

Regulatory Analysis Form

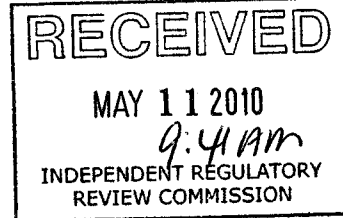
(Completed by Promulgating Agency)



IRRC

INDEPENDENT REGULATORY REVIEW COMMISSION

SECTION I: PROFILE



(1) Agency:

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

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

Identification Number:

5320

IRRC Number:

2849

(3) Short Title:

Perfusionist

(4) PA Code Cite:

49 Pa. Code §§ 25.231, 25.611-25.621

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

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

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

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

(717)783-4858; P.O. Box 2649, Harrisburg, PA 17105-2649; (717)787-7769; st-osteopathic@state.pa.us

(All Comments will appear on IRRC'S website)

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

- Proposed Regulation
- Final Regulation
- Final Omitted Regulation
- Emergency Certification Regulation;
 - Certification by the Governor
 - Certification by the Attorney General

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

The act of June 11, 2008 (P.L. 161, No. 20) (Act 20) amended the Osteopathic Medical Practice Act (the act) (63 P.S. §§ 271.1 et seq.) to provide for licensure of perfusionists. This proposed rulemaking would implement licensing of perfusionists under Act 20.

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

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

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

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

SECTION II: STATEMENT OF NEED

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

This rulemaking is authorized by sections 13.3 and 16 of the act (63 P.S. §§ 271.13c and 271.16).

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

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

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

The proposed rulemaking is required to implement licensure of perfusionists as mandated by the Act 20 amendments to the act. The General Assembly recognized the benefits of perfusionist licensure in amending the act.

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

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

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

Persons currently practicing perfusion in this Commonwealth will be adversely affected by the rulemaking by being required to become licensed, as required by the Act 20 amendments to the act. The Board does not foresee any other groups being adversely affected by the rulemaking.

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

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

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SECTION III: COST AND IMPACT ANALYSIS

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

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

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

Initial license application fees of \$12,500 [$\$50 \times (\frac{1}{2} 500)$] in each fiscal year beginning 2010-11. Temporary graduate license application fees of \$1250 [$\$50 \times \frac{1}{2} 50$] in each fiscal year beginning 2010-11; and temporary provisional license application fees of \$500 [$\$40 \times \frac{1}{2} 25$] in each fiscal year beginning 2010-11. Renewal application fees of \$23,125 [$\$50 \times (500 - 50 + \frac{1}{4} 50)$] in fiscal year 2010-11, \$1250 [$\$50 \times \frac{1}{2} 50$] in 2012-13, \$23,750 [$\$50 \times (500 - 50 + \frac{1}{2} 50)$] in fiscal year 2013-14 and repeating in two-year cycles. Reactivation application fees of \$625 [$\$50 \times \frac{1}{4} 50$] in fiscal year 2010-11, and \$1250 [$\$50 \times \frac{1}{2} 50$] in each subsequent fiscal year.

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

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

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

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

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

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

There are no other costs or savings to state government associated with compliance with the rulemaking.

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

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS:	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15
Regulated Community						
Local Government						
State Government						
Total Savings	NA	NA	NA	NA	NA	NA
COSTS:						
Regulated Community	N/A	N/A	\$38,000	\$16,750	\$39,250	\$16,750
Local Government	N/A	N/A	N/A	N/A	N/A	N/A
State Government	N/A	N/A	N/A	N/A	N/A	N/A
Total Costs	N/A	N/A	\$38,000	\$16,750	\$39,250	\$16,750

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REVENUE LOSSES:						
Regulated Community						
Local Government						
State Government						
Total Revenue Losses	NA	NA	NA	NA	NA	NA

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

Program	FY -3 (FY 06-07) actual	FY -2 (FY 07-08) projected	FY -1 (FY 08-09) budgeted	Current FY (FY 09-10) budgeted
Pa. State Board of Osteopathic Medicine	\$822,869	\$761,791	\$1,349,000	\$1,389,000

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

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

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

The Board did not send an exposure draft of the proposed rulemaking or solicit input from interested parties. However, the Board discussed the proposed rulemaking at public meetings of the Board, which are routinely attended by members of the regulated community and their professional associations.

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

No alternative regulatory schemes were considered.

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

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

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

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

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

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

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

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

Because this proposed rulemaking implements licensure for perfusionists, persons practicing perfusion will be required to obtain licensure by submitting appropriate applications.

