

MARYLAND REGISTER

Proposed Action on Regulations

Transmittal Sheet PROPOSED OR REPROPOSED Actions on Regulations	Date Filed with AELR Committee	TO BE COMPLETED BY DSD
	04/22/2014	Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

1. Desired date of publication in Maryland Register: 5/30/2014

2. COMAR Codification

Title Subtitle Chapter Regulation

10 32 20 01-.19

3. Name of Promulgating Authority

Department of Health and Mental Hygiene

4. Name of Regulations Coordinator Telephone Number
Michele Phinney 410-767-5623

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5. Name of Person to Call About this Document Telephone No.
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6. Check applicable items:
 X- New Regulations

- Amendments to Existing Regulations
 - Date when existing text was downloaded from COMAR online: .
 - Repeal of Existing Regulations
 - Recodification
 - Incorporation by Reference of Documents Requiring DSD Approval
 - Reproposal of Substantively Different Text:
 - : Md. R
 - (vol.) (issue) (page nos) (date)
- Under Maryland Register docket no.: --P.

7. Is there emergency text which is identical to this proposal:

- Yes No

8. Incorporation by Reference

Check if applicable: Incorporation by Reference (IBR) approval form(s) attached and 18 copies of documents proposed for incorporation submitted to DSD. (Submit 18 paper copies of IBR document to DSD and one copy to AELR.)

9. Public Body - Open Meeting

- OPTIONAL - If promulgating authority is a public body, check to include a sentence in the Notice of Proposed Action that proposed action was considered at an open meeting held pursuant to State Government Article, §10-506(c), Annotated Code of Maryland.

OPTIONAL - If promulgating authority is a public body, check to include a paragraph that final action will be considered at an open meeting.

10. Children's Environmental Health and Protection

Check if the system should send a copy of the proposal to the Children's Environmental Health and Protection Advisory Council.

11. Certificate of Authorized Officer

I certify that the attached document is in compliance with the Administrative Procedure Act. I also certify that the attached text has been approved for legality by Noreen M. Rubin, Assistant Attorney General, (telephone #410-767-6917) on October 3, 2013. A written copy of the approval is on file at this agency.

Name of Authorized Officer

Joshua M. Sharfstein, M.D.

Title

Secretary

Telephone No.

410-767-6500

Date

April 22, 2014

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 32 BOARD OF PHYSICIANS

10.32.20 Licensure of Perfusionists

Authority: Health Occupations Article, §§1-606, 14-205, 14-5E-01, and 14-5E-03—14-5E-25, Annotated Code of Maryland

Notice of Proposed Action

□

The Secretary of Health and Mental Hygiene proposes to adopt new Regulations .01—.19 in a new chapter COMAR 10.32.20 Licensure of Perfusionists.

This action was considered by the Board of Physicians at a public meeting held on June 26, 2013, notice of which was given by publication in 40:12 Md. R. June 14, 2013 pursuant to State Government Article, §10-506(c)(1), Annotated Code of Maryland.

Statement of Purpose

The purpose of this action is to establish requirements for the licensure and discipline of a new allied health profession, perfusion. The regulations include requirements for the advisory committee, requirements for licensure and scope of practice for a perfusionist, grounds for discipline for perfusionists, sanctioning guidelines and other matters pertaining to the practice of perfusion.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact.

The Board of Physicians will incur expenses as a result of establishing a new licensure program, reviewing applications, responding to inquiries, maintaining a data system, handling any disciplinary actions, etc. A moderate licensure fee will be imposed on perfusionists to offset the cost of these services.

II. Types of Economic Impact.	Revenue (R+/R-)	Magnitude
	Expenditure (E+/E-)	
A. On issuing agency:	(R+)	\$18,900
(2)	(E+)	\$41,076
B. On other State agencies:	NONE	
C. On local governments:	NONE	

	Benefit (+) Cost (-)	Magnitude
D. On regulated industries or trade groups:	(-)	\$18,900
E. On other industries or trade groups:	NONE	
F. Direct and indirect effects on public:	(+)	Unquantifiable

III. Assumptions. (Identified by Impact Letter and Number from Section II.)

A(1). Income results from initial applications for an estimated 63 perfusionists who are already certified by the national organization and practicing in Maryland. Initial licensing fee is \$300 (for a 2-year period).

$$63 \times \$300 = \$18,900$$

Renewals and reinstatements will not occur during the initial phase of implementing licensure since initial licenses will cover a 2-year period.

A(2). Staff time will be needed to support this program, including preparing documents for use by the program, reviewing applications for licensure, verifying information of the applications, contacting applicants with questions, reviewing evaluation and treatment protocols, issuing licenses. The secretary will maintain all paperwork and files, handle telephone inquiries, prepare packets for committee meetings and maintain minutes of those meetings, and prepare documents to be submitted to the Board each month. An additional staff member will be required to assist with these duties and the cost of licensure, due to the low number of practitioners, will not cover the cost of operations. The fees generated will not cover expenditures and will have to be adjusted accordingly before October of 2015.

D. See III.A(1) above

F. Impact of public will be to insure that the public can assume that a “perfusionist” is a licensed professional meeting specified criteria. This is not quantifiable.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Michele A. Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499; TTY:800-735-2258, or email to dhmh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through June 30, 2014. A public hearing has not been scheduled.

Economic Impact Statement Part C

A. Fiscal Year in which regulations will become effective: FY 2014

B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?

No

C. If 'yes', state whether general, special (exact name), or federal funds will be used:

D. If 'no', identify the source(s) of funds necessary for implementation of these regulations:

Revenue will be generated by this program and will be deposited into the Board of Physicians Fund, a non-reverting special fund. Expenses will be paid with special funds from this source.

E. If these regulations have no economic impact under Part A, indicate reason briefly:

F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.

Perfusionists are generally hired by hospitals and they do not operate as independent business entities.

G. Small Business Worksheet:

Attached Document:

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 32 BOARD OF PHYSICIANS

10.32.20 Licensure of Perfusionists

Authority: Health Occupations Article, §§1-606, 14-205, 14-5E-01, and 14-5E-03—14-5E-25, Annotated Code of Maryland

.01 Scope.

