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

July 2, 2008

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

Re: Regulation #16A-4924 (IRRC #2690)

State Board of Medicine Acupuncture Registration

Dear Chairman Bates:

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



State Board of Medicine #16A-4924 (IRRC #2690)

Acupuncture Registration

July 2, 2008

We submit for your consideration the following comments on the proposed rulemaking published in the May 3, 2008 *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. General - Statutory authority.

In the Preamble, the Board's statutory authority is identified as Act 186 of 2006 (Act 186) which amended the Acupuncture Registration Act (Act) (63 P.S. §§ 1801-1806). The Board's specific rulemaking authority is found in Section 3 of the Act (63 P.S. § 1803). Section 3 should be included in the explanation of statutory authority in the Preamble and the Regulatory Analysis Form that are submitted with the final-form regulation. If the Board is relying on any other provisions for statutory authority, it should specifically cite them as well.

2. Section 18.15. Practice responsibilities of acupuncturist and practitioner of Oriental medicine who are not medical doctors. - Public health and safety; Reasonableness; Consistency; Clarity.

The proposed regulation contains a new Subsection (a)(4) which states that an acupuncturist or practitioner of Oriental medicine:

Shall, within 60 calendar days from the date of first treatment, refer the patient to a physician, dentist or podiatrist, as appropriate to the patient's condition, if the acupuncturist or practitioner of Oriental medicine determines that further acupuncture or Oriental medicine treatment is contraindicated for the patient or determines that the patient's condition has worsened. (Emphasis added.)

It is our understanding that, at least in part, the intent of this provision is to have the acupuncturist or practitioner of Oriental medicine refer a patient to

another health care professional if medically necessary before the 60-day period has expired. However, the use of the phrase "within 60 calendar days from the date of first treatment" is unclear. We have two concerns.

First, the phrase "within 60 calendar days" could be interpreted as allowing an acupuncturist to wait until the 60th day before referring even though an earlier referral might be appropriate and necessary to protect the health and safety of the patient. Subsection (a)(4) also indicates that a referral to a doctor shall be made only when the acupuncturist determines the following:

- 1) Acupuncture or Oriental medicine is contraindicated; or
- 2) The patient's condition has worsened.

Acupuncturists should not wait until their patient's condition worsens if they can immediately determine that care from a medical doctor is appropriate and necessary to protect or improve the patient's health. The acupuncturist should refer a patient to a different provider as soon as he or she knows that the patient's condition is beyond the scope of acupuncture or herbal therapy. Even though acupuncture treatment may occur up to 60 days without one, Act 186 still requires a medical diagnosis. Hence, the statute recognizes the need for medical involvement. There is no limitation on the Board requiring an acupuncturist to make the proper referral at any time it is necessary.

There are examples of similar provisions in existing regulations. Current mandates at 49 Pa. Code §§ 18.6(6) and 18.509(a)(7) require midwives and athletic trainers to refer a patient to a physician if the patient presents a medical problem that is beyond their scope of practice. Another example is an existing regulation for physical therapists at 49 Pa. Code § 40.61(d)(3), which requires referral to a physician if a patient's case is beyond the education, expertise or experience of the physical therapist.

Second, the requirements of Subsection (a)(4) should not be limited to "within 60 days." Even after the patient receives a diagnosis from a doctor, a situation may arise during acupuncture treatment when there is a need for the acupuncturist to refer the patient back to the doctor.

In the final-form regulation, the Board should delete the phrase "within 60 days" from Subsection (a)(4), and it should direct the acupuncturist and practitioner of Oriental medicine to refer a patient to a physician, dentist, or podiatrist as soon as it is appropriate and necessary to protect the patient. In addition, the Board should provide clear and thorough direction for when these referrals should occur.

FAX NO.

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Facsimile Cover Sheet



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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

3-3394 (Cynthia Montgomery)

Fax: 7-0251

Date: July 2, 2008

Pages: 1...

Comments: We are submitting the Independent Regulatory Review Commission's comments on the State Board of Medicine's regulation #16A-4924 (IRRC #2690). 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: Ungela Johnston Date: 7/2/08