

# RULES AND REGULATIONS

## Title 49—PROFESSIONAL AND VOCATIONAL STANDARDS

### STATE BOARD OF MEDICINE [ 49 PA. CODE CHS. 16 AND 18 ] Perfusionist

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

#### *Effective Date*

This final-form rulemaking will be effective upon publication in the *Pennsylvania Bulletin*.

#### *Statutory Authority*

The final-form 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)). The act of June 11, 2008 (P. L. 154, No. 19) (Act 19) amended the act to provide for licensure of perfusionists. This final-form rulemaking effectuates Act 19.

#### *Summary of Comments to Proposed Rulemaking*

The Board published notice of proposed rulemaking at 42 Pa.B. 3597 (June 23, 2012), with a 30-day public comment period. The Board did not receive comments from the public.

The House Professional Licensure Committee (HPLC) reviewed the proposed rulemaking and submitted comments to the Board on July 27, 2012. The Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) did not submit comments. The Independent Regulatory Review Commission (IRRC) submitted comments to the Board on August 22, 2012. The Board reviewed the comments and proposed amendments at its meeting on September 11, 2012, and voted to promulgate this final-form rulemaking.

The HPLC noted that the proposed rulemaking was published approximately 18 months after the effective date of Act 19. The Board published a proposed rulemaking at 40 Pa.B. 2652 (May 22, 2010) and delivered a final-form rulemaking to the HPLC, the SCP/PLC and IRRC on September 12, 2011. On October 20, 2011, IRRC disapproved the final-form rulemaking for lack of clarity. On January 6, 2012, the Board withdrew the rulemaking to address IRRC's concerns. As previously noted, the new version of the proposed rulemaking was published at 42 Pa.B. 3597. The Board acknowledges that the regulatory process has been lengthy and suggests that much of the delay was beyond the Board's control.

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

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

practice with an acknowledgement that the out-of-State perfusionist is subject to the jurisdiction of the Board. This acknowledgement is part of the registration form that an applicant for temporary emergency practice shall submit. To address this concern, the Board clarified in § 18.606(b) that an out-of-State perfusionist shall verify by personal or electronic signature the completed registration form. The HPLC also noted that the act specifies that the health care facility shall certify certain information to the Board. The certifications that the act requires be made by the health care facility are part of the registration form that shall be submitted by the health care facility. Therefore, the Board added § 18.606(e) to clarify that the application for temporary emergency registration of the out-of-State perfusionist is not complete unless the health care facility licensed by the Department of Health has submitted to the Board the certification required under the act. The HPLC also questioned whether there is a fee for an out-of-State emergency service perfusionist registration. There is not a fee for the registration; therefore, a fee is not listed in § 16.13(l).

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

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

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

§ 18.610(b)(6) for clarity. The HPLC recommended correcting “visit” in § 18.610(b)(11) to “visitor.” The Board made the correction.

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

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

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

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

IRRC suggested that the Board use “may” instead of “will” in § 18.610(b)(13) (final-form § 18.610(d)), regarding the biennial audit performed for continuing education compliance. The Board made the suggested amendment.

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

IRRC suggested that the language in § 18.610(c)(2)(vii) (final-form § 18.610(e)(2)(vii)), regarding counting credits for site visits, was unclear as to whether all site visits counted for five credits or whether five was the maximum number of credits. A site visit is an extensive, multiday evaluation and the Board intended that participation in a

site visit would be credited with five credits. The Board also intended that an individual not be permitted to earn these five credits more than once in a biennial period. The Board clarified this subsection.

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

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

In § 18.606(b), the Board added a requirement for registration of temporary emergency perfusionist service that the out-of-State perfusionist verify the completed registration form by personal or electronic signature. The application form requires that the out-of-State perfusionist verify that the registrant is subject to the authority of the Board. In § 18.606(e), the Board added a requirement for registration of temporary emergency perfusionist service that the health care facility have completed the certification required under section 13.3(j)(1)(ii) of the act. This certification is part of the application form for registration of temporary emergency perfusionist service.