A. This chapter governs the practice of perfusion.

B. Except as provided in §C or D of this regulation, on or after October 1, 2013, an individual shall be licensed by the Board before the individual may practice perfusion.

C. This chapter does not prohibit any student who is currently enrolled in an accredited educational program to qualify for a license as a perfusionist from performing any of the procedures described in this chapter as part of that program's clinical curriculum on perfusion.

D. This chapter does not prohibit an individual from practicing a health occupation that the individual is authorized to practice under Health Occupations Article, Annotated Code of Maryland.

.02 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

- (1) "Accredited educational program" means a program accredited by The Commission on Accreditation of Allied Health Education Programs (CAAHEP), or its successor accrediting agency.
- (2) "Board" means the State Board of Physicians.
- (3) "Certified clinical perfusionist" means an individual holding a certificate issued by the national certifying board.
- (4) "Certification" means recognition of an individual who has satisfied certain standards required by the national certifying board.
- (5) "Committee" means the Perfusion Advisory Committee established under Health Occupations Article, §14-5E-05, Annotated Code of Maryland.
- (6) "Conversion" means changing a license from licensed perfusionist-basic to licensed perfusionist-advanced.
- (7) "Immediately available direction" means the responsibility of a licensed physician to provide necessary direction for a licensed perfusionist in person, by telephone, or by other electronic means.
- (8) "Joint Commission" means the organization formerly known as the Joint Commission on the Accreditation of Health Care Organizations.
- (9) "License" means a license issued by the Board to practice perfusion.
- (10) "Licensed perfusionist" means a perfusionist who is licensed by the Board, in accordance with Health Occupations Article, Title 14, Subtitle 5E, Annotated Code of Maryland, to practice perfusion as a:
- (a) Licensed perfusionist-advanced; or
- (b) Licensed perfusionist-basic.
- (11) "Licensed perfusionist-advanced" means an individual who is licensed by the Board as a perfusionist based on current certification as a certified clinical perfusionist.
- (12) "Licensed perfusionist-basic" means an individual who:
- (a) Is licensed by the Board as a perfusionist for a limited time based on graduation from an accredited perfusion educational program; and
- (b) Has not yet passed the national certifying examinations given by the national certifying board.
- (13) "Licensed physician" means a physician licensed by the Board.
- (14) "National certifying board" means the American Board of Cardiovascular Perfusion or its successor.
- (15) "National certifying examinations" means the two examinations given by the national certifying board.
- (16) "On-site direction" means the responsibility of a licensed physician to provide necessary direction for a licensed perfusionist when the physician is:
- (a) Physically present in the procedure room or in the facility; and
- (b) Able to respond if the perfusionist needs assistance during a procedure.
- (17) Practice Perfusion.
- (a) "Practice perfusion" means to perform the functions necessary for the support, treatment, measurement, or supplementation of the cardiovascular, circulatory, or respiratory systems, or other organs to ensure the safe management of physiologic functions by monitoring and analyzing the parameters of the systems under an order and the supervision of a licensed physician.
- (b) "Practice perfusion" includes:
- (i) Cardiopulmonary bypass for adult, pediatric, and neonatal patients;
- (ii) Extracorporeal circulatory support for renal, neurological, hepatic, and vascular surgery;
- (iii) Extracorporeal resuscitation;
- (iv) Extracorporeal circulation for long-term support of failing respiratory or cardiac function;
- (v) Extracorporeal membrane oxygenation;
- (vi) Extracorporeal carbon dioxide removal;
- (vii) Myocardial protection;
- (viii) Perfusion-assisted direct coronary artery bypass;
- (ix) Hemofiltration and hemodialysis;
- (x) Anticoagulation and hemostasis monitoring, analysis, and intervention;
- (xi) Thermal regulation;
- (xii) Blood gas and blood chemistry monitoring, analysis, and intervention;
- (xiii) Physiological monitoring, analysis, and intervention;
- (xiv) Administration of blood components and pharmaceuticals;
- (xv) Administration of anesthetic agents through a heart lung machine at the direction of an anesthesiologist;
- (xvi) Ventricular assist device and mechanical circulatory support management;
- (xvii) Intra-aortic balloon counterpulsation;
- (xviii) Temporary pacemaker management;
- (xix) Periodic flow augmentation therapy;
- (xx) Autotransfusion;
- (xxi) Platelet gel production, autologous hemocyte tissue matrix production;
- (xxii) Nondifferentiated progenitor cell harvest bone marrow aspirate concentration;
- (xxiii) Acute normovolemic hemodilution;

(xxiv) *Isolated limb or organ delivery of chemotherapeutics, progenitor cells, gene therapy vectors, and other items;*

(xxv) *Organ procurement and preservation;*

(xxvi) *Thermogenic lavage;*

(xxvii) *Electrophysiological analysis;*

(xxviii) *Therapeutic hyperthermia;*

(xxix) *Intravascular membrane oxygenation; and*

(xxx) *Renal perfusion.*

(18) *“Student” means an individual who, in accordance with Health Occupations Article, §14-5E-09(c), Annotated Code of Maryland, is:*

(a) *Enrolled in an accredited educational program to qualify for a license; and*

(b) *Performing perfusion services within the accredited program under the supervision of a licensed perfusionist and without compensation.*

(19) *“Supervision” means the responsibility of a licensed physician to exercise on-site direction or immediately available direction for a licensed perfusionist to ensure the safety and welfare of patients during the course of perfusion.*

.03 Perfusion Advisory Committee.

