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

January 4, 2006

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

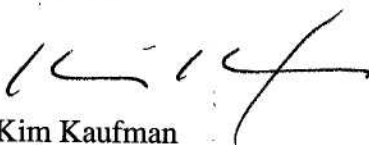
Re: Regulation #16A-4916 (IRRC #2505)
State Board of Medicine
Physician Assistants

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 www.irrc.state.pa.us. 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 Thomas P. Gannon, Majority Chairman, House Professional Licensure Committee
Honorable William W. Rieger, Democratic 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-4916 (IRRC #2505)

Physician Assistants

January 4, 2006

We submit for your consideration the following comments on the proposed rulemaking published in the November 5, 2005 *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 from the House Professional Licensure Committee. - Statutory authority; Legislative intent; Public health and safety; Consistency with the statute; Reasonableness; Implementation procedure; Need; Clarity; Comments, objections or recommendations of a committee.

The House Professional Licensure Committee (House Committee) submitted comments on this regulation in a letter dated December 15, 2005. It listed comments, concerns and questions in 18 separate points. The House Committee noted that “the General Assembly intended there to be supervision of a physician assistant (PA) by a physician,” quoting provisions from Sections 13 and 36 of the Medical Practice Act (Act) (63 P.S. §§ 422.13 and 422.36). It identified several areas of concern in the proposed regulation where there is a need for additional information and further clarification. It also referenced concerns raised by public commentators.

For example, the existing regulations at Section 18.161(b) state that a “physician assistant may not be responsible to more than three physician assistant supervisors [supervising physicians] in a medical care facility.” The proposed regulation will delete this provision. In the Preamble, the Board explains this deletion by asserting that “regulations should allow for flexible and creative innovation and appropriate use of all members of the workforce.” However, the Board neglected the specific limitations of the Act at 63 P.S. § 422.13(g) which states “a physician assistant [employed by a medical care facility] shall not be responsible to more than three physicians.” If this limitation is too restrictive, then the Act needs to be amended. Barring any change in the statute, this language should be retained in the regulation.

While we support amending the regulation to reflect the capabilities of PAs, this must be done within the limits of the Act. We also believe more explanation is needed in several areas of PA practice. Therefore, we concur with the comments, concerns and questions of the House Committee and incorporate them into our comments by reference.

2. Section 18.122. Definitions. - Legislative intent; Consistency with the statute; Reasonableness; Implementation procedure; Clarity.

Direct Supervision and Supervision

The existing “direct supervision” definition reads:

The physical presence of the physician assistant supervisor on the premises so that the physician assistant supervisor is immediately available to the physician assistant when needed.

The proposed regulation deletes this definition in its entirety. It also revises the existing definition of “supervision” by removing the words “personal direction.”

In contrast, Section 13(d) of the Act (63 P.S. § 422.13(d)), entitled “supervision,” begins with this statement: “A physician assistant shall not perform a medical service without the supervision and **personal direction** of an approved physician.” [Emphasis added.] The second sentence of Subsection (d) gives the Board the authority to “promulgate regulations which define the supervision and **personal direction** required by the standards of acceptable medical practice....” [Emphasis added.]

Although we recognize the Board’s discretion to define “supervision,” the statute uses the words “personal direction” twice in the same subsection on “supervision.” We recommend that the words “personal direction” be retained in the definition of “supervision” in the regulation.

Paragraph (C) of the “supervision” definition reads:

Personal and regular[**--at least weekly--**] review by the [**physician assistant supervisor**] **supervising physician** of the patient records upon which entries are made by the physician assistant.

In the proposed regulation, the words “at least weekly” are being deleted from the existing regulations even though they provide guidance as to the meaning of the word “regular.” We have two concerns.

First, we suggest that the Board add the minimum standard of “at least weekly” or the specific period that is consistent with the minimum standards of acceptable medical practice for the supervising physician’s “timely review” of the medical records prepared by the physician assistant pursuant to Section 18.159 relating to medical records.

Second, given the deletion of the definition of “direct supervision,” the Board needs to explain its interpretation of terms such as “personal direction” in the statute and “personal contact” in Section 18.142(a)(3). Does the Board intend that supervising physicians and PAs shall at some point and with some frequency be on the same premises for review and supervision? If not, does the Board foresee situations when all contact between physicians and PAs could be accomplished via telecommunications, or written, electronic or other means?

Supervising physician

The new definition of “supervising physician” seems to imply that there is only one supervising physician per each PA. However, the definitions section also includes definitions of “primary supervising physicians” and “substitute supervising physicians.” Also, under 63 P.S. § 422.13(g) a PA may be responsible to three physicians. In addition, the House Committee asked for clarification that all physicians assisted by PAs are “supervising physicians.”

Therefore, the definition of “supervising physician” should indicate that all physicians assisted by PAs are “supervising physicians” and also be clarified to indicate that there may be more than one supervising physician.

3. Section 18.158. Prescribing and dispensing drugs, pharmaceutical aids and devices. - Reasonableness; Need; Clarity.

The third sentence of Subsection (a)(3) states that a PA “may write a prescription for a Schedule II controlled substance for up to a 30-day supply if it was originally prescribed by the supervising physician **and** approved by the supervising physician for ongoing therapy.” [Emphasis added.] A commentator stated that requiring an original prescription from the physician would be restrictive in rural clinics when the physician is not on site and is redundant since the physician must approve the prescription. The Board needs to explain the need to require both the original prescription and approval by the physician.

Facsimile Cover Sheet

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

To: Suzanne Hoy
Agency: Department of State
Licensing Boards and Commissions
Phone: 7-2628
Fax: 7-0251
Date: January 4, 2006
Pages: 5

Comments: We are submitting the Independent Regulatory Review Commission's comments on the State Board of Medicine's regulation #16A-4916 (IRRC #2505). 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: _____

Suzanne Hoy

Date: _____

1/4/06