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

August 18, 2004

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

Re: Regulation #16A-5410 (IRRC #2405)
State Board of Pharmacy
Technology and Automation

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-5410 (IRRC #2405)

Technology and Automation

August 18, 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 July 19, 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regulation is not delivered within two years of the close of the public comment period, the regulation will be deemed withdrawn.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. General. – Possible conflict with existing regulations; Implementation procedures.

The Department of Health (DOH) commented that its regulations may conflict with changes being proposed by the Board. For example, DOH regulations require handwritten notations, use of indelible ink, separation of records, and use of red ink to mark prescription orders (28 Pa. Code §§ 25.53 (b) and (d) and 25.56 (a) and (b)). DOH requests "that the Board either amend the proposed regulations or address any differences between the two regulations in the preamble."

The House Professional Licensure Committee (House Committee) requests that the Board consult with DOH regarding its concerns before final regulations are submitted. We concur with the House Committee and suggest that these discussions should take into consideration provisions of the Electronic Transactions Act (ETA) (73 P.S. § 2260.303) that state electronic records can be substituted for written records.

2. Broad requirements to meet state and federal laws and regulations. – Clarity.

Several provisions require compliance with "state and federal laws and regulations" or contain similar language. These broad references are found in Sections 27.14(c)(11), 27.201(b)(2)(i), 27.201(b)(5), 27.202(a), 27.203(a)(2)(i), 27.203(a)(3) and 27.204(c)(5).

In the Preamble, the Board states its belief that these broad references are more accurate than specific citations. We disagree. Broad references do not give the regulated community guidance as to what requirements must be met. The broad references noted above should be replaced with specific citations to the applicable regulations or laws.

3. Section 27.1. Definitions. – Need; Reasonableness; Clarity.

Automated medication system

There are two concerns.

First, this definition excludes compounding. A commentator questions whether this definition would exclude inpatient pharmacies that use automated compounding systems. Is it the Board's intent to exclude these compounding processes?

Second, the definition of "automated medication system" states the term does not mean an "automatic counting device." Since the term "automatic counting device" is not defined in regulation, it is unclear what is not included. A definition of the term "automatic counting device" should be added to the regulation.

Central processing center

It is not clear why a central processing center must engage "solely in centralized prescription processing." Could a central processing center perform the functions of an originating pharmacy or a delivering pharmacy? The Board should explain the need for this limitation.

Originating pharmacy

The House Committee commented that this definition should be re-written so that licensees can clearly determine when a central fill pharmacy or a central processing center is an originating pharmacy. We agree. Additionally, the second sentence uses the undefined term "centralized pharmacy." The Board should re-write this definition to make it clearer.

Prescription

The existing regulatory definition, consistent with the Pharmacy Act (63 P.S. § 390-2), limits prescriptions to a "written or oral order." This regulatory definition should be amended to include an "electronic order," consistent with this proposal.

4. Section 27.14. Supplies. – Clarity.

The House Committee commented that this section should reference the exemption in Section 27.203(b). This section would be clearer with a reference to that exemption.

5. Section 27.201. Electronically transmitted prescriptions. – Feasibility; Reasonableness; Protection of the public; Clarity.

Subsection (a)

We have three concerns with Subsection (a).

First, this subsection limits electronic transmittals to a "data base exchange or e-mail." Given the rapid advance of communications technology described by commentators, a limitation to "data base exchange or e-mail" is already outdated and would be burdensome. The ETA contains a broad definition of "electronic" as "relating to technology having electrical, digital, magnetic, wireless, optical, electromagnetic or similar capabilities" (73 P.S. § 2260.103). Subsection (a) should allow any method of electronic communication that can reliably provide the information required in Subsection (b). Alternatively, if there is a need to limit the methods of transmission, the regulation should provide the flexibility to petition the Board for approval of new technologies.

Second, this subsection requires the electronic prescription to not be "altered, accessed, viewed, screened or manipulated by an intervening entity or person unless authorized by law." A commentator described a system that verifies the prescriber and confirms that a prescription contains the required data before the prescription is routed to the pharmacy. Is it the Board's intent to prohibit this system?

Finally, the meaning of this subsection is difficult to comprehend. Subsection (a) is a single sentence that contains 80 words and multiple concepts. Rewriting the subsection would improve its clarity. For example, the requirement to use a pharmacy of the patient's choice could be placed in a separate subsection.

Subsection (b)

There are three concerns.

First, Subsection (b)(1) appropriately permits the use of electronic signatures under the ETA. However, there are other prescription requirements that the regulation does not address. For example, the regulation does not address the prescription requirements under 35 P.S. § 960.3(a). Specifically, Subsection (a) of that Act states,

> . . . unless the prescriber handwrites "brand necessary" or "brand medically necessary," shall designate approval of substitution of a drug by a pharmacist pursuant to this act. Imprinted conspicuously on the prescription blanks shall be the words: "In order for a brand name product to be dispensed, the prescriber must handwrite 'brand necessary' or 'brand medically necessary' in the space below." . . .

The regulation should address the requirements of 35 P.S. § 960.3(a), as well as other concerns raised by commentators concerning the use of electronic prescriptions. Given the importance of the ETA to this regulation, it would be appropriate to address electronic prescription requirements in a separate subsection.

Second, a subparagraph should be added to Paragraph (2) to specify how the requirement discussed above will be addressed.

Finally, because Paragraph (5) applies to all of Section 27.201, it should be a separate subsection.

6. **Section 27.202. Computerized recordkeeping systems. – Protection of the public; Need; Clarity.**

Subsections (d) and (e) address computer down time and safeguards, but neither requires back up of information entered into a computerized recordkeeping system. In the event of a system failure, records could be lost or could no longer be reliably audited. Why isn't the Board requiring back up of computerized recordkeeping systems?

Also, we question if the last sentence in Subsection (d) is needed because prescriptions can only be refilled if "the number of refills authorized by the prescriber has not been exceeded" at any time, not just when the system is down.

7. **Section 27.204. Automated medication systems. – Protection of the public; Reasonableness; Clarity.**

Policies, procedures and written plans

Subsections (c), (d), (f), (g), (h), (i) and (j) all require the use of a policy, procedure or written plan in one form or another. The House Committee commented that the regulation should assign an affirmative duty to the pharmacy to create these policies, procedures or written plans. We agree. For example, Subsection (c)(1) places the responsibility on the pharmacist manager to review and approve certain policies and procedures. However, who has the responsibility to write the policies and procedures?

Subsection (b)

Paragraph (4) contains the phrase, ". . . with the time, date and initials or other identifier . . . ." What "other identifier" does the Board consider to be an adequate method of electronically recording the activity of each pharmacist, technician or other authorized personnel?

Also, Paragraph (4) concludes with the sentence, "It is the intent of this section to hold responsible each pharmacist for the transaction performed by that pharmacist, precluding the need for a final check of a prescription by one individual pharmacist prior to delivery." The House Committee commented that this sentence is not clear, and we agree. How does this sentence relate to the first sentence of the paragraph?

Subsection (d)

Paragraph (6) limits access for stocking and removal of medications to licensed pharmacists or "qualified support personnel." Who are considered "qualified support personnel"? Is it the Board's intent to limit access to individuals supervised by the licensed pharmacist? Would healthcare professionals such as physicians, nurses or others legally authorized to administer drugs be allowed to access an automated medication system? The regulation should specifically state who may access the automated medication system.

Facsimile Cover Sheet

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Date: **August 18, 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-5410 (IRRC #2405). 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: Malana E Dixon **Date:** 8/18/04
Secretary to the Senior Deputy Chief Counsel
Dept of State

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