PROPOSED RULEMAKING

DEPARTMENT OF ENVIRONMENTAL PROTECTION

[25 PA. CODE CHS. 121, 123 AND 139]
Commercial Fuel Oil Sulfur Limits for Combustion
Units; Advance Notice of Final Rulemaking

The Department of Environmental Protection (Department) is soliciting comments on changes it recommends be made to the commercial fuel oil sulfur limits for combustion units proposed rulemaking published at 40 Pa.B. 5456 (September 25, 2010).

The draft final rulemaking establishes in Chapter 123 (relating to standards for contaminants) lower maximum allowable sulfur limits in commercial fuel oils used in oil-burning combustion units in this Commonwealth by replacing existing area-specific sulfur content limits with a Statewide sulfur content limit. The draft final rulemaking adds two terms and revises definitions of eight terms in Chapter 121 (relating to general provisions). The new terms are "ASTM" and "ultimate consumer" and the revised terms are "carrier," "commercial fuel oil," "distributor," "noncommercial fuel," "retail outlet," "terminal," "transferee" and "transferor." The draft final rulemaking also updates methods for testing sulfur in petroleum products in Chapter 139 (relating to sampling and testing). The American Society for Testing and Materials documents referenced in this chapter are available for public review at the Department's headquarters at the Rachel Carson State Office Building, 400 Market Street, Harrisburg, PA.

Combustion of sulfur-containing commercial fuel oils releases sulfur dioxide (SO₂) emissions, which contribute to the formation of regional haze and fine particulate matter $(PM_{2.5})$, both of which are serious human health and public welfare threats. The control measure in the draft final rulemaking is an important part of the Commonwealth's efforts to meet the 2018 reasonable progress goals for reducing regional haze established by the Commonwealth in consultation with the member states of the Mid-Atlantic/Northeast Visibility Union (MANE-VU). The control measure in the draft final rulemaking is also reasonably necessary to attain and maintain the National Ambient Air Quality Standards in this Commonwealth. If published in the Pennsylvania Bulletin as a final-form rulemaking, the regulations will be submitted to the United States Environmental Protection Agency (EPA) as a revision to the State Implementation Plan (SIP).

A. Summary of the Advance Notice of Final Rulemaking Changes

In response to comments received during the official public comment period on the proposed rulemaking for commercial fuel oil limits for combustion units and following the Department's review of other related information, the Department has prepared a draft final rulemaking for public comment. The draft final rulemaking contains significant changes in several areas. These changes include the following:

- The proposed rulemaking contained a sulfur limit of 15 parts per million (ppm) for No. 2 and lighter commercial fuel oil. The draft final rulemaking changes this limit to 500 ppm. The Department received a number of comments indicating that the 15 ppm limit was not necessary to reduce SO_2 and $PM_{2.5}$ emissions from heating oil and was not necessary for use in high efficiency boilers. Representatives of refineries commenting on the proposed rulemaking also pointed out that the cost of lowering the maximum sulfur content to 15 ppm was significantly greater than the cost of lowering the maximum content to 500 ppm and that the cost effectiveness (cost per ton) was too high for a reduction to 15 ppm. Several commentators indicated support for a 500 ppm sulfur limit in conjunction with a revised compliance date. Sulfur limits for fuel oils heavier than No. 2 are not changed in the draft final rulemaking. The draft final rulemaking expresses the new maximum allowable sulfur content limits in both ppm and percentages to improve clarity. The Department seeks updated information from commentators on the cost of the limits contained in the proposed final rulemaking.
- The proposed rulemaking contained a compliance date of May 1, 2012, for revised sulfur limits. The draft final rulemaking changes the compliance date for revised sulfur content limits to July 1, 2016. The Department received a number of comments indicating that the proposed compliance date and the timespan for compliance would present significant challenges to fuel producers to provide an adequate supply of compliant fuel at the 15 ppm content limit. In addition to providing an additional 2 years to achieve compliance, the Department changed the month in the draft final rulemaking to be consistent with the timing of requirements in New York and New Jersey. The Department seeks comment on the ability of the industry to meet the new compliance date taking into account the change in maximum allowable sulfur content limit.
- The proposed rulemaking included a provision for temporary suspension of the fuel limit and the ability of the Department to increase the applicable limit in certain conditions. The Department is making two changes to this provision. First, the Department removed the requirement that the Department would implement the provision only "with the written concurrence of the Administrator of the EPA." While consultation with the EPA will be necessary if and when the EPA approves the final-form rulemaking as a SIP revision, the Department does not believe that this consultation needs to be formalized in the regulation itself. Second, the Department removed the requirement that establishes a maximum allowable sulfur content of 500 ppm for a temporary increase. This change resolves the inconsistency in setting a temporary content limit that is the same as a permanent content limit. More importantly, the Department intends this provision to be rarely used and only after consideration of supply factors in an air basin; a specific content maximum above 500 ppm would not adequately allow the Department to consider use of fuel from all available sources.
- The proposed rulemaking would have required terminal owners or operators to develop and implement written procedures for sampling and testing to be made available to the Department upon request. These requirements

would have been in addition to the testing required of refineries that produce fuel oil intended for use in this Commonwealth. It was the intention of the Department to ensure that parties, including the ultimate consumer, could be assured that records of sulfur content required to be provided by transferor to transferee were supported by sampling and testing. The Department received comments that these requirements were duplicative. The Department agrees. Therefore, the draft final rulemaking requires sampling, testing and calculating of the sulfur content by a transferor only if records of sulfur content are not otherwise provided with the shipment of commercial fuel oil.

• In the draft final rulemaking, recordkeeping and reporting requirements specify that the sulfur content may be recorded in either ppm by weight or weight percent and clarify that the actual sulfur content (not the regulated maximum allowable sulfur content) must be in the record.

In performing the analysis for MANE-VU in February 2008, the Northeast States for Coordinated Air Use Management (NESCAUM) estimated that the annual SO₂ emission reduction benefits in this Commonwealth from the proposed rulemaking sulfur content limits (that is, 15 ppm sulfur content by 2018 and proposed limits for heavier oils) would be approximately 29,000 tons per year and that reducing sulfur content in No. 2 oil from existing levels to 500 ppm would account for approximately 21,000 tons per year of that reduction. An additional 4,000 tons per year reduction was for the decrease from 500 ppm to 15 ppm and 4,000 tons per year reduction for the decrease from existing levels to 500 ppm for Nos. 4 and 6 commercial fuel oils. Removing the requirement of 15 ppm sulfur content in commercial fuel oil in the draft final rulemaking from consideration at this time reduces the estimated maximum annual SO2 emission reduction from 29,000 tons per year to 25,000 tons per year. However, because the use of commercial fuel oils has been declining overall in this Commonwealth since the time frame of the analysis performed by NESCAUM for MANE-VU, the actual annual reduction in SO2 is expected to be less than the estimated maximum.

While there is not a legal requirement to provide an opportunity to comment upon the Department's recommendations for final-form rulemaking, the Department believes comments on the draft final rulemaking would serve the public interest in this instance. The Department particularly seeks comments on the issues of cost and fuel availability.

B. Contact Persons

For further information or to request a copy of the draft final rulemaking, contact Arleen Shulman, Division of Air Resource Management, Bureau of Air Quality, Rachel Carson State Office Building, 12th Floor, P. O. Box 8468, Harrisburg, PA 17101-8468, (717) 772-3436, ashulman@pa.gov; or Kristen Furlan, Assistant Counsel, Bureau of Regulatory Counsel, 9th Floor, Rachel Carson State Office Building, P. O. Box 8464, Harrisburg, PA 17105-8464, (717) 787-7060, kfurlan@pa.gov. Persons with a disability may use the AT&T Relay Service, (800) 654-5984 (TDD users) or (800) 654-5988 (voice users). The draft final rulemaking is available on the Department's website at http://www.dep.state.pa.us.

C. Public Comments

Written or electronic comments should be sent to Arleen Shulman at the previous address. Comments must be received by July 23, 2012. A subject heading of the rulemaking and a return name and address must be included in each letter or transmission. Comments will not be accepted by facsimile or voice mail.

MICHAEL L. KRANCER, Secretary

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STATE BOARD OF MEDICINE

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

The State Board of Medicine (Board) proposes to amend §§ 16.1, 16.11 and 16.13 (relating to definitions; licenses, certificates and registrations; and licensure, certification, examination and registration fees) and to add §§ 18.601—18.611 (relating to perfusionists) to read as set forth in Annex A.

Effective Date

The proposed rulemaking will be effective upon finalform publication in the *Pennsylvania Bulletin*.

