the Board has added a requirement for registration of temporary emergency perfusionist service that the health care facility have completed the certification required by section 13.3(j)(ii) of the act (63 P.S. § 422.13c(j)(ii)). This certification is part of the application form for registration of temporary emergency perfusionist service.

The Board has added the term “district” to the list including other states and territories in § 18.607(b)(2).

The Board has also amended § 18.608 (relating to inactive status of perfusionist license; reactivation of inactive license) to reflect the distinction made by the Board between inactive and expired licenses. A license becomes inactive by licensee request. A license becomes expired by the failure of a licensee to register the license biennially. Upon review, it became apparent to the Board that the distinction should be clarified in these regulations.

The Board has corrected the spelling of “complete” in § 18.610(b)(5) and changed the term “sponsor” to “provider” in § 18.610(b)(6). The Board has corrected the term “visit” to “visitor” in § 18.610(b)(11). The Board has renumbered § 18.610(b)(12) and (13) as §18.610(c) and (d), and has renumbered § 18.610(c) as § 18.610(e). In § 18.610(d), the Board has changed the word “will” to “may,” indicating that it does not always audit 100% of licensees for CE compliance. In § 18.610(e)(2)(vi), the Board has clarified that working as a clinical or didactic instructor in an accredited school will earn two CE credits for teaching a single course. In § 18.610(e)(2)(vii), the Board has clarified that five CE credits may be earned for participation in a site visitor’s workshop or as an official site visitor for perfusion program accreditation.

### **Fiscal Impact and Paperwork Requirements**

The rulemaking will not have an 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 in the form of required fees and costs associated with obtaining the required continuing education and professional liability insurance.

The act and these regulations require perfusionists to maintain records of their participation in continuing education activities to present to the Board as evidence of their completion of statutorily-mandated continuing education. The act and the regulations require the

Board and the Department of State to maintain licensure records, including application forms, on all applicants for licensure and licensees. The act and the regulations required health care facilities licensed by the Department of Health who intend to utilize the perfusion services of an out-of-State perfusionist to certify certain information to the Board as part of the process for registration of the out-of-State perfusionist. It is anticipated that these requirements will have a very minimal fiscal impact on affected parties.

### **Sunset Date**

The Board continuously monitors 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 the notice of proposed rulemaking, published at 42 Pa. B. 3597, to the Independent Regulatory Review Commission and the Chairpersons of the House Professional Licensure Committee (HPLC) and the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) for review and comment.

The Board received no comments from the public. The HPLC and IRRC submitted comments. The SCP/PLC did not comment. In preparing the final-form rulemaking, the Board considered all comments.

Under section 5.1(j.2) of the Regulatory Review Act (71 P.S. § 745.5a(j.2)), on \_\_\_\_\_, 2013, the final-form rulemaking was approved by HPLC. On \_\_\_\_\_, 2013, the final-form rulemaking was deemed approved by the SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on \_\_\_\_\_, 2013, and approved the final-form rulemaking.

### **Findings**

The Board finds that:

1. Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240), (45 P.S. §§ 1201 – 1202), and the regulations promulgated thereunder, 1 Pa. Code §§ 7.1 – 7.2.
2. A public comment period was provided as required by law and all comments were considered.
3. The amendments to the final-form rulemaking do not enlarge the purpose of proposed rulemaking published at 42 Pa. B. 3597.
4. This final-form rulemaking is necessary and appropriate for administering and enforcing the authorizing act identified in this Preamble.

**Order**

The Board, acting under its authorizing statute, orders that:

- (A) The regulations of the Board at 49 Pa. Code §§ 16.1, 16.11, 16.13 and 18.601 – 18.611 are amended to read as set forth in Annex A.
- (B) The Board shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General as required by law.
- (C) The Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.
- (D) This order shall take effect immediately upon publication in the *Pennsylvania Bulletin*.

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 A. BASIC DEFINITIONS AND INFORMATION**

**§ 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.

\* \* \* \* \*

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

\* \* \* \* \*

**§ 16.11. Licenses, certificates and registrations.**

\* \* \* \* \*

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

\* \* \* \* \*

(6) Behavior specialist license.

(7) Perfusionist license.

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

\* \* \* \* \*

(10) Biennial registration of a behavior specialist license.

(11) Biennial registration of a perfusionist license.

\* \* \* \* \*

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

\* \* \* \* \*

(k) *Examination Fees:*

The Board has adopted Nationally recognized examinations in each licensing class. Fees are established by the National owners/providers of the examinations and are indicated in the examination applications.

(l) 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>

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

\* \* \* \* \*



## Subchapter J. PERFUSIONISTS

### § 18.601. Purpose.

This subchapter implements section 13.3 of the act (63 P.S. § 422.13c), regarding perfusionists.

### § 18.602. Definitions.

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

*ABCP*—The 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.

*CAAHEP*—The 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 organ.