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

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

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

#### *Fiscal Impact and Paperwork Requirements*

The final-form rulemaking will not have an adverse fiscal impact on the Commonwealth or its political subdivisions. Perfusionists who wish to become licensed to practice in this Commonwealth will bear the fiscal impact in the form of required fees and costs associated with obtaining the required continuing education and professional liability insurance.

The act and these regulations require perfusionists to maintain records of their participation in continuing education activities to present to the Board as evidence of their completion of statutorily-mandated continuing education. The act and the regulations require the Board and the Department of State to maintain licensure records, including application forms, on applicants for licensure and licensees. The act and the regulations require health care facilities licensed by the Department of Health who intend to utilize the perfusion services of an out-of-State perfusionist to certify certain information to the Board as part of the process for registration of the out-of-State

perfusionist. It is anticipated that these requirements will have a very minimal fiscal impact on affected parties.

*Sunset Date*

The Board continuously monitors its regulations. Therefore, 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 the notice of proposed rulemaking, published at 42 Pa.B. 3597, to IRRC and the Chairpersons of the HPLC and the SCP/PLC for review and comment.

Under section 5(c) of the Regulatory Review Act, IRRC, the HPLC and the SCP/PLC were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Board has considered all comments from IRRC, the HPLC, the SCP/PLC and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P. S. § 745.5a(j.2)), on June 19, 2013, the final-form rulemaking was deemed approved by the HPLC and the SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on June 20, 2013, and approved the final-form rulemaking.

*Findings*

The Board finds that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. §§ 1201 and 1202) and the regulations promulgated thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law and the comments were considered.

(3) The amendments to the final-form rulemaking do not enlarge the purpose of proposed rulemaking published at 42 Pa.B. 3597.

(4) This final-form rulemaking is necessary and appropriate for administering and enforcing the authorizing act.

*Order*

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

(a) The regulations of the Board, 49 Pa. Code Chapters 16 and 18, are amended by adding §§ 18.601—18.611 and by amending §§ 16.1, 16.11 and 16.13 to read as set forth in Annex A, with ellipses referring to the existing text of the regulations.

(b) The Board shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General as required by law.

(c) The Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(d) This order shall take effect upon publication in the *Pennsylvania Bulletin*.

ANDREW J. BEHNKE, MD,  
*Chairperson*

*(Editor's Note: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 43 Pa.B. 3857 (July 6, 2013).)*

**Fiscal Note:** Fiscal Note 16A-4935 remains valid for the final adoption of the subject regulations.

**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:

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*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.**

(a) The following medical doctor licenses are issued by the Board:

- (1) License without restriction.
- (2) Institutional license.
- (3) Extraterritorial license.
- (4) Graduate license.
- (5) Temporary license.
- (6) Interim limited license.

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

- (1) Nurse-midwife license.
- (2) Nurse-midwife certificate of prescriptive authority.
- (3) Physician assistant license.
- (4) Acupuncturist license.
- (5) Practitioner of Oriental medicine license.
- (6) Behavior specialist license.
- (7) Athletic trainer license.

(8) Perfusionist license.

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

- (1) Registration as a supervising physician of a physician assistant.
- (2) Biennial registration of a license without restriction.
- (3) Biennial registration of an extraterritorial license.
- (4) Biennial registration of a midwife license.

- (5) Biennial registration of a physician assistant license.
- (6) Biennial registration of a drugless therapist license.
- (7) Biennial registration of a limited license-permanent.
- (8) Biennial registration of an acupuncturist license.
- (9) Biennial registration of a practitioner of Oriental medicine license.
- (10) Biennial registration of a behavior specialist license.
- (11) Biennial registration of athletic trainer license.
- (12) 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**

**Subchapter J. PERFUSIONISTS**

Sec.	Purpose.
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 and expired status of perfusionist license; reactivation of inactive or expired license.
18.609.	Disciplinary action for licensed perfusionists.
18.610.	Continuing education for licensed perfusionists.
18.611.	Professional liability insurance coverage for licensed perfusionists.

**§ 18.601. Purpose.**

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

**§ 18.602. Definitions.**

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

*ABCP*—The American Board of Cardiovascular Perfusion.