Statutory Authority

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

Background and Need for the Amendment

The act of June 11, 2008 (P. L. 154, No. 19) (Act 19) amended the act to provide for licensure of perfusionists. Section 2 of the act (63 P. S. § 422.2) defines the term "perfusion" as "the functions necessary for the support, treatment, measurement or supplementation of the cardiovascular system or other organs, or a combination of those functions, and for ensuring the safe management of physiologic functions by monitoring and analyzing the parameters of the systems under the supervision of a physician..." This proposed rulemaking is intended to implement licensure of perfusionists. This proposed rulemaking is also designed to provide to prospective licensees adequate notice of the requirements for licensure as a perfusionist.

Section 13.3(a) of the act provides that "two years after the effective date of this section, it shall be unlawful for any person to hold himself out to the public as a perfusionist or to practice or offer to practice perfusion unless the person holds a valid, current license issued by the board or the State Board of Osteopathic Medicine." The Board did not propose a rulemaking to incorporate the "grandfather" provision of section 13.3(g) of the act. That section provided that, during the first 2 years after the effective date of Act 19, a person who was not a graduate of an accredited program prior to 1981, but who met the then-current eligibility requirements for certification as a certified clinical perfusionist and subsequently was certified, could become licensed if the person otherwise complies with the requirements for licensure. This

statutory provision is self-executing on this particular issue and the qualifications for licensure in the act are clear and unambiguous.

Practice of perfusion in this Commonwealth without a license from the Board was prohibited after August 10, 2010. In June 2010, the Board, in conjunction with the State Board of Osteopathic Medicine (Osteopathic Board), developed an application for licensure, which was placed on the Board's and the Osteopathic Board's web sites. With the cooperation of stakeholders, including the Pennsylvania State Perfusion Society and the American Society of ExtraCorporeal Technology (AmSECT), the Board and the Osteopathic Board notified the perfusionist community of the availability of the application process and the statutory deadline, as well as the availability of the application forms electronically and by mail. The Board has worked to facilitate and expedite the access and transmittal of documentation of certification, education and insurance coverage. The Board also agreed on this occasion to consider the date of filing of the application as the controlling date, even if supporting documentation remained in transit. The application and license issuance procedure concluded with every applicant who was eligible under the "grandfather" provision, and was otherwise qualified for licensure, receiving a license.

Description of the Proposed Rulemaking

The proposed rulemaking would amend § 16.1 to add perfusionist to the list of other Board-regulated practitioners. Section 16.11(b) identifies those licenses that the Board issues. The proposed rulemaking would add licensure as a perfusionist. Similarly, § 16.11(c) identifies registrations that the Board issues and the proposed rulemaking would add biennial registration of perfusionist licenses. The proposed rulemaking would also add § 16.13(k) to set forth the fees associated with perfusionist licensure to be charged by the Board, as authorized by section 13.3 of the act. To recover the costs of providing those services, the fee for applications for perfusionist license, reactivation of perfusionist license and temporary graduate perfusionist license would each be \$50 and the fee for application for temporary provisional perfusionist license would be \$40. Because the Board believes that the cost to provide the service would be minimal and does not want to delay application, the Board has not set a fee for notification of emergency practice as a perfusionist. To provide for an appropriate share of the general costs of operating the Board, the biennial renewal fee for a perfusionist would be \$50.

The proposed rulemaking would also add Subchapter J (relating to perfusionists) to Chapter 18 (relating to State Board of Medicine—practitioners other than medical doctors). Proposed § 18.601 (relating to purpose) would identify the purpose of the subchapter as providing for licensure of perfusionists. Proposed § 18.602 (relating to definitions) would provide necessary definitions. These include the statutory definitions of "extracorporeal circulation," "perfusion," "perfusionist" and "ventricular assist device" as used in the subchapter. Additionally, the Board would define "ABCP" as the American Board of Cardiovascular Perfusion (ABCP), the National body that administers the exam and certifies perfusionists. The Board would define "CAAHEP" as the Commission on Accreditation of Allied Health Education Programs (CAAHEP), which accredits perfusion education programs. The Board proposes to define "accredited perfusion program approved by the Board" as a perfusion program accredited by a Nationally-recognized accrediting agency approved by the Board. The Board would further define

"Nationally-recognized accrediting agency approved by the Board" as CAAHEP or other organization for which the Board publishes notice that the organization is approved by the Board as an accrediting agency for perfusionist programs. The Board would also define "Nationally-recognized certifying agency approved by the Board" as ABCP or other organization for which the Board publishes notice that the organization is approved by the Board as a certifying agency for perfusionists. The Board also proposes to define an "hour of continuing education" to consist of at least 50 minutes of instruction (including question and answer sessions) in an approved course of continuing education or an equivalent time that an online or correspondence course would be presented live. This time is consistent with the standards for continuing education that is required by ABCP for recertification. Finally, the Board defines "out-of-State perfusionist" as an individual who holds a current license as a perfusionist in another state, the District of Columbia or a territory of the United States or has obtained certification by a certifying agency approved by a Nationally-recognized accrediting agency. The Board determined that it is necessary to define the term "out-of-State perfusionist" because section 13.3(j)(1) of the act contains the phrase "in another state, the District of Columbia or a territory of the United States" and uses the phrase "out-of-State perfusionist" throughout the remainder of section 13.3(j)(1)(i) and (ii), (2) and (3) of the act. Therefore, the Board defined "out-of-State perfusionist" as including these geographic entities and used the phrase "out-of-State perfusionist" in § 18.606 (relating to registration of temporary emergency perfusionist service).

Proposed § 18.603 (relating to application for perfusionist license) would address the application for licensure as perfusionist. Under proposed § 18.603(a), an applicant shall submit a completed application form, including necessary supporting documents, and pay the required application fee. Section 13.3(f) of the act sets five criteria for licensure as a perfusionist: 1) be at least 18 years of age; 2) be of good moral character; 3) have graduated from an accredited perfusion program approved by the Board; 4) be certified by a certifying agency approved by a Nationally-recognized accrediting agency approved by the Board; and 5) complete an application form and pay the appropriate fee. Accordingly, proposed § 18.603(b)(1), in conjunction with § 18.603(a), would provide that the Board will license as a perfusionist an applicant who demonstrates that the applicant satisfies the requirements of section 13.3(f) of the act for licensure as a perfusionist. Because section 13.3(k) of the act requires a perfusionist to carry a minimum level of professional liability insurance, proposed § 18.603(b)(4) would require that an applicant provide proof of liability insurance. Because the Board is also setting forth in this proposed rulemaking grounds for disciplinary action, proposed § 18.603(c) would provide that the Board may deny an application for perfusionist licensure upon those grounds for disciplinary action in § 18.609 (relating to disciplinary action for licensed perfusionists).

Proposed § 18.604 (relating to application for temporary graduate perfusionist license) would address the application for temporary graduate perfusionist license as provided in section 13.3(h) of the act. Under proposed § 18.604(a), an applicant shall submit a completed application form, including necessary supporting documents, and pay the required application fee. Because section 13.3(h)(1)(ii) of the act requires that an individual's

authorization to practice perfusion is granted only under the supervision and direction of a perfusionist licensed under the act, the Board would place this requirement at the beginning of proposed § 18.604(b). Section 13.3(h)(1) of the act provides that an individual who has graduated from an educational program in compliance with the education requirements may receive a temporary graduate license. This requirement, along with good moral character and being at least 18 years of age, as required under section 13.3(f)(1) and (2) of the act, and the requirement in section 13.3(h)(1)(i) of the act that the individual has applied for and is eligible to take the examination would be in proposed § 18.604(b)(1)—(3) as the basic requirements for a temporary graduate license. Because section 13.3(k) of the act requires a perfusionist to carry a minimum level of professional liability insurance, proposed § 18.604(b)(4) would require that an applicant provide proof of liability insurance. Because the Board is also setting forth in this proposed rulemaking grounds for disciplinary action, proposed § 18.604(c) would provide that the Board may, in its discretion, deny an application for temporary graduate perfusionist license upon those grounds for disciplinary action in § 18.609. Due to the fact that section 13.3(h)(1)(iii) of the act provides that a temporary graduate license is to be issued for 2 years but not be renewable, proposed § 18.604(d) would provide that a temporary graduate perfusionist license expires 2 years after the date of issuance and may not be renewed. Because section 13.3(h)(1)(iv) of the act provides that a temporary graduate license is to expire upon notice of failing the required examination, proposed § 18.604(e) would provide that a temporary graduate perfusionist license expires upon notice to the Board that the holder failed the Nationally-recognized certifying agency's certification examination. The Board receives perfusionist test results directly from ABCP, the organization that administers the two-part examination. (For example, during 2011, the Board received the results of the March exam in April and the results of the October exam in December. As of December 22, 2011, there were only two licensed temporary graduate perfusionists in the Commonwealth.) If the Board were to receive a report that an individual has failed one of the two parts of the examination, the Board staff would determine if the individual holds a temporary graduate perfusionist license and, if so, would take appropriate steps to inform the license holder that the license was null and void and request return of the license. Furthermore, the Board would clarify in the last sentence of proposed § 18.604(e) that a perfusionist who fails the examination shall immediately cease practice and return the temporary graduate perfusionist license to the Board.

