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## INDEPENDENT REGULATORY REVIEW COMMISSION

333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

July 21, 2010

Carol E. Rose, M.D., Chair  
State Board of Medicine  
2601 North 3rd Street  
Harrisburg, PA 17110

Re: Regulation #16A-4931 (IRRC #2848)  
State Board of Medicine  
Perfusionist

Dear Ms. Rose:

Enclosed are the Commission's comments for consideration when you prepare the final version of this regulation. These comments are not a formal approval or disapproval of the regulation. However, they specify the regulatory review criteria that have not been met.

The comments will be available on our website at [www.irrc.state.pa.us](http://www.irrc.state.pa.us). If you would like to discuss them, please contact me.

Sincerely,

Kim Kaufman  
Executive Director  
wbg  
Enclosure

cc: Honorable Robert M. Tomlinson, Majority Chairman, Senate Consumer Protection and Professional Licensure Committee  
Honorable Lisa M. Boscola, Minority Chairman, Senate Consumer Protection and Professional Licensure Committee  
Honorable Michael P. McGeehan, Majority Chairman, House Professional Licensure Committee  
Honorable Julie Harhart, Minority Chairman, House Professional Licensure Committee  
Honorable Basil L. Merenda, Acting Secretary, Department of State  
Robert A. Mulle, Esq., Office of Attorney General  
Andrew Clark, Esq., Office of General Counsel

## **Comments of the Independent Regulatory Review Commission**



### **State Board of Medicine Regulation #16A-4931 (IRRC #2848)**

#### **Perfusionist**

**July 21, 2010**

We submit for your consideration the following comments on the proposed rulemaking published in the May 22, 2010 *Pennsylvania Bulletin*. Our comments are based on criteria in Section 5.2 of the Regulatory Review Act (71 P.S. § 745.5b). Section 5.1(a) of the Regulatory Review Act (71 P.S. § 745.5a(a)) directs the State Board of Medicine (Board) to respond to all comments received from us or any other source.

#### **1. Comments of the House Professional Licensure Committee. – Consistency with statute; Reasonableness; Protection of the public welfare; Implementation procedure; Clarity.**

On June 23, 2010, the House Professional Licensure Committee (Committee) voted to submit the following comments to the Board:

- The Committee brings to the Board's attention that proposed Regulation 16A- 4931 was published in the May 22, 2010 issue of the *Pennsylvania Bulletin*, approximately 101 days past the eighteen (18) months from the effective date of Act 19 of 2008.
- The Committee requests an explanation as to how the Board will enforce Section 13.3 (a) of the Act. It reads: "[T]wo years after the effective date of this section, it shall be unlawful for any person to hold himself out to the public as a perfusionist or to practice or offer to practice perfusionist unless the person holds a valid, current license issued by the board or the State Board of Osteopathic Medicine." What happens in the likely circumstance that final rulemaking does not occur before August 11, 2010?
- The Committee requests an explanation of how the Board is notified when a temporary graduate perfusionist fails the Nationally-recognized certifying agency's certification examination upon which failure the license expires.



- The Committee brings to the Board's attention that in § 18.535 (c), Application for temporary provisional perfusionist license, there is a reference to an application for certification as a perfusionist. Act 19 of 2008 which amended the Medical Practice Act of 1985 provides for the licensure of perfusionists not certification.
- The Committee recommends that, for consistency, language referring to various jurisdictional entities read "another state (even though, Commonwealth is used), U.S. territory or possession, the District of Columbia or another country" with similar descriptions for the courts.
- The Committee requests an explanation as to how continuing education other than category I credit hours are quantified since it can include, in particular, reading or viewing medical journals, audio-visual, or other educational materials, participation in electronic forums.
- The Committee questions why "working as a clinical or didactic instructor in an accredited school of perfusion" should earn continuing education credit. How many hours can be earned? Can a full-time instructor complete the entire amount of continuing education by working as a clinical or didactic instructor?
- The Committee requests a rationale for not allowing some minimum amount of surplus continuing education credits from being carried over into the next biennial registration period.
- The Committee requests an explanation as to how the Board will handle the implementation of Section 13.3(g) of the Medical Practice Act of 1985. It permits licensure of an applicant who was not a graduate of an accredited program prior to 1981, but met the then-current eligibility requirements for certification as a certified clinical perfusionist and subsequently was certified within two years of the effective date of the Act which basically creates a "grandfather clause." Act 19 became effective on August 11, 2008, and the statutory two years expire on August 11, 2010. The time frame for notice and issuing licenses to those who may wish to take advantage of this opportunity is closing in quickly.

