Regulatory Analysis Form

This space for use by IRRC

(1) Agency

Department of State, Bureau of Professional and Occupational Affairs, State Board of Pharmacy

(2) I.D. Number (Governor's Office Use)

16A-5418

IRRC Number: 2625

(3) Short Title

Sales of Hypodermic Needles and Syringes

(4) PA Code Cite

49 Pa. Code § 27.18(s)

(5) Agency Contacts & Telephone Numbers

Primary Contact: **Carole L. Clarke, Counsel State Board of Pharmacy (717) 783-7200**

Secondary Contact: **Joyce McKeever, Deputy Chief Counsel, Department of State (717) 783-7200**

(6) Type of Rulemaking (check one)

X Proposed Rulemaking
___Final Order Adopting Regulation
___Policy Statement

(7) Is a 120-Day Emergency Certification Attached?

X No
Yes: By the Attorney General
Yes: By the Governor

(8) Briefly explain the regulation in clear and nontechnical language.

The proposed regulation will amend the Board's regulations to allow pharmacists to dispense up to 30 hypodermic needles and syringes to anyone over the age of 18 without a prescription. The proposed regulation also removes outdated reporting requirements and duplicative standards of unprofessional conduct.

(9) State the statutory authority for the regulation and any relevant state or federal court decisions.

The amendment is authorized under Sections 4(j) and 6(k)(1) and (9) of the Pharmacy Act (Act) (63 P.S. §§ 390-(4)(j) and 390-6(k)(1) and (9)).

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(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

No.

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

Distribution of clean hypodermic needles and syringes has been proven to reduce transmission of hepatitis C and HIV without increasing drug use. In 2000, the National Association of Boards of Pharmacy encouraged all boards of pharmacy to revise laws and regulations to permit the sale and distribution of sterile needles and syringes. Pennsylvania is one of only four states that still prohibits the sale of hypodermic needles and syringes without a prescription. Through 2004, Pennsylvania was the seventh leading state reporting the highest number of cumulative AIDS cases among residents, with 30,174 reported cases.

The Board recognizes that there is a compelling public health interest in reducing the spread of hepatitis C and HIV. Removing the requirement that hypodermic needles and syringes only be sold with a prescription in Pennsylvania pharmacies will effectuate this interest. To this end, the Board proposes amending the requirement of a prescription by allowing Pennsylvania pharmacies to sell up to 30 hypodermic needles and syringes to persons 18 years of age or older without a prescription. Persons who use needles and syringes for injecting medications may still obtain more than 30 by presenting a prescription.

(12) State the public health, safety, environmental or general welfare risks associated with nonregulation.

Continuing to restrict access to hypodermic needles and syringes could exacerbate the spread of hepatitis C and HIV.

(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

The general public benefits if the spread of hepatitis C and HIV can be reduced.

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(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effects as completely as possible and approximate the number of people who will be adversely affected.)

There are no perceived groups who will be adversely affected.

(15) List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)

All licensed pharmacies and pharmacists who work in pharmacies that dispense hypodermic needles and syringes will be required to comply with the regulation.

(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

The Pennsylvanians for the Deregulation of Syringe Sales petitioned the Board to initiate rulemaking to remove the requirement of a prescription for dispensing hypodermic needles and syringes. The Board heard testimony relating to removing the prescription requirement from various supporters at the August 16-17, 2005, Board meeting. In developing and drafting the regulation, the Board sent out the draft regulation for pre-draft comment to its list of stakeholders. The Board received several comments from supporters of removing the requirement of a prescription for dispensing hypodermic needles and syringes.

(17) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures which may be required.

It is anticipated that there are no costs or savings to the regulated community.

Regulatory Analysis Form

(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures which may be required.

Local governments would not be affected by this regulation.

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required.

The state could eventually see a savings in health-care programs by reducing the spread of hepatitis C and HIV.

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(20) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS:	**$ N/A**	**$ N/A**	**$ N/A**	**$ N/A**	**$ N/A**	**$ N/A**
Regulated Community						
Local Government						
State Government						
Total Savings						
COSTS:						
Regulated Community	**$N/A**	**$N/A**	**$N/A**	**$N/A**	**$N/A**	**$N/A**
Local Government						
State Government						
Total Costs						
REVENUE LOSSES:	**$N/A**	**$N/A**	**$N/A**	**$N/A**	**$N/A**	**$N/A**
Regulated Community						
Local Government						
State Government						
Total Revenue Losses						

(20a) Explain how the cost estimates listed above were derived.

It is difficult to estimate the costs and savings to the regulated community. There may be additional costs in that pharmacies could dispense more hypodermic needles and syringes than they currently do. However, any additional costs in acquiring additional needles and syringes will most likely be offset by income from the sale of those needles and syringes. It is also difficult to estimate the costs and savings to government.