*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 online or correspondence course would be presented live.

*Nationally-recognized accrediting agency approved by the Board*—CAAHEP or 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 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 through counterpulsation.

**§ 18.603. 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 the necessary supporting documents, for a license to practice as a perfusionist and pay the fee in § 16.13(kL) (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 (63 P.S. § 422.13c(k)).

(5) Otherwise complies with this subchapter.

(c) The Board may deny an application for licensure as a perfusionist upon the grounds for disciplinary action in § 18.609 (relating to disciplinary action for licensed perfusionists).

**§ 18.604. 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 the necessary supporting documents, and pay the fee in § 16.13(kL) (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 the 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 under 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 in § 18.609 (relating to disciplinary action for licensed perfusionists).

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

(e) A temporary graduate perfusionist license expires 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.

**§ 18.605. 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 the necessary supporting documents, and pay the fee in § 16.13(kL) (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 under 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 temporary provisional perfusionist licensure upon the grounds for disciplinary action in § 18.609 (relating to disciplinary action for licensed perfusionists).

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

**§ 18.606. 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 made available by the Board, a completed registration form

with the questions fully answered WHICH SHALL BE VERIFIED BY THE OUT-OF-STATE PERFUSIONIST BY PERSONAL OR ELECTRONIC SIGNATURE. The completed registration form shall be submitted by electronic means, including computer-to-computer, computer-to-facsimile FACSIMILE machine or e-mail transmission.

(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 no longer than 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 § 18.603, § 18.604 or § 18.605 (relating to application for perfusionist license; application for temporary graduate perfusionist license; and application for temporary provisional perfusionist license).

(e) A REGISTRATION FOR AN OUT-OF-STATE PERFUSIONIST WILL NOT BE COMPLETE UNLESS THE HEALTH CARE FACILITY LICENSED BY THE DEPARTMENT OF HEALTH HAS SUBMITTED THE CERTIFICATION REQUIRED BY SECTION 13.3(j)(ii) OF THE ACT (63 P.S. § 422.13c(j)(ii)) TO THE BOARD BY ELECTRONIC MEANS, INCLUDING COMPUTER-TO-COMPUTER, COMPUTER TO FACSIMILE MACHINE OR E-MAIL TRANSMISSION.

**§ 18.607. Biennial registration of perfusionist license.**

(a) The license of a perfusionist expires 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 in § 16.13(kL) (relating to licensure, certification, examination and registration fees), for application for biennial registration of perfusionist license.

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

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

(4) Disclose on the application pending criminal charges and a finding or verdict of guilt, admission of guilt, plea of nolo contendere, probation without verdict, disposition instead of trial or accelerated rehabilitative disposition in a 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 under section 13.3(n) of the act (63 P.S. § 422.13c(n)) during the biennial period immediately preceding the period for which registration is sought in accordance with § 18.610 (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.

**§ 18.608. Inactive AND EXPIRED status of perfusionist license; reactivation of inactive OR EXPIRED license.**

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

(1) The THE licensee requests in writing that the Board place the license on inactive status. THE BOARD WILL PROVIDE ~~Written~~ WRITTEN confirmation of inactive status will be forwarded to the licensee AT THE LICENSEE’S LAST KNOWN ADDRESS ON FILE WITH THE BOARD.

(2) (B) A PERFUSIONIST LICENSE WILL BE CLASSIFIED AS EXPIRED IF ~~The~~ THE licensee fails to register the license by the expiration of the biennial registration period on December 31 of each even-numbered year. THE BOARD WILL PROVIDE WRITTEN NOTICE TO A LICENSEE WHO FAILS TO MAKE BIENNIAL REGISTRATION BY SENDING A NOTICE TO THE LICENSEE’S LAST KNOWN ADDRESS ON FILE WITH THE BOARD.

(b) (C) A perfusionist whose license has become inactive OR EXPIRED may not practice as a perfusionist in this Commonwealth until the license has been reactivated.

(e) (D) To reactivate an inactive OR EXPIRED license, the licensee shall apply on forms made available by the Board and fully answer the questions. The licensee shall:

(1) Include the documentation required under § 18.610(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 a 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 in § 16.13(k) (L) (relating to licensure, certification, examination and registration fees).

(3) Verify that the licensee did not practice as a perfusionist in this Commonwealth while the license was inactive OR EXPIRED except as provided in subsection (d) (E).

(d) (E) A licensee who has practiced with an inactive OR EXPIRED license and who cannot make the verification required under subsection (e) (D)(3) shall also pay the fees required under 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 OR EXPIRED 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 OR EXPIRED 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 OR EXPIRED until the date the reactivation application is filed.

**§ 18.609. 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 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 in accordance with 2 Pa.C.S. §§ 501—508 and 701—704

(relating to Administrative Agency Law), the Board may impose a corrective action in section 42 of the act (63 P.S. § 422.42).