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

*CAAHEP*—The Commission on Accreditation of Allied Health Education Programs.

*Extracorporeal circulation*—The diversion of a patient’s blood through a heart-lung machine or similar device that assumes the functions of the patient’s heart, lungs, kidneys, liver or other organ.

*Hour of continuing education*—At least 50 minutes of instruction, including relevant question and answer sessions, in an approved course of continuing education or an equivalent time that an online or correspondence course would be presented live.

*Nationally-recognized accrediting agency approved by the Board*—CAAHEP or other organization for which the Board publishes notice that the organization is approved by the Board as an accrediting agency for perfusionist programs.

*Nationally-recognized certifying agency approved by the Board*—ABCP or other organization for which the Board publishes notice that the organization is approved by the Board as a certifying agency for perfusionists.

*Out-of-State perfusionist*—An individual who holds a current license as a perfusionist in another state, the District of Columbia or a territory of the United States or has obtained certification by a certifying agency approved by a Nationally-recognized accrediting agency.

*Perfusion*—The functions necessary for the support, treatment, measurement or supplementation of the cardiovascular system or other organs, or a combination of those functions, and for ensuring the safe management of physiologic functions by monitoring and analyzing the parameters of the systems under the supervision of a physician licensed under the act or the Osteopathic Medical Practice Act (63 P. S. §§ 271.1—271.18).

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

*Ventricular assist device*—

(i) A mechanical device used to partially or completely replace the function of a failing heart through connections to the heart and great vessels that may be located intracorporeally or extracorporeally.

(ii) The term includes a device that is placed intravascularly or extravascularly and provides support through direct means or through counterpulsation.

**§ 18.603. Application for perfusionist license.**

(a) An applicant for a license to practice as a perfusionist shall submit, on forms made available by the Board, a completed application, including the necessary supporting documents, for a license to practice as a perfusionist and pay the fee in § 16.13(l) (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(l) (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(l) (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 prior to providing temporary emergency perfusionist service in this Commonwealth in accordance with section 13.3(j) of the act (63 P. S. § 422.13c(j)).

(b) The out-of-State perfusionist or another person acting on behalf of the out-of-State perfusionist shall submit, on forms made available by the Board, a completed registration form with the questions fully answered which shall be verified by the out-of-State perfusionist by personal or electronic signature. The completed registration form shall be submitted by electronic means, including computer-to-computer, computer-to-facsimile machine or e-mail transmission.

(c) Although not limited to a single procedure or single patient or group of related patients, an out-of-State perfusionist may provide temporary emergency perfusionist services in this Commonwealth for no longer than 72 hours.

(d) An out-of-State perfusionist may not provide temporary emergency perfusionist service in this Commonwealth more than once without being licensed in accordance with § 18.603, § 18.604 or § 18.605 (relating to application for perfusionist license; application for temporary graduate perfusionist license; and application for temporary provisional perfusionist license).

(e) A registration for an out-of-State perfusionist is not complete unless the health care facility licensed by the Department of Health has submitted the certification required under section 13.3(j)(1)(ii) of the act to the Board by electronic means, including computer-to-computer, computer-to-facsimile machine or e-mail transmission.

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

(a) The license of a perfusionist expires biennially on December 31 of each even-numbered year in accordance with § 16.15 (relating to biennial registration; inactive status and unregistered status). A perfusionist may not practice after December 31 of an even-numbered year unless the perfusionist has completed the biennial registration process and the Board has issued a renewed registration.

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

(1) Submit a completed application, including payment of the biennial registration fee in § 16.13(l) (relating to licensure, certification, examination and registration fees), for application for biennial registration of a perfusionist license.

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

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

(4) Disclose on the application pending criminal charges and a finding or verdict of guilt, admission of guilt, plea of nolo contendere, probation without verdict, disposition instead of trial or accelerated rehabilitative disposition in a criminal matter since the most recent application for biennial registration.