This proposed rulemaking would not require any legal, accounting or consulting procedures or any additional recordkeeping or other paperwork.

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

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

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU
(Pursuant to Commonwealth Documents Law)

RECEIVED
MAY 11 2010
9:4 AM
INDEPENDENT REGULATORY
REVIEW COMMISSION

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 Agencies.

[Signature]

State Board of Osteopathic Medicine

[Signature]

BY: _____
(DEPUTY ATTORNEY GENERAL)

(AGENCY)

BY: _____

APR 29 2010

DOCUMENT/FISCAL NOTE NO. 16A-5320

Andrew C. Clark
MAR - 9 2010

DATE OF APPROVAL

DATE OF APPROVAL

DATE OF ADOPTION:

BY: *[Signature]*
Joseph C. Gallagher, Jr., DO

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

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

TITLE: Chairman
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

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

PROPOSED RULEMAKING

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

49 Pa. Code §§ 25.231, 25.611-25.618
PERFUSIONIST

The State Board of Osteopathic Medicine (Board) proposes to amend § 25.231 (relating to schedule of fees) and to add §§ 25.611-25.618 (relating to perfusionists), to read as set forth in Annex A.

Effective date

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

Statutory Authority

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

Background and Need for the Amendment

The act of June 11, 2008 (P.L. 161, No. 20) (Act 20) amended the act to provide for licensure of perfusionists. Section 2 of the act now defines the term “perfusion” as “the functions necessary for the support, treatment, measurement or supplementation of the cardiovascular systems or other organs, or a combination of those functions by monitoring and analyzing the parameters of the systems under the supervision of a physician.” This proposed rulemaking would amend the Board’s regulations to implement licensure of perfusionists under the act as amended by Act 20. Practice of perfusion in this Commonwealth without a license from the Board will be prohibited after August 10, 2010. This rulemaking is also designed to provide to prospective licensees adequate notice of the requirements for licensure as a perfusionist.

Description of the Proposed Amendments

The proposed rulemaking would add licensure as a perfusionist. The proposed rulemaking would first amend § 25.231 (relating to schedule of fees) to set forth the fees associated with perfusionist licensure to be charged by the Board, as authorized by section 13.3(l) of the act (63 P.S. § 271.13c(l)). In order to recover the costs of providing those services, the fee for applications for perfusionist license, reactivation of perfusionist license, and temporary graduate perfusionist license would each be \$50, and the fee for application for temporary provisional perfusionist license would be \$40. Because the Board believes that the cost to provide the service would be minimal and does not want to delay application, the Board has not set any fee for notification of emergency practice as a perfusionist. In order to provide for an appropriate share of the general costs of operating the Board, the biennial renewal fee for a perfusionist would be \$50.

The proposed rulemaking would also add a new Subchapter M (relating to perfusionists). Proposed § 25.611 (relating to purpose) would identify the purpose of the subchapter as providing for licensure of perfusionists. Proposed § 25.312 (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 defines “ABCP” as the American Board of Cardiovascular Perfusion, the national body that both accredits perfusion education programs and certifies perfusionists. The Board defines “accredited

perfusion program approved by the Board” as a perfusion program accredited by a nationally recognized accrediting agency approved by the Board. The Board further defines “nationally recognized accrediting agency approved by the Board” as ABCP, or any other organization for which the Board publishes notice that the organization is approved by the Board as an accrediting agency for perfusionist programs; and defines “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 perfusionist programs. Finally, the Board defines an “hour of continuing education” as “at least 50 minutes of instruction (including question and answer sessions) in an approved course of continuing education or an equivalent time that an on-line or correspondence course would be presented live.” This time is consistent with the standards for continuing education that is required by ABCP for recertification.

Proposed § 25.613 would address the application for licensure as perfusionist. Under proposed § 25.613(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. § 271.13c(f) sets five criteria for licensure as a perfusionist: at least 18 years of age, good moral character, graduation from an accredited perfusion program approved by the Board, and certification by a certifying agency approved by a nationally recognized accrediting agency approved by the Board. Accordingly, proposed § 25.613(b)(1) would provide that the Board will license as a perfusionist an applicant who demonstrates that the applicant satisfies the requirements of section 13.3(f) of the act for licensure as a perfusionist. Because as discussed below for proposed § 25.621 (relating to professional liability insurance coverage for licensed perfusionist), section 13.3(k) of the act (63 P.S. § 271.13c(k)) requires a perfusionist to carry a minimum level of professional liability insurance, proposed § 25.613(b)(2) would require that an applicant provide proof of liability insurance. Because as discussed below the Board is also setting forth in its proposed rulemaking grounds for disciplinary action in proposed § 25.619 (relating to disciplinary action for licensed perfusionist), proposed § 25.613(c) would provide that the Board may, in its discretion, deny an application for perfusionist licensure upon those grounds for disciplinary action.