(b) Unprofessional conduct includes:

- (1) Engaging in conduct prohibited under § 16.110 (relating to sexual misconduct).
- (2) Performing an act in a health care 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 health care practice beyond the licensee's authority to practice.
- (5) Representing oneself to be a physician, physician assistant, certified registered nurse practitioner or other health care 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 under statute or regulation.
- (8) Failing to provide supervision as required under 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 the Commonwealth, the United States, 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.

**§ 18.610. 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. An hour of continuing education may not be used to satisfy the requirement of paragraph (1) for more than 1 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 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 shall 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 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 consists 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 consists 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 consists of a copy of the program agenda.

- (4) Proof of participation in an ABCP knowledge base survey consists of a letter from ABCP.
- (5) Proof of reading or viewing medical journals, audio-visual or other educational materials consists of a list of the ~~complete~~ COMPLETE citation reference for the materials read or reviewed.
- (6) Proof of participation in a perfusion-related self-study module or electronic forum consists of a copy of the printed completion document supplied by the ~~sponsor~~ PROVIDER.
- (7) Proof of participation in a perfusion-related journal club consists of the meeting agenda with topic and date.
- (8) Proof of completion of an academic course consists 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 consists of a copy of the meeting agenda.
- (10) Proof of participation as a clinical or didactic instructor in an accredited program consists 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~~ VISITOR consists of a letter from the ABCP.
- (12) (C) 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) (D) The Board will MAY audit licensees to verify compliance with continuing education requirements. A licensee shall submit proof of continuing education activities upon request by the Board.

(e) (E) 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. 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. Five continuing education credits may be earned for each publication.

(iii) Presentation at an ABCP-approved or international, National, regional, state or local perfusion meeting. Five continuing education credits may be earned for each presentation. Two credits may be earned for each poster presentation or exhibit.

(iv) Completion of an ABCP-knowledge base survey. Five continuing education hours may be earned for completing the continuing education activity. The activity may only be counted for credit once in a 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. 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.

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. 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 health care-related academic course at a regionally accredited college or university. One continuing education credit may be earned biennially.

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

(vi) Working as a clinical or didactic instructor in an accredited school of perfusion. Two continuing education credits may be earned FOR TEACHING A SINGLE COURSE with a maximum of four credits biennially.

(vii) Participation in a site visitors' workshop or as an official site visitor for perfusion program accreditation. Five continuing education credits may be earned FOR PARTICIPATION IN A SITE VISITOR'S WORKSHOP OR AS AN OFFICIAL SITE VISITOR FOR PERFUSION PROGRAM ACCREDITATION. The activity may only be counted for credit once in a biennial period.

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

**§ 18.611. Professional liability insurance coverage for licensed perfusionists.**

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

(b) Proof of professional liability insurance coverage 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 Insurance Department in 31 Pa.Code Chapter 243 (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~~ OF the license if the licensee has not provided proof of professional liability insurance coverage and will remain inactive until the licensee provides proof of insurance coverage.

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



STATE BOARD OF MEDICINE

FINAL RULEMAKING

16A-4935 – PERFUSIONISTS

Public commentators

There were no public comments received relating to this rulemaking.



**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 10, 2013

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

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

Dear Chairman Lutkewitte:

Enclosed is a copy of a final 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 "Andrew J. Behnke".

Andrew J. Behnke, MD, Chair  
State Board of Medicine

CKM/TL:aaw

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  
Teresa Lazo, 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: PERFUSIONISTS  
 AGENCY: DEPARTMENT OF STATE  
 BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS  
 STATE BOARD OF MEDICINE


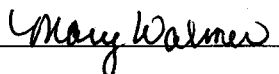
**TYPE OF REGULATION**

- Proposed Regulation
- X Final Regulation
- Final Regulation with Notice of Proposed Rulemaking Omitted
- 120-day Emergency Certification of the Attorney General
- 120-day Emergency Certification of the Governor
- Delivery of Tolled Regulation
  - a. With Revisions
  - b. Without Revisions

2013 MAY 10 AM 10:47

RECEIVED  
IRRC

**FILING OF REGULATION**

<u>DATE</u>	<u>SIGNATURE</u>	<u>DESIGNATION</u>
		<i>HOUSE COMMITTEE ON PROFESSIONAL LICENSURE</i>
5/10/13		MAJORITY CHAIR <u>Julie Harhart</u>
		MINORITY CHAIR
		<i>SENATE COMMITTEE ON CONSUMER PROTECTION &amp; PROFESSIONAL LICENSURE</i>
5/10/13		MAJORITY CHAIR <u>Robert M. Tomlinson</u>
		MINORITY CHAIR
		<i>INDEPENDENT REGULATORY REVIEW COMMISSION</i>
		ATTORNEY GENERAL (for Final Omitted only)
		LEGISLATIVE REFERENCE BUREAU (for Proposed only)