(5) Verify on the application that the licensed perfusionist has complied with the continuing education requirements mandated under section 13.3(n) of the act (63 P. S. § 422.13c(n)) during the biennial period immediately preceding the period for which registration is sought in accordance with § 18.610 (relating to continuing education for licensed perfusionists).

(6) Verify on the application that, if practicing as a perfusionist in this Commonwealth, the licensee maintains professional liability insurance coverage in accordance with section 13.3(k) of the act.

**§ 18.608. Inactive and expired status of perfusionist license; reactivation of inactive or expired license.**

(a) A perfusionist license will become inactive if the licensee requests in writing that the Board place the license on inactive status. The Board will provide written confirmation of inactive status to the licensee at the licensee's last known address on file with the Board.

(b) A perfusionist license will be classified as expired if the licensee fails to register the license by the expiration of the biennial registration period on December 31 of each even-numbered year. The Board will provide written notice to a licensee who fails to make biennial registration by sending a notice to the licensee's last known address on file with the Board.

(c) A perfusionist whose license has become inactive or expired may not practice as a perfusionist in this Commonwealth until the license has been reactivated.

(d) To reactivate an inactive or expired license, the licensee shall apply on forms made available by the Board and fully answer the questions. The licensee shall:

(1) Include the documentation required under § 18.610(b) (relating to continuing education for licensed perfusionists) for the immediately preceding biennium, which may be completed during the current biennium. Unless waived by the Board under section 13.3(n)(4) of the act (63 P. S. § 422.13c(n)(4)), the Board will not reactivate a license until the required continuing education for the preceding biennium has been successfully completed.

(2) Pay the current biennial registration fee and the reactivation application fee in § 16.13(l) (relating to licensure, certification, examination and registration fees).

(3) Verify that the licensee did not practice as a perfusionist in this Commonwealth while the license was inactive or expired except as provided in subsection (e).

(e) A licensee who has practiced with an inactive or expired license and who cannot make the verification required under subsection (d)(3) shall also pay the fees

required under this subsection. Payment of a late fee does not preclude the Board from taking disciplinary action for practicing as a perfusionist without a currently registered license.

(1) A licensee whose license was active at the end of the immediately preceding biennial registration period and who practiced after the license became inactive or expired shall pay a late fee of \$5 for each month or part of a month from the beginning of the current biennium until the date the reactivation application is filed.

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

**§ 18.609. Disciplinary action for licensed perfusionists.**

(a) A licensed perfusionist, including a perfusionist holding a temporary graduate license or a temporary provisional license, is subject to disciplinary action under section 41 of the act (63 P. S. § 422.41). Following a final determination subject to the right of notice, hearing and adjudication and the right of appeal in accordance with 2 Pa.C.S. §§ 501—508 and 701—704 (relating to Administrative Agency Law), the Board may impose a corrective action in section 42 of the act (63 P. S. § 422.42).

(b) Unprofessional conduct includes:

(1) Engaging in conduct prohibited under § 16.110 (relating to sexual misconduct).

(2) Performing an act in a health care profession in a fraudulent, incompetent or negligent manner.

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

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

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

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

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

(8) Failing to provide supervision as required under section 13.3(e)(2) of the act (63 P. S. § 422.13c(e)(2)) of a perfusion student or failing to provide supervision as required under section 13.3(e)(3) of the act of a perfusion graduate who is not otherwise licensed by the Board to perform perfusion in this Commonwealth.

(c) Immoral conduct includes:

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

(2) Being convicted of a crime involving moral turpitude, dishonesty or corruption in the courts of the

Commonwealth, the United States, another state, the District of Columbia, a territory of the United States or another country.

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

**§ 18.610. Continuing education for licensed perfusionists.**

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

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

(2) Except when reactivating an inactive license, when the Board has granted a waiver or when ordered by the Board, continuing education credits may be used to satisfy the continuing education credit hour requirements only for the biennial period in which the credits were earned. An hour of continuing education may not be used to satisfy the requirement of paragraph (1) for more than 1 biennium.

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

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

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

(1) Proof of attendance at an ABCP-approved perfusion meeting consists of a certified record issued by the provider, including:

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

(2) Proof of a perfusion-related publication consists of the complete citation reference to the book, chapter or paper in a professional publication.

