

**Maryland General Assembly
Department of Legislative Services**

**Proposed Regulations
Department of Health and Mental Hygiene
(DLS Control No. 14-084)**

Overview and Legal and Fiscal Impact

The Secretary of Health and Mental Hygiene proposes to adopt new COMAR 10.32.20 to govern the licensure and practice of perfusionists in the State. The regulations include, among other things, requirements for licensure, grounds for discipline, and sanctioning guidelines.

These regulations present a possible minor legal issue of concern.

No fiscal impact on State or local agencies beyond that already accounted for in the fiscal and policy note for Chapter 588 of 2011 (HB 287).

Regulations of COMAR Affected

Department of Health and Mental Hygiene:

Board of Physicians: Licensure of Perfusionists: COMAR 10.32.20.01-.19

Legal Analysis

Background

Chapter 588 of 2011 required the State Board of Physicians to adopt regulations for the licensure and practice of perfusionists and established a Perfusion Advisory Committee within the board. The chapter also required that, on or after October 1, 2013, an individual be licensed in order to practice perfusion in the State, with some exceptions.

Summary of Regulations

The Secretary of Health and Mental Hygiene is adopting regulations under new COMAR 10.32.20 to govern the licensure and practice of perfusionists in the State. Perfusionists run the heart-lung machines during cardiac and other surgeries that require cardiopulmonary bypass.

General Provisions

Regulation .01 requires an individual, on or after October 1, 2013, to be licensed by the board before the individual can practice perfusion. The regulation also provides that the chapter does not prohibit (1) a student from performing procedures described in the chapter as part of an accredited education program's clinical curriculum on perfusion or (2) an individual from

practicing a health occupation that the individual is authorized to practice under the Health Occupations Article.

Regulation .02 contains terms and definitions that are used in the chapter. The defined terms include “licensed perfusionist-advanced,” “licensed perfusionist-basic,” “national certifying board,” and “national certifying examinations.”

Regulation .03 governs the Perfusion Advisory Committee. The regulation specifies the membership of the committee, the terms of the members, and what happens when there is a vacancy in the membership. The regulation also requires the committee to elect a chair every two years. A majority of the members serving is a quorum and business may not be conducted unless there is a quorum. Additionally, the regulation requires the committee to develop and make recommendations to the board in certain areas, such as regulations governing the practice of perfusion, a code of ethics, and standards of care. The committee is required to (1) review, at the request of the board, selected applications for licensure and make recommendations regarding the applications and (2) review, at the request of the board or a disciplinary panel, complaints and respond to questions. Finally, the committee must keep a record of its proceedings and submit an annual report to the board.

Regulation .04 contains the code of ethics for perfusionists. The regulation states that the ethical responsibilities of perfusionists include compliance with the principles set out in the regulation. The list includes (1) practicing medically acceptable methods of treatment; (2) respecting the patient’s rights and dignity; and (3) maintaining patient confidentiality and protecting privileged information. The list also prohibits, among other things, a licensed perfusionist from falsifying documentation on patient records and falsifying reports submitted to the board. Services are required to be provided with respect and dignity for the patient, unrestricted by considerations of social or economic status, personal attributes, or the nature of health problems. Finally, a breach of the ethical principles may be considered immoral or unprofessional conduct in the practice of perfusion.

Regulation .05 relates to standards of care. In evaluating standards of care, the board may consider the guidelines published by the American Society of Extracorporeal Technology. If a particular issue has not been addressed in the guidelines, the board may consult with a licensed perfusionist-advanced.

Licensure

Regulation .06 governs initial licensure as a licensed perfusionist-basic or a licensed perfusionist-advanced. The regulation contains the basic requirements an individual must meet for licensure, including completing an application, paying the required fee, and being of good moral character. Also, an applicant for a license as a perfusionist-basic must submit evidence of graduation from an accredited perfusion educational program and an applicant for a license as a perfusionist-advanced must submit evidence of current national certification from the national certifying board.

Regulation .07 governs the scope of practice. The regulation provides that a licensed perfusionist may practice only under the supervision of a licensed physician. The regulation also states what the scope of practice is, which is identical to the definition of “practice perfusion” that is contained in the Maryland Perfusion Act.