Proposed § 18.605 (relating to application for temporary provisional perfusionist license) would address the application for temporary provisional perfusionist license, as provided in section 13.3(i) of the act. Under proposed § 18.605(a), an applicant shall submit a completed application form, including necessary supporting documents, and pay the required application fee. Section 13.3(i)(1) of the act provides that an individual who holds a current license in good standing under the laws of another state, which includes certification by a certifying agency approved by a Nationally-recognized accrediting agency, may receive a temporary provisional license if the applicant meets the requirements of section 13.3(f) of the act that the applicant is at least 18 years of age and of good moral character and has graduated from an accredited perfusion program approved by the Board. These criteria are in proposed § 18.605(b)(1)—(3) as the basic requirements for a temporary provisional license. Because section 13.3(k) of the act requires a perfusionist to carry a minimum level of professional liability insurance, proposed § 18.605(b)(4) would require that an applicant provide proof of liability insurance. Because the Board is also setting forth in this proposed rulemaking grounds for disciplinary action, proposed § 18.605(c) would provide that the Board may deny an application for perfusionist temporary provisional license upon those grounds for disciplinary action in § 18.609. Because section 13.3(i)(2) of the act provides that a temporary provisional license is to be issued for 1 year but not be renewable, proposed § 18.605(d) would provide that a temporary provisional perfusionist license expires 1 year after the date of issuance and may not be renewed thereafter.

Section 13.3(j) of the act provides an exemption to the general prohibition against unlicensed practice for one-time temporary emergency services by an out-of-State licensed perfusionist 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)(1)(i) and (ii) of the act requires the out-of-State perfusionist to provide to the Board electronic notice of the emergency and acknowledgment that the out-of-State perfusionist is subject to jurisdiction of the Board as if licensed by the Board and requires the health care facility to provide to the Board electronic notice that services were provided and the grounds for the exemption. Proposed § 18.606(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 § 18.606(b), the out-of-State perfusionist or other person acting on behalf of the out-of-State perfusionist (such as health care facility staff) shall submit by electronic means a completed registration on forms provided by the Board. It is anticipated that this registration will be done almost exclusively from the Board's web site. To provide clarity, the Board would state in § 18.602(b) what is meant by electronic means as including "computer-to-computer, computer-to-facsimile machine or e-mail transmission." Because "one-time emergency perfusionist service" is not defined in section 13.3(j) of the act, proposed § 18.606(c) would provide that although the services are not limited to a single procedure or patient or group of related patients, the out-of-State perfusionist may not provide emergency services for a period longer than 72 hours. The Board chose this method because it provides a bright-line rule and would be more applicable to the situations for which emergency services would be needed. As to its selection of the 72-hour time limit, the Board believes that surgeons and health care facilities plan for groups of patients with procedures requiring perfusionist services, not necessarily a single patient with a single procedure. Should the planned perfusionist suddenly become unavailable, this would affect multiple patients and procedures, not just a single patient for a single procedure. An upper limit of 72 hours provides adequate time to perform those procedures that cannot wait and also to make alternative arrangements with one or more perfusionists licensed in this Commonwealth. The Board acknowledges that section 13.3(j)(1)(ii)(A) and (D) of the act requires the health care facility to certify that "the emergency perfusionist services were provided for a patient of the health care facility," and that the "out-of-State perfusionist provided only the emergency perfusionist services for the patient of the health care facility and no other perfusionist services at the health care facility." The Board interprets this language to limit perfusionist services to those that are emergencies as otherwise required under section 13.3(j) of

the act even if not for only a single patient. Section 13.3(j)(3) of the act prohibits the out-of-State perfusionist from providing services other than emergency services. Consistent with section 13.3(j)(2) of the act, proposed § 18.606(d) would provide that the out-of-State perfusionist may not provide further perfusionist service in this Commonwealth without being licensed as a perfusionist or holding a temporary graduate license or temporary provisional license.

Because licenses issued by the Board shall be registered biennially as a condition of continued practice in accordance with section 25(b) of the act (63 P.S. § 422.25(b)) and § 16.15 (relating to biennial registration; inactive status and unregistered status), proposed § 18.607 (relating to biennial registration of perfusionist license) would address biennial registration of perfusionist licenses. Proposed § 18.607(a) would provide that licensed perfusionists shall register biennially by December 31 of each even-numbered year. Under proposed § 18.607(b), a licensed perfusionist is required to complete and submit an application for biennial registration, including the required fee, and disclose the following on the application itself: a license to practice as a perfusionist in another jurisdiction; a disciplinary action pending before or taken by the appropriate health care licensing authority in another jurisdiction; pending criminal charges; and convictions. A licensed perfusionist shall also verify on the application that the licensee has complied with the continuing education requirements and finally verify on the application that, if practicing as a perfusionist in this Commonwealth, the licensed perfusionist maintains professional liability insurance coverage as required under section 13.3(k) of the act.

Proposed § 18.608 (relating to inactive status of perfusionist license; reactivation of inactive license) would address inactive status of perfusionist licenses. Proposed § 18.608(a) would provide that a license may become inactive either by the licensee's request or by expiration at the end of the biennial registration period. To minimize the opportunity or consequence of a license being incorrectly placed on inactive status at what appears to be the request of the licensee, proposed § 18.608(a)(1) would provide that the Board will forward written confirmation of inactive status to the licensee. Proposed § 18.608(b) would provide that a perfusionist whose license is inactive may not practice as a perfusionist in this Commonwealth until the license has been reactivated. Proposed § 18.608(c) would provide the general requirement for reactivation of an inactive perfusionist license that the licensee shall apply on forms supplied by the Board, answer the questions fully, provide documentation of completion of the required amount of continuing education for the preceding biennium, as required under section 13.3(n)(5) of the act, pay the current biennial registration fee and the reactivation fee specified in § 16.13(k) and verify that the licensee did not practice as a perfusionist in this Commonwealth while the license was inactive. If the licensee cannot verify that the licensee did not practice during the period of lapse, the license may be reactivated under proposed § 18.608(d). Under subsection (d), in addition to the requirements of subsection (c), the licensee shall pay the biennial registration fee for past registration periods and a late fee of \$5 per month. This late fee is the standard late fee of section 225 of the Bureau of Professional and Occupational Affairs Fee Act (63 P.S. § 1401-225). However, as provided in proposed § 18.608(d), payment of late fees will not preclude the Board from taking disciplinary action for practicing while the license was inactive.

Proposed § 18.609 addresses disciplinary action. Section 41 of the act (63 P.S. § 422.41) authorizes the Board "to impose disciplinary or corrective measures on a board-regulated practitioner" for a variety of grounds. Therefore, the Board proposes to amend the definition of "Board-regulated practitioner" in § 16.1 to add perfusionists. Further, proposed § 18.609(a) would provide that a licensed perfusionist, including one holding a temporary graduate license or temporary provisional license, is subject to disciplinary action under section 41 of the act and that the Board may impose any of the corrective actions in section 42 of the act (63 P.S. § 422.42). Because section 41(8) of the act authorizes the Board to take disciplinary action for immoral or unprofessional conduct, proposed § 18.609(b) would define unprofessional conduct and proposed § 18.609(c) would define immoral conduct. Modeled upon §§ 16.61 and 18.181 (relating to unprofessional and immoral conduct; and disciplinary and corrective measures), unprofessional conduct would include the following: performing acts in a health care profession in a fraudulent or incompetent or negligent manner; violating a provision of the act or regulation of the Board setting a standard of professional conduct; engaging in health care practice beyond the licensee's authority to practice; representing oneself to be a licensed physician or other health care provider; practicing while the licensee's ability to do so is impaired by alcohol, drugs, physical disability or mental instability; and revealing personally identifiable facts obtained as the result of the practitioner-patient relationship. Additionally, unprofessional conduct would include engaging in conduct prohibited by § 16.110 (relating to sexual misconduct). Section 13.3(e)(2) of the act exempts from the general prohibition against practicing perfusion without a license a perfusion student who, among other requirements, is performing under the direct supervision of a perfusionist who is assigned to supervise the student. Section 13.3(e)(3) of the act exempts a perfusion graduate who, among other requirements, is performing under the supervision and responsibility of a perfusionist. Accordingly, proposed § 18.609(b)(8) would include as unprofessional conduct failing to provide supervision as required under section 13.3(e)(2) of the act of a perfusion student or failing to provide supervision as required under section 13.3(e)(3) of the act of a perfusion graduate who is not otherwise licensed by the Board to practice perfusion. Immoral conduct would include the following: misrepresenting or concealing a material fact in obtaining a license or reactivating or renewing the biennial registration of the license; being convicted of a crime involving moral turpitude; or committing an act involving moral turpitude, dishonesty or corruption.