(3) Proof of presentation at an ABCP-approved or international perfusion meeting consists of a copy of the program agenda.

(4) Proof of participation in an ABCP knowledge base survey consists of a letter from ABCP.

(5) Proof of reading or viewing medical journals, audio-visual or other educational materials consists of a list of the complete 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 provider.

(7) Proof of participation in a perfusion-related journal club consists of the meeting agenda with topic and date.

(8) Proof of completion of an academic course consists of a copy of the official college or university transcript.

(9) Proof of presentation of a perfusion topic at a meeting that is not approved by 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 visitor consists of a letter from ABCP.

(c) *Proof of completion of continuing education.* 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.

(d) *Verification of compliance.* The Board may audit licensees to verify compliance with continuing education requirements. A licensee shall submit proof of continuing education activities upon request by the Board.

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

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

(i) Attendance at an ABCP-approved perfusion meeting. One continuing education credit may be earned for each hour of continuing education.

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

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

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

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

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

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

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

(iv) Completion of a science or health care-related academic course at a regionally accredited college or university. One continuing education credit may be earned biennially.

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

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

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

(3) Continuing education credit may not be earned in a 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 of the license if the licensee has not provided proof of professional liability insurance coverage and will remain inactive until the licensee provides proof of insurance coverage.

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

[Pa.B. Doc. No. 13-1439. Filed for public inspection August 2, 2013, 9:00 a.m.]

**STATE BOARD OF OSTEOPATHIC MEDICINE**  
**[ 49 PA. CODE CH. 25 ]**  
**Perfusionist**

The State Board of Osteopathic Medicine (Board) amends §§ 25.215 and 25.231 (relating to definitions; and schedule of fees) and adds §§ 25.801—25.811 (relating to perfusionists) to read as set forth in Annex A.

*Effective Date*

This final-form rulemaking will be effective upon publication in the *Pennsylvania Bulletin*.

*Statutory Authority*

The final-form rulemaking is authorized under sections 13.3 and 16 of the Osteopathic Medical Practice Act (act) (63 P. S. §§ 271.13c and 271.16). The act of June 11, 2008 (P. L. 161, No. 20) (Act 20) amended the act to provide for licensure of perfusionists. This final-form rulemaking effectuates Act 20.

*Summary of Comments to Proposed Rulemaking*

The Board published notice of proposed rulemaking at 42 Pa.B. 3607 (June 23, 2012), with a 30-day public comment period. The Board did not receive comments from the public.

The House Professional Licensure Committee (HPLC) reviewed the proposed rulemaking and submitted comments to the Board on July 27, 2012. The Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) did not submit comments. The Independent Regulatory Review Commission (IRRC) submitted comments to the Board on August 22, 2012. The Board reviewed the comments and proposed amendments at its meeting on October 25, 2012, and voted to promulgate this final-form rulemaking.

The HPLC noted that the proposed rulemaking was published approximately 18 months after the effective date of Act 20. Drafting the initial proposed rulemaking was accomplished over a 14-month period, including solicitation of input from interested parties and stakeholders, and multiple revisions. The Board published a proposed rulemaking at 40 Pa.B. 2660 (May 22, 2010) and delivered a final-form rulemaking to the HPLC, the SCP/PLC and IRRC on September 12, 2011. On October 20, 2011, IRRC disapproved the final-form rulemaking for lack of clarity. On January 31, 2012, the Board withdrew the rulemaking to address IRRC's concerns. As previously noted, the new version of the proposed rulemaking was published at 42 Pa.B. 3607. The Board acknowledges that the regulatory process has been lengthy and suggests that much of the delay was beyond the Board's control.