Regulation .08 requires a licensed perfusionist to wear an identification tag or badge that identifies that the individual is a licensed perfusionist. Also, the perfusionist must post the license in the office or place of employment of the perfusionist. If the perfusionist has multiple places of employment, copies of the license may be posted. Finally, a licensed perfusionist is required to notify the board in writing of any changes in name or mailing address within 60 days. The board is authorized to impose a fine of \$100 for failure to notify the board of a change in name or mailing address.

Regulation .09 provides for the term, expiration, and conversion of a perfusionist-basic license. A perfusionist-basic license expires two years after it is issued and cannot be renewed or extended beyond the initial period. An individual who previously had a perfusionist-basic license cannot be granted a new one. Also, on expiration of the license, an individual who does not meet the requirements for a perfusionist-advanced license is prohibited from practicing perfusion in the State until the perfusionist meets the requirements for a perfusionist-advanced license and is issued the license. A holder of a perfusionist-basic license may convert it to a perfusionist-advanced license at any time before it expires after meeting the requirements for conversion. To convert the license, the individual must ensure that the national certifying board submits evidence that the individual is currently nationally certified by the national certifying board. If the license is not converted before it expires, the individual must file a new application for a perfusionist-advanced license. At least one month before the perfusionist-basic license expires, the board must send a notice that (1) states the date the license will expire; (2) states the date by which notice of being nationally certified must be received by the board in order to convert the license; and (3) includes a notice that, if the license is not converted before expiration, the perfusionist may no longer practice in the State.

Regulation .10 governs the renewal and reinstatement of licensure as a perfusionist-advanced. At least one month before the license expires, the board is required to send out a renewal notice. The board cannot renew a license until the Comptroller has verified that the individual has paid all undisputed taxes and unemployment insurance contributions, or arranged for repayment. A license may be renewed every two years on or before the date specified by the board by submitting an application, paying the fee, and attesting to current certification by the national certifying board. The board shall reinstate the license of a perfusionist who fails to renew a license if the perfusionist applies for reinstatement within 30 days after the license expires, meets the renewal requirements, and pays the reinstatement fee. If the perfusionist does not apply within 30 days, the perfusionist must meet the current requirements for licensure that are in effect when the perfusionist applies for reinstatement. If the license was revoked, the board or a disciplinary panel, on the affirmative vote of a majority of the quorum, may in its discretion reinstate the license on application of the individual whose license was revoked. The regulation also states when the reinstatement of a revoked license may take place.

Regulation .11 provides that the continuing education requirements apply to all renewal applications. The board is prohibited from renewing or reinstating a license unless the licensee has met the requirement for continuing education described in the regulation. A licensed perfusionist-advance is required to meet the continuing education requirements sufficient to maintain current national certification. A current certificate from the national certifying board serves a documentation of continuing education credits earned.

Regulation .12 governs clinical activity required for renewal. The board is prohibited from renewing or reinstating a license unless the licensee has met the requirement for clinical

activity described in the regulation. A licensed perfusionist-advance is required to meet the clinical activity requirements sufficient to maintain current national certification. A current certificate from the national certifying board serves as documentation of clinical activities performed.

Regulation .13 lists the fees that are applicable to perfusionists. The fee for initial licensure before October 1, 2015, is \$300. The initial licensure fee that will be in effect after that date, as well as the amount of the renewal fees and the fees for reinstatement after October 1, 2015, are to be determined and promulgated in regulations by the board at a later date. The fee for written verification of licensure is \$25, as is the fee for the replacement of a license.

Prohibited Conduct and Disciplinary Action

Regulation .14 lists prohibited conduct for which the board is authorized to deny a license to an applicant, reprimand a licensee, place a license on probation, or suspend or revoke a license. The conduct listed is the same as conduct that is prohibited in the Maryland Perfusion Act. The regulation also requires the board to order the suspension of a license on the filing of certified docket entries with the board by the Office of the Attorney General, if the licensee is convicted of, or pleads guilty or nolo contendere, with respect to a crime involving moral turpitude. If the conviction is not reversed or the plea has not been set aside after completion of the appellate process, the board is required to revoke the license. Finally, unless a disciplinary panel agrees to accept the surrender of a license, a licensed perfusionist is prohibited from surrendering the license and the license may not lapse by operation of law while the licensee is under investigation or while charges are pending.