Section 13.3(n) of the act provides for required continuing education and proposed § 18.610 (relating to continuing education for licensed perfusionists) would address that topic. Proposed $\S~18.610(a)$ would set forth the general credit hour requirements. As required under section 13.3(n)(2) of the act, proposed § 18.610(a)(1) would require each licensed perfusionist to complete during each biennial registration period at least 30 hours of continuing education—including at least 10 hours in category I continuing education—applicable to the practice of perfusion. Consistent with section 13.3(n)(3) of the act, a licensee would not be required to complete continuing education during the biennial registration period in which the licensee was first licensed. In keeping with the statutory requirement for completing the continuing education requirement during each 2-year license period in section 13.3(n)(2) of the act, a licensee would not be permitted to carry over continuing education credit into a

subsequent renewal period in proposed § 18.610(a)(2). The Board views the statutorily-mandated number of hours of continuing education for biennial license renewal as a minimum to maintain competence during each biennial period and encourages its licensees to take as much continuing education as each licensee believes assists in maintaining excellence in practice. Consistent with this view, the Board's continuing education regulations for medical doctors, respiratory care practitioners and athletic trainers, as well as the continuing education regulations for other health care practitioners, such as nurses, do not provide for the carryover of continuing education credits taken over the minimum required for license renewal.

As a practical consideration, this section would recognize that a licensee may need to make up deficient continuing education credit to reactivate an inactive license or if otherwise ordered by the Board. However, a particular hour of continuing education taken in a given biennial registration period may not be used to satisfy the requirement both for that period and to make up a deficiency for a prior period. Section 13.3(n)(4) of the act permits a licensee to submit a written request for waiver of the continuing education requirement due to serious illness, military service or other demonstrated hardship. Proposed § 18.610(a)(3) would permit a licensee to request a waiver under these circumstances and would require that the request for a waiver be submitted at least 90 days before the end of the biennial registration period so that the Board could address the request and, if it is denied, give the licensee adequate opportunity to complete the required continuing education before the end of the period. Additionally, this proposed section would explicitly note that a waiver may include extending the deadline rather than simply relieving the licensee of the obligation to take continuing education. Proposed § 18.610(a)(4) would provide that a licensee would be subject to disciplinary action if the licensee submits false information to the Board regarding completion of the continuing education credit hour requirements or if a licensee fails to complete the required continuing education and practices as a perfusionist after the end of the biennial period.

Proposed § 18.610(b) would set forth the standards for documentation of continuing education that will be required for licensees to prove compliance with the continuing education requirements. In determining these requirements, representatives of the Board met with representatives of the Pennsylvania State Perfusion Society on November 10, 2011, and included detailed information in the regulatory provisions based on the documentation required by ABCP. Under proposed § 18.610(b)(1), a licensee shall receive a certified record of completion from the continuing education provider for attendance at an ABCP-approved perfusion meeting setting forth the participant's name, the provider's name, the date of the course, the name of the course and the number of hours of continuing education. Proposed § 18.610(b)(2)—(11) would set forth the documentation that a licensee shall retain for the following types of continuing education: publication of a book, chapter or paper in a perfusionrelated publication; a presentation at an ABCP-approved or international perfusion meeting; participation in an ABCP knowledge base survey; reading or viewing medical journals, audio-visual or other educational materials; participation in a perfusion-related self-study module or electronic forum; participation in a perfusion-related journal club; completion of an academic course; presentation of a perfusion topic at a meeting that is not approved by

ABCP; participation as a clinical or didactic instructor in an accredited program; and participation in a site visitors' workshop or as an official site visit. Proposed § 18.610(b)(12) would require the licensee to retain the required documentation for at least 5 years after completion of the continuing education course or biennial registration period for which the continuing education was required, whichever is later. Because the Board will conduct postrenewal audits of licensees to verify compliance with the continuing education requirements, proposed § 18.610(b)(13) would require the licensee to submit proof of continuing education activities upon request by the Board.

Proposed § 18.610(c) would set forth the types of activities for which continuing education credit may be earned detailing how these continuing education activities will be quantified and the number of continuing education credits that a licensee may earn for completing each of the enumerated types of continuing education. In determining these requirements, representatives of the Board met with representatives of the Pennsylvania State Perfusion Society and included in the regulatory provisions the quantification of continuing education used by ABCP. In some instances, the Board's provisions are not identical to those of ABCP because ABCP requires continuing education on a triennial, rather than biennial, basis, thereby making an identical match difficult. However, the specific quantification of the credits would provide licensees with notice of how continuing education activities will be quantified for license renewal. Under proposed § 18.610(c)(1), specific hours of category I continuing education (which must provide at least 10 of the required 30 hours) could be earned by attendance at ABCP-approved perfusion meetings, publication of a perfusion-related book, chapter or paper in a professional publication, presentation at an ABCP-approved or international perfusion meeting or completion of an ABCPknowledge base survey. Under proposed § 18.610(c)(2), other continuing education specific hours to reach the required total could be earned by reading or viewing medical journals, audio-visual or other educational materials, participating in perfusion-related self-study modules, electronic forums or journal clubs, completion of a science or health care-related academic course at a regionally accredited college or university, presentation of a perfusion topic at a meeting that is not approved by ABCP, working as a clinical or didactic instructor in an accredited school of perfusion or participating in a site visitors' workshop or as an official site visitor for perfusion program accreditation. However, as required under section 13.3(n)(6) of the act, proposed § 18.610(c)(3) would prohibit continuing education credit for a course in office management.

Because section 13.3(k) of the act provides for required professional liability insurance for perfusionists, proposed § 18.611(a) (relating to professional liability insurance coverage for licensed perfusionists) would require a licensed perfusionist to maintain professional liability insurance. Proposed § 18.611(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. Section 13.3(k)(1) of the act requires evidence of insurance in the form of self-insurance, personally purchased liability insurance or professional liability insurance coverage provided by the perfusionist's employer or similar insurance coverage acceptable to the Board. Accordingly, proposed § 18.611(b) would set forth the two possible options that proof of liability insurance may include. Proposed § 18.611(b)(1) would require either a certificate of insurance or a copy of the declarations page from the insurance policy setting forth the effective and expiration dates and the dollar amounts of coverage. Proposed § 18.611(b)(2) would allow for evidence of a plan of self-insurance as approved by the Insurance Commissioner of the Commonwealth under regulations of the Insurance Department in 31 Pa. Code Chapter 243 (relating to medical malpractice and health-related selfinsurance plans). Section 13.3(k)(2) of the act permits an applicant to file with the application a letter from an insurance carrier stating that the applicant will be covered in the required amounts effective upon issuance of the license, but the applicant shall then submit the certificate of insurance or copy of the declaration page within 30 days after issuance of the license. To effectuate this provision, proposed § 18.611(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 inactivated and not suspended, because it is not a disciplinary action, as insurance is required only if practicing as a perfusionist in this Commonwealth.

Fiscal Impact and Paperwork Requirements

The proposed rulemaking will not have adverse fiscal impact on the Commonwealth or its political subdivisions. Perfusionists who wish to become licensed to practice in this Commonwealth will bear the fiscal impact of the proposed rulemaking in the form of required fees and costs associated with obtaining the required continuing education. The Board has developed forms required to implement the proposed rulemaking. The proposed rulemaking will not impose additional paperwork requirements upon the Commonwealth, political subdivisions or the private sector.

Sunset Date

The Board continuously monitors the effectiveness of its regulations. Therefore, a sunset date has not been assigned.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on June 12, 2012, the Board submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House Professional Licensure Committee and the Senate Consumer Protection and Professional Licensure Committee. A copy of this material is available to the public upon request.

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

Public Comment

Interested persons are invited to submit written comments, suggestions or objections regarding this proposed rulemaking to the Regulatory Unit Counsel, Department of State, P.O. Box 2649, Harrisburg, PA 17105-2649,

st-medicine@pa.gov within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*. Reference No. 16A-4935 (perfusionist) when submitting comments.

 $\begin{array}{c} \text{CAROL E. ROSE, M.D.,} \\ & \textit{Chairperson} \end{array}$

Fiscal Note: 16A-4935. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 16. STATE BOARD OF MEDICINE—GENERAL PROVISIONS

Subchapter 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.

* * * * *

 $\mbox{(b)}$ 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.

Application for perfusionist license	\$ 50
Biennial registration of perfusionist license	\$ 50
Application for reactivation of perfusionist license	\$ 50
Application for temporary graduate perfusionist license	\$ 50
Application for temporary provisional perfusionist license	\$ 40

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

 $(Editor's\ Note:$ Subchapter J is new and printed in regular type to enhance readability.)