We will review the Board's responses to these issues in our determination of whether the final regulation is in the public interest.

## **2. Section 18.534. Application for temporary graduate perfusionist license. – Clarity.**

### *Supervision*

Section 18.534 does not include the statutory requirement for supervision under 63 P.S. § 422.13c(h)(1)(ii) which states, "...authorization to practice

perfusion is granted only under supervision and direction of a perfusionist licensed under this act.” We recommend including this limitation in the regulation.

#### *Cross-reference*

Paragraph (b)(1) cross-references “section 13.3(h)(1)(i) of the act (63 P.S. § 422.13c(h)(1)(i).” This cross-reference does not appear to be broad enough. Did the Board intend to require the applicant to satisfy several requirements included in 63 P.S. § 422.13c(h)(1), or only the single requirement in Subparagraph (i) relating to examination?

### **3. Section 18.536. Registration of temporary emergency perfusionist service. – Statutory authority; Consistency with statute; Clarity.**

#### *“Another state, the District of Columbia or a territory of the United States”*

The phrase “...another state, the District of Columbia or a territory of the United States....” is used in the statute (63 P.S. § 422.13c(j)(1)). The statute also uses the phrase “out-of-State” in 63 P.S. § 422.13c(j)(1)(i), (2) and (3). The regulation uses the phrase “out-of-State” in Subsections (a), (b) and (d). We question whether the phrase “out-of-State” could be misinterpreted to allow licenses from other countries, whereas the phrase “another state, the District of Columbia or a territory of the United States” provides clearer direction. For clarity, the Board should consider using the phrase “another state, the District of Columbia or a territory of the United States” throughout this section of the regulation.

#### *Electronic means*

The statute (63 P.S. §422.13c(j)(1)(i) and (ii)) provides for submittal “by electronic means.” The regulation, and in particular Subsection (b), does not include this statutory provision. How will an applicant submit, and how will the Board accept or reject submissions by electronic means? Given the circumstances that would necessitate an emergency exemption, we recommend that the Board include in the regulation its interpretation of submittal by electronic means.

#### *“A one-time emergency perfusionist service”*

Under 63 P.S. § 422.13c(j)(1), a perfusionist licensed in another state, the District of Columbia or a territory of the United States “may provide a one-time emergency perfusionist service in this Commonwealth....” Subsection (c) of the regulation states services are not limited to “a single procedure or single patient or group of related patients.” The Board should explain how the regulation is consistent with the statutory language.

#### **4. Miscellaneous Clarity.**

- Section 18.535(a) concludes with the phrase “temporary **graduate** perfusionist license.” This should be corrected to “temporary **provisional** perfusionist license.”
- In Paragraph 18.537(a)(3), the word “trail” should be corrected to “trial.”
- The first sentence of Paragraph 18.538(a)(1) should be reviewed for clarity.
- The word “earning” should be replaced with “earned” in Paragraph 18.540(c)(2).



**Facsimile Cover Sheet**

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**INDEPENDENT REGULATORY REVIEW COMMISSION**  
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**To: Tom Blackburn****Cynthia Montgomery****Agency: Department of State****Licensing Boards and Commissions****Phone: 3-7200****3-3394 (Cynthia Montgomery)****Fax: 7-0251****Date: July 21, 2010****Pages: 6**

**Comments:** We are submitting the Independent Regulatory Review Commission's comments on the State Board of Medicine's regulation #16A-4931 (IRRC #2848). Upon receipt, please sign below and return to me immediately at our fax number 783-2664. We have sent the original through interdepartmental mail. You should expect delivery in a few days. Thank you.

**Accepted by:**

*Christine Lerety*  
*Receptionist*

**Date:**

*7/21/10*