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INDEPENDENT REGULATORY REVIEW COMMISSION 333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

October 24, 2007

Charles D. Hummer, Jr., M.D., Chairman State Board of Medicine 2601 North 3rd Street Harrisburg, PA 17110

Re: Regulation #16A-4923 (IRRC #2630)

State Board of Medicine

Kill

Expert Witness

Dear Chairman Hummer:

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 <u>www.irrc.state.pa.us</u>. If you would like to discuss them, please contact me.

Sincerely,

Kim Kaufman

Executive Director

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Enclosure

cc: Honorable Robert M. Tomlinson, Chairman, Senate Consumer Protection and Professional Licensure Committee

Honorable Lisa M. Boscola, Minority Chairman, Senate Consumer Protection and Professional Licensure Committee

Honorable P. Michael Sturla, Majority Chairman, House Professional Licensure Committee Honorable William F. Adolph, Jr., Minority Chairman, House Professional Licensure Committee

Honorable Pedro A. Cortes, Secretary, Department of State

Comments of the Independent Regulatory Review Commission

on

State Board of Medicine Regulation #16A-4923 (IRRC #2630)

Expert Witness

October 24, 2007

We submit for your consideration the following comments on the proposed rulemaking published in the August 25, 2007 *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.

Section 16.52 Expert witnesses. - Reasonableness; Implementation procedures; Clarity.

The proposed rulemaking adopts the criteria for expert qualifications established by the Medical Care Availability and Reduction of Error Act (Mcare Act) (40 P.S. § 1303.512). While we recognize that the majority of the language contained in the proposed regulation is similar to provisions in the Mcare Act, we have four concerns.

Formatting of the Subsections

It appears that the titles of the subsections for the proposed rulemaking do not follow the appropriate alpha-numeric order. For example, Subsection (c) refers to "subsections (a) and (b)," but these sections are not included in the proposed regulation. We note that the following comments reference the *Pennsylvania Bulletin* version of the proposed rulemaking. In the submittal and publication of the final-form regulation, this formatting should be reviewed.

Paragraph (1) General rule

This paragraph states that: "[a] person will not be competent to offer an expert medical opinion in a disciplinary action before the Board unless that person possesses **sufficient** education, training, knowledge, and experience...." (Emphasis added.) How will the Board determine what is "sufficient?"

Waiver requirements

The proposed regulation provides that the Board may waive the requisite qualifications for an expert. However, the waiver language is vague. For example, Paragraph (2)(ii) states that the Board may waive the requirements for an expert if the Board determines the expert is "otherwise competent" to testify. (Emphasis added.) How the Board will make such a determination?

In Subsection (e), the Board may waive various requirements for an expert if the Board determines that the expert possesses: "sufficient training, experience and knowledge to provide the testimony" as a result of "active involvement" in or full-time teaching of medicine. (Emphasis added.) The final-form regulation should specify how the Board will determine what is "sufficient." Additionally, we note that Paragraph (1) includes "education" as one of the qualifications the Board must determine as "sufficient" before a person can offer an expert medical opinion. Why isn't "education" a criterion for waiver in Subsection (e)? Finally, the Board should clarify what would constitute "active involvement."

Subsection (f)

This subsection allows the Board to apply "its own expertise in determining the applicable standard of care in disciplinary matters before the Board." A commentator raised the issue of what qualifies Board members as "experts" in individual cases. Like the commentator, we question not only whether permitting the Board to make such determinations would render the proposed expert witness requirements moot, but also how this application would impact a respondent physician's right to cross-examine the expert against him/her. The Board should explain these concerns in the final-form regulation. It should be noted that the language contained in Subsection (f) is not included in the Mcare Act.

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INDEPENDENT REGULATORY REVIEW COMMISSION 333 MARKET STREET, 14th Floor, Harrisburg, PA 17101

To: Tom Blackburn

Cynthia Montgomery

Agency: Department of State

Licensing Boards and Commissions

Phone: 3-7200 or 3-3394 (Cynthia)

Fax: 7-0251

Date: October 24, 2007

Pages: 4

Comments: We are submitting the Independent Regulatory Review Commission's comments on the State Board of Medicine's regulation #16A-4923 (IRRC #2630). 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: Cynthia Marty

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