Subchapter J. PERFUSIONISTS

Sec.	
18.601.	Purpose.
18.602.	Definitions.
18.603.	Application for perfusionist license.
18.604.	Application for temporary graduate perfusionist license.
18.605.	Application for temporary provisional perfusionist license.
18.606.	Registration of temporary emergency perfusionist service.
18.607.	Biennial registration of perfusionist license.
18.608.	Inactive status of perfusionist license; reactivation of inactive
	license.
18.609.	Disciplinary action for licensed perfusionists.
18.610.	Continuing education for licensed perfusionists.
18.611.	Professional liability insurance coverage for licensed perfusion-
	ists.

§ 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(k) (relating to licensure, certification, examination and registration fees) for application for a perfusionist license.
- (b) The Board may issue a license to practice as a perfusionist to an applicant who:
- (1) Demonstrates that the applicant holds a current certification by a certifying agency approved by a Nationally-recognized accrediting agency approved by the Board.
- (2) Demonstrates that the applicant has graduated from an accredited perfusion program approved by the Board.
- (3) Demonstrates that the applicant is at least 18 years of age and of good moral character.
- (4) Demonstrates that the applicant has obtained professional liability insurance as required under section 13.3(k) of the act (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(k) (relating to licensure, certification, examination and registration fees) for an application for a temporary graduate perfusionist license.
- (b) The Board may grant a temporary graduate perfusionist license, which authorizes the license holder

to practice only under the supervision and direction of a perfusionist licensed under 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(k) (relating to licensure, certification, examination and registration fees) for application for a temporary provisional perfusionist license.
- (b) The Board may grant a temporary provisional perfusionist license to an applicant who:
- (1) Demonstrates that the applicant holds a current license in good standing under the laws of another state, the District of Columbia or a territory of the United States that includes certification by a certifying agency approved by a Nationally-recognized accrediting agency.
- (2) Demonstrates that the applicant has graduated from an accredited perfusion program approved by the Board.
- (3) Demonstrates that the applicant is at least 18 years of age and of good moral character.
- (4) Demonstrates that the applicant has obtained professional liability insurance as required 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 $(63\ P.\ S.\ \S\ 422.13c(j))$.
- (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. The completed registration form shall be submitted by electronic means, including computer-to-computer, computer-to-fascimile 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).

§ 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(k) (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, 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 status of perfusionist license; reactivation of inactive license.

- (a) A perfusionist license will become inactive upon either of the following:
- (1) The licensee requests in writing that the Board place the license on inactive status. Written confirmation of inactive status will be forwarded to the licensee.
- (2) The licensee fails to register the license by the expiration of the biennial registration period on December 31 of each even-numbered year.
- (b) A perfusionist whose license has become inactive may not practice as a perfusionist in this Commonwealth until the license has been reactivated.
- (c) To reactivate an inactive license, the licensee shall apply on forms made available by the Board 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) (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 except as provided in subsection (d).
- (d) A licensee who has practiced with an inactive license and who cannot make the verification required under subsection (c)(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 shall pay a late fee of \$5 for each month or part of a month from the beginning of the current biennium until the date the reactivation application is filed.
- (2) A licensee whose license has been inactive since before the beginning of the current biennium shall pay the biennial registration fee for each biennial registration period during which the licensee practiced and shall pay a late fee of \$5 for each month or part of a month from the first date the licensee practiced as a perfusionist in this Commonwealth after the license became inactive until the date the reactivation application is filed.

§ 18.609. 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, audiovisual or other educational materials consists of a list of the compete 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.
- (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 consists of a letter from the ABCP.
- (12) A licensee shall retain proof of completion of continuing education for 5 years after completion of the continuing education or after the completion of the biennial registration period for which the continuing education was required, whichever is later.
- (13) The Board will audit licensees to verify compliance with continuing education requirements. A licensee shall submit proof of continuing education activities upon request by the Board.

- (c) Continuing education activities. Credit for continuing education may be earned in the following activities.
 - (1) Category I continuing education may be earned by:
- (i) Attendance at an ABCP-approved perfusion meeting. 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, audiovisual 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 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. 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 the license if the licensee has not provided proof of professional liability insurance coverage and will remain inactive until the licensee provides proof of insurance coverage.
- (d) A licensee who does not have professional liability insurance coverage as required under section 13.3(k) of the act may not practice as a perfusionist in this Commonwealth.

[Pa.B. Doc. No. 12-1163. Filed for public inspection June 22, 2012, 9:00 a.m.]

STATE BOARD OF OSTEOPATHIC MEDICINE

[49 PA. CODE CH. 25] Perfusionist

The State Board of Osteopathic Medicine (Board) proposes to amend §§ 25.215 and 25.231 (relating to definitions; and schedule of fees) and to add §§ 25.801—25.811 (relating to perfusionists) to read as set forth in Annex A. *Effective Date*

The proposed rulemaking will be effective upon finalform publication in the *Pennsylvania Bulletin*.

Statutory Authority

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

Background and Need for the Proposed Rulemaking

The act of June 11, 2008 (P. L. 161, No. 20) (Act 20) amended the act to provide for licensure of perfusionists. Section 2 of the act (63 P. S. § 271.2) now defines the term "perfusion" as "the functions necessary for the support, treatment, measurement or supplementation of the cardiovascular system or other organs, or a combination of those functions, and for ensuring the safe management of physiologic functions by monitoring and analyzing the parameters of the systems under the supervision of a physician. . ." This proposed rulemaking would amend the Board's regulations to implement licensure of perfusionists under the act as amended by Act 20. This proposed rulemaking is also designed to provide to prospective licensees adequate notice of the requirements for licensure as a perfusionist.

Section 13.3(a) of the act provides that "two years after the effective date of this section, it shall be unlawful for any person to hold himself out to the public as a perfusionist or to practice or offer to practice perfusion unless the person holds a valid, current license issued by the board or the State Board of Medicine." The Board did not propose a rulemaking to incorporate the "grandfather" provision of section 13.3(g) of the act. That section provided that, during the first 2 years after the effective date of Act 20, a person who was not a graduate of an accredited program prior to 1981, but who met the then-current eligibility requirements for certification as a certified clinical perfusionist and subsequently was certified, could become licensed if the person otherwise complies with the requirements for licensure. This statutory provision is self-executing on this particular issue and the qualifications for licensure in the act are clear and unambiguous.

Practice of perfusion in this Commonwealth without a license from the Board was prohibited after August 10, 2010. In June 2010, the Board, in conjunction with the State Board of Medicine (Medical Board), developed an application for licensure, which was placed on the Board's and the Medical Board's web sites. With the cooperation of stakeholders, including the Pennsylvania State Perfusion Society and the American Society of ExtraCorporeal Technology, the Board and the Medical Board notified the perfusionist community of the availability of the application process and the statutory deadline as well as the availability of the application forms electronically and by mail. The Board has worked to facilitate and expedite the access and transmittal of documentation of certification, education and insurance coverage. The Board also agreed on this occasion to consider the date of filing of the application as the controlling date, even if supporting documentation remained in transit. The application and license issuance procedure concluded with every applicant who was eligible under the "grandfather" provision and was otherwise qualified for licensure, receiving a license.

Description of the Proposed Rulemaking

The proposed rulemaking would add licensure as a perfusionist. The proposed rulemaking would first amend § 25.215 to add perfusionist to the list of other Boardregulated practitioners. Section 25.231 would set forth the fees associated with perfusionist licensure to be charged by the Board as authorized by section 13.3(l) of the act. To recover the costs of providing those services, the fee for applications for perfusionist license, reactivation of perfusionist license and temporary graduate perfusionist license would each be \$50 and the fee for application for temporary provisional perfusionist license would be \$40. Because the Board believes that the cost to provide the service would be minimal and does not want to delay application, the Board has not set a fee for notification of emergency practice as a perfusionist. To provide for an appropriate share of the general costs of operating the Board, the biennial renewal fee for a perfusionist would

The proposed rulemaking would also add Subchapter N (relating to perfusionists). Proposed § 25.801 (relating to purpose) would identify the purpose of the subchapter as providing for licensure of perfusionists. Proposed § 25.802 (relating to definitions) would provide necessary definitions. These include the statutory definitions of "extracorporeal circulation," "perfusion," "perfusionist" and "ventricular assist device" as used in the subchapter. Additionally, the Board would define "ABCP" as the American Board of Cardiovascular Perfusion (ABCP), the National body that both administers the exam and certifies perfusionists. The Board would define "CAAHEP" as the Commission on Accreditation of Allied Health Education Programs (CAAHEP), which accredits perfusion education program approved by the Board" as a perfusion program accredited by a Nationally recognized accrediting

agency approved by the Board. The Board would further define "Nationally-recognized accrediting agency approved by the Board" as CAAHEP or other organization for which the Board publishes notice that the organization is approved by the Board as an accrediting agency for perfusionist programs. The Board would also define "Nationally-recognized certifying agency approved by the Board" as ABCP or other organization for which the Board publishes notice that the organization is approved by the Board as a certifying agency for perfusionist programs. Furthermore, the Board would define 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 online or correspondence course would be presented live." This time is consistent with the standards for continuing education that is required by ABCP for recertification. Finally, the Board defines "out-of-State perfusionist" as an individual who holds a current license as a perfusionist in another state, the District of Columbia or a territory of the United States or has obtained certification by a certifying agency approved by a Nationally-recognized accrediting agency. The Board determined that it is necessary to define the term "out-of-State perfusionist" because section 13.3(j)(1) of the act contains the phrase "in another state, the District of Columbia or a territory of the United States" and uses the phrase "out-of-State perfusionist" throughout the remainder of section 13.3(j)(1)(i) and (ii), (2) and (3) of the act. Therefore, the Board defined "out-of-State perfusionist" as including these geographic entities and used the phrase "out-of-State perfusionist" in § 25.806 (relating to registration of temporary emergency perfusionist service).