The Board has not proposed any rulemaking to incorporate the grandfather provision of section 13.3(g) of the act (63 P.S. § 271.13c(g)), which, during the first two years after the effective date of Act 20, permits a person who was not a graduate of an accredited program prior to 1981, but who met the then-current eligibility requirements for certification as a certified clinical perfusionist and subsequently was certified, to become licensed if the person otherwise complies with the requirements for licensure. Not only is this statutory provision self-executing, but the opportunity to take advantage of it will expire August 10, 2010, not long after final promulgation of the regulation.

Proposed § 25.614 would address the application for temporary graduate perfusionist license, as provided in section 13.3(h) of the act (63 P.S. § 271.13c(h)). Under proposed § 25.614(a), an applicant must submit a completed application form, including any necessary supporting documents, and pay the required application fee. Section 13.3(h)(1)(i) of the act (63 P.S. § 271.13c(h)(1)(i)) provides that an individual who has graduated from an educational program in compliance with the education requirements and is eligible for and has applied for the examination may receive a temporary graduate license. These criteria, along with good moral character and being at least 18 years of age, would be set forth in proposed § 25.214(b)(1) as the basic requirements for a temporary graduate license. Because as discussed below for proposed § 25.621 (relating to professional

liability insurance coverage for licensed perfusionist), section 13.3(k) of the act (63 P.S. § 271.13c(k)) requires a perfusionist to carry a minimum level of professional liability insurance, proposed § 25.614(b)(2) would require that an applicant provide proof of liability insurance. Because as discussed below the Board is also setting forth in its proposed rulemaking grounds for disciplinary action in proposed § 25.619 (relating to disciplinary action for licensed perfusionist), proposed § 25.614(c) provides that the Board may, in its discretion, deny an application for perfusionist temporary graduate license upon those grounds for disciplinary action. Because section 13.3(h)(1)(iii) of the act (63 P.S. § 271.13c(h)(1)(iii)) provides that a temporary graduate license is to be issued for two years but not be renewable, proposed § 25.614(d) would provide that a temporary graduate perfusionist license will expire two years after the date of issuance and may not be renewed. Because section 13.3(h)(1)(iv) of the act (63 P.S. § 271.13c(h)(1)(iv)) provides that a temporary graduate license is to expire upon notice of failing the required examination, proposed § 25.614(e) would provide that a temporary graduate perfusionist license will expire upon notice to the Board that the holder failed the nationally recognized accrediting agency's certification examination.

Proposed § 25.615 would address the application for temporary provisional perfusionist license, as provided in section 13.3(i) of the act (63 P.S. § 271.13c(i)). Under proposed § 25.615(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 (63 P.S. § 271.13c(i)(1)) 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, along with good moral character and being at least 18 years of age, are set forth in proposed § 25.615(b)(1) as the basic requirements for a temporary provisional license. Because as discussed below for proposed § 25.611 (relating to professional liability insurance coverage for licensed perfusionist), section 13.3(k) of the act requires a perfusionist to carry a minimum level of professional liability insurance, proposed § 25.615(b)(2) would require that an applicant provide proof of liability insurance. Because as discussed below the Board is also setting forth in its proposed rulemaking grounds for disciplinary action in proposed § 25.619 (relating to disciplinary action for licensed perfusionist), proposed § 25.615(c) would provide that the Board may, in its discretion, deny an application for perfusionist temporary provisional license upon those grounds for disciplinary action. Because section 13.3(i)(2) of the act provides that a temporary provisional license is to be issued for one year but not be renewable, proposed § 25.615(d) would provide that a temporary provisional perfusionist license will expire one year after the date of issuance and may not be renewed thereafter.