The HPLC raised an issue with § 25.806 (relating to registration of temporary emergency perfusionist service). The HPLC noted that the act requires that an out-of-State perfusionist submit a notification of emergency practice with an acknowledgement that the out-of-State perfusionist is subject to the jurisdiction of the Board. This acknowledgement is part of the registration form that an applicant for temporary emergency practice shall submit. To address this concern, the Board clarified in § 25.806(b) that an out-of-State perfusionist shall verify by personal or electronic signature the completed registration form. The HPLC also noted that the act specifies that the health care facility shall certify certain information to the Board. The certifications that the act requires be made by the health care facility are part of the registration form that shall be submitted by the health care facility. Therefore, the Board added § 25.606(e) to clarify that the registration of the out-of-State perfusionist is not complete unless the health care facility licensed by the Department of Health has submitted to the Board the certification required under the act. The HPLC also questioned whether there is a fee for an out-of-State emergency service perfusionist registration. There is not a fee for the registration; therefore, a fee is not listed in § 25.231.



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

The HPLC asked if the District of Columbia should be named on the list of other states and jurisdictions in § 25.807(b)(2) (relating to renewal of perfusionist license). The Board notes that the definition of "state" in 1 Pa.C.S. § 1991 (relating to definitions) provides that "[w]hen used in reference to the different parts of the United States, [the term] includes the District of Columbia and the several territories of the United States." Therefore, the use of "state" in section 6.1 of the act (63 P.S. § 271.6a), regarding reporting of multiple licensure or certificate, which is the statutory basis for the requirement, includes the District of Columbia. However, for added clarity, the Board added "district" to the listed jurisdictions in § 25.807(b)(2).

The HPLC recommended a typographical correction in § 25.810(b)(5) (relating to continuing education for licensed perfusionist), which has been made. The HPLC questioned if a reference to a continuing education "sponsor" in § 25.810(b)(6) referred to a continuing education provider discussed elsewhere in the section. It does and the Board changed "sponsor" to "provider" in § 25.810(b)(6) for clarity. The HPLC recommended correcting "visit" in § 25.810(b)(11) to "visitor." The Board made the correction.

The HPLC suggested that § 25.810(b)(12) be written to read: "Proof of completion of continuing education shall be retained by a licensee for 5 years after completion of the continuing education or after the completion of the biennial registration period for which the continuing education as required, whichever is later." Upon review of § 25.810, the Board realized that neither paragraph (12) nor paragraph (13) should be part of subsection (b). Accordingly, rather than rewrite paragraph (12), the Board renumbered paragraph (12) as subsection (c) and renumbered paragraph (13) as subsection (d). Proposed subsection (c) was renumbered as subsection (e).

The HPLC asked if there are sanctions for a licensee who fails to submit proof of meeting continuing education requirements upon the Board's request under § 25.810(b)(13) (final-form § 25.810(d)). A licensee who cannot submit proof of meeting the continuing education requirements is subject to discipline under section 15(a)(1) and (6) of the act (63 P.S. § 271.15(a)(1) and (6)), which authorizes the Board to discipline a licensee for failing to demonstrate the qualifications for a license and

for violating a lawful regulation promulgated by the Board. Currently, individuals who have failed to meet the continuing education requirement are most frequently disciplined by means of a consent agreement, when the individual pays a fine and agrees to make up the deficiency in addition to completing the continuing education required for the current biennial period.

The HPLC pointed out a typographical error in § 25.811(c) (relating to professional liability insurance coverage for licensed perfusionist), which has been corrected.

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

IRRC suggested that the Board use "may" instead of "will" in § 25.810(b)(13) (final-form § 25.810(d)), regarding the biennial audit performed for continuing education compliance. The Board made the suggested amendment.

IRRC also commented that the limitation on counting continuing education credits for teaching was not clear in § 25.810(c)(2)(vi) (final-form § 25.810(e)(2)(vi)). The Board amended the section to clarify that two continuing education credits may be earned for teaching a single course, with a maximum of four credits earned biennially under the subsection.

IRRC suggested that the language in § 25.810(c)(2)(vii) (final-form § 25.810(e)(2)(vii)), regarding counting credits for site visits, was unclear as to whether all site visits counted for five credits or whether five was the maximum number of credits. A site visit is an extensive, multiday evaluation and the Board intended that participation in a site visit would be credited with five credits. The Board also intended that an individual not be permitted to earn these five credits more than once in a biennial period. The Board clarified this subparagraph.