Regulatory Analysis Form

(20b) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY -3	FY -2	FY -1	Current FY
Pharmacy Board	**$1,389,387.68**	**$1,619,513.81**	**$1,532,828.53**	**$1,850,000.00**

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

The benefits described above associated with increased access to hypodermic needles and syringes and the reduction in the spread of Hepatitis C and HIV outweighs the minimal adverse effects and costs. Studies show that increased access to clean needles does not result in an increase in the amount of drug use.

(22) Describe the nonregulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

Nonregulatory alternatives were not considered because amending the regulations is necessary to accomplish the goal of more accessibility to hypodermic needles and syringes

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

The only alternative regulatory scheme considered by the Board was not placing a limit on the number of hypodermic needles and syringes that can be dispensed at any one time. The Board dismissed that scheme and adopted a limit of 30 needles and syringes because each time someone comes to a pharmacy to purchase hypodermic needles and syringes is a teachable moment where counseling can be provided for drug rehabilitation.

Regulatory Analysis Form

(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulation.

No.

(25) How does this regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

Pennsylvania is one of the last states in the country to remove the requirement of a prescription for dispensing hypodermic needles and syringes. The following are comparable regulatory provisions regarding needle and syringe sales in neighboring states:

State	Restriction
New York	Pharmacies may sell 10 or fewer syringes without a prescription.
New Jersey	Requires a prescription.
Delaware	Requires a prescription.
Ohio	No prescription required, no limit on the number of needles and syringes sold.
West Virginia	No prescription required, no limit on the number of needles and syringes sold.
Maryland	No prescription required, no limit on the number of needles and syringes sold.

(26) Will the regulation affect existing or proposed regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

The proposed regulation should not affect any existing or proposed regulation of this agency. The proposed regulation may conflict with section 13(a)(33) of the Controlled Substance, Drug, Device and Cosmetic Act. However the Board sent a pre-draft copy of the annex to the Pennsylvania District Attorneys Association and received no comment from them. The Board also received comment from the Attorney General opposing the policy behind this proposal, but did not oppose based on a legal objection.

(27) Will any public hearings or informational meetings be scheduled? Please provide the dates, times, and locations, if available.

The Board provides an opportunity for public input into its activities, including its rulemaking proposals, at its regularly scheduled monthly meetings. The dates, times and locations of the Board's meetings are available at the Department of State's website, www.state.pa.us/bpoa.

Regulatory Analysis Form

(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports which will be required as a result of implementation, if available.

It will change the current requirement to report the sale of accessories found in illegal traffic when sold in unusually large quantities. However, the current Executive Secretary to the Board has never received such a report from any licensee.

(29) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

The Board has not identified particular needs for which special provisions need to be developed or anticipated in connection with the proposed regulation.

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

The proposed regulation will be effective upon final publication in the Pennsylvania Bulletin.

(31) Provide the schedule for continual review of the regulation.

The Board will review the effectiveness of this regulation as part of its annual review of its fiscal operations.

CDL-1

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

2625

DO NOT WRITE IN THIS SPACE

Copy below is hereby approved as to form and legality. Attorney General

BY: Amy M. Elliott
(DEPUTY ATTORNEY GENERAL)

JUN 12 2007
DATE OF APPROVAL

[ ] Check if applicable
Copy not approved.
Objections attached.

Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:

State Board of Pharmacy
(AGENCY)

DOCUMENT/FISCAL NOTE NO. 16A-5418

DATE OF ADOPTION:

BY: Edward J. Bechtel, R.Ph.

TITLE: Chairman
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

Copy below is approved as to form and legality. Executive or Independent Agencies.

BY: Andrew C. Clark

MAR 5 2007
DATE OF APPROVAL

(Deputy General Counsel
~~(Strike inapplicable title)~~

[ ] Check if applicable. No Attorney General approval or objection within 30 day after submission.

PROPOSED RULEMAKING
COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF PHARMACY
49 PA. CODE, CHAPTER 27
SALES OF HYPODERMIC NEEDLES AND SYRINGES

The State Board of Pharmacy (Board) proposes to amend §27.18 (relating to standards of practice) to read as set forth in Annex A. The proposed rulemaking would alter the current requirements relating to the sale of hypodermic needles and syringes in pharmacies. The proposed rulemaking would permit a pharmacist to sell up to 30 hypodermic needles and syringes to persons 18 years of age or older without a prescription.

Effective Date

The amendments will be effective upon final-form publication in the Pennsylvania Bulletin.

Statutory Authority

The amendments are authorized under Sections 4(j) and 6(k)(1) and (9) of the Pharmacy Act (act) (63 P.S. §§ 390-(4)(j) and 390-6(k)(1) and (9)).

Background and Need for Amendment

In February 2005, Pennsylvanians for the Deregulation of Syringe Sales petitioned the Board under authority of 1 Pa. Code §35.18 (relating to petition for issuance, waiver or deletion of regulations) to amend its regulation at §27.18(s)(2) to eliminate the prescription requirement for the sale of hypodermic needles and syringes. The Board subsequently heard testimony in support of the proposed amendment at its August 16-17, 2005, meeting from Dr. Scott Burris of Pennsylvania Coalition to Save Lives Now; Renee Cox of Prevention Point Pittsburgh; and Janice Kopelman, Director of the Pennsylvania Department of Health's Bureau of Communicable Diseases.