A. *The Board shall appoint members of the Committee as follows:*

(1) *Three individuals who:*

(a) *On or before September 30, 2013, practice perfusion and who:*

(i) *Are certified by a national certifying board; and*

(ii) *Have a minimum of 2 years of perfusion experience; and*

(b) *On or after October 1, 2013, are licensed perfusionists-advanced;*

(2) *Three physicians, at least one of whom performs cardiac or cardio-thoracic surgery; and*

(3) *One consumer member who:*

(a) *Shall be a member of the general public; and*

(b) *May not:*

(i) *Practice, or ever have practiced perfusion, or any other health care profession;*

(ii) *Be, or ever have been, in training to practice perfusion or any other health care profession;*

(iii) *Have a household member who is a health care professional or is in training to be a health care professional;*

(iv) *Participate, or ever have participated, in a commercial or professional field related to perfusion;*

(v) *Have a household member who participates in a commercial or professional field related to perfusion;*

(vi) *Have had, within 2 years before appointment, a financial interest in a person regulated by the Board;*

or

(vii) *Have had, within 2 years of appointment, a financial interest in the provision of goods or services to perfusionists or to the field of perfusion.*

B. *Tenure.*

(1) *The term of a member is 3 years.*

(2) *The terms of the members are staggered.*

(3) *At the end of a term, a member continues to serve until a successor is appointed and qualifies.*

(4) *An individual may be reappointed for a second 3-year term, but the individual may not serve more than two consecutive 3-year terms.*

(5) *The terms of the initial members of the Perfusion Advisory Committee shall expire as follows:*

(a) *Two members in 2013;*

(b) *Two members in 2014; and*

(c) *Three members in 2015.*

C. *Vacancy.*

(1) *If a vacancy occurs, the Board shall appoint a new member to serve.*

(2) *The successor member shall only serve for the remainder of the term, unless reappointed.*

D. *Chair. From among its members, the Committee shall elect a chair every 2 years.*

E. *Quorum.*

(1) *A majority of the members then serving on the Committee is a quorum.*

(2) *Business may not be conducted at a Committee meeting unless there is a quorum.*

F. *The Committee shall develop and make recommendations to the Board in the following areas:*

(1) *Regulations governing the practice of perfusion;*

(2) *Code of ethics requirements for the practice of perfusion;*

(3) *Standards of care requirements for the practice of perfusion;*

(4) *Continuing education requirements for license renewal;*

(5) *Any other educational or clinical requirements for licensure and practice as a perfusionist;*

- (6) *At the request of the Board, review selected applications for licensure as a perfusionist and make recommendations to the Board on the applications;*
- (7) *At the request of the Board, review complaints against perfusionists and respond to the Board's questions;*
- and
- (8) *Keep a record of the Committee's proceedings.*

.04 Code of Ethics.

A. *The ethical responsibilities of a licensed perfusionist include, but are not limited to, compliance with the principles set forth in §B of this regulation.*

B. *A licensed perfusionist:*

(1) *Shall:*

- (a) *Practice medically acceptable methods of treatment and may not endeavor to practice beyond the competence and the authority vested in the perfusionist by the physician;*
- (b) *Report:*
 - (i) *Known illegal, unethical, or incompetent conduct; or*
 - (ii) *In good faith, suspected illegal, unethical, or incompetent conduct;*
- (c) *Respect the patient's rights and dignity;*
- (d) *Maintain patient confidentiality and protect privileged information;*
- (e) *Place the patient's best interest ahead of all else;*
- (f) *Guard against conflicts of interest including avoiding those involving financial or personal gain;*
- (g) *Uphold the dignity and honor of the profession and abide by its ethical principles; and*
- (h) *Be familiar with existing state and federal laws governing the practice of perfusion and comply with those laws; and*

(2) *May not:*

- (a) *Delegate any perfusion duty to an individual not having the appropriate training and skill to undertake such responsibility;*
- (b) *Falsify documentation on patient records; and*
- (c) *Falsify reports submitted to the Board.*

C. *All services shall be provided with respect for the dignity of the patient, unrestricted by considerations of:*

- (a) *Social or economic status;*
- (b) *Personal attributes; or*
- (c) *The nature of health problems.*

D. *A breach of ethical principles may be considered immoral or unprofessional conduct in the practice of perfusion.*

.05 Standards of Care.

A. *In evaluating the standards of care for the practice of a licensed perfusionist, the Board may consider, but is not limited to, the guidelines published by the American Society of Extracorporeal Technology (AmSECT).*

B. *If a particular practice issue has not yet been addressed in the AmSECT guidelines, the Board may consult with a licensed perfusionist-advanced.*

.06 Application for Initial Licensure as a Perfusionist.

A. *An applicant for either a license as a perfusionist-basic or perfusionist-advanced shall:*

- (1) *Complete an application on a form supplied by the Board;*
- (2) *Pay the required application fee set by the Board in Regulation .13 of this chapter;*
- (3) *Be 18 years old or older;*
- (4) *Be of good moral character;*
- (5) *Demonstrate spoken and written competency in English by any of the following:*
 - (a) *Documentation of graduation from a recognized English-speaking high school or undergraduate school after at least 3 years of enrollment;*
 - (b) *Documentation of graduation from a recognized English-speaking professional school; or*
 - (c) *Documentation of receiving a grade of at least:*
 - (i) *26 on the "Speaking Section" of the Internet-based Test of English as a Foreign Language; and*
 - (ii) *79 on the total score of the Internet-based Test of English as a Foreign Language;*
- (6) *If applicable, provide documentation of licensure, certification, or registration from all states and jurisdictions where the applicant has ever held a license, certificate, or registration in any health profession; and*
- (7) *Have no history of public disciplinary action taken, or pending, against any license currently or previously held or expired.*

B. *An applicant for a license as:*

(1) *A perfusionist-basic shall submit satisfactory evidence of graduation from a perfusion educational program that is accredited by the Commission on Accreditation of the Allied Health Education Program, or the Commission's predecessor or successor;*

(2) *A perfusionist-advanced shall submit satisfactory evidence of current national certification from the national certifying board.*

.07 Scope of Practice.

A. A licensed perfusionist may practice only under the supervision of a licensed physician.

B. The scope of practice of a licensed perfusionist is performance of the functions necessary for the support, treatment, measurement, or supplementation of the cardiovascular, circulatory, or respiratory systems, or other organs to ensure the safe management of physiologic functions by monitoring and analyzing the parameters of the systems.