Proposed § 25.803 (relating to application for perfusionist license) would address the application for licensure as perfusionist. Under proposed § 25.803(a), an applicant shall submit a completed application form, including necessary supporting documents, and pay the required application fee. Section 13.3(f) of the act sets five criteria for licensure as a perfusionist: 1) the applicant must be at least 18 years of age; 2) be of good moral character; 3) have graduated from an accredited perfusion program approved by the Board; 4) be certified by a certifying agency approved by a Nationally recognized accrediting agency approved by the Board; and 5) complete an application form and pay the appropriate fee. Accordingly, proposed § 25.803(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 for proposed § 25.811 (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 § 25.803(b)(4) would require that an applicant provide proof of liability insurance. Because the Board is also setting forth in its proposed rulemaking grounds for disciplinary action in proposed § 25.809 (relating to disciplinary action for licensed perfusionist), proposed § 25.803(c) would provide that the Board may deny an application for perfusionist licensure upon those grounds for disciplinary action.

Proposed § 25.804 (relating to application for temporary graduate perfusionist license) would address the application for temporary graduate perfusionist license as provided in section 13.3(h) of the act. Under proposed § 25.804(a), an applicant shall submit a completed application form, including necessary supporting documents, and pay the required application fee. Because section

13.3(h)(1)(i) of the act provides that an individual's authorization to practice perfusion is granted only under the supervision and direction of a perfusionist licensed under the act, the Board would place this requirement at the beginning of proposed § 25.804(b). Section 13.3(h)(1) of the act provides that an individual who has graduated from an educational program in compliance with the education requirements 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 §§ 25.804(b)(1)—(3) as the basic requirements for a temporary graduate license. Because for proposed § 25.811, section 13.3(k) of the act requires a perfusionist to carry a minimum level of professional liability insurance, proposed § 25.804(b)(2) would require that an applicant provide proof of liability insurance. Because the Board is also setting forth in its proposed rulemaking grounds for disciplinary action in proposed § 25.809, proposed § 25.804(c) would provide that the Board may deny an application for perfusionist temporary graduate license upon those grounds for disciplinary action. Because section 13.3(h)(3) of the act provides that a temporary graduate license is to be issued for 2 years but not be renewable, proposed § 25.804(d) would provide that a temporary graduate perfusionist license expires 2 years after the date of issuance and may not be renewed. Because section 13.3(h)(4) of the act provides that a temporary graduate license is to expire upon notice of failing the required examination, proposed § 25.804(e) would provide that a temporary graduate perfusionist license expires upon notice to the Board that the holder failed the Nationally recognized accrediting agency's certification examination. The Board receives perfusionist test results directly from ABCP, the organization that administers the two-part examination. (For example, during 2011, the Board received the results of the March exam in April and the results of the October exam in December. As of December 22, 2011, there were only two licensed temporary graduate perfusionists in this Commonwealth.) If the Board were to receive a report that an individual has failed one of the two parts of the examination, the Board staff would determine if the individual holds a temporary graduate perfusionist license and, if so, would take appropriate steps to inform the license holder that the license was null and void and request return of the license. Furthermore, the Board would clarify in the last sentence of proposed § 25.804(e) that a perfusionist who fails the examination must immediately cease practice and return the temporary graduate perfusionist license to the Board.

Proposed § 25.805 (relating to application for temporary provisional perfusionist license) would address the application for temporary provisional perfusionist license, as provided in section 13.3(i) of the act. Under proposed § 25.805(a), an applicant shall submit a completed application form, including necessary supporting documents, and pay the required application fee. Section 13.3(i)(1)(i) and (ii) of the act provides that an individual who holds a current license in good standing under the laws of another state, which includes certification by a certifying agency approved by a Nationally recognized accrediting agency, may receive a temporary provisional license if the applicant meets the requirements of section 13.3(f)(1)—(3) of the act that the applicant is at least 18 years of age and of good moral character and has graduated from an accredited perfusion program approved by the Board. These criteria are in proposed § 25.805(b)(1)—(3) as the basic requirements for a temporary provisional license. Because section 13.3(k) of the act requires a perfusionist

to carry a minimum level of professional liability insurance, proposed § 25.805(b)(4) would require that an applicant provide proof of liability insurance. Because the Board is also setting forth in this proposed rulemaking grounds for disciplinary action in proposed § 25.809, proposed § 25.805(c) would provide that the Board may deny an application for perfusionist temporary provisional license upon those grounds for disciplinary action in § 25.809. Because section 13.3(i)(2) of the act provides that a temporary provisional license is to be issued for 1 year but not be renewable, proposed § 25.805(d) would provide that a temporary provisional perfusionist license expires 1 year after the date of issuance and may not be renewed thereafter.

Section 13.3(j) of the act provides an exemption to the general prohibition against unlicensed practice for onetime temporary emergency services by an out-of-State licensed perfusionist when the licensed perfusionist that would normally have provided the services is unavailable or incapable of providing services and no other licensed perfusionist is available or capable of providing services. Section 13.3(j)(1)(i) and (ii) of the act requires the out-of-State perfusionist to provide to the Board electronic notice of the emergency and acknowledgment that the out-of-State perfusionist is subject to jurisdiction of the Board as if licensed by the Board and requires the health care facility to provide to the Board electronic notice that services were provided and the grounds for the exemption. Proposed § 25.806(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 § 25.806(b), the out-of-State perfusionist or other person acting on behalf of the out-of-State perfusionist (such as health care facility staff) shall submit by electronic means a completed registration on forms provided by the Board. It is anticipated that this registration will be done almost exclusively from the Board's web site. To provide clarity, the Board would state in § 25.806(b) what is meant by electronic means, including "computer-to-computer, computer-to-facsimile machine or e-mail transmission." Because "one-time emergency perfusionist service" is not defined in section 13.3(j) of the act, proposed § 25.806(c) would provide that although the services are not limited to a single procedure or patient or group of related patients, the out-of-State perfusionist may not provide emergency services for longer than 72 hours. The Board chose this method because it provides a bright-line rule and would be more applicable to the situations for which emergency services would be needed. As to its selection of the 72-hour time limit, the Board believes that surgeons and health care facilities plan for groups of patients with procedures requiring perfusionist services, not necessarily a single patient with a single procedure. Should the planned perfusionist suddenly become unavailable, this would affect multiple patients and procedures, not just a single patient for a single procedure. An upper limit of 72 hours provides adequate time to perform those procedures that cannot wait and also to make alternative arrangements with one or more perfusionists licensed in this Commonwealth. The Board acknowledges that section 13.3(j)(1)(ii)(A) and (D) of the act requires the health care facility to certify that "the emergency perfusionist services were provided for a patient of the health care facility," and that the "out-of-State perfusionist provided only the emergency perfusionist services for the patient of the health care facility and no other perfusionist services at the health care facility." The Board interprets this language to limit perfusionist services to those that are emergencies as otherwise required in section 13.3(j) of the act, even if not for only a single

patient. Section 13.3(j)(3) of the act prohibits the out-of-State perfusionist from providing services other than emergency services. Consistent with section 13.3(j)(2) of the act, proposed § 25.806(d) would provide that the out-of-State perfusionist may not provide further perfusionist service in this Commonwealth without being licensed as a perfusionist or holding a temporary graduate license or temporary provisional license.