Regulation .15 prohibits an individual from practicing, attempting to practice, or offering to practice perfusion in the State unless licensed to practice perfusion by the board. An individual violates the prohibition is subject to a civil fine of not more than \$5,000 to be levied by the board. The board is required to pay any penalty collected under the regulation into the Board of Physicians Fund.

Regulation .16 requires that complaints alleging prohibited conduct must be referred to the board to be investigated according to the board's procedures. A hearing on charges issued must be held in accordance with the hearing provisions of § 14-405 of the Health Occupations Article. Additionally, proceedings for crimes of moral turpitude must be held in accordance with COMAR 10.32.02.08. Finally, appeals from a final board decision must be taken in accordance with § 14-5E-17 of the Health Occupations Article.

Regulation .17 requires hospitals, related institutions, alternative health systems, and employers to file with the board certain reports regarding action taken against licensed perfusionists and specifies the circumstances under which the reporting is not required. Additionally, the regulation requires a licensed perfusionist to notify the entity regarding the perfusionist's decision to enter into an accredited or licensed alcohol or drug treatment program and states what happens if the licensed perfusionist fails to make the notification as required or comply with the treatment program. The regulation specifies that a person is not required to make any report that would be in violation of any law concerning the confidentiality of alcohol and drug abuse patient records. A report made under the 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. Finally, the board can impose a civil penalty of up to \$1,000 for the failure to report as required.

Regulation .18 governs sanctioning. The regulation provides that the Sections A and B of the regulation and Regulation .19 do not apply to offenses for which a mandatory sanction is set by statute or regulation. The board is required to impose a sanction not less severe than the minimum listed in the sanctioning guidelines nor more severe than the maximum listed for each offense. The regulation also (1) ranks the sanctions in order of severity; (2) authorizes the board to impose more than one sanction under certain circumstances; and (3) specifies that a sanction may be accompanied by conditions reasonably related to the offense or the rehabilitation of the offender. Notwithstanding the sanctioning guidelines, the board or a disciplinary panel and licensee may agree to a surrender of license or a consent order in order to resolve a pending disciplinary action. The regulation also sets out mitigating and aggravating factors that may be considered by the board. The mitigating factors include the absence of a prior disciplinary record and that the offender self-reported the incident. The aggravating factors include that the offense was part of a pattern of detrimental conduct and that the patient was especially vulnerable. Additionally, the regulation provides that the licensee may be charged with certain grounds for discipline if the licensee willfully falsified an application with respect to continuing medical education or clinical activities and that the board may impose sanctions against the licensee. Finally, if the licensee was previously disciplined for falsifying continuing medical education or clinical activities information, the board may not apply the previous sanction in determining a sanction for a subsequent offense.

Regulation .19 contains the sanctioning guidelines for perfusionists. The board is authorized to impose sanctions as outlined in the sanctioning guidelines if the licensed perfusionist engaged in prohibited conduct. For each ground for discipline, the sanctioning guidelines state the maximum sanction and minimum sanction that may be imposed.

Fee Justification

The Department of Health and Mental Hygiene provided a fee justification as required by § 10-110 of the State Government Article. The Maryland Perfusion Act requires the board to charge a fee to perfusionists for licensing and related services that are provided by the board. The board estimates the start up cost for a new allied health profession is \$100,000. Even though the profession only has about 63 practitioners who will be seeking licensure, the board states that it has kept the licensure cost to the bare minimum and that the fees will not cover operating costs. The board also notes that perfusionists may face future fiscal challenges if the overall number of practitioners does not increase. Finally, in determining the amount of the fees, the board worked with the Perfusionist Advisory Committee and sent the regulations to interested stakeholders for informal comment.