C. The scope of practice of a licensed perfusionist includes the following special procedures, performed on the order of and under the supervision of a licensed physician:

- (1) Cardiopulmonary bypass for adult, pediatric, and neonatal patients;
- (2) Extracorporeal circulatory support for renal, neurological, hepatic, and vascular surgery;
- (3) Extracorporeal resuscitation;
- (4) Extracorporeal circulation for long-term support of failing respiratory or cardiac function;
- (5) Extracorporeal membrane oxygenation;
- (6) Extracorporeal carbon dioxide removal;
- (7) Myocardial protection;
- (8) Perfusion-assisted direct coronary artery bypass;
- (9) Hemofiltration and hemodialysis;
- (10) Anticoagulation and hemostasis monitoring, analysis, and intervention;
- (11) Thermal regulation;
- (12) Blood gas and blood chemistry monitoring, analysis, and intervention;
- (13) Physiological monitoring, analysis, and intervention;
- (14) Administration of blood components and pharmaceuticals;
- (15) Administration of anesthetic agents through a heart lung machine at the direction of an anesthesiologist;
- (16) Ventricular assist device and mechanical circulatory support management;
- (17) Intra-aortic balloon counterpulsation;
- (18) Temporary pacemaker management;
- (19) Periodic flow augmentation therapy;
- (20) Autotransfusion;
- (21) Platelet gel production, autologous hemocyte tissue matrix production;
- (22) Nondifferentiated progenitor cell harvest bone marrow aspirate concentration;
- (23) Acute normovolemic hemodilution;
- (24) Isolated limb or organ delivery of chemotherapeutics, progenitor cells, gene therapy vectors, and other items;
- (25) Organ procurement and preservation;
- (26) Thermogenic lavage;
- (27) Electrophysiological analysis;
- (28) Therapeutic hyperthermia;
- (29) Intravascular membrane oxygenation; and
- (30) Renal perfusion.

.08 Identification; Notice.

A. A licensed perfusionist shall wear an identification tag or a badge which identifies that individual as a licensed perfusionist.

B. Posting of License.

(1) A licensed perfusionist shall post the perfusionist's license in the office or place of employment of the perfusionist.

(2) If the perfusionist has multiple places of employment, copies of the license may be posted in accordance with §B(1) of this regulation.

C. Change of Name or Address.

(1) A licensed perfusionist shall notify the Board in writing of any changes in name or mailing address within 60 days.

(2) The Board may impose a fine of \$100 for failure to notify the Board of a change in name or mailing address.

.09 Terms of Perfusionist-Basic License.

A. Term and Expiration.

(1) A perfusionist-basic license shall expire 2 years after it is issued.

(2) A perfusionist-basic license may not be renewed or extended beyond the 2-year expiration date.

(3) An individual who previously held a perfusionist-basic license may not be granted a new perfusionist-basic license.

(4) Upon expiration of the perfusionist-basic license, an individual who does not meet the requirements for a perfusionist-advanced license is ineligible for licensure and may not practice perfusion in this State.

B. Conversion.

(1) The holder of a perfusionist-basic license shall convert the license to a perfusionist-advanced license at any time before the expiration after meeting the requirements outlined in Regulation .06B(2) of this chapter.

(2) The individual shall ensure that the national certifying board submits evidence, satisfactory to the Board, that the individual meets the requirements of Regulation .06B(2) of this chapter.

(3) If the Board receives the notification specified in §B(2) of this regulation, the Board shall issue a perfusionist-advanced license to the individual at no additional charge.

(4) If the holder of the perfusionist-basic license fails to convert the license to a perfusionist-advanced license before the expiration date, the individual shall file a new application for a perfusionist-advanced license.

C. Conversion-or-Expiration Notice. At least 1 month before the expiration of the perfusionist-basic license, the Board shall send notice to the licensed perfusionist-basic that states:

(1) The date on which the current perfusionist-basic license expires;

(2) The date by which notification of meeting requirements outlined in Regulation .06B(2) shall be received in order to convert to a perfusionist-advanced license before the perfusionist-basic license expires; and

(3) Notice that upon expiration of the perfusionist-basic license, if the holder does not qualify for a perfusionist-advanced license, the holder is no longer permitted to practice perfusion in this State.

.10 Renewal and Reinstatement of Licensure as a Perfusionist-Advanced.

A. Renewal Notice. At least 1 month before the license expires, the Board shall send a renewal notice to the licensed perfusionist-advanced that states:

(1) The date on which the current license expires;

(2) The date by which the renewal application shall be received by the Board for the renewal to be issued and mailed before the license expires; and

(3) The amount of the renewal fee set by the Board in Regulation .13 of this chapter.

B. Renewal.

(1) The Board may not renew a license until the Comptroller of Maryland has verified that the individual has paid all undisputed taxes and unemployment insurance contributions, or arranged for repayment, as required by COMAR 10.31.02.

(2) An individual licensed as a perfusionist-basic may not renew the license.

(3) An individual who has been licensed by the Board as a perfusionist-advanced may renew the license every 2 years on or before the date specified by the Board by:

(a) Submitting a renewal application online or on a form supplied by the Board;

(b) Paying the required renewal fee set by the Board in Regulation .13 of this chapter; and

(c) Attesting to current certification by the national certifying board.

C. Reinstatement within 30 Days. The Board shall reinstate the license of a perfusionist-advanced who has failed to renew the license for any reason if the perfusionist-advanced:

(1) Applies for reinstatement within 30 days after the date the license expires;

(2) Meets the renewal requirements of §A of this regulation; and

(3) Pays to the Board the reinstatement fee set by the Board in Regulation .13 of this chapter.

D. License Expiration After 30 days. An individual who fails to renew or reinstate a perfusionist-advanced license within 30 days after expiration shall meet the current requirements for licensure as a perfusionist-advanced.

E. Reinstatement of a Revoked License.

(1) On the application of an individual whose license has been revoked, the Board, on the affirmative vote of a majority of the quorum, may in its discretion reinstate a revoked license.

(2) When a time period is not stated in an order for revocation:

(a) The Board may not entertain an application for post-disciplinary reinstatement until at least 3 years after the date of the order; and

(b) A revocation of a license may not be for less than 1 year.

(3) The Board may not entertain an application for post-disciplinary reinstatement after an order of revocation unless:

(a) Any time period stated in the order has expired;

(b) Any condition set out in the order has been fulfilled;

(c) The applicant has filed a formal application and paid the fee set by the Board in Regulation .13 of this chapter; and

(d) The applicant meets all of the requirements for reinstatement set out in §D of this regulation.

(4) The Board shall entertain applications for reinstatement pursuant to the procedures and standards of COMAR 10.32.02.06B.

(5) The Board may not entertain applications for reinstatement if a revocation is permanent.

.11 Continuing Education.

A. Application.

(1) The continuing education requirements apply to all renewal applications.