Section 13.3(j) of the act (63 P.S. § 271.13c(j)) provides an exemption to the general prohibition against unlicensed practice for one-time temporary emergency services by an out-of-state licensed perfusionist where the licensed perfusionist that would normally have provided the services is unavailable or incapable of providing services and no other licensed perfusionist is available or capable of providing services. Section 13.3(j) requires the out-of-state perfusionist to provide to the Board electronic notice of the emergency and acknowledgment that the out-of-state perfusionist is subject to jurisdiction of the Board as if licensed by the Board and requires the healthcare facility to

provide to the Board electronic notice that services were provided and the grounds for the exemption. Proposed § 25.616(a) 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 § 25.616(b), the out-of-state perfusionist or other person acting on behalf of the out-of-state perfusionist (such as healthcare facility staff) must submit a completed registration on forms provided by the Board. It is anticipated that this registration will be done almost exclusively from the Board's website. Because "one-time emergency perfusionist service" is not defined in section 13.3(j), proposed § 25.616(c) would provide that the services are not limited to a single procedure or patient or group of related patients, the out-of-state perfusionist may not provide emergency services for a period longer than 72 hours. However, section 13.3(j)(3) of the act prohibits the out-of-state perfusionist from providing services other than the emergency services. Consistent with section 13.3(j)(2) (out-of-state perfusionist shall obtain license if providing any future perfusionist service), proposed § 25.616(d) would provide that the out-of-state perfusionist may not provide temporary emergency perfusionist service in this Commonwealth without being licensed as a perfusionist or holding a temporary graduate license or temporary provisional license.

Because all licenses and certifications issued by the Board within the Bureau of Professional and Occupational Affairs expire after two years and must be renewed biennially, proposed § 25.617 would address renewal of perfusionist license. Proposed § 25.617(a) would require the licensed perfusionist to register by October 31 of each even-numbered year, the expiration date for all other licenses and certifications issued by the Board. Additionally, this subsection would require a licensed perfusionist to notify the Board within 10 business days of any change in name or address. Substantially identical to existing § 25.272 (relating to name and address changes) for licensed doctors of osteopathy, this subsection permits the Board to properly send notices, including notices of renewal, to the licensees. Under proposed § 25.617(b), a licensed perfusionist is required to complete and submit the renewal application, including the required renewal fee, and disclose any license to practice as a perfusionist in any other state, disclose any disciplinary action pending before or taken by the appropriate healthcare licensing authority in another state, disclose any pending criminal charges and any convictions, verify that the licensee has complied with the continuing education requirements of § 13.3(n) of the act (63 P.S. § 271.13c(n)), and verify that if practicing as a perfusionist in this Commonwealth the licensee maintains professional liability insurance coverage as required by section 13.3(k) of the act. Because ABCP requires a perfusionist to complete a minimum number of procedures each year in order to maintain certification, the Board has chosen not to require continued national certification as a condition of renewal.

Proposed § 25.618 would address inactive status of perfusionist licensure. Proposed § 25.618(a) would provide that license may become inactive either by the licensee's request or by expiration at the end of the biennial renewal 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 § 25.618(a)(1) would provide that the Board will provide written notice to the licensee. Proposed § 25.618(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 § 25.618(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. § 271.13c(n)(5)), pay the

current renewal fee and the reactivation fee specified in § 25.231 (relating to schedule of fees), and verify that the licensee did not practice as a perfusionist in this Commonwealth while the license was inactive. If the licensee does not verify that the licensee did not practice during the period of lapse, the license may be reactivated under proposed § 25.618(d) by paying additional fees. Under that proposed section, in addition to the requirements of subsection (c), the licensee must pay the renewal fee for passed renewal periods and a late fee of \$5 per month. This late fee is the standard late renewal fee of section 225 of the Bureau of Professional and Occupational Affairs Fee Act (63 P.S. § 1401-225). However, as provided in proposed § 25.618(d), payment of late fees will not preclude the Board from taking disciplinary action for practicing while the license was inactive.

