

**INDEPENDENT REGULATORY REVIEW COMMISSION
DISAPPROVAL ORDER**

Commissioners Voting:

Public Meeting Held October 20, 2011

Silvan B. Lutkewitte, III, Chairman
George D. Bedwick, Vice Chairman
John F. Mizner, Esq.
Lawrence J. Tabas, Esq.

Regulation No. 16A-4931 (#2848)
State Board of Medicine
Perfusionist

On May 11, 2010, the Independent Regulatory Review Commission (Commission) received this proposed regulation from the State Board of Medicine (Board). This rulemaking amends 49 Pa. Code §§ 16.11, 16.13 and adds §§ 18.531 to 18.541. The proposed regulation was published in the May 22, 2010 *Pennsylvania Bulletin* with a 30-day public comment period. The final-form regulation was submitted to the Commission on September 12, 2011.

This regulation implements Act 19 of 2008 which established licensure of perfusionists. The regulation sets forth requirements for several types of licenses, including a general license, a temporary graduate license, a temporary provisional license and a one-time temporary emergency exemption from licensure. It also addresses requirements for continuing education and liability insurance.

We have identified three areas where this regulation does not meet the criterion of clarity in the Regulatory Review Act (71 P.S. § 745.5b(b)(3)(ii)). First, 63 P.S. § 422.13c(n)(1) states:

The board shall adopt, promulgate and enforce rules and **regulations consistent with the provisions of this act** establishing requirements of continuing education to be met by individuals licensed as perfusionists under this act **as a condition for renewal of their licenses....** (Emphasis added.)

Paragraph 18.537(b)(4) requires the licensee to verify compliance with the continuing education provisions in the act, but does not clearly state that completion of continuing education is a condition for license renewal. In addition, Paragraph 18.537(b)(4) cross-references Section 18.540 which imposes the vague penalty of “discipline” at Paragraph 18.540(a)(3) for failure to complete continuing education. Direct and clear notice in the wording of the regulation will benefit both the Board and licensees in obtaining compliance. Clear notice can also avoid the expense of the Board taking actions against the licensee and the potential loss of income for the licensee. Therefore, while the intent and actions of the Board may be to not renew a license, we find that clear notice to licensees is needed in the regulation that the Board cannot renew a license if the licensee fails to complete the required continuing education.

The second provision that needs to be clearer is Paragraph 18.539(b)(3). The paragraphs under Subsection (b) establish what constitutes unprofessional conduct. Paragraph (3), as amended, establishes the following as unprofessional conduct:

Performing acts in the practice of a healthcare profession in violation of a statute or regulation in this Commonwealth, the United States, or another state, the District of Columbia, a territory of the United States, or another country.

As worded, regardless of where the licensee is practicing, the licensee would have to comply with all statutes and regulations in all jurisdictions. We do not believe this was the Board's intent. However, the language of the regulation needs to be amended to avoid the impractical situation where, for example, a licensee practicing in Pennsylvania who performs a procedure in full compliance with Pennsylvania's statutes and regulations, could technically be found under Paragraph (3) to have engaged in unprofessional conduct because the procedure violates the statute or regulations of another state or country. The Board should review and clarify Paragraph (3).


The third area that should be clarified is the conditions for waiver of the continuing education requirements in Paragraph 18.540(a)(4). This provision relies on a cross-reference to 63 P.S. § 422.13c(n)(4). Although 63 P.S. § 422.13c(n)(4) provides the conditions for waiver, which are "serious illness, military service or other demonstrated hardship," we believe the regulation would be clearer by including these specific statutory conditions for waiver in the regulation. Again, we believe that direct and clear notice in the wording of the regulation will benefit both the Board and licensees in successfully implementing a waiver.

We have determined this regulation is consistent with the statutory authority of the Board and the intention of the General Assembly. However, we find that the regulation does not meet the Regulatory Review Act criterion of clarity (71 P.S. § 745.5b(b)(3)(ii)). Therefore,

BY ORDER OF THE COMMISSION:

The regulation # 16A-4931 (IRRC # 2848) from the State Board of Medicine

was disapproved on 10/20/11.



Silvan B. Lutkewitte, III, Chairman