Possible Minor Legal Issue

As stated above, Regulation .08 requires a licensed perfusionist to wear an identification tag or badge that identifies that the individual is a licensed perfusionist. The statutory authority cited by the Secretary for these regulations does not contain authority for an identification badge requirement. However, there is a statutory provision which requires that health care practitioners wear identification when working in certain facilities. Section 1-221 of the Health Occupations Article requires health care practitioners to wear certain identification if the health care practitioner practices in a freestanding ambulatory care facility, a physician's office, or an urgent care facility. The section also provides that identification is not required to be worn if (1) the

patient is seen in a office of a solo practitioner and the name and license of the practitioner can be readily determined by the patient from a posted license or sign in the office or (2) the patient is being seen in an operating room or other setting where surgical or other invasive procedures are performed or any other setting where maintain a sterile environment is medically necessary. When contacted regarding this issue, the board stated that a perfusionist would probably not practice in any of the facilities that are covered by the identification requirement, but if a perfusionist did practice in one of the facilities, the perfusionist would probably fall under the second exception to the requirement that is noted above. The board was unable to provide any other statutory authority for the regulatory requirement. This may be a minor point because the facilities that perfusionists practice in most likely require employees to wear identification anyway. The board should, however, either remove the requirement for lack of statutory authority or change the requirement to more accurately reflect the provisions of § 1-221 and add that section as statutory authority.

Statutory Authority and Legislative Intent

The department cites §§ 1-606, 14-205, 14-5E-01, and 14-5E-03 through 14-5E-25 of the Health Occupations Article as legal authority for the regulations. More specifically, § 1-606 requires each health occupations board to adopt specific sanctioning guidelines, including a range of sanctions and a list of mitigating and aggravating circumstances. Under § 14-205, the board is required to adopt regulations to carry out the provisions of Titles 14 and 15 of the Health Occupations Article. Section 14-5E-01 contains definitions for terms used in the Maryland Perfusion Act. Section 14-5E-03 requires the board to adopt regulations for the licensure and practice of perfusion. Section 14-5E-04 requires the board to set reasonable fees for the issuance and renewal of licenses and other services it provides to perfusionists. Section 14-5E-05 provides that there is a Perfusion Advisory Committee within the board. Section 14-5E-06 governs the composition of the board and the terms of the members and requires the committee to elect a chair every two years. Under § 14-5E-07, the committee is required to develop and recommend to the board regulations, a code of ethics, continuing education requirements, and recommendations concerning the practice of perfusion, including standards of care. The committee must also keep a record of its proceedings and submit an annual report to the board. Section 14-5E-08 requires an individual to be licensed on or after October 1, 2013, to practice perfusion. The requirement, however, does not apply to a student enrolled in an education program while practicing perfusion in that program. Section 14-5E-09 requires that an applicant meet the requirements of the section to qualify for a license and lists the qualifications. Section 14-5E-10 provides that an applicant who otherwise qualifies for a license is entitled to be licensed for a single two-year term before taking a national certifying examination. Section 14-5E-11 requires an applicant to submit an application and pay an application fee and the board to issue a license to an applicant who meets the requirements of the subtitle. Section 14-5E-12 provides that a license authorizes an individual to practice perfusion in the State while the license is effective. Section 14-5E-13 governs the expiration and renewal of a license. Under § 14-5E-14, a licensed perfusionist is required to notify the board in writing of a change in name or address writing 60 days after the change and is subject to an administrative penalty of \$100 for a failure to comply. Also, each licensed perfusionist is required to display the license conspicuously in the office or place of employment of the licensee. Section 14-5E-15 prohibits a licensed perfusionist from surrendering the license and the license from lapsing under operation of law while the licensee is under investigation or while charges are pending, unless a disciplinary panel agrees to the surrender. Section 14-5E-16 authorizes the board to deny a license to an applicant or take disciplinary action against a licensee if the applicant or licensee

engages in the conduct listed in the section. The section also requires the board or a disciplinary panel to give the individual an opportunity for a hearing and governs disciplinary action against a licensee who is convicted of or pleads guilty or nolo contendere with respect to a crime involving moral turpitude. Section 14-5E-17 governs judicial appeals from board decisions. Section 14-5E-18 governs reporting of performance issues regarding a licensed perfusionist by certain entities. Under § 14-5E-19, a disciplinary panel may reinstate a revoked license on application and the affirmative vote of a majority of its full authorized membership. 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. Section 14-5E-23 provides that a person who violates the provision of law regarding unlicensed practice of perfusion is subject to a civil fine of not more than \$5,000 to be levied by the board. The fine is to be paid into the Board of Physicians Fund.

Sections 14-5E-18.1, 14-5E-21, 14-5E-22, 14-5E-24, and 14-5E-25 of the Health Occupations Article do not relate to anything included in the regulations and, therefore, are not needed as legal authority for the regulations.

