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

July 12, 2001

Honorable Michael A. Podgurski, Chairman
State Board of Pharmacy
116 Pine Street
Harrisburg, PA 17105

Re: Regulation #16A-549 (IRRC #2197)
State Board of Pharmacy
Reference Libraries; Facsimile Machines

Dear Chairman Podgurski:

Enclosed are our Comments. They will soon be available on our website at www.irrc.state.pa.us.

Our Comments list objections and suggestions for consideration when you prepare the final version of this regulation. We have also specified the regulatory criteria which have not been met. These Comments are not a formal approval or disapproval of the proposed version of this regulation.

If you would like to discuss these Comments, please contact my office at 783-5417.

Sincerely,

Robert E. Nyce

Robert E. Nyce
Executive Director
evp
Enclosure
cc: Honorable Mario J. Civera, Jr., Majority Chairman, House Professional Licensure Committee
Honorable William W. Rieger, Democratic Chairman, House Professional Licensure Committee
Honorable Clarence D. Bell, Chairman, Senate Consumer Protection & Professional Licensure Committee
Honorable Lisa M. Boscola, Minority Chairman, Senate Consumer Protection & Professional Licensure Committee
Honorable Kim Pizzingrilli, Secretary, Department of State

Comments of the Independent Regulatory Review Commission

on

State Board of Pharmacy Regulation No. 16A-549

Reference Libraries; Facsimile Machines

July 12, 2001

We submit for your consideration the following objections and recommendations regarding this regulation. Each objection or recommendation includes a reference to the criteria in the Regulatory Review Act (71 P.S. § 745.5a(h) and (i)) which have not been met. The State Board of Pharmacy (Board) must respond to these Comments when it submits the final-form regulation. If the final-form regulation is not delivered by June 11, 2003, the regulation will be deemed withdrawn.

1. Section 27.14. Supplies. – Clarity.

Section 27.14 describes the required materials all pharmacies must have in their reference libraries. We have two concerns with this section. First, Subsection (c)(14)(iii)(A) requires the library to "Enable the pharmacist to compound medications in a *safe and effective manner.*" (Emphasis added.) The phrase "safe and effective manner" is unclear. For clarity, the Board should include examples of what it considers a "safe and effective manner."

Second, Subsection (c)(14) requires a pharmacy to maintain "An adequate reference library...." Subsection (c)(14)(i) also states "A pharmacy shall maintain an adequate reference library...." For greater readability, and less repetition, the Board should consider deleting repeated references to "an adequate reference library" in the final-form regulation.

2. Section 27.20. Facsimile machines. – Consistency with Federal regulations; and Clarity.

This section allows a pharmacist to fill prescriptions for Schedule II controlled substances which are received by a facsimile machine for hospice patients. We have two issues with this section. First, Sections 27.20(a)(2)(i) and (iii) use the phrase "which will be administered to." Did the Board intend to exclude self-administered medications? If not, the phrase "which will be administered to" should be replaced in both subsections with "for the direct administration," the phrase used in the federal regulations.

Second, the phrase "to a hospice patient" in Section 27.20(a)(2)(iii) is inconsistent with the federal regulations. The federal regulations at 21 C.F.R. § 1306.11(g), states that "A prescription...written for a Schedule II narcotic substance for a patient enrolled in a hospice care

program...." For consistency with the federal regulations, the phrase "to a hospice patient" should be replaced with "for a patient enrolled in a hospice care program."