(2) The Board may not renew or reinstate the license of a perfusionist-advanced unless the perfusionist-advanced has met the requirements for continuing education described in §B of this regulation.

B. Requirements. A licensed perfusionist-advanced shall meet continuing education requirements sufficient to maintain current national certification from the national certifying board.

C. *Documentation of Continuing Education Credits.* A current certificate from the national certifying board will serve as documentation of continuing education credits earned.

.12 Clinical Activity.

A. *Application.*

(1) *The clinical activity requirements apply to all renewal applications.*

(2) *The Board may not renew or reinstate the license of a perfusionist-advanced unless the perfusionist-advanced has met the requirements for clinical activity described in §B of this regulation.*

B. *Requirements.* A licensed perfusionist-advanced shall meet clinical activity requirements sufficient to maintain current national certification from the national certifying board.

C. *Documentation of Clinical Activity.* A current certificate from the national certifying board will serve as documentation of clinical activities performed.

.13 Fees.

The following non-refundable fees are applicable to perfusionists:

A. *Perfusionist initial license application fee:*

(1) *Before October 1, 2015 . . . \$300; and*

(2) *After October 1, 2015 . . . To be determined and promulgated in regulations by the Board in accordance with Health Occupations Article, §14-205(a)(16), Annotated Code of Maryland (Supp. 2013);*

B. *Perfusionist license renewal fees, after October 1, 2015:*

(1) *License renewal fee. . . To be determined and promulgated in regulations by the Board in accordance with Health Occupations Article, §14-205(a)(16), Annotated Code of Maryland (Supp. 2013);*

(2) *Maryland Health Care Commission (MHCC) fee . . . As determined by MHCC under COMAR 10.25.03;*

C. *Reinstatement fee, after October 1, 2015. . . To be determined and promulgated in regulations by the Board in accordance with Health Occupations Article, §14-205(a)(16), Annotated Code of Maryland (Supp. 2013);*

D. *Written verification of licensure fee . . . \$25; and*

E. *Replacement of license fee . . . \$25*

.14 Prohibited Conduct.

A. *Subject to the hearing provision of Health Occupations Article, §14-405, Annotated Code of Maryland, the Board may deny a license to any applicant, reprimand any licensee, place any licensee on probation, or suspend or revoke a license if the applicant or licensee:*

(1) *Fraudulently or deceptively obtains or attempts to obtain a license for the applicant or licensee or for another;*

(2) *Fraudulently or deceptively uses a license;*

(3) *Is guilty of unprofessional or immoral conduct in the practice of perfusion;*

(4) *Is professionally, physically, or mentally incompetent;*

(5) *Abandons a patient;*

(6) *Is habitually intoxicated;*

(7) *Is addicted to, or habitually abuses, any narcotic or controlled dangerous substance as defined in Criminal Law Article, §5-101, Annotated Code of Maryland;*

(8) *Provides professional services while:*

(a) *Under the influence of alcohol; or*

(b) *Using any narcotic or controlled dangerous substance as defined in Criminal Law Article, §5-101, Annotated Code of Maryland, or any other drug that is in excess of therapeutic amounts or without valid medical indication;*

(9) *Promotes the sale of services, drugs, devices, appliances, or goods to a patient so as to exploit the patient for financial gain;*

(10) *Willfully makes or files a false report or record in the practice of perfusion;*

(11) *Willfully fails to file or record any report as required under law, willfully impedes or obstructs the filing or recording of a report, or induces another to fail to file or record a report;*

(12) *Breaches patient confidentiality;*

(13) *Pays or agrees to pay any sum or provide any form of remuneration or material benefit to any person for bringing or referring a patient or accepts or agrees to accept any sum or any form of remuneration or material benefit from an individual for bringing or referring a patient;*

(14) *Knowingly makes a misrepresentation while practicing perfusion;*

(15) *Knowingly practices perfusion with an unauthorized individual or aids an unauthorized individual in the practice of perfusion;*

(16) *Knowingly delegates a perfusion duty to an unlicensed individual;*

(17) *Offers, undertakes, or agrees to cure or treat disease by a secret method, treatment or medicine;*

(18) *Is disciplined by a licensing or disciplinary authority or is convicted or disciplined by a court of any state or country or is disciplined by any branch of the United States uniformed services or the US Department of Veterans Affairs for an act that would be grounds for disciplinary action under the Board's disciplinary statutes;*

(19) Fails to meet appropriate standards for the delivery of perfusion services;
(20) Knowingly submits false statements to collect fees for which services are not provided;
(21) Has been subject to investigation or disciplinary action by a licensing or disciplinary authority or by a court of any state or country for an act that would be grounds for disciplinary action under the Board's disciplinary statutes; and has:

(a) Surrendered the license, if any, issued by the state or country; or

(b) Allowed the license, if any, issued by the state or country to expire or lapse;

(22) Knowingly fails to report suspected child abuse in violation of Family Law Article, §5-704, Annotated Code of Maryland;

(23) Sells, prescribes, gives away, or administers drugs for illegal or illegitimate medical purposes;

(24) Practices or attempts to practice beyond the authorized scope of practice;

(25) Is convicted of or pleads *nolo contendere* to a felony or to a crime involving moral turpitude, whether or not any appeal or other proceeding is pending to have the conviction or plea set aside;

(26) Refuses, withholds from, denies, or discriminates against an individual with regard to the provision of professional services for which the licensee is licensed and qualified to render because the individual is HIV positive;

(27) Practices or attempts to practice a perfusion procedure or uses or attempts to use perfusion equipment if the applicant or licensee has not received education and training in the performance of the procedure or the use of the equipment; or

(28) Fails to cooperate with a lawful investigation of the Board.

B. Crimes of Moral Turpitude.

(1) On the filing of certified docket entries with the Board by the Office of the Attorney General, the Board shall order the suspension of a license if the licensee is convicted of, or pleads guilty or *nolo contendere* with respect to, a crime involving moral turpitude, whether or not any appeal or other proceeding is pending to have the conviction or plea set aside.

(2) After completion of the appellate process, if the conviction has not been reversed or the plea has not been set aside with respect to a crime involving moral turpitude, the Board shall order the revocation of a license on the certification by the Office of the Attorney General.

