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

December 8, 2004

Michael J. Romano, R.Ph., Chairman
State Board of Pharmacy
2601 North 3rd Street
Harrisburg, PA 17110

Re: Regulation #16A-5412 (IRRC #2437)
State Board of Pharmacy
Drug Therapy and Injectable Medications, Biologicals and Immunizations

Dear Chairman Romano:

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 regulation 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 my office at 783-5417.

Sincerely,

Robert E. Nyce
Executive Director
evp
Enclosure
cc: Honorable Thomas P. Gannon, Majority Chairman, House Professional Licensure Committee
Honorable William W. Rieger, Democratic Chairman, House Professional Licensure Committee
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 Pedro A. Cortes, Secretary, Department of State

Comments of the Independent Regulatory Review Commission

on

State Board of Pharmacy Regulation #16A-5412 (IRRC #2437)

Drug Therapy and Injectable Medications, Biologicals and Immunizations

December 8, 2004

We submit for your consideration the following comments that include references to the criteria in the Regulatory Review Act (71 P.S. § 745.5b) which have not been met. The State Board of Pharmacy (Board) must respond to these comments when it submits the final-form regulation. The public comment period for this regulation closed on November 8, 2004. If the final-form regulation is not delivered within two years of the close of the public comment period, the regulation will be deemed withdrawn.

1. **Comments from the House Professional Licensure Committee. – Consistency with the statute; Reasonableness; Implementation procedure; Need; Clarity.**

The House Professional Licensure Committee (House Committee), in a letter dated November 10, 2004, identified several concerns and questions with this regulation. We share many of the concerns identified by the House Committee. Some of these issues are also discussed further in the following paragraphs. The Board should carefully revise the final-form regulation in order to address the concerns and recommendations of the House Committee.

2. **Section 27.1. Definitions. – Consistency with the statute; Reasonableness; Need; Clarity.**

Drug Order

The House Committee noted that the existing regulations of the Board include a definition of the term "drug order" (see 49 Pa. Code § 27.1). In several places, the proposed regulation uses the term "order." The House Committee recommends that if the term "order" has the same meaning as the defined term "drug order," then the regulation should use the term "drug order" in place of "order." We agree.

Institution

The statutory definition of "institution" in Section 2(15) of the Pharmacy Act (63 P.S. § 390-2(15))(Act) reads:

> "Institution" means a health care facility as defined in section 103 of the act of July 19, 1979 (P.L. 130, No. 48), known as the "Health Care Facilities Act," which offers care and medical treatment to **patients who require food, board and overnight sleeping facilities**. [Emphasis added.]

The definition of this term in the proposed regulation does not mirror the definition in the Act. It includes "ambulatory surgical facilities" and "cancer treatment centers using radiation therapy on an ambulatory basis." We question the basis for the inclusion of these facilities in this definition since the statutory definition in the Act limits the term "institution" to a facility that "offers care and medical treatment to patients who require food, board and overnight sleeping facilities." The final-form regulation should use the definition in the Act or reference the statutory definition.

Use of statutory definitions

In its comments, the House Committee recommended that a definition of "managing drug therapy" be added to this regulation. This term is defined in Section 2(14) of the Act (63 P.S. § 390-2(14)). In addition, the proposed regulation contains a definition of the "practice of pharmacy" that is practically, but not completely, identical to the statutory definition in Section 2(11) of the Act (63 P.S. § 390-2(11)). The final-form regulation should include the two definitions from the Act or reference the statutory definitions for these two terms.

3. Section 27.301. Written protocol. – Protection of public health and safety; Reasonableness; Clarity.

Subsections (a)(5) and (a)(6) require that the physician be notified within 72 hours of each intervention or "changes in dose, duration or frequency of medication prescribed." The House Committee and Pennsylvania Academy of Family Physicians (PAFP) commented that this timeframe should be shortened given the effect these changes may have on a patient. Section 9.1(3)(9) of the Act requires that the Board by regulation:

> Establish an **appropriate** time frame, not to exceed seventy-two hours, within which the licensed pharmacist must notify the licensed physician of any changes in dose, duration or frequency of medication prescribed. [Emphasis added.]

Although the Act provides a maximum of 72 hours, we question whether the proposed timeframe is appropriate. PAFP states that the use of the maximum appears "somewhat inconsistent with good medical documentation practices." The Board should shorten the timeframe or explain why its use of the maximum timeframe is consistent with good medical practice.

