

**Maryland General Assembly  
Department of Legislative Services**

**Proposed Regulations  
Department of Health and Mental Hygiene  
(DLS Control No. 16-065)**

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**Overview and Legal and Fiscal Impact**

The regulations alter provisions that govern the practice of perfusion in the State. Among other changes, the regulations authorize the State Board of Physicians to levy a civil fine for violation of provisions governing the practice of perfusion, modify requirements for reinstatement of a license, and provide for an extension of a temporary license for an individual who has not taken a national certifying examination.

The regulations present no legal issues of concern.

There is no fiscal impact on State or local agencies.

**Regulations of COMAR Affected**

**Department of Health and Mental Hygiene:**

Board of Physicians: Licensure of Perfusionists:  
COMAR 10.32.20.03, .08-.10, .15, .17, and .18

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**Legal Analysis**

**Background**

Perfusionists offer a variety of clinical services to patients under the prescription and supervision of a physician. As defined in statute, the practice of 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 the supervision of a licensed physician. The most common perfusion services are cardiopulmonary bypass (use of a heart-lung machine) and extracorporeal membrane oxygenation (long-term use of an artificial blood oxygenator to support or replace undeveloped, failing, damaged, or infected lungs to allow treatment and healing).

An individual must be licensed by the board in order to practice perfusion in the State. To qualify for a license, an individual must submit evidence either of certification as a certified perfusionist or other national certification approved by the board or of graduation from a perfusion education program that meets specified criteria.

## **Summary of Regulations**

The regulations alter criteria for membership on the Perfusion Advisory Committee; requirements for providing notice of licensure; provisions governing the terms, renewal, and reinstatement of licenses; provisions relating to reports that must be filed for conduct by a licensed perfusionist that might be grounds for discipline; and provisions providing for the imposition of fines, penalties, and sanctions for certain offenses by a licensed perfusionist and the unlicensed practice of perfusion. Specific and noteworthy changes to the regulations are summarized below.

### **Perfusion Advisory Committee**

The regulations alter the required physician membership of the committee by specifying that at least one of the three physician members must perform cardiac or cardio-thoracic surgery or be a *cardiac anesthesiologist*.

### **Notice of Licensure**

A licensed perfusionist is no longer required to post the perfusionist's license in the office or place of employment of the perfusionist and, instead, must keep a copy of the license in the licensee's employment file and make it available for inspection upon request.

### **Terms, Renewal, and Reinstatement of Licenses**

Under current regulations, a perfusionist-basic license expires two years after it is issued and may not be renewed or extended beyond the two-year expiration date. Upon expiration of a 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 the State. An applicant for a perfusionist-basic license must submit evidence of graduation from an accredited perfusion educational program whereas an applicant for a perfusionist-advanced license must submit evidence of current national certification from the national certifying board.

The proposed regulations authorize the board to allow a perfusionist with a basic license to continue to practice with that license if extenuating circumstances prevented the applicant for an advanced license from taking the national certifying examination given by the American Board of Cardiovascular Perfusion. A petition for extension of a perfusionist-basic license, at the discretion of the board, may be considered if (1) the licensee incurs a hardship that prevents the licensee from active use of the perfusionist-basic license for period of at least 45 consecutive calendar days, provides a written request stating the extenuating circumstances that will prohibit or have prohibited active use of the license, and provides an anticipated date for resuming activity on the perfusionist-basic license and (2) the national certifying examination has not been administered during no more than three testing windows from the time the application for the perfusionist-basic license was approved. The board may grant an extension if it determines that failure to fulfill the license requirements is clearly the result of specified circumstances, such as functional impairment, prolonged and serious illness, or a mandatory military service or deployment.

The regulations also modify requirements for reinstatement of a license of a perfusionist-advanced who has failed to renew the license by striking a requirement that the individual apply for reinstatement within 30 days after expiration of the license.

### **Required Reporting**

Current regulations require hospitals, related institutions, alternative health systems, and employers to file with the Board a report if certain action is taken against a licensed perfusionist for any reason that might be grounds for disciplinary action under statutory provisions governing the practice of perfusion. Reporting is not required if the action relates to alcohol or drug impairment and the entity or employer knows that the licensed perfusionist is in an alcohol or drug treatment program accredited by the Joint Commission or certified by the department. The proposed regulations modify this requirement and a related provision by specifying that reporting is not required if the treatment program is accredited by the Joint Commission or its successor and certified by the department.

### **Fines, Penalties, and Sanctions**

The regulations authorize the board to impose a civil fine of up to \$5,000 for violation of any provision of the regulations governing the practice of perfusion in the State. The regulations also provide that for certain violations specified in statute that are listed in the sanctioning guidelines, the board must 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. The regulations further provide that a fine listed in the sanctioning guidelines may be imposed in addition to, but not as a substitute for a sanction. If a fine is listed, then at least the minimum fine will be imposed in addition to the sanction.