Because licenses issued by the Board must be registered biennially as a condition of practice in accordance with section 10(c) of the act (63 P.S. § 271.10(c)) expire after 2 years and must be renewed biennially, proposed § 25.807 (relating to renewal of perfusionist license) would address biennial registration of perfusionist licenses. Proposed § 25.807(a) would require the licensed perfusionist to register by December 31 of each evennumbered year, which is the same expiration date for other perfusionist licenses issued by the Medical Board. Additionally, this subsection would require a licensed perfusionist to notify the Board within 10 business days of a change in name or address. Under proposed § 25.807(b), a licensed perfusionist is required to complete and submit the renewal application, including the required renewal fee, and disclose the following on the application: a license to practice as a perfusionist in any other jurisdiction; disciplinary action pending before or taken by the appropriate health care licensing authority in another jurisdiction; pending criminal charges; and convictions. A licensed perfusionist shall also verify on the application that the licensee has complied with the continuing education requirements and verify that if practicing as a perfusionist in this Commonwealth the licensee maintains professional liability insurance coverage as required under section 13.3(k) of the act.

Proposed § 25.808 (relating to inactive status of perfusionist license; reactivation of inactive license) would address inactive status of perfusionist licenses. Proposed § 25.808(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. 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 § 25.808(a)(1) would provide that the Board will forward written confirmation of inactive status to the licensee. Proposed § 25.808(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 § 25.808(c) would provide the general requirement for reactivation of an inactive perfusionist license that the licensee shall apply on forms supplied by the Board, answer the questions fully, provide documentation of completion of the required amount of continuing education for the preceding biennium, as required under section 13.3(n)(5) of the act, pay the current renewal fee and the reactivation fee specified in § 25.231 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 § 25.808(d) by paying additional fees. Under that proposed section, in addition to the requirements of subsection (c), the licensee shall pay the renewal fee for past 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 § 25.808(d), payment of late fees

will not preclude the Board from taking disciplinary action for practicing while the license was inactive.

Proposed § 25.809 addresses disciplinary action. Although section 13.3 of the act does not specifically authorize the Board to take disciplinary action against a licensed perfusionist, section 13.3(m) of the act provides that disciplinary action taken by the Board against a perfusionist shall be enforceable by the Medical Board 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, respiratory therapist or athletic trainer," that is, the other nonphysicians licensed by the Board, for a variety of grounds. Accordingly, proposed § 25.809(a) would provide that a licensed perfusionist, including one holding a temporary graduate license or temporary provisional license, is subject to disciplinary action under section 15(b) of the act and that the Board may impose a corrective action in section 15(c) of the act. Because section 15(b)(9) of the act authorizes the Board to take disciplinary action for immoral or unprofessional conduct, proposed § 25.809(b) would define unprofessional conduct and proposed § 25.809(c) would define immoral conduct. Modeled upon § 25.201 (relating to grounds for complaint), unprofessional conduct would include the following: performing acts in a health care profession in a fraudulent or incompetent or negligent manner; violating a provision of the act or a regulation of the Board setting a standard of professional conduct; engaging in health care practice beyond the licensee's authority to practice; representing oneself to be a licensed physician or other health care provider; practicing while the licensee's ability to do so is impaired by alcohol, drugs, physical disability or mental instability; or revealing personally identifiable facts obtained as the result of the practitioner-patient relationship. Immoral conduct would include the following: 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, dishonesty or corruption. Additionally, unprofessional conduct would include engaging in conduct prohibited by § 25.216 (relating to sexual misconduct). Section 13.3(e)(2) of the act exempts from the general prohibition against practicing perfusion without a license a perfusion student who, among other requirements, is performing under the direct supervision of a perfusionist who is assigned to supervise the student. Likewise, section 13.3(e)(3) of the act exempts a perfusion graduate who, among other requirements, is performing under the supervision and responsibility of a perfusionist. Accordingly, proposed § 25.809(b)(8) 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 under section 13.3(e)(3) of the act of a perfusion graduate who is not otherwise licensed by the Board to practice perfusion.

Section 13.3(n) of the act provides for required continuing education and proposed § 25.810 (relating to continuing education for licensed perfusionist) would address that topic. Proposed § 25.810(a) would set forth the general credit hour requirements. As required under section 13.3(n)(2) of the act, proposed § 25.810(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. In keeping with the statutory requirement for completing the continuing education requirement during each 2-year license period in section 13.3(n)(2) of the act, a licensee would not be permitted to carry over continuing education credit into a subsequent renewal period in proposed § 25.810(a)(2). The Board views the statutorily-mandated number of hours of continuing education for biennial license renewal as a minimum to maintain competence during each biennial period and encourages its licensees to take as much continuing education as each licensee believes assists in maintaining excellence in practice. Consistent with this view, the Board's continuing education regulations for medical doctors, respiratory care practitioners and athletic trainers, as well as the continuing education regulations for other health care practitioners, such as nurses, do not provide for the carryover of continuing education credits taken over the minimum required for license renewal.

As a practical consideration, this section would recognize that a licensee may need to make up deficient continuing education credit to reactivate an inactive license or if otherwise ordered by the Board. However, a particular hour of continuing education taken in a given biennial renewal period may not be used to satisfy the requirement both for that period and to make up a deficiency for a prior period. Section 13.3(n)(4) of the act permits a licensee to submit a written request for waiver of the continuing education requirement due to serious illness, military service or other demonstrated hardship. Proposed § 25.810(a)(3) would permit a licensee to request a waiver under these circumstances and would require that the waiver 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 § 25.810(a)(4) would provide that a licensee would be subject to disciplinary action if the licensee submits false information to the Board regarding completion of the continuing education credit hour requirements or if a licensee fails to complete the required continuing education and practices as a perfusionist after the end of the biennial period.

Proposed § 25.810(b) would set forth the standards for documentation of continuing education that will be required for licensees to prove compliance with the continuing education requirements. In determining these requirements, representatives of the Board met with representatives of the Pennsylvania State Perfusion Society on November 10, 2011, and included detailed information in the regulatory provisions based on the documentation required by ABCP. Under proposed § 25.810(b)(1), a licensee shall receive a certified record of completion from the continuing education provider for attendance at an ABCP-approved perfusion meeting, setting forth the participant's name, the provider's name, the date of the course, the name of the course and the number of hours of continuing education. Proposed § 25.810(b)(2)—(11) would set forth the documentation that a licensee shall retain for the following types of continuing education: publication of a book, chapter or paper in a perfusionrelated publication; a presentation at an ABCP-approved or international perfusion meeting; participation in an ABCP knowledge base survey; reading or viewing medical journals, audio-visual or other educational materials;

participation in a perfusion-related self-study module or electronic forum; participation in a perfusion-related journal club; completion of an academic course; presentation of a perfusion topic at a meeting that is not approved by ABCP; participation as a clinical or didactic instructor in an accredited program; and participation in a site visitors' workshop or as an official site visit. Proposed § 25.810(b)(12) would require the licensee to retain the record for at least 5 years after completion of the continuing education course or biennial registration period for which the continuing education was required, whichever is later. Because the Board will conduct post-renewal audits of licensees to verify compliance with the continuing education requirements, proposed § 25.810(b)(13) would require the licensee to submit proof of continuing education activities upon request by the Board.

Proposed 25.810(c) would set forth the types of activities for which continuing education credit may be earned detailing how these continuing education activities will be quantified and the number of continuing education credits that a licensee may earn for completing each of the enumerated types of continuing education. In determining these requirements, representatives of the Board met with representatives of the Pennsylvania State Perfusion Society and included in the regulatory provisions the quantification of continuing education used by ABCP. In some instances, the Board's provisions are not identical to those of ABCP because ABCP requires continuing education on a triennial, rather than biennial, basis, thereby making an identical match difficult. However, the specific quantification of the credits would provide licensees with notice of how continuing education activities will be quantified for license renewal. Under proposed § 25.810(c)(1), category I continuing education (which must provide at least 10 of the required 30 hours) could be earned by attendance at ABCP-approved perfusion meetings, publication of a perfusion-related book, chapter or paper in a professional publication, presentation at an ABCP-approved or international perfusion meeting or completion of an ABCP-knowledge base survey. Under proposed § 25.810(c)(2), other continuing education to reach the required total could be earned by reading or viewing medical journals, audio-visual or other educational materials, participating in perfusion-related selfstudy modules, electronic forums or journal clubs, completion of a science or health care-related academic course at a regionally accredited college or university, presentation of a perfusion topic at a meeting that is not approved by ABCP, working as a clinical or didactic instructor in an accredited school of perfusion or participating in site visitor workshop or as an official site visitor for perfusion program accreditation. However, as noted in section 13.3(n)(6) of the act, proposed § 25.810(c)(3) would prohibit continuing education credit for a course in office management.