4. Section 27.401. Qualifications for authority. – Reasonableness, Implementation procedure; Clarity.

Section 9.2(a) of the Act states that the Board must, by regulation, establish education and training standards and practice guidelines for pharmacists to be authorized to administer injectable medications. The House Committee expressed concern that Section 27.401(2) in the proposed regulation does not match the statutory requirement. We note that the language of Sections 27.401(2) and (3) are similar to Sections 9.2(a)(1) and (2) of the Act. However, Section 9.2(a)(1) of the Act begins as follows:

> Satisfactory completion of an academic and practical curriculum approved by the Board that includes the current guidelines and recommendations of the Centers for Disease Control and Prevention [CDC] . . . the American Council on Pharmaceutical Education [ACPE] or a similar health authority or professional body . . . .

The Act appears to envision an academic and practical curriculum established and approved by the Board. On the other hand, the proposed regulation simply requires completion of a course of education and training which includes the current guidelines of the CDC, or a similar body accredited by the ACPE or approved by the Board. We have two concerns.

First, the Board needs to identify the specific minimum education and training requirements that must be included in an approved course. This type of provision could include specific topic contents for courses and minimum hour requirements for course work and training. Examples of these provisions can be found in existing regulations for other licensees seeking additional authority at 49 Pa. Code § 23.202 (relating to optometrists) and 49 Pa. Code § 21.283 (relating to certified registered nurse practitioners).

Second, both the proposed regulation and the Board's existing regulations are silent concerning the procedure that a course provider would follow to apply for approval by the Board. Examples of such procedures can be found in the existing regulations at 49 Pa. Code § 39.13 (relating to nursing home administrators) and 49 Pa. Code § 23.84 (relating to optometrists). The Board should add procedures to its regulation that explain how course providers may apply for its approval.

5. Section 27.402. Application and renewal procedures. – Clarity.

Section 9.1(d) of the Act (63 P.S. § 390-9.1(d)) requires that pharmacists obtain and maintain professional liability insurance coverage in the minimum amount of $1 million when they are parties to written agreements for management of drug therapy. The House Committee recommends that this regulation require pharmacists to submit proof of insurance to the Board. Section 9.1(d)(2) of the Act identifies the types of evidence of insurance that would be satisfactory.

Section 27.402 of the proposed regulation addresses application and renewal procedures for the authority to administer injectable medications. This section should be amended in the final-form regulation to reference the statutory requirements for liability coverage and require submittal of proof of insurance to the Board.

6. Section 27.405. Recordkeeping. – Clarity.

PAFP suggests amending the recordkeeping requirement from two years to seven years. It claims a seven-year period is more appropriate for medical records. The Board should make this change in the final-form regulation or justify the two-year requirement.

7. Section 27.406. Notification requirements. Protection of public health and safety; Consistency with existing regulations; Reasonableness; Clarity.

The House Committee recommended that the regulation require a physician be contacted as soon as possible when there is an adverse reaction by the patient. In addition, PAFP questioned the reasonableness of the timeframes of 72 hours under an order and 14 days under a written protocol. PAFP wrote that "[n]either of the notification periods seems to be consistent with good medical care."

The proposed timeframes are also inconsistent with existing regulations for hospitals at 28 Pa. Code § 109.65 (relating to recording of drugs administered). Section 109.65(b) reads in part:

> Any medication error or apparent drug reaction shall be reported **immediately** to the practitioner who ordered the drug. Any entry of the medication given in error or the apparent drug reaction, or both, shall be properly recorded in the medical record of the patient. Any adverse drug reaction shall be **immediately** noted on the medical record of the patient in the most conspicuous manner possible, in order to notify everyone treating the patient throughout the duration of his hospitalization of his drug sensitivity and thereby prevent a recurrence of adverse reaction . . . . [Emphasis added.]

We have two concerns with this Section 27.406 of the proposed regulation.

First, the Board should change the timeframes in the proposed regulation to require a pharmacist to report an adverse reaction or medication error as soon as practicable, but no later than 24 hours.

Second, the Board should consider reducing the 72-hour and 14-day time periods for notice as warranted to maintain good medical care.

Facsimile Cover Sheet

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Date: December 8, 2004
Pages: 6

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Comments: We are submitting the Independent Regulatory Review Commission's comments on the State Board of Pharmacy regulation #16A-5412 (IRRC #2437). 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:** 12/8/04