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

As previously noted, the Board made amendments to the final-form rulemaking to address the comments made by the HPLC and IRRC. In § 25.806(b), the Board added a requirement for registration of temporary emergency perfusionist service that the out-of-State perfusionist verify the completed registration form by personal or electronic signature. The application form requires that the out-of-State perfusionist verify that the registrant is subject to the authority of the Board. Likewise, in § 25.806(e), the Board added a requirement for registration of temporary emergency perfusionist service that the health care facility have completed the certification required under section 13.3(j)(1)(ii) of the act. This certification is part of the application form for registration of temporary emergency perfusionist service.

The Board added "district" to the list including other states and territories in § 25.807(b)(2).

The Board amended § 25.808 (relating to inactive and expired status of perfusionist license; reactivation of

inactive or expired license) to reflect the distinction made by the Board between inactive and expired licenses. A license becomes inactive at the request of the licensee. A license becomes expired by the failure of a licensee to register the license biennially. Upon review, it became apparent to the Board that the distinction should be clarified in the regulations.

The Board corrected the spelling of “complete” in § 25.810(b)(5) and changed “sponsor” to “provider” in § 25.810(b)(6). The Board renumbered § 25.810(b)(12) and (13) as § 25.810(c) and (d) and renumbered § 25.810(c) as § 25.810(e). In § 25.810(d), the Board changed “will” to “may,” indicating that it does not always audit 100% of licensees for continuing education compliance. In § 25.810(e)(2)(vi), the Board clarified that working as a clinical or didactic instructor in an accredited school will earn two continuing education credits for teaching a single course. In § 25.810(e)(2)(vii), the Board clarified that five continuing education credits may be earned for participation in a site visitor’s workshop or as an official site visitor for perfusion program accreditation.

#### *Fiscal Impact and Paperwork Requirements*

The final-form rulemaking will not have an adverse fiscal impact on the Commonwealth or its political subdivisions. Perfusionists who wish to become licensed to practice in this Commonwealth will bear the fiscal impact in the form of required fees and costs associated with obtaining the required continuing education and professional liability insurance.

The act and these regulations require perfusionists to maintain records of their participation in continuing education activities to present to the Board as evidence of their completion of statutorily-mandated continuing education. The act and the regulations require the Board and the Department of State to maintain licensure records, including application forms, on applicants for licensure and licensees. The act and the regulations require health care facilities licensed by the Department of Health who intend to utilize the perfusion services of an out-of-State perfusionist to certify certain information to the Board as part of the process for registration of the out-of-State perfusionist. It is anticipated that these requirements will have a very minimal fiscal impact on affected parties.

#### *Sunset Date*

The Board continuously monitors its regulations. Therefore, 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 the notice of proposed rulemaking, published at 42 Pa.B. 3607, to IRRC and the Chairpersons of the HPLC and the SCP/PLC for review and comment.

Under section 5(c) of the Regulatory Review Act, IRRC, the HPLC and the SCP/PLC were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Board has considered all comments from IRRC, the HPLC, the SCP/PLC and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P. S. § 745.5a(j.2)), on June 19, 2013, the final-form rulemaking was deemed approved by the HPLC and the SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on June 20, 2013, and approved the final-form rulemaking.

#### *Findings*

The Board finds that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. §§ 1201 and 1202) and the regulations promulgated thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law and the comments were considered.

(3) The amendments to the final-form rulemaking do not enlarge the purpose of proposed rulemaking published at 42 Pa. B. 3607.

(4) This final-form rulemaking is necessary and appropriate for administering and enforcing the authorizing act.

#### *Order*

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

(a) The regulations of the Board, 49 Pa. Code Chapter 25, are amended by adding §§ 25.801—25.811 and by amending §§ 25.215 and 25.231 to read as set forth in Annex A, with ellipses referring to the existing text of the regulations.

(b) The Board shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General as required by law.

(c) The Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(d) This order shall take effect upon publication in the *Pennsylvania Bulletin*.