Because section 13.3(k) of the act provides for required professional liability insurance for perfusionists, proposed \S 25.811(a) would require a licensed perfusionist to maintain a level of professional liability insurance. Proposed \S 25.811(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. Section 13.3(k)(1)(i)—(iii) of the act requires evidence of insurance in the form of self-insurance, personally purchased liability insurance or professional liability insurance coverage provided by the perfusionist's em-

ployer or similar insurance coverage acceptable to the Board. Accordingly, proposed § 25.811(b) would set forth the two possible options that proof of liability insurance may include. Proposed § 25.811(b)(1) would require either a certificate of insurance or a copy of the declarations page from the insurance policy setting forth the effective and expiration dates and the dollar amounts of coverage. Proposed § 25.811(b)(2) would allow for evidence of a plan of self-insurance as approved by the Insurance Commissioner of the Commonwealth under regulations of the Insurance Department in 31 Pa. Code Chapter 243 (relating to medical malpractice and health-related self-insurance plans). Section 13.3(k)(2) of the act permits an applicant to file with the application a letter from an insurance carrier stating that the applicant will be covered in the required amounts effective upon issuance of the license, but the applicant shall then submit the certificate of insurance or copy of the declaration page within 30 days after issuance of the license. To effectuate this provision, proposed § 25.801(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 rulemaking will not have adverse fiscal impact on the Commonwealth or its political subdivisions. Perfusionists who wish to become licensed to practice in this Commonwealth will bear the fiscal impact of the proposed rulemaking in the form of required fees and costs associated with obtaining the required continuing education. The Board has developed forms required to implement the proposed rulemaking. The proposed rulemaking will not impose additional paperwork requirements upon the Commonwealth, political subdivisions or the private sector.

Sunset Date

The Board continuously monitors the effectiveness of its regulations. Therefore, a sunset date has not been assigned.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on June 12, 2012, the Board submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House Professional Licensure Committee and the Senate Consumer Protection and Professional Licensure Committee. A copy of this material is available to the public upon request.

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

Public Comment

Interested persons are invited to submit written comments, suggestions or objections regarding this proposed rulemaking to the Regulatory Unit Counsel, Department of State, P.O. Box 2649, Harrisburg, PA 17105-2649, st-osteopathic@state.pa.us within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*. Reference No. 16A-5324 (perfusionist) when submitting comments.

ALFRED J. POGGI, D.O., Chairperson

Fiscal Note: 16A-5324. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 25. STATE BOARD OF OSTEOPATHIC MEDICINE

Subchapter D. MINIMUM STANDARDS OF PRACTICE

§ 25.215. Definitions.

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

Board-regulated practitioner—An osteopathic physician, **perfusionist**, physician assistant, respiratory care practitioner, athletic trainer, acupuncturist or an applicant for a license or certificate issued by the Board.

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:

* * * * *

Application for acupuncturist supervisor registration	30
Application for perfusionist license \$ 5	
Biennial renewal of perfusionist license \$ 5	0
Application for reactivation of perfusionist license \$ 5	60
Application for temporary graduate perfusionist license	60
Application for temporary provisional perfusionist license\$4	10
(Editor's Note: Subshantor N is now and printed i	'n

(*Editor's Note*: Subchapter N is new and printed in regular type to enhance readability.)

Subchapter N. PERFUSIONISTS

Sec. 25.801.	
25 201	
20.001.	Purpose.
25.802.	Definitions.
25.803.	Application for perfusionist license.
25.804.	Application for temporary graduate perfusionist license.
25.805.	Application for temporary provisional perfusionist license.
25.806.	Registration of temporary emergency perfusionist service.
25.807.	Renewal of perfusionist license.
25.808.	Inactive status of perfusionist license; reactivation of inactive license.
25.809.	Disciplinary action for licensed perfusionist.
25.810.	Continuing education for licensed perfusionist.
25.811.	Professional liability insurance coverage for licensed perfusion ist.

§ 25.801. Purpose.

This subchapter implements section 13.3 of the act (63 P. S. § 271.13c), regarding perfusionists.

§ 25.802. 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.

 ${\it CAAHEP}$ —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, lung, kidney, 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 perfusionists.

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 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 Medical Practice Act of 1985 (63 P. S. §§ 422.1—422.51a).

Perfusionist—An individual who is licensed to practice perfusion by the Board or the State Board of 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.

§ 25.803. 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 license to practice as a perfusionist and pay the fee in § 25.231 (relating to schedule of 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. § 271.13c(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 § 25.809 (relating to disciplinary action for licensed perfusionist).

§ 25.804. 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 § 25.231 (relating to schedule of fees) for 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. § 271.13c(k)).
 - (5) Otherwise complies with this subchapter.
- (c) The Board may deny an application for temporary graduate perfusionist license upon the grounds for disciplinary action in § 25.809 (relating to disciplinary action for licensed perfusionist).
- (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.

§ 25.805. 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 § 25.231

- (relating to schedule of 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. § 271.13c(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 § 25.809 (relating to disciplinary action for licensed perfusionist).
- (d) A temporary provisional perfusionist license expires 1 year after the date of issuance and may not be renewed.

§ 25.806. 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 made available by the Board, a completed registration form with the questions fully answered. The completed registered form shall be submitted by electronic means, including computer-to-computer, computer-to-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 § 25.803, § 25.804 or § 25.805 (relating to application for perfusionist license; application for temporary graduate perfusionist license; and application for temporary provisional perfusionist license).

§ 25.807. Renewal of perfusionist license.

- (a) The license of a perfusionist expires biennially on December 31 of each even-numbered year. It is the responsibility of the licensee to notify the Board of a change in name or mailing address within 10 business days of the change. 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 perfusionst shall:

- (1) Submit a completed application, including payment of the biennial renewal fee in § 25.231 (relating to schedule of fees), for application for biennial renewal of a perfusionist license.
- (2) Disclose on the application a license to practice as a perfusionist in another state, territory, possession or country.
- (3) Disclose on the application disciplinary action pending before or taken by the appropriate health care licensing authority in another jurisdiction or taken since the most recent application for renewal, 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 or other criminal conviction since the most recent application for renewal.
- (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. § 271.13c(n)) during the biennial period immediately preceding the period for which renewal is sought in accordance with § 25.810 (relating to continuing education for licensed perfusionist).
- (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.

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

- (a) A perfusionist license will become inactive upon either of the following:
- (1) The licensee requests in writing that the Board place the license on inactive status. Written confirmation of inactive status will be forwarded to the licensee.
- (2) The licensee fails to renew the certificate by the expiration of the renewal period on December 31 of each even-numbered year.
- (b) A perfusionist whose license has become inactive may not practice as a perfusionist in this Commonwealth until the license has been reactivated.
- (c) To reactivate an inactive license, the licensee shall apply on forms made available by the Board with the questions fully answered. The licensee shall:
- (1) Include the documentation required under $\S 25.810(b)$ (relating to continuing education for licensed perfusionist) for the immediately preceding biennium, which may be completed during the current biennium. Unless waived by the Board under section 13.3(n)(4) of the act (63 P.S. $\S 271.13c(n)(4)$), the Board will not reactivate a license until the required continuing education for the preceding biennium has been successfully completed.
- (2) Pay the current renewal fee and the reactivation application fee in § 25.231 (relating to schedule of fees).
- (3) Verify that the licensee did not practice as a perfusionist in this Commonwealth while the license was inactive except as provided in subsection (d).
- (d) A licensee who has practiced with an inactive license and who cannot make the verification required under subsection (c)(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 current license.

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

§ 25.809. 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 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 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 15(c) of the act.
 - (b) Unprofessional conduct includes:
- (1) Engaging in conduct prohibited by § 25.216 (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. § 271.13c(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.

§ 25.810. Continuing education for licensed perfusionist.

- (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 15 of the act (63 P.S. § 271.15), 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, audiovisual or other educational materials consists of a list of the compete citation reference for the materials read or reviewed.
- (6) Proof of participation in a perfusion-related selfstudy module or electronic forum consists of a copy of the printed completion document supplied by the sponsor.

- (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 consists of a letter from the ABCP.
- (12) A licensee shall retain proof of completion of continuing education for 5 years after completion of the continuing education or after the completion of the biennial renewal period during which the continuing education was required, whichever is later.
- (13) The Board will audit licensees to verify compliance with continuing education requirements. A licensee shall submit proof of continuing education activities upon request by the Board.
- (c) Continuing education activities. Credit for continuing education may be earned in the following activities.
 - (1) Category I continuing education may be earned by:
- (i) Attendance at an ABCP-approved perfusion meeting. 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, audiovisual 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 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. The activity may only be counted for credit once in a biennial period.
- (3) Continuing education credit may not be earned in a course in office management.

§ 25.811. Professional liability insurance coverage for licensed perfusionist.

- (a) A licensed perfusionist shall maintain a level of professional liability insurance coverage as required under section 13.3(k) of the act (63 P. S. § 271.13c(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 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.

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