Proposed § 25.619 next addresses disciplinary action. Although section 13.3 of the act does not specifically authorize the Board to take disciplinary action against a licensed perfusionist, section 13.3(m) of the act (63 P.S. § 271.13c(m)) provides that disciplinary action taken by the Board against a perfusionist shall be enforceable by the State Board of Osteopathic Medicine if the perfusionist seeks licensure by that board. Section 15(b) of the act (63 P.S. § 271.15(b)) authorizes the Board “to refuse, revoke or suspend the license of a physician assistant or respiratory therapist, or the certification of a certified athletic trainer,” i.e., the other non-physicians licensed by the Board, for a variety of grounds. Accordingly, proposed § 25.619(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 15(b) of the act and that the Board may impose any of the corrective actions of section 15(c) of the act (63 P.S. § 271.15(c)). Because section 15(b)(9) of the act authorizes the Board to take disciplinary action for immoral or unprofessional conduct, proposed § 25.619(b) would define unprofessional conduct and proposed § 25.619(c) would define immoral conduct. Modeled upon § 25.201 (grounds for complaint against physician assistant), unprofessional conduct would include: performing acts in a healthcare profession in a fraudulent or incompetent or negligent manner, performing acts in the practice of a healthcare profession in violation of statute or regulation in this or another state, violating a provision of the act or regulation of the Board setting a standard of professional conduct, engaging in healthcare practice beyond the licensee’s authority to practice, representing oneself to be a licensed physician or other healthcare provider, practicing while the licensee’s ability to do so is impaired by alcohol or drugs or disability, and revealing personally identifiable facts obtained as the result of the practitioner-patient relationship; and immoral conduct would include: misrepresenting or concealing a material fact in obtaining a license or reactivating or renewing the license, being convicted of a crime involving moral turpitude, or committing an act involving moral turpitude or dishonesty or corruption. Additionally, unprofessional conduct would include engaging in any conduct prohibited by § 25.216 (relating to sexual misconduct). Section 13.3(e)(2) of the act (63 P.S. § 271.13c(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. And section 13.3(e)(3) of the act (63 P.S. § 271.13c(e)(3)) exempts a perfusion graduate who, among other requirements, is performing under the supervision and responsibility of a perfusionist. Accordingly, proposed § 25.619(b)(9) would include in unprofessional conduct failing to provide supervision as required by section 13.3(e)(2) of the act of a perfusion student or failing to provide supervision as required by section 13.3(e)(3) of the act of a perfusion graduate who is not otherwise licensed by the Board to practice perfusion.

Section 13.3(n) of the act provides for required continuing education, and proposed § 25.620

would address that topic. Proposed § 25.620(a) would set forth the general credit hour requirements. As required by section 13.3(n)(2) of the act, proposed § 25.620(a)(1) would require each licensed perfusionist to complete at least 30 hours of continuing education – including at least 10 hours in category I continuing education - applicable to the practice of perfusion during each biennial renewal period. Consistent with section 13.3(n)(3) of the act, a licensee would not be required to complete continuing education during the biennial renewal period in which the licensee was first licensed. Although a licensee would not be permitted to carry over continuing education credit into a subsequent renewal period, proposed § 25.620(a)(2) would recognize that a licensee may need to make up deficient continuing education credit in order to reactivate an inactive license or if otherwise ordered by the Board. However, a particular hour of continuing education taken in a given biennial renewal period may not be used to satisfy the requirement both for that period and to make up a deficiency for a prior period. Proposed § 25.620(a)(3) would identify that a licensee who failed to complete the required continuing education is subject to disciplinary action. Section 13.3(n)(4) 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 § 25.620(a)(4) would require that the request be submitted at least 90 days before the end of the renewal 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 license would expire. Additionally, this proposed section would explicitly note that waiver may include extending the deadline, rather than simply relieving the licensee of the obligation to take continuing education. Proposed § 25.620(b) would set forth the standards for documentation of continuing education. Under proposed § 25.620(b)(1), a licensee must receive a record of completion from the continuing education provider, setting forth the participant's name, the provider's name, the date of the course, the name of the course and the number of hours of continuing education. Proposed § 25.620(b)(2) would require the licensee to retain the record for at least 5 years after completion of the continuing education course or renewal period for the continuing education was required, whichever is later. Because records of continuing education will not be sent to the Board and the Board will not track licensees' completion of required continuing education, the Board will conduct post-renewal audits of licensees to verify compliance. Proposed § 25.620(c) would set forth the types of activities for which continuing education credit may be earned. In order to better facilitate compliance with the requirements, these standards are modeled upon those of ABCP. Under proposed § 25.620(c)(1), category I continuing education (which must provide at least 10 of the required 30 hours) could be earned by attendance at perfusion meetings, publication of a perfusion-related book chapter or paper in a professional journal, presentation at a perfusion meeting, participation in site visitor workshop or as a site visitor for perfusion program accreditation, or completion of an ABCP-approved self-directed continuing education course for which the licensee scores at least 80% on an examination. Under proposed § 25.620(c)(2), other continuing education to reach the required total could be earned by reading journals or other educational materials, participating in electronic forums or journal clubs, participation in degree-oriented professional-related course work, presentation of perfusion topics at a non-perfusion meeting, or work as a clinical or didactic instructor in an accredited school of perfusion. However, as noted in section 13.3(n)(6) of the act, proposed § 25.620(c)(3) would prohibit continuing education credit for a course in office management.