JEFFREY A. HEEBNER, DO,  
*Chairperson*

*(Editor’s Note: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 43 Pa.B. 3857 (July 6, 2013).)*

**Fiscal Note:** Fiscal Note 16A-5324 remains valid for the final adoption of the subject regulations.

#### **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.

*Immediate family member*—A parent or guardian, child, sibling, spouse or other family member, whether related by blood or marriage, with whom a patient resides.

*Sexual behavior*—Any sexual conduct which is nondiagnostic and nontherapeutic; it may be verbal or physical and may include expressions of thoughts and feelings or gestures that are sexual in nature or that reasonably may be construed by a patient as sexual in nature.

*Sexual exploitation*—Any sexual behavior that uses trust, knowledge, emotions or influence derived from the professional relationship.

**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.....		\$50
Biennial renewal 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

**Subchapter N. PERFUSIONISTS**

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

**§ 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.

*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 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 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 a 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 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. § 271.13c(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 § 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 which shall be verified by the out-of-State perfusionist by personal or electronic signature. The completed registration form shall be submitted by electronic means, including computer-to-computer, computer-to-facsimile 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).

(e) A registration for an out-of-State perfusionist is not complete unless the health care facility licensed by the Department of Health has submitted the certification required under section 13.3(j)(1)(ii) of the act to the Board by electronic means, including computer-to-computer, computer-to-facsimile machine or e-mail transmission.

#### **§ 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 perfusionist 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, district, 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 immedi-

ately 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 and expired status of perfusionist license; reactivation of inactive or expired license.**

(a) A perfusionist license will become inactive if the licensee requests in writing that the Board place the license on inactive status. The Board will provide written confirmation of inactive status to the licensee at the licensee's last known address on file with the Board.

(b) A perfusionist license will be classified as expired if the licensee fails to renew the certificate by the expiration of the renewal period on December 31 of each even-numbered year. The Board will provide written notice to a licensee who fails to renew by sending a notice to the licensee's last known address on file with the Board.

(c) A perfusionist whose license has become inactive or expired may not practice as a perfusionist in this Commonwealth until the license has been reactivated.

(d) To reactivate an inactive or expired 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 § 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. § 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 or expired except as provided in subsection (e).

(e) A licensee who has practiced with an inactive or expired license and who cannot make the verification required under subsection (d)(3) shall also pay the fees required under this subsection. Payment of a late fee does not preclude the Board from taking disciplinary action for practicing as a perfusionist without a 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 or expired shall pay a late fee of \$5 for each month or part of a month from the beginning of the current biennium until the date the reactivation application is filed.

(2) A licensee whose license has been inactive or expired since before the beginning of the current biennium shall pay the 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 or expired 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 is 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, audio-visual or other educational materials consists of a list of the complete citation reference for the materials read or reviewed.

(6) Proof of participation in a perfusion-related self-study module or electronic forum consists of a copy of the printed completion document supplied by the provider.

(7) Proof of participation in a perfusion-related journal club consists of the meeting agenda with topic and date.

(8) Proof of completion of an academic course consists of a copy of the official college or university transcript.

(9) Proof of presentation of a perfusion topic at a meeting that is not approved by the ABCP consists of a copy of the meeting agenda.

(10) Proof of participation as a clinical or didactic instructor in an accredited program consists of a letter of confirmation of the instructor's status from the program director.

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

(c) *Proof of completion of continuing education.* A licensee shall retain proof of completion of continuing education for 5 years after completion of the continuing educa-

tion or after the completion of the biennial renewal period during which the continuing education was required, whichever is later.

(d) *Verification of compliance.* The Board may audit licensees to verify compliance with continuing education requirements. A licensee shall submit proof of continuing education activities upon request by the Board.

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

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

(i) Attendance at an ABCP-approved perfusion meeting. One continuing education credit may be earned for each hour of continuing education.

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

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

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

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

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

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

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

(iv) Completion of a science or health care-related academic course at a regionally accredited college or university. One continuing education credit may be earned biennially.

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

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

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

(3) Continuing education credit may not be earned in 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 of the license if the licensee has not provided proof of professional liability insurance coverage and will remain inactive until the licensee provides proof of insurance coverage.

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

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