C. Unless the Board agrees to accept the surrender of a license, a licensed perfusionist may not surrender the license nor may the license lapse by operation of law while the licensee is under investigation or while charges are pending against the licensee.

.15 Penalty for Unlicensed Practice.

A. Except as otherwise provided in Health Occupations Article §14-5E-01(g), Annotated Code of Maryland, an individual may not practice, attempt to practice, or offer to practice perfusion in this State unless licensed to practice perfusion by the Board.

B. An individual who violates §A of this regulation is subject to a civil fine of not more than \$5,000 to be levied by the Board.

C. The Board shall pay any penalty collected under this regulation into the Board of Physicians Fund.

.16 Investigations, Hearings, and Appeals.

A. Complaints alleging prohibited conduct shall be referred to the Board to be investigated according to the Board's procedures.

B. A hearing on charges issued under Regulation .14 of this chapter or Health Occupations Article, §14-5E-16(a), Annotated Code of Maryland, shall be held in accordance with the hearing provisions of Health Occupations Article, §14-405, Annotated Code of Maryland.

C. Proceedings for crimes of moral turpitude under Health Occupations Article, §14-5E-16 (c), Annotated Code of Maryland, or Regulation .14B of this chapter, shall be held in accordance with COMAR 10.32.02.08.

D. Appeals from a final Board decision shall be taken in accordance with Health Occupations Article, §14-5E-17, Annotated Code of Maryland.

.17 Required Reports.

A. Except as provided in §B, C, or F of this regulation, hospitals, related institutions, alternative health systems as defined in Health Occupations Article, §1-401, Annotated Code of Maryland, and employers shall file with the Board a report that the hospital, related institution, alternative health system, or employer limited, reduced, otherwise changed, or terminated any licensed perfusionist for any reason that might be grounds for disciplinary action under Health Occupations Article, §14-5E-16, Annotated Code of Maryland, or any regulation in this chapter.

B. If the action taken by a hospital, related institution, alternative health system, or employer under §A of this regulation relates to alcohol or drug impairment, the hospital, related institution, alternative health system or employer is not required to report the perfusionist to the Board if:

(1) The hospital, related institution, alternative health system, or employer knows that the licensed perfusionist is:

(a) In an alcohol or drug treatment program that is accredited by the Joint Commission or is certified by the Department of Health and Mental Hygiene; or

(b) Under the care of a health care practitioner who is competent and capable of dealing with alcoholism and drug abuse;

(2) The perfusionist takes appropriate steps to permit the hospital, related institution, alternative health system, or employer to verify that the licensed perfusionist remains in the treatment program and is compliant with the requirements of that program until discharge; and

(3) The action of condition of the licensed perfusionist has not caused injury to an individual while the perfusionist is practicing as a licensed perfusionist.

C. If a licensed perfusionist enters or is considering entering an alcohol or drug treatment program that is accredited by the Joint Commission or that is certified by the Department of Health and Mental Hygiene, the licensed perfusionist shall notify the hospital, related institution, alternative health system, or employer of the licensed perfusionist's decision to enter the treatment program.

D. If the licensed perfusionist fails to provide the notice required under §C of this regulation, and the hospital, related institution, alternative health system, or employer learns that the licensed perfusionist has entered a treatment program, the hospital related institution, alternative health system, or employer shall report to the Board that the licensed perfusionist has:

(1) Entered a treatment program; and

(2) Failed to provide the required notice.

E. If the perfusionist has failed to take appropriate steps or has failed to remain compliant under §B(2) of this regulation or has failed to provide the required notice under §C of this regulation, the perfusionist may not use his or her participation in the treatment program as a mitigating circumstance in any disciplinary action.

F. Noncompliance.

(1) If the licensed perfusionist is found to be noncompliant with the treatment program's policies and procedures while in the treatment program, the treatment program shall notify the hospital, related institution, alternative health system, or employer of the licensed perfusionist's noncompliance.

(2) On receipt of the notification required under §C of this regulation, the hospital, related institution, alternative health system, or employer of the licensed perfusionist shall report the licensed perfusionist's noncompliance to the Board.

G. A person as defined in Health Occupations Article, §14-101(h), Annotated Code of Maryland, is not required under this regulation to make any report that would be in violation of any federal or state law, rule, or regulation concerning the confidentiality of alcohol and drug abuse patient records.

H. The hospital, related institution, alternative health system, or employer shall submit a required report within 10 days of any action described in this regulation.

I. A report made under this regulation is not subject to subpoena or discovery in a civil action other than a proceeding arising out of a hearing and decision of the Board under Health Occupations Article, Title 14, Annotated Code of Maryland.

.18 Sanctioning.

A. General Application of Sanctioning Guidelines.

(1) Sections A and B of this regulation and Regulation .19 of this chapter do not apply to offenses for which a mandatory sanction is set by statute or regulation.

(2) Except as provided in §B of this regulation, for violations of Health Occupations Article §14-5E-16(a), Annotated Code of Maryland, the Board shall impose a sanction not less severe than the minimum listed in the sanctioning guidelines nor more severe than the maximum listed in the sanctioning guidelines for each offense.

(3) Ranking of Sanctions.

(a) For the purposes of this regulation, the severity of sanctions is ranked as follows, from the least severe to the most severe:

(i) Reprimand;

(ii) Probation;

(iii) Suspension; and

(iv) Revocation.

(b) A stayed suspension in which the stay is conditioned on the completion of certain requirements is ranked as probation.

(c) A stayed suspension not meeting the criteria for §A(3)(b) of this regulation is ranked as a reprimand.

(4) The Board may impose more than one sanction, provided that the most severe sanction neither exceeds the maximum nor is less than the minimum sanction permitted in the chart.

(5) Any sanction may be accompanied by conditions reasonably related to the offense or to the rehabilitation of the offender. The inclusion of conditions does not change the ranking of the sanction.

(6) If a licensee has violated more than one ground for discipline as set out in the sanctioning guidelines:

(i) The sanction with the highest severity ranking should be used to determine which ground will be used in developing a sanction; and

(ii) The Board may impose concurrent sanctions based on other grounds violated.

