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House of Representatives
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Professional Licensure Committee

August 3, 2004

John R. McGinley, Jr., Chairman
Independent Regulatory Review Commission
14th Floor, Harrisstown 2
333 Market Street
Harrisburg, PA 17101

Dear Chairman McGinley:

The Professional Licensure Committee held an informational meeting on July 29, 2004, to discuss Regulation 16A-6802, proposed rulemaking of the State Board of Examiners in Speech-Language & Hearing, and Regulation 16A-5410, proposed rulemaking of the State Board of Pharmacy. While no votes were taken, I am submitting comments on behalf of myself and the members of the committee present at the informational meeting. To my knowledge, there are no additional comments forthcoming from committee members. Accordingly, below please find our comments.

Regulation 16A-6802 – Proposed rulemaking of the State Board of Examiners in Speech-Language & Hearing, relating to continuing education. The members present at the meeting and I submit the following comments:

1. For consistency, the committee recommends that the definition of “continuing education record” found in Section 45.2 mirror the language of Section 45.506(b), as the latter section lists the minimum requirements of a “continuing education record.” Accordingly, the language of Section 45.506(b)(6) regarding the course of approval number or an indication of pre-approved status should be added to the definition of “continuing education record” in Section 45.2.
2. The committee seeks a clarification regarding Section 45.506(a)(10) with respect to the “name of the entity that approved the program...” It is the committee’s understanding that the board approves programs.
3. The committee notes a drafting error in Section 45.505(b) (“Anyone, to include colleges, universities, associations, professional societies and organizations seeking approval to offer programs of continuing education...”) The committee recommends that if the board chooses to keep this list after reading this comment in its entirety, the language be modified so that it reads, “An entity, including a college, a university, an association, a professional society or organization, seeking approval to offer programs in continuing education...”

In addition, the term “provider” is defined in Section 45.2 as, “An agency, organization, institution, association or center approved by the Board to offer an organized continuing education course or program.” However, Section 45.505(b), the section which lists those entities that may apply to become a “provider” – colleges, universities, and professional societies – are not listed in the definition of “provider” found in Section 45.2. The committee recommends that the board make both sections consistent with one another as they are both dealing with “providers.”

4. The committee notes a drafting error in Section 45.505. Specifically, the parentheses should be removed in subsection (d) (“including (but not limited to):” and a comma added so that the phrase reads, “including, but not limited to...”
5. The committee notes a drafting error in paragraph (1) of subsection (e) of Section 45.505. The paragraph reads, “Continuing education programs approved or sponsored by the American Speech-Language and Hearing.” The committee questions whether that should read the “American Speech-Language and Hearing Association” or other similar language.

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6. For consistency, the committee recommends that a reference be made to waiver in subsection (b) of Section 45.507, *Disciplinary Action Authorized*. That section states that a licensee who fails to complete continuing education requirements may be subject to discipline. However, Section 45.507 must be read together with Section 45.502, *Exemption and Waiver*.
7. For clarity, the committee recommends that subsections (c) and (d) of Section 45.507, which discusses the board's ability to revoke approval of a provider, be moved to the section on approval of providers, Section 45.505.

Regulation 16A-5410 – Proposed rulemaking of the State Board of Pharmacy, pertaining to technology and automation. The members present at the meeting and I submit the following comments:

1. The committee notes the comments submitted by the Pennsylvania Department of Health and requests that the board consult with the department regarding its concerns before final regulations are submitted.
2. The committee notes a drafting error in the definition of "Automated medication system" found in Section 27.1 Definitions. The committee recommends that the definition be re-written so that the term is defined as, "a process that performs operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing or distribution of medications, and which collects, controls and maintains all transaction information. The term does not include an automatic counting device."

Similarly, the committee notes a drafting error in the definition of "originating pharmacy." The committee recommends that the definition be re-written so that a licensee can clearly determine when a central fill pharmacy or a central processing center is an "originating pharmacy."

3. The committee notes a drafting error in Section 27.201. The committee recommends that subsection (a) be re-written so that the subsection does not contain language in parentheses. (Similarly, parentheses are found in Section 27.202. The committee recommends that language be re-written.) Further, the committee notes a drafting error in subsection (b) of the same section. The committee recommends the comma be removed after the word "prescription."
4. The committee notes a drafting error in Section 27.203. The committee recommends the word "provided" in subsection (a) be replaced with, "if the following requirements are met."
5. The committee notes that in a number of places the proposed regulation requires pharmacies to have certain policies and procedures in place, to have policies of operation, and to operate according to a written program. However, the committee notes that in the places where this or similar language appears, there is no duty imposed on the pharmacies to actually create these policies or programs.

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Accordingly, the committee recommends that where the proposed regulation mentions that a pharmacy have policies and procedures or programs, an affirmative duty to create such a policy or program be placed on the pharmacy.

6. The committee notes a drafting error in Section 27.204(b)(4). The committee recommends that the language reading, "It is the intent of this section to hold responsible each pharmacist for the transaction performed by that pharmacist, precluding the need for final check of a prescription by one individual pharmacist prior to delivery" be re-written so that the language contained in that section clearly and accurately reflect the board's policy.
7. The committee notes that the proposed regulation states that the requirements regarding inventory found at Section 27.14(a) do not apply to a central processing center. The committee recommends that language be added to Section 27.14 so that both Section 27.14 and Section 27.203(b) are consistent with one another. In other words, Section 27.14 should contain language that makes it clear that there is an exception to the rule found in Section 27.203(b).

Please feel free to contact my office should any questions arise.

Sincerely,

A handwritten signature in black ink that reads "Thomas P. Gannon".

Thomas P. Gannon
Chairman
Professional Licensure Committee

cc: Hon. Pedro A. Cortes, Secretary of the Commonwealth
Department of State
Richard R. Smiga, R.Ph., Chairman, State Board of Pharmacy
Sonya Wilt, Ph.D., CCC/SL, Chairperson, State Board of Examiners-Language&Hearing