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House of Representatives
COMMONWEALTH OF PENNSYLVANIA
HARRISBURG

2625

October 3, 2007

Mr. Kim Kaufman
Executive Director
Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, PA 17101

RE: Proposed Regulation 16A-5418
State Board of Pharmacy
Sale of Hypodermic Needles and Syringes

Dear Mr. Kaufman:

The House Professional Licensure Committee on this date voted to take no formal action on Regulation 16A-5418 until final regulation is promulgated and submit the following comments:

1. It is noted that in the Regulatory Analysis Form, the State Board of Pharmacy decided against not placing a limit on the number of syringes available for distribution to a person without a prescription. Instead, 30 is the number of syringes available without prescription. The Committee questions the reasoning behind permitting an individual to purchase 30 syringes. Other states, such as California, Connecticut, Minnesota, and New York all have a limit of ten syringes.
2. The Committee would like to know what method of record keeping will be used to keep track of the number of syringes dispensed to individuals. If there is no method of record keeping, the Committee would like to know the reasoning for foregoing the requirement.
3. Since there is a limit of the number of syringes dispensed, the Committee would like to know if there is a specified time in which a person can purchase these syringes; is it 30 syringes per day, 30 per month, or are 30 syringes the maximum number of syringes a person can purchase in their lifetime without a prescription?

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4. In § 27.12(b)(2), “a pharmacist shall provide direct, immediate, and personal supervision to pharmacy interns and pharmacy technicians. Direct, immediate and personal supervision means that the supervising pharmacist has reviewed the prescription or drug order prior to its being dispensed, has verified the final product and is immediately available on the premises to direct the work of interns and technicians and respond to questions and problems.” However, in the proposed regulation, the standard is lower, requiring only the direct supervision of a pharmacist. The Committee would like to know if there is there a reason for the difference in standards. Presumably the same standard would be consistent with the definitions of the rest of the act, but the Committee requests clarification.

Sincerely,



P. Michael Sturla
Chairman, House Professional Licensure Committee