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

November 8, 2001

Charles D. Hummer, Jr., M.D., Chairman
State Board of Medicine
116 Pine Street
Harrisburg, PA 17105

Re: Regulation #16A-4912 (IRRC #2212)
State Board of Medicine
Physician Delegation of Medical Services

Dear Chairman Hummer:

Enclosed are our Comments. They will soon be available on our website at www.irrc.state.pa.us.

Our Comments list objections and suggestions for consideration when you prepare the final version of this regulation. We have also specified the regulatory criteria which have not been met. These Comments are not a formal approval or disapproval of the proposed version of this regulation.

If you would like to discuss these Comments, please contact my office at 783-5417.

Sincerely,

A handwritten signature in black ink that reads "Robert E. Nyce".

Robert E. Nyce
Executive Director

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Enclosure

cc: Honorable Mario J. Civera, Jr., Majority Chairman, House Professional Licensure Committee
Honorable William W. Rieger, Democratic Chairman, House Professional Licensure Committee
Honorable Clarence D. Bell, Chairman, Senate Consumer Protection & Professional Licensure Committee
Honorable Lisa M. Boscola, Minority Chairman, Senate Consumer Protection & Professional Licensure Committee
Honorable Kim Pizzingrilli, Secretary, Department of State

Comments of the Independent Regulatory Review Commission

on

State Board of Medicine Regulation No. 16A-4912

Physician Delegation of Medical Services

November 8, 2001

We submit for your consideration the following objections and recommendations regarding this regulation. Each objection or recommendation includes a reference to the criteria in the Regulatory Review Act (71 P.S. § 745.5a(h) and (i)) which have not been met. The State Board of Medicine must respond to these Comments when it submits the final-form regulation. If the final-form regulation is not delivered by October 9, 2003, the regulation will be deemed withdrawn.

1. General. - Need.

This regulation is designed to implement Section 422.17(a) of The Medical Practice Act (Act) (63 P.S. §422.17(a)) which provides: "A medical doctor may delegate to a health care practitioner or technician the performance of a medical service" if certain conditions are met. Further, Section 422.17(b) of the Act provides: "The board may **promulgate regulations which establish criteria** pursuant to which a medical doctor may delegate the performance of medical services...." (Emphasis added).

However, the regulation essentially incorporates the statutory language without adding specific criteria to guide the delegation. The Board states in the Preamble that this regulation is necessary because it has received inquiries concerning delegation. We question how a regulation that reiterates a statutory provision can be responsive to any concerns or inquiries.

However, if the Board submits the final-form regulation, it should explain the need for this regulation and respond to the following concerns.

2. Definitions. - Clarity.

The regulation does not define the terms "medical service," "health care practitioner" or "technician." We recommend that the Board add a new "Definitions" section to Chapter 18. This section should reference the definitions of the terms contained in the Act.

3. Section 18.401. Delegation. - Clarity.

Subsection (a)(1)

This subsection states delegation must be consistent "with the standards of acceptable medical practice...." This phrase is unclear. In the Preamble, the Board explains "[S]tandards of acceptable medical practice may be discerned from current medical literature and texts, medical

teaching facilities publications and faculty, expert practitioners in the field and the commonly accepted practice of practitioners experienced in the field.” This language clarifies the requirement in Subsection (a)(1). The Board should consider including the explanatory language from the Preamble in Subsection (a)(1).

Subsection (a)(4)

Subsection (a)(4) allows the medical doctor to delegate medical services once he has “determined that the delegatee is competent to perform the medical service.” Does the Board have a set criteria to assist medical doctors in making such determinations? The Board should explain.

Subsection (a)(5)

This subsection allows the medical doctor to determine that the delegation “does not create an undue risk to that patient.” Should the regulation require that the medical doctor’s determination be documented in the patient’s records?

Subsection (a)(6)

Subsection (a)(6) allows “[T]he nature of the service and the delegation of the service has been explained to the patient and the patient does not object....” Will it be explained to the patient that the patient has the right to object? The Board should explain what constitutes an explanation of the nature and delegation of the service sufficient to enable a patient to object in the Preamble to the final-form regulation.

Subsection (a)(7)

This subsection allows the medical doctor to be “available as appropriate to the difficulty of the procedure, the skill of the delegatee and risk level to the particular patient.” We have two concerns with this subsection. First, it is not clear what the phrase “available as appropriate to the difficulty” means. Second, Section 422.17(c) of the Act establishes that the “medical doctor shall be responsible for the medical services delegated to the health care practitioner or technician....” We agree with the House Professional Licensure Committee’s comments that Subsection (a)(7) should be amended so that it is consistent with Section 422.17(c) of the Act.

Subsection (b)

Subsection (b) provides that a medical doctor may not delegate a medical service if recognition of the complications or risks that may result from the service “requires medical doctor education and training.” This provision would seem to unduly restrict a doctor’s ability to delegate, since all medical functions carry a certain degree of risk. The phrase “technical knowledge and skill not ordinarily possessed by non-physicians” has been suggested to the Board as a replacement for the phrase “medical doctor education and training.” We recommend that the new language be considered.

Subsections (e) and (f)

The Board refers to “health care provider” in these subsections rather than the term “health care practitioner.” To be consistent throughout the regulation and with the language in the Act, the Board should change the references from “health care provider” to “health care practitioner.”