Section 13.3(k) of the act (63 P.S. § 271.13c(k)) provides for required professional liability insurance for perfusionists, and proposed § 25.611(a) would require a licensed perfusionist to maintain a level of professional liability insurance as required by section 13.3(k) of the act.

Conversely, proposed § 25.611(d) would prohibit a perfusionist who does not have the required amount of liability insurance from practicing as a perfusionist in this Commonwealth. Section 13.3(k)(2) of the act requires an applicant to provide proof that the applicant has obtained the liability insurance. Proposed § 25.611(b) would set forth the general requirement that proof of liability insurance consists of a certificate of insurance of a copy of the declarations page from the insurance policy setting forth the effective and expiration dates and the dollar amounts of coverage. However, section 13.3(k)(2) permits an applicant to file with the application a letter from an insurance carrier stating that the applicant will be covered in the required amounts effective upon issuance of the license, but the applicant must then provide submit the certificate of insurance of copy of the declaration page within 30 days after issuance of the license. In order to effectuate this provision, proposed § 25.611(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 inactive 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. The amendments will impose no additional paperwork requirements upon the Commonwealth, political subdivisions or the private sector.

Sunset Date

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

Regulatory Review

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

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

Public Comment

Interested persons are invited to submit written comments, suggestions or objections regarding this proposed rulemaking to Regulatory Unit Counsel, Department of State, by mail at P.O. Box 2649, Harrisburg, PA 17105-2649, or by email at st-osteopathic@state.pa.us, within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*. Please reference No. 16A-5323 (perfusionist), when submitting comments.

Joseph C. Gallagher, Jr., DO
Chairman

ANNEX A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

SUBPART A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 25. STATE BOARD OF OSTEOPATHIC MEDICINE

* * * * *

Subchapter F. FEES

§ 25.231. Schedule of fees.

An applicant for a license, certificate, registration or service shall pay the following fees at the time of application:

* * * * *

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

* * * * *

Subchapter M. PERFUSIONISTS

§ 25.611. Purpose.

This subchapter implements section 13.3 of the act (63 P.S. § 271.13c) pertaining to perfusionists, which was added by the act of June 11, 2008 (P.L. 161, No. 20), effective August 10, 2008.

§ 25.612. Definitions.

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

ABCP – American Board of Cardiovascular Perfusion.

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

Extracorporeal circulation – As defined in section 2 of the act (63 P.S. § 271.2), the diversion of a patient’s blood through a heart-lung machine or similar device that assumes the functions of the patient’s heart, lung, kidney, liver or other organs.

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

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

Perfusion – As defined in section 2 of the act (63 P.S. § 271.2), the functions necessary for the support, treatment, measurement or supplementation of the cardiovascular systems 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 act of December 20, 1985 (P.L. 457, No. 112), known as the Medical Practice Act of 1985.

Perfusionist – As defined in section 2 of the act (63 P.S. § 271.2), an individual who is licensed to practice perfusion by the Board or the State Board of Medicine.

Ventricular assist device – As defined in section 2 of the act (63 P.S. § 271.2), a mechanical device used to partially or completely replace the function of a failing heart through connections to the heart and great vessels that may be located intracorporeally or extracorporeally. The term includes a device that is placed intravascularly or extravascularly and provides support through direct means or via counterpulsation.

§ 25.613. Application for perfusionist license.

(a) An applicant for a license to practice as a perfusionist shall submit, on forms supplied by the Board, a completed application, including all necessary supporting documents, for license to practice as a perfusionist and pay the fee of § 25.231 (relating to schedule of fees) for application for perfusionist license.

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

(1) Demonstrates that the applicant satisfies the requirements of section 13.3(f) of the act (63 P.S. § 271.13c(f)) for licensure to practice as a perfusionist, including the following:

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

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

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

(2) Provides proof as set forth in § 25.621 (relating to professional liability insurance coverage for licensed perfusionist) that the applicant has obtained professional

liability insurance as required by section 13.3(k) of the act (63 P.S. § 271.13c(k)).

(3) Otherwise complies with this subchapter.

(c) In its discretion, the Board may deny an application for licensure as a perfusionist upon the grounds for disciplinary action set forth in § 25.619 (relating to disciplinary action for licensed perfusionist).

§ 25.614. Application for temporary graduate perfusionist license.