The regulations also modify provisions governing the imposition of sanctions for offenses relating to continuing medical education credits and clinical activity. Among other changes, the regulations strike provisions expressly stating the board's authority to require completion of missing continuing education credits and clinical activities.

### **Legal Issues**

The regulations present no legal issues of concern.

### **Statutory Authority and Legislative Intent**

The Department of Health and Mental Hygiene cites §§ 14-5E-01 through 14-5E-20 of the Health Occupations Article as authority for the regulations. More specifically, § 14-5E-03 requires the board to adopt regulations for the licensure and practice of perfusion. Section 14-5E-06 establishes the committee and specifies the membership of the committee, which includes three physicians, at least one of whom performs cardiac or cardiothoracic surgery or is a cardiac anesthesiologist. Section 14-5E-08 generally requires an individual to be licensed by the board before the individual may practice perfusion in the State.

Section 14-5E-09 establishes requirements an individual must meet to qualify for a license to practice perfusion in the State, including a requirement that an applicant submit to the board satisfactory evidence of certification as a certified perfusionist or other national certification approved by the board and meet any other educational or clinical requirements established by the committee and approved by the board, or submit to the board satisfactory evidence of graduation from an accredited perfusion educational program and meet any other educational or clinical requirements established by the committee and approved by the board.

Section 14-5E-10 provides that an applicant who otherwise qualifies for a license by meeting certain educational requirements specified in statute is entitled to be licensed for a single two-year term before taking the national certifying examination given by the American Board of Cardiovascular Perfusion or its successor organization or another examination given or approved by the board. This section also specifies that if an applicant was prevented from taking the national certifying examination before the single two-year license expires because of extenuating circumstances, the applicant may apply to the board for an extension of the term of the license. The section further requires the board to adopt regulations to carry out the provision providing for an extension, including criteria that an applicant must meet to receive an extension and provisions as to the length of time that a license may be extended.

Section 14-15E-13(f) requires the board to reinstate the license of an individual who has failed to renew the license for any reason if the applies for reinstatement after the date the license expires, meets other specified requirements, and pays to the board a certain reinstatement fee.

Section 14-5E-16 authorizes the board to deny a license to any applicant, and authorizes a disciplinary panel to reprimand any licensee, place any licensee on probation, or suspend or revoke a license, if the applicant or licensee engages in specified misconduct.

Section 14-5E-18 requires hospitals, related institutions, alternative health systems, and employers to file with the board a report if certain action is taken against a licensed perfusionist for any reason that might be grounds for disciplinary action under statutory provisions governing the practice of perfusion. Reporting is not required if the action relates to alcohol or drug impairment, the entity or employer knows that the licensed perfusionist is in an alcohol or drug treatment program accredited by the Joint Commission or its successor or is certified by the department, and other requirements are met.

Section 14-5E-20 prohibits a person from practicing, attempting to practice, or offering to practice perfusion in the State unless licensed to practice perfusion by the board.

Although not cited by the department, § 1-606 of the Health Occupations Article requires each health occupations board to adopt specific sanctioning guidelines. The sanctioning guidelines must conform to a general framework or incorporate common elements and be used as a guide for sanctioning licensees in formal and informal proceedings. In addition, § 14-5E-23 of the Health Occupations Article provides that a person who violates any provision of the subtitle that governs the practice of perfusion in the State is subject to a civil fine of not more than \$5,000 to be levied by the board.

With the addition of §§ 1-606 and 14-5E-23, the authority cited by the department is correct and complete. The regulations comply with the legislative intent of the law.

## **Fiscal Analysis**

There is no fiscal impact on State or local agencies.

### **Agency Estimate of Projected Fiscal Impact**

The regulations implement provisions of Chapter 609 of 2014, which (1) expanded the civil fine authority of the State Board of Physicians over licensed perfusionists; (2) altered the circumstances under which the board must reinstate a perfusionist license; (3) provided an extension of a temporary perfusionist license under specified circumstances; (4) altered the requirements for perfusionist license display; and (5) altered the membership requirements of the Perfusion Advisory Committee. Any fiscal impact has already been assumed under the fiscal and policy note for House Bill 692 of 2014 (enacted as Chapter 609), which noted a potential minimal increase in special fund revenues for the board as a result of expansion of the civil fine authority and no impact on expenditures.

### **Impact on Budget**

There is no impact on the State operating or capital budget.

### **Agency Estimate of Projected Small Business Impact**

The department advises that the regulations have minimal or no economic impact on small businesses in the State. The Department of Legislative Services concurs.

## **Contact Information**

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