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House of Representatives
COMMONWEALTH OF PENNSYLVANIA
HARRISBURG

CHAIRMAN
PROFESSIONAL LICENSURE COMMITTEE

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INDEPENDENT REGULATORY
REVIEW COMMISSION

November 10, 2004

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

Dear Chairman McGinley:

The Professional Licensure Committee held a meeting on November 9, 2004, to consider the following:

Regulation 16A-647 – Final rulemaking of the State Board of Auctioneer Examiners relating to deletion of exam fee. The committee voted to approve the regulation.

Regulation 16-32 – Proposed rulemaking of the Commissioner of the Bureau of Professional and Occupational Affairs relating to Act 48 of 1993 civil penalty schedules. The committee voted to take no formal action until the final regulation is promulgated. The committee submits the following comments:

1. With respect to the schedule of penalties for the State Real Estate Commission, the committee seeks an explanation from the Commissioner regarding his rationale for lowering the penalties for the offense of failing to include the business name and phone number in at least equal size on an advertisement. Further, the committee seeks clarification regarding the phrase, "in at least equal size." Does that phrase indicate that the name and phone number have to be of equal size to each other or to the rest of the wording of the advertisement.
2. With respect to the schedule of penalties for the State Board of Vehicle Manufacturers, Dealers and Salespersons, the committee seeks an explanation from the Commissioner regarding the difference in severity of the penalty for an auction and a dealer with respect to permitting an unlicensed person to represent the auction or dealer. With respect to dealers, for example, the penalty for a third offense is formal disciplinary action while the penalty for a third offense by an auction is \$1,000.

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Regulation 16A-4615 – Proposed rulemaking of the State Board of Dentistry relating to biennial renewal fees. The committee voted to take no formal action until the final regulation is promulgated.

Regulation 16A-5412 – Proposed rulemaking of the State Board of Pharmacy relating to drug therapy and injectable medications, biologicals, and immunizations. The committee voted to take no formal action until the final regulation is promulgated. The committee submits the following comments:

1. With respect to Section 27.1 Definitions, the committee recommends that the board use the language found in Act 102 of 2002 with respect to the definition of “institutions.”
2. The committee notes there is no definition of the term “order.” However, there is a definition of the term “drug order” in the regulation. Because there are many places in the proposed regulation where the term “order” appears, the committee recommends that a definition of “order” be added or, if the board means “drug order” when it says “order,” that the term “drug order” be substituted for “order,” if that is appropriate.
3. The committee recommends a definition of “managing drug therapy” be added to the regulation.
4. With respect to Section 27.32 Continuing education, the committee notes that a minimum of two hours are required regarding the administration of injectable medications. The committee also notes that under Act 102 of 2002, the board is required to “establish education and training standards and practice guidelines pursuant to which pharmacists shall be authorized to administer injectable medications, biologicals and immunizations...” Section 9.2(a) of the Pharmacy Act. Further, such standards and guidelines must include “an academic and practical curriculum approved by the board that includes the current guidelines of the Centers for Disease Control and Prevention in the Public Health Service...” Section 9.2(a)(1) of the Pharmacy Act. The committee notes that the regulation is silent as to these provisions.

The committee notes that the regulations must include the education and training standards which the board must establish, as well as the academic and practical curriculum which the board must approve. The committee therefore recommends that the proposed regulation include these items.

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5. The committee recommends that in Section 27.301 Written protocol that the provision state that drug therapy management may only take place in an institutional setting.
6. The committee seeks clarification from the board that it included in the proposed regulation the statutory requirement that the protocol for drug therapy management include "the functions and tasks which are the subject of the written agreement or protocol." Section 9.1(e)(7) of the Pharmacy Act.
7. The committee notes that Section 27.301 of the proposed regulation gives a pharmacist up to 72 hours to notify a physician of a decision made by a pharmacist with respect to drug therapy, as well up to 72 hours to notify a physician of a change in dosage. The committee notes that the statute authorizes the board to set an appropriate time, provided it is no more than 72 hours, for such notification. The committee asks whether the board has considered requiring notice of a change in dosage being made in a much shorter time than 72 hours, given the effect such change may have on a patient. The committee asks whether the board should change the time for notification in such a case to a shorter duration. Further, the committee requests that the board provide its rationale for choosing 72 hours.
8. The committee notes that Act 102 of 2002 requires, as a condition precedent to managing drug therapy, that a pharmacist "shall obtain and maintain, to the satisfaction of the board, professional liability insurance in the minimum amount of one million dollars..." Section 9.1(d)(1) of the Pharmacy Act. Failure to obtain and maintain professional liability insurance is a ground for revocation or suspension of a license. Id.