In addition to the statutory provisions cited, § 14-5E-02 of the Health Occupations Article needs to be cited. More specifically, § 14-5E-02 provides that the Maryland Perfusionist Act does not limit the right of an individual to practice a health occupation that the individual is authorized to practice under the Health Occupations Article.

Except for the possible minor legal issue discussed above, the authority is complete and the regulations comply with the legislative intent of the law.

Technical Corrections and Special Notes

The board was contacted regarding technical and substantive changes that needed to be made to the regulations. The technical changes include reorganizing two regulations and correcting internal and external cross-references. There are several substantive changes that need to be made as well. First, Regulation .03 contains duties of the Perfusion Advisory Committee. The requirement that the committee submit an annual report to the board needs to be added. Second, the regulations make several references to “the board” in regard to disciplinary actions and procedures. However, due to statutory changes made in the 2013 session of the General Assembly, the disciplinary activities of the board were split between the board and disciplinary panels which are made up of board members. In light of this new structure, references to “a disciplinary panel” need to be added to or substituted for references to “the board” in several of the regulations. Third, Regulation .17 contains reporting requirements for certain health care institutions that employ perfusionists. The regulation needs to be amended to include the penalty for failing to report as required. Fourth, Regulation .09A(4) states that an individual is ineligible for licensure and may not practice perfusion in the State on the expiration of the perfusionist-basic license. However, this contradicts Regulation .09B(4), which states that an individual who fails to convert a perfusionist-basic license to a perfusionist-advanced license before the expiration date must file a new application. The intention is that a perfusionist who fails to convert the basic license before it expires cannot practice in the State until the perfusionist qualifies for and is issued an advanced license, but can still apply for and receive an advanced license. The wording of Regulation .09A(4) needs to be changed to accurately reflect the board’s intent. Finally, as discussed above, § 14-5E-02 needs to

be added as statutory authority. The board indicated that it will make the changes before the regulations are published in the *Maryland Register*.

The board was also contacted regarding other issues related to the regulations. Regulation .16C states that proceedings for crimes of moral turpitude must be held in accordance with COMAR 10.32.02.08. COMAR 10.32.02.08 applies to certain health professionals that are regulated by the board; however, perfusionists are not included in the list. The board has stated that the regulation will be updated in a separate action. Also, Chapter 609 of 2014 makes numerous changes to the Maryland Perfusion Act. The regulations do not reflect those changes; however, the board intends to amend the regulations to do so. Finally, as noted above, the regulations state that the licensure fees that would be in effect after October 1, 2015, are to be determined and adopted in regulations by the board at a later time. The board stated that this was due to concerns the perfusionists in the State had concerning the amount of the revised fees. The perfusionists felt that the amount was unduly high and the board felt that the amount was needed to accurately cover costs due to the low number of perfusionists practicing in the State. The board is working on this issue.

Fiscal Analysis

No fiscal impact on State or local agencies beyond that already accounted for in the fiscal and policy note for Chapter 588 of 2011 (HB 287).

Agency Estimate of Projected Fiscal Impact

The regulations implement Chapter 588 of 2011 (HB 287), which requires the State Board of Physicians to license and regulate the practice of perfusion and establishes a Perfusion Advisory Committee within the board. The board advises that that the regulations increase special fund expenditures by an estimated \$41,076 for additional personnel and increase special fund revenues by an estimated \$18,900 from license fees. The Department of Legislative Services disagrees as the fiscal impact of the regulations has already been accounted for in the fiscal and policy note for Chapter 588. The note estimated that board special fund expenditures increase by \$35,750 in the first fiscal year of implementation of the bill, which includes a salary for one part-time (50%) program manager, and that, due to the low number of perfusionists anticipated to seek licensure, once the licensing program and advisory committee are operational, this position will become only 20% time. The fiscal and policy note also assumed that board special fund revenues would increase by \$12,400 in the first year of implementation from a \$200 biennial licensure fee.

Impact on Budget

No impact on the State operating or capital budget beyond that already accounted for in the fiscal and policy note for Chapter 588. The department advises that these revenues and expenditures have not been accounted for in the fiscal 2014 budget.

Agency Estimate of Projected Small Business Impact

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

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