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

November 28, 2007

Edward J. Bechtel, R.Ph., Chairperson
State Board of Pharmacy
2601 North 3rd Street
Harrisburg, PA 17110

Re: Regulation #16A-5416 (IRRC #2640)
State Board of Pharmacy
Revisions Regarding Current Pharmacy Practice

Dear Chairperson Bechtel:

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
wbg
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 Pharmacy Regulation #16A-5416 (IRRC #2640)

Revisions Regarding Current Pharmacy Practice

November 28, 2007

We submit for your consideration the following comments on the proposed rulemaking published in the September 29, 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 Pharmacy (Board) to respond to all comments received from us or any other source.

1. Section 27.12 - Practice of pharmacy and delegation of duties. - Implementation procedures; Clarity.

The proposed changes to this section specifically relate to the duties and responsibilities of pharmacy interns. Has the Board considered adding specific penalty provisions to this section pertaining to failure of the pharmacist to appropriately supervise a pharmacy intern?

The proposed rulemaking also deletes the prohibition on pharmacy interns accepting and transcribing oral orders and prescriptions. Has the Board considered including this duty in Subsection (c)(3) as one of the procedures pharmacy interns may now perform? It should be noted that these duties are included in the proposed changes to Subsections 27.18(n) and (o).

2. Section 27.17 - Security for Schedule II controlled substances. - Implementation procedures; Clarity.

This section relates to security for Schedule II controlled substances. We raise three issues.

First, the proposed changes to Subsection (b) appear to be contradictory. This Subsection requires that: “[S]chedule II controlled substances **shall** be stored in securely locked, substantially constructed cabinets,” but also provides that these substances: “[**m**]ay be dispersed throughout the stock of noncontrolled substances in a manner that obstructs the theft or diversion of the controlled substances.” (Emphasis added.) In the final-form regulation, the Board should clarify not only how it is possible to lock these substances, while at the same time dispersing them with noncontrolled substances, but also how this method is an adequate safety measure. The final-form regulation also should clarify what a “substantially constructed cabinet” is.

Second, how will the Board enforce these storage provisions?

Finally, has the Board considered specifying which categories of medical professionals can access Schedule II controlled substances in facilities under the jurisdiction of the Board? Why or why not?

3. Section 27.18 - Standards of practice. - Statutory authority; Reasonableness; Implementation procedures; Clarity.

Subsection (j)

This Subsection (j) provides that: “[p]rescriptions for Schedule II controlled substances may not be filled more than 6 months from the date of the prescription.” What is the Board’s statutory authority for this provision? Also, how did the Board determine that six months is an appropriate timeframe in which to honor this type of prescription?

Subsection (l)

Subsection (l)(3) refers to the mailing of medications, prescription drugs, etc. The proposed rulemaking indicates that such mailings are permissible if “[s]hipped in a manner which would preserve the integrity of the drug.” This phrase is vague, and more specific language is needed in the final-form regulation. Also, how will the Board enforce this provision?

Subsection (r)

Subsection (r)(6) refers to advertising of special prices for prescriptions, etc. The proposed language replaces “a pharmacist or pharmacy” with “any person,” with respect to who is responsible for the advertising. Why did the Board propose this change to the regulation?

4. Section 27.19 - Prospective drug review and patient counseling. - Clarity.

Subsection (d)

Subsections (d)(1), (2) and (3) provide what a prospective drug review (PDR) does not extend to, examples of situations when a PDR is required and examples of when a PDR is not required. A commentator noted that it is confusing to have examples of when a PDR is not used in two separate subsections. Clarity would be improved by combining (d)(1) and (3) into one subsection.

5. Section 27.25-Licensure by reciprocity. - Clarity.

Subsection (c) refers to abbreviations for what appears to be pharmacy licensure exams. These abbreviations should be defined in this section.

Facsimile Cover Sheet



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INDEPENDENT REGULATORY REVIEW COMMISSION
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To: Tom Blackburn
Cynthia Montgomery
Agency: Department of State
Licensing Boards and Commissions
Phone: 3-7200 or 3-3394 (Cynthia)
Fax: 7-0251
Date: November 28, 2007
Pages: 4

Comments: We are submitting the Independent Regulatory Review Commission's comments on the State Board of Pharmacy's regulation #16A-5416 (IRRC #2640). 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 Montgomery* Date: 11/28/07