The committee notes that the proposed regulation is silent as to this requirement. The committee notes the board stated in the annex that future regulations will address the issue of self-insurance. The committee notes that the issue of liability insurance must be included in the proposed regulation, even if the part about self-insurance is delayed. Self-insurance is but one sub-set of insurance. Since the statute requires that liability insurance be obtained, the committee recommends that the board include a provision regarding the requirement of obtaining insurance in the amount of \$1,000,000, as well as the proof which must be submitted to the board.

9. The committee requests an explanation from the board regarding its discussions/work with the Insurance Commissioner regarding self-insurance. Further, the committee

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asks that the board give its best estimate regarding the promulgation of regulations regarding self-insurance.

10. The committee notes that Act 102 of 2002 requires that the written protocol for management of drug therapy be provided, upon request, to the State Board of Medicine, the State Board of Osteopathic Medicine and the State Board of Pharmacy. The committee therefore recommends that Section 27.301(b)(5) include these entities.
11. The committee notes that Act 102 of 2002 requires that the education and training standards and the practice guidelines established by the board with respect to the administration of injectable medications, biologicals and immunizations include a set of treatment guidelines established by a physician and approved by the board. Section 9.2(a) of the Pharmacy Act. The committee notes the proposed regulation is silent as to this statutory requirement. The committee therefore recommends that "the administration of injectable medications, biologicals and immunizations be in accordance with a definitive set of treatment guidelines established by a physician and approved by the board" as mandated by statute. Section 9.2(a)(3) of the Pharmacy Act.
12. The committee seeks an explanation from the board regarding the board's intention with respect to Section 27.401(b). The committee notes that under the statute the board must establish education and training standards and practice-guidelines. The language of Section 27.401(b) is, however, different than the statutory requirement. If it is the board's intention to establish education and training standards and practice guidelines in this section, then the board should change the language so that the statutory requirements are met. As required by statute, the education and training standards and practice guidelines which the board must establish must include a "definitive set of treatment guidelines established by a physician and approved by the board," as well as "an academic and practical curriculum approved by the board." Section 9.2(a) of the Pharmacy Act.
13. The committee seeks an explanation from the board regarding the board's intention with respect to Section 27.404(c). Is it the board's intention to address the management of drug therapy in an institutional setting pursuant to Section 9.1(f) of the Pharmacy Act? If so, the committee notes the language of Section 27.404(c) does not track the language of Section 9.1(f) of the Pharmacy Act.

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14. With respect to Section 27.405(a) of the proposed regulation, the committee recommends that the words "or identifiable initials" be removed from paragraph (5), and that the words "of provision" be removed from paragraph (6).
15. With respect to Section 27.406, the committee recommends that the rule regarding notification of a physician be changed in paragraphs (1) and (2) with respect to an adverse reaction on the part of the patient. The committee recommends that, in the case of an adverse reaction, the pharmacist notify the physician as soon as is practicable.

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

Sincerely,

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

Thomas P. Gannon
Chairman
Professional Licensure Committee

cc: The Honorable Pedro A. Cortes, Secretary of the Commonwealth
PA Department of State
The Honorable Basil L. Merenda, Commissioner
Bureau of Professional and Occupational Affairs
Cynthia K. Montgomery, Regulatory Counsel
Department of State
Veasey B. Cullen, Jr., D.M.D., M.S., Chairman
State Board of Dentistry
Richard R. Smiga, R.Ph., Chairman
State Board of Pharmacy
Kenyon B. Brown, Chairperson
State Board of Auctioneer Examiners