(7) Notwithstanding the sanctioning guidelines set forth in Regulation .19 of this chapter, in order to resolve a pending disciplinary action, the Board and the licensee may agree to a surrender of license or a consent order with terms and sanction agreed to by the Board, the administrative prosecutor, and the licensee.

B. Aggravating and Mitigating Factors.

(1) Depending on the facts and circumstances of each case, and to the extent that the facts and circumstances apply, the Board may consider the aggravating and mitigating factors set out in §B(4) and (5) of this regulation and may in its discretion determine, based on those factors, that an exception should be made and that the sanction in a particular case should fall outside the range of sanctions listed in the sanctioning guidelines.

(2) Nothing in this regulation requires the Board or an Administrative Law Judge to make findings of fact with respect to any of these factors.

(3) The existence of one or more of these factors does not impose on the Board or an Administrative Law Judge any requirement to articulate its reasoning for not exercising its discretion to impose a sanction outside of the range of sanctions set out in the sanctioning guidelines.

(4) Mitigating factors may include, but are not limited to, the following:

(a) The absence of a prior disciplinary record;

(b) The offender self-reported the incident;

(c) The offender voluntarily admitted the misconduct, made full disclosure to the Board and was cooperative during the Board proceedings;

(d) The offender implemented remedial measures to correct or mitigate the harm arising from the misconduct;

(e) The offender made good faith efforts to make restitution or to rectify the consequences of the misconduct;

(f) The offender has been rehabilitated or exhibits rehabilitative potential;

(g) The misconduct was not premeditated;

(h) There was no potential harm to patients or the public or other adverse impact; or

(i) The incident was isolated and is not likely to recur.

(5) Aggravating factors may include, but are not limited to, the following:

(a) The offender has a previous criminal or administrative disciplinary history;

(b) The offense was committed deliberately or with gross negligence or recklessness;

(c) The offense had the potential for or actually did cause patient harm;

(d) The offense was part of a pattern of detrimental conduct;

(e) The offender committed a combination of factually discrete offenses adjudicated in a single action;

(f) The offender pursued his or her financial gain over the patient's welfare;

(g) The patient was especially vulnerable;

(h) The offender attempted to hide the error or misconduct from patients or others;

(i) The offender concealed, falsified, or destroyed evidence or presented false testimony or evidence;

(j) The offender did not cooperate with the investigation; or

(k) Previous attempts to rehabilitate the offender were unsuccessful.

C. Offenses Related to Continuing Medical Education Credits.

(1) Section C(2) and (3) of this regulation does not limit the Board's authority to require completion of the missing continuing education credits.

(2) Willful Falsification.

(a) If a licensee has willfully falsified an application with respect to continuing medical education credits, the licensee may be charged under one or more of the following, as appropriate:

(i) Health Occupations Article, §14-5E-16 (a)(1), Annotated Code of Maryland;

(ii) Health Occupations Article, §14-5E-16(a)(3), Annotated Code of Maryland;

(iii) Health Occupations Article, §14-5E-16(a)(10), Annotated Code of Maryland; and

(iv) Health Occupations Article, §14-5E-16(a)(11), Annotated Code of Maryland.

(b) Upon a finding of a violation, the Board may impose any discipline authorized under Health Occupations Article, §14-5E-16, Annotated Code of Maryland, and the sanctioning guidelines.

(3) Licensees Previously Disciplined Under §C(2) of this regulation.

(a) Upon a finding of a violation, the Board may impose any discipline authorized under Health Occupations Article, §14-5E-16, Annotated Code of Maryland, and the sanctioning guidelines for a subsequent offense.

(b) The Board may not apply the sanction described in §C(2) of this regulation in determining a sanction for a licensee previously disciplined for an offense related to continuing medical education credits.

D. Offenses Related to Clinical Activity.

(1) Section D(2) and (3) of this regulation does not limit the Board's authority to require completion of the missing clinical activities.

(2) Willful Falsification.

(a) If a licensee has willfully falsified an application with respect to clinical activities, the licensee may be charged under one or more of the following, as appropriate:

(i) Health Occupations Article, §14-5E-16 (a)(1), Annotated Code of Maryland;

(ii) Health Occupations Article, §14-5E-16(a)(3), Annotated Code of Maryland;

(iii) Health Occupations Article, §14-5E-16(a)(10), Annotated Code of Maryland; and

(iv) Health Occupations Article, §14-5E-16(a)(11), Annotated Code of Maryland.

(b) Upon a finding of a violation, the Board may impose any discipline authorized under Health Occupations Article, §14-5E-16, Annotated Code of Maryland, and the sanctioning guidelines.

(3) Licensees Previously Disciplined Under §D(2) of this regulation.

(a) Upon a finding of a violation, the Board may impose any discipline authorized under Health Occupations Article, §14-5E-16, Annotated Code of Maryland, and the sanctioning guidelines.

(b) The Board may not apply the sanction described in §D(2) of this regulation in determining a sanction for a licensee previously disciplined for an offense related to clinical activities.

.19 Sanctioning Guidelines for Perfusionists.

A. Subject to provisions of Regulation .18A and B of this chapter, the Board may impose sanctions as outlined in §B of this regulation on perfusionists for violations of Health Occupations Article, §14-5E-16, Annotated Code of Maryland, or Regulation .14 of this chapter.

B. Range of Sanctions.

Ground	Maximum Sanction	Minimum Sanction
(1) Fraudulently or deceptively obtains or attempts to obtain a license for the applicant or licensee or for another	Revocation	Reprimand with 2 years of probation
(2) Fraudulently or deceptively uses a license	Revocation	Probation
(3) Is guilty of unprofessional or immoral conduct in the practice of perfusion	Revocation	Reprimand
(4) Incompetence. (a) Is professionally incompetent	Revocation	Suspension until professional incompetence is addressed to the Board's satisfaction
(b) Is physically or mentally incompetent	Revocation	Suspension until physical or mental incompetence is addressed to the Board's satisfaction
(5) Abandons a patient	Revocation	Reprimand
(6) Is habitually intoxicated	Revocation	Suspension until professional is in treatment and abstinent for 6 months
(7) Is addicted to, or habitually abuses, any narcotic or controlled dangerous substance as defined in Criminal Law Article, §5-101, Annotated Code of Maryland	Revocation	Suspension until professional is in treatment and abstinent for 6 months
(8) Provides professional services while: (a) Under the influence of alcohol; or (b) Using any narcotic or controlled dangerous substance as defined in Criminal Law Article, §5-101, Annotated Code of Maryland, or any other drug that is in excess of therapeutic amounts or without valid medical indication	Revocation	Suspension until professional is in treatment and abstinent for 6 months
(9) Promotes the sale of services, drugs, devices, appliances, or goods to a patient so as to exploit the patient for financial gain	Revocation	Reprimand
(10) Willfully makes or files a false report or record in the practice of perfusion	Revocation	Reprimand
(11) Willfully fails to file or record any report as required under law, willfully impedes or obstructs the filing or recording of the report, or induces another to fail to file or record the report	Revocation	Reprimand

