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House of Representatives
COMMONWEALTH OF PENNSYLVANIA
HARRISBURG

COMMITTEES

PROFESSIONAL LICENSURE,
MAJORITY CHAIRMAN
LIQUOR CONTROL
FIREFIGHTERS' CAUCUS,
COCHAIRMAN EMERITUS

ORIGINAL: 2197

December 21, 2001

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

Dear Chairman McGinley:

This is to advise you that the House Professional Licensure Committee was unable to convene a quorum in time to take formal action on Regulation 16A-444 and Regulation 16A-549. Committee members were forwarded a copy of the regulations and asked that they contact the Chairman with any comments or suggestions, however, none were received. Therefore, the Committee submits no comments.

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

Sincerely,

Mario J. Civera

Mario J. Civera, Chairman
House Professional Licensure Committee

MJC/sms
Enclosures
cc: Jeffrey S. Gerland, D.P.M., Chairperson
State Board of Podiatry
Michael A. Podgurski, R.Ph., Chairperson
State Board of Pharmacy
Honorable Kim H. Pizzingrilli, Secretary of the Commonwealth
Department of State

Regulation 16A-549

State Board of Pharmacy

PROPOSAL: Regulation 16A-549 amends 49 PA Code, Chapter 27, regulations of the State Board of Pharmacy. The amendment deletes the list of the 13 specific reference materials that pharmacies are required to maintain in their reference libraries, and replaces it with language that would allow pharmacies to maintain references that are more appropriate to that pharmacy's area of practice. The amendment would also bring state regulations into accord with federal law regarding the use of facsimile prescriptions as the original prescription for Schedule II controlled substances.

Regulation 16A-549 is Final Rulemaking which was delivered to the Professional Licensure Committee on December 6, 2001. The Professional Licensure Committee has until December 26, 2001 to approve or disapprove the regulation.

ANALYSIS: Proposed Section 27.14(c)(14) would delete the list of 13 specific reference materials from which the current regulation requires a pharmacy to maintain the latest editions of at least two. The Board notes that many references are not listed in the current regulation which are more comprehensive and/or pertinent to current pharmacy practice or more appropriate to a pharmacy's particular area of practice. The Board states that the proposed regulation would eliminate the unnecessary cost of maintaining required, yet unused, references while allowing and encouraging pharmacies to maintain references more pertinent to their area of practice.

Pursuant to current Section 27.20, a pharmacist may fill a prescription for a Schedule II controlled substance received on a facsimile machine, if the original prescription signed by the medical practitioner is presented to the pharmacist prior to dispensing the drug. Currently, the original prescription does not have to be presented before dispensing if the prescription is for an "injectable" Schedule II controlled substance which will be administered in a patient's home or in a hospice, or if it is prescribed for a resident of a long-term care facility. The regulation is consistent with federal law regarding "injectable only" Schedule II drugs in a patient's home, and for all Schedule II drugs in a long term care facility. However, federal law also allows the practice for all Schedule II drugs in hospices. The Board proposes to amend this section to allow this additional exemption.

The Committee noted a public comment forwarded to the Board by Richard B. Greene, R.Ph., regarding the term "Schedule II controlled narcotic substance" in current Sec. 27.20(a)(2)(i) and proposed Sec. 27.20(a)(2)(iii). Mr. Greene indicates that corresponding DEA regulations will be applicable to newer, non-narcotic Schedule II controlled substances. In that regard, the Committee questioned whether the Board should consider removing the word "narcotic" from

these sections. The Board declined to make the change, noting that the word is included in the most current version of the DEA regulations.

The Committee noted another comment of Mr. Greene, that patients often self-administer their medications. In that regard, the Committee questioned whether the Board should consider changing the phrase "which will be administered to" in order to more clearly indicate that self-administration is permitted. The Board has changed the phrase to "for the direct administration to."

In proposed Sec. 27.20(a)(2)(iii), the Committee recommended that the term "hospice patient" be changed to "patient in a hospice." The Board has changed the phrase to "patient enrolled in a hospice care program."

RECOMMENDATIONS: It is recommended that the Professional Licensure Committee approve the regulation.

House of Representatives
Professional Licensure Committee
December 17, 2001