(a) An applicant for a temporary graduate perfusionist license shall submit, on forms supplied by the Board, a completed application, including all necessary supporting documents, and pay the fee set forth in § 25.231 (relating to schedule of fees) for application for temporary graduate perfusionist license.

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

(1) Demonstrates that the applicant satisfies the requirements of section 13.3(h)(1)(i) of the act (63 P.S. § 271.13c(h)(1)(i)) for temporary graduate licensure to practice as a perfusionist, including all of the following:

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

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

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

(2) Provides proof as set forth in § 25.621 (relating to professional liability

insurance coverage for licensed perfusionist) that the applicant has obtained professional liability insurance as required by section 13.3(k) of the act (63 P.S. § 271.13c(k)).

(3) Otherwise complies with this subchapter.

(c) In its discretion, the Board may deny an application for temporary graduate perfusionist license upon the grounds for disciplinary action set forth in § 25.619 (relating to disciplinary action for licensed perfusionist).

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

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

§ 25.615. Application for temporary provisional perfusionist license.

(a) An applicant for a temporary provisional perfusionist license shall submit, on forms supplied by the Board, a completed application, including all necessary supporting documents, and pay the fee set forth in § 25.231 (relating to schedule of fees) for application for temporary graduate perfusionist license.

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

(1) Demonstrates that the applicant satisfies the requirements of section 13.3(i) of the act (63 P.S. § 271.13c(i)) for temporary provisional licensure to practice as a perfusionist, including the following:

(i) The applicant holds a current license in good standing under the laws of another state, the District of Columbia or a territory of the United States

that includes certification by a certifying agency approved by a Nationally-recognized accrediting agency.

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

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

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

(3) Otherwise complies with this subchapter.

(c) In its discretion, the Board may deny an application for certification as a perfusionist upon the grounds for disciplinary action set forth in § 25.619 (relating to disciplinary action for licensed perfusionist).

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

§ 25.616. 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. § 271.13c(j)).

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

(c) Although not limited to a single procedure or single patient or group of related

patients, an out-of-state perfusionist may provide temporary emergency perfusionist services in this Commonwealth for not longer than a period of 72 hours.

(d) An out-of-state perfusionist may not provide temporary emergency perfusionist service in this Commonwealth more than once without being licensed in accordance with §§ 25.613, 25.614 or 25.615 (relating to application for perfusionist license; application for temporary graduate perfusionist license; and application for temporary provisional perfusionist license).

§ 25.617. Renewal of perfusionist license.

(a) A licensed perfusionist shall register biennially by October 31 of each even-numbered year to retain the right to engage in practice. It is the responsibility of the licensee to notify the Board of any change in name or mailing address within 10 business days of the change.

(b) A licensee applying for biennial license renewal shall submit a completed application, including payment of the biennial renewal fee as set forth in § 25.231 (relating to schedule of fees) for application for biennial renewal of perfusionist license. On the biennial registration application, the licensed perfusionist shall:

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

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

(3) Disclose any pending criminal charges and any finding or verdict of guilt.

admission of guilt, plea of *nolo contendere*, or other criminal conviction since the most recent application for renewal.

(4) Verify that the licensed perfusionist has complied with the continuing education requirements mandated by section 13.3(n) of the act (63 P.S. § 271.13c(n)) during the biennial period immediately preceding the period for which renewal is sought in accordance with § 25.620 (relating to continuing education for licensed perfusionist).

(5) Verify that, if practicing as a perfusionist in this Commonwealth, the licensee maintains professional liability insurance coverage in accordance with section 13.3(k) of the act (63 P.S. § 271.13c(k)).

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

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

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

(2) The licensee fails to renew the certificate by the expiration of the renewal period, that is by December 31 of each even-numbered year.

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

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

(1) Include the documentation required by § 25.620(b) (relating to documentation of continuing education) 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. § 271.13c(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 renewal fee and the reactivation application fee specified in § 25.231 (relating to schedule of fees).

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

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

(1) A licensee whose license was active at the end of the immediately preceding biennial renewal period and who practiced after the license became inactive shall pay a late fee of \$5 for each month or part of 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 renewal fee for each biennial renewal period during which the licensee practiced and shall pay a late fee of \$5 for each month or part of 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.

§ 25.619. Disciplinary action for licensed perfusionist.

