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INDEPENDENT REGULATORY REVIEW COMMISSION

333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

October 24, 2007

Edward J. Bechtel, R.Ph., Chairperson
State Board of Pharmacy
2601 North 3rd Street
Harrisburg, PA 17110

Re: Regulation #16A-5418 (IRRC #2625)
State Board of Pharmacy
Sales of Hypodermic Needles and Syringes

Dear Chairperson Bechtel:

Enclosed are the Commission's comments for consideration when you prepare the final version of this regulation. These comments are not a formal approval or disapproval of the regulation. However, they specify the regulatory review criteria that have not been met.

The comments will be available on our website at www.irrc.state.pa.us. If you would like to discuss them, please contact me.

Sincerely,

Kim Kaufman
Executive Director
wbg
Enclosure

cc: Honorable Robert M. Tomlinson, Chairman, Senate Consumer Protection and Professional Licensure Committee
Honorable Lisa M. Boscola, Minority Chairman, Senate Consumer Protection and Professional Licensure Committee
Honorable P. Michael Sturla, Majority Chairman, House Professional Licensure Committee
Honorable William F. Adolph, Jr., Minority Chairman, House Professional Licensure Committee
Honorable Pedro A. Cortes, Secretary, Department of State

Comments of the Independent Regulatory Review Commission

on

State Board of Pharmacy Regulation #16A-5418 (IRRC #2625)

Sales of Hypodermic Needles and Syringes

October 24, 2007

We submit for your consideration the following comments on the proposed rulemaking published in the August 25, 2007 *Pennsylvania Bulletin*. Our comments are based on criteria in Section 5.2 of the Regulatory Review Act (71 P.S. § 745.5b). Section 5.1(a) of the Regulatory Review Act (71 P.S. § 745.5a(a)) directs the State Board of Pharmacy (Board) to respond to all comments received from us or any other source.

1. Section 27.18. – Protection of the public health, safety and welfare; Need.

Subsection (s)(1) limits the number of hypodermic needles and syringes that may be sold to a person 18 years of age or older without a prescription to 30. In the Regulatory Analysis Form (RAF) submitted with the proposed rulemaking, the Board has indicated that they considered not placing a limit on the number of needles and syringes but decided to place a limit of 30 needles and syringes because each sale is a “teachable moment where counseling can be provided for drug rehabilitation.”

Subsection (s)(3) prohibits the sale of needles and syringes to persons under the age of 18 without a prescription. Several commentators, including Representative Babette Josephs, have questioned the need for this provision. We note that the Board has not provided an explanation for this provision in the RAF or the Preamble to the regulation. We request that the Board explain why the prohibition on sales to persons under the age of 18 is needed and how it protects the health of all citizens of the Commonwealth.

2. Fiscal impact.

The Preamble to the proposed rulemaking notes the following: “It is anticipated that many patients will continue to present a prescription to obtain prescription benefits in paying for hypodermic needles and syringes.” The Pennsylvania Medical Society has suggested a study to determine whether insurers should be mandated to preserve reimbursement for diabetics and people with other medical conditions requiring injected medications. We question how this rulemaking will affect people who currently obtain needles and syringes with a prescription and the assistance of some type of medical insurance. We urge the Board to work with necessary authorities to ensure that this rulemaking does not have a negative fiscal impact on people who obtain needles and syringes with a prescription and the assistance of medical insurance.

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Facsimile Cover Sheet



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

To: Tom Blackburn
Cynthia Montgomery
Agency: Department of State
Licensing Boards and Commissions
Phone: 3-7200 or 3-3394 (Cynthia)
Fax: 7-0251
Date: October 24, 2007
Pages: 3

Comments: We are submitting the Independent Regulatory Review Commission's comments on the State Board of Pharmacy's regulation #16A-5418 (IRRC #2625). Upon receipt, please sign below and return to me immediately at our fax number 783-2664. We have sent the original through interdepartmental mail. You should expect delivery in a few days. Thank you.

Accepted by: Cynthia K. Matz Date: 10/24/07