<i>(12) Breaches patient confidentiality</i>	<i>Revocation</i>	<i>Reprimand</i>
<i>(13) Pays or agrees to pay any sum or provide any form of remuneration or material benefit to any individual for bringing or referring a patient or accepts or agrees to accept any sum or any form of remuneration or material benefit from an individual for bringing or referring a patient</i>	<i>Revocation</i>	<i>Reprimand</i>
<i>(14) Knowingly makes a misrepresentation while practicing perfusion</i>	<i>Revocation</i>	<i>Reprimand</i>
<i>(15) Knowingly practices perfusion with an unauthorized individual or aids an unauthorized individual in the practice of perfusion</i>	<i>Revocation</i>	<i>Reprimand</i>
<i>(16) Knowingly delegates a perfusion duty to an unlicensed individual</i>	<i>Revocation</i>	<i>Reprimand</i>
<i>(17) Offers, undertakes, or agrees to cure or treat disease by a secret method, treatment, or medicine</i>	<i>Revocation</i>	<i>Reprimand</i>
<i>(18) Is disciplined by a licensing or disciplinary authority or is convicted or disciplined by a court of any state or country or is disciplined by any branch of the United States uniformed services or the Veterans Administration for an act that would be grounds for disciplinary action under this section</i>	<i>Penalty comparable to what the Board imposes under equivalent Maryland ground for discipline</i>	<i>Penalty equivalent to that imposed by original licensing authority if this is less than the Board sanction would be</i>
<i>(19) Fails to meet appropriate standards for the delivery of perfusion services</i>	<i>Revocation</i>	<i>Reprimand</i>
<i>(20) Knowingly submits false statements to collect fees for which services have not been provided</i>	<i>Revocation</i>	<i>Reprimand</i>
<i>(21) Has been subject to investigation or disciplinary action by a licensing or disciplinary authority or by a court of any state or country for an act that would be grounds for disciplinary action under the Board's disciplinary statutes; and has:</i> <i>(a) Surrendered the license, if any, issued by the state or country; or</i> <i>(b) Allowed the license, if any, issued by the state or country to expire or lapse</i>	<i>Penalty comparable to what the Board imposes under equivalent Maryland ground for discipline</i>	<i>Penalty equivalent to that imposed by original licensing authority if this is less than the Board sanction would be</i>
<i>(22) Knowingly fails to report suspected child abuse in violation of Family Law Article, §5-704, Annotated Code of Maryland</i>	<i>Revocation</i>	<i>Reprimand</i>
<i>(23) Sells, prescribes, gives away, or administers drugs for illegal or illegitimate medical purposes</i>	<i>Revocation</i>	<i>Reprimand and 3 years of probation with practice oversight</i>
<i>(24) Practices or attempts to practice beyond the authorized scope of practice</i>	<i>Revocation</i>	<i>Suspension for 3 months</i>
<i>(25) Is convicted or pleads nolo contendere to a felony or to a crime involving moral turpitude, whether or not any appeal or other proceeding is pending to have the conviction or plea set aside</i>	<i>Revocation</i>	<i>Suspension for 3 months</i>
<i>(26) Refuses, withholds from, denies, or discriminates against an individual with regard to the provision of professional services for which the licensee is licensed and qualified to render because the individual is HIV positive</i>	<i>Suspension for 1 year</i>	<i>Reprimand</i>
<i>(27) Practices or attempts to practice a perfusion procedure or uses or attempts to use perfusion equipment if the applicant or licensee has not received education and training in the performance of the procedure or the use of the equipment</i>	<i>Revocation</i>	<i>Suspension for 3 months</i>

<i>(28) Fails to cooperate with a lawful investigation conducted by the Board</i>	<i>Revocation</i>	<i>Reprimand</i>
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JOSHUA M. SHARFSTEIN, M.D.

Secretary of Health and Mental Hygiene

FEE JUSTIFICATION

(1) Explain/justify why an increase or decrease is necessary:

This is a new allied health profession and the licensing fees are required to supplement the costs associated with licensure such as office space, staff, supplies, etc.

(2) How much money is needed to operate effectively or to eliminate an operating fund deficit?

The Board estimates the start up cost for a new allied health profession is approximately \$100,000.

(3) In what year was the most recent fee increase?

There have not been any increases because this is a new profession.

(4) Is the fee revenue retained by the Proposing Unit or passed through to a national organization that administers a uniform licensing exam?

The fee is retained by the Proposing Unit.

(5) Describe any measures taken to mitigate the need for increased revenue:

The Board has kept the licensure cost to the bare minimum despite the fact that this profession only has approximately 63 practitioners who will be seeking licensure and the cost of their licenses will not cover the cost of their operation.

(6) Describe any special circumstances that have had an adverse impact on the Proposing Unit's operating expenses.

As stated in Question #5, above, this profession has a low number of practitioners who will be seeking licensure and the cost of their license will not cover their operating costs.

(7) Describe any consideration given by the Proposing Unit as to the hardship a fee increase may have on the regulated profession.

The Board has made every effort to streamline the costs associated with licensing perfusionists, however, the Board is mandated by statute to adopt a budget reflective of revenues that support the costs associated with regulating allied health professions. Perfusionists may face future fiscal challenges as new practitioners seeking licensure and existing licensees renew their license if the overall number of practitioners does not increase.

(8) Describe any efforts to solicit the opinions of licensees regarding the Proposing Unit's effectiveness and performance.

The Board has worked with the Perfusionist Advisory Committee and sent the regulations out to interested stakeholders for informal comment before publication.