Under the current regulation, which has not been revised for a number of years, the sale of hypodermic needles and syringes in Pennsylvania pharmacies may only occur pursuant to the presentation of a prescription. More recently, studies have shown that increased access to clean needles and syringes has been proven to reduce the transmission of hepatitis C and HIV (Human Immunodeficiency Virus). The evidence also suggests that drug use will not increase if the prescription requirement is removed. See, Douglas A. McVay, (ed.). Drug War Facts 2006, (citing National Commission on AIDS, The Twin Epidemics of Substance Abuse and HIV (Washington DC: National Commission on AIDS, 1991); General Accounting Office, Needle Exchange Programs: Research Suggests Promise as an AIDS Prevention Strategy (Washington DC: US Government Printing Office, 1993); Lurie, P. & Reingold, A.L., et al., The Public Health Impact of Needle Exchange Programs in the United States and Abroad (San Francisco, CA: University of California, 1993); Satcher, David, MD, (Note to Jo Ivey Bouffard), The Clinton Administration's

Internal Reviews of Research on Needle Exchange Programs (Atlanta, GA: Centers for Disease Control, December 10, 1993); National Research Council and Institute of Medicine, Normand, J., Vlahov, D. & Moses, L. (eds.), Preventing HIV Transmission: The Role of Sterile Needles and Bleach (Washington DC: National Academy Press, 1995); Office of Technology Assessment of the U.S. Congress, The Effectiveness of AIDS Prevention Efforts (Springfield, VA: National Technology Information Service, 1995); National Institutes of Health Consensus Panel, Interventions to Prevent HIV Risk Behaviors (Kensington, MD: National Institutes of Health Consensus Program Information Center, February 1997).

In 2000, the National Association of Boards of Pharmacy encouraged all boards of pharmacy to revise laws and regulations to permit the sale and distribution of sterile needles and syringes. Pennsylvania is one of only four states that still prohibit the sale of hypodermic needles and syringes in pharmacies without a prescription. Through 2004, Pennsylvania was the seventh leading state reporting the highest number of cumulative AIDS cases among residents, with 30,174 cases. See, Centers for Disease Control and Prevention, *HIV/AIDS Surveillance Report, 2004*, Vol. 16. Atlanta: US department of Health and Human Services, Centers for Disease Control and Prevention; 2005: page 27. (Also available at: http://www.cdc.gov/hiv/stats/hasrlink.htm.)

The Board recognizes that there is a compelling public health interest in reducing the spread of hepatitis C and HIV. Increased access to clean needles and syringes is essential to this interest. The studies have shown that removing the requirement that hypodermic needles and syringes only be sold with a prescription in Pennsylvania pharmacies would not lead to increased drug use. To this end, the Board proposes amending the prescription requirement by permitting Pennsylvania pharmacists to sell up to 30 hypodermic needles and syringes to persons 18 years of age or older without a prescription. Persons who use hypodermic needles and syringes for injecting medications may still obtain more than 30 by presenting a prescription. It is anticipated that many patients will continue to present a prescription in order to obtain prescription benefits in paying for hypodermic needles and syringes.

Description of Proposed Amendments

The proposed amendments would amend § 27.18(s)(2) to eliminate the requirement that a prescription be presented in all cases for a pharmacist to sell hypodermic needles and syringes to persons 18 years of age and older. Further, the proposed amendments would require that these needles and syringes be kept in the prescription area of the pharmacy. The current regulations at § 27.1 (relating to definitions) define the prescription area as the area of the pharmacy used for compounding, legend drug storage and other activities necessary to the practice of pharmacy. The term does not include waiting counters or display space attached to the waiting counter. Hypodermic needles and syringes would have to be stored behind the counter and accessible only by pharmacists

and pharmacy personnel authorized to be behind the counter while the pharmacy is open. Anyone under 18 would still need to present a prescription to purchase hypodermic needles and syringes in a pharmacy.

The proposed amendments would also remove the current § 27.18(s)(1), which requires pharmacists to report to the Board the sale of accessories found in illegal traffic when sold in unusually large quantities; as well as the language that deems it unprofessional conduct to sell, give away or otherwise dispose of accessories, chemicals or proprietary products when the pharmacist knows or has reason to know of their intended use for illegal purposes. The Board proposes to remove this language because it has not served as the basis for disciplinary action in the recent history of the Board, nor has the Board received any report as currently required by this section. The reporting requirement is unenforceable and counterintuitive to the goal of the proposed amendments. The language that deems it unprofessional conduct to sell, give away or otherwise dispose of accessories, chemicals or proprietary products when the pharmacist knows or has reason to know of their intended use for illegal purposes is also counterintuitive to the goal of the proposed amendments. Furthermore, it is duplicative in that §