(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 15(b) of the act (63 P.S. § 271.15(b)). Following a final determination subject to the

right of notice, hearing and adjudication and the right of appeal therefrom in accordance with Title 2 of the Pennsylvania Consolidated Statutes (relating to administrative law and procedure), the Board may impose any of the corrective actions of section 15(c) of the act (63 P.S. § 271.15(c)).

(b) Unprofessional conduct includes:

(1) Engaging in any conduct prohibited by § 25.216 (relating to sexual misconduct).

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

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

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

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

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

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

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

(9) Failing to provide supervision as required by section 13.3(e)(2) of the act (63 P.S. § 271.13c(e)(2)) of a perfusion student or failing to provide supervision as required by section 13.3(e)(3) of the act (63 P.S. § 271.13c(e)(3)) of a perfusion graduate who is not otherwise licensed by the Board to perform perfusion in this Commonwealth.

(c) Immoral conduct includes:

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

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

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

§ 25.620. Continuing education for licensed perfusionist.

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

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

(2) Except as permitted in § 25.618(c)(1) (relating to inactive status of perfusionist license; reactivation of inactive license), paragraph (4) or as directed by the Board, continuing education may satisfy the requirement of paragraph (1) only for the biennium during which it was completed. No hour of continuing education may be used to satisfy the requirement of paragraph (1) for more than one biennium.

(3) Unless otherwise excused by the act or this subchapter, failure to complete the minimum required amount of continuing education during the applicable renewal period as required by section 13.3(n) of the act (63 P.S. § 271.13.3(n)) and this section will subject the licensee to discipline under section 15(b)(7) of the act (63 P.S. § 271.15(b)(7)).

(4) A licensee seeking waiver of the continuing education requirements under section 13.3(n)(4) of the act (63 P.S. § 271.13c(n)(4)) shall submit the request with all supporting documentation to the Board at least 90 days prior to end of the renewal period for which waiver is sought. Waiver may include extending the deadline by which the required continuing education must be completed.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(ii) Participation in electronic forums.

(iii) Participation in a journal club.

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

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

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

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

§ 25.621. 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. § 271.13c(k)).

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

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

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

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE

DATE: January 14, 2010

SUBJECT: Proposed Rulemaking:
State Board of Osteopathic Medicine
Perfusionist (16A-5320)

TO: Andrew C. Clark, Deputy General Counsel
Office of General Counsel

FROM: Thomas A. Blackburn, Regulatory Unit counsel
Department of State

AND

There are no significant legal and policy issues presented by this proposed rulemaking of the State Board of Osteopathic Medicine. The proposed rulemaking would implement the provisions of Act 20 of 2008 providing for licensure of perfusionists.

I certify that I have reviewed this regulation for form and legality, that I have discussed any legal and policy issues with the administrative officers responsible for the program, and that all information contained in the Preamble and Annex is correct and accurate.

TAB



COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF OSTEOPATHIC MEDICINE
Post Office Box 2649
Harrisburg, Pennsylvania 17105-2649
(717) 783-4858

May 11, 2010

The Honorable Arthur Coccodrilli, Chairman
INDEPENDENT REGULATORY REVIEW COMMISSION
14th Floor, Harrisstown 2, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Proposed Regulation
State Board of Osteopathic Medicine
16A-5320: PERFUSIONIST

Dear Chairman Coccodrilli:

Enclosed is a copy of a proposed rulemaking package of the State Board of Osteopathic 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 "Joseph C. Gallagher, Jr. DO".

Joseph C. Gallagher, Jr., DO, Chairperson
State Board of Osteopathic Medicine

JCG/TAB:rs

Enclosure

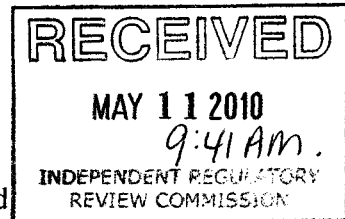
cc: Basil L. Merenda, Commissioner
Bureau of Professional and Occupational Affairs
Steven V. Turner, Chief Counsel
Department of State
Joyce McKeever, Deputy Chief Counsel
Department of State
Cynthia Montgomery, Regulatory Counsel & Senior Counsel in Charge
Department of State
Thomas A. Blackburn, Counsel
State Board of Osteopathic Medicine
State Board of Osteopathic Medicine

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

I.D. NUMBER: 16A-5320
 SUBJECT: PERFUSIONIST
 AGENCY: DEPARTMENT OF STATE
 STATE BOARD OF OSTEOPATHIC MEDICINE

TYPE OF REGULATION

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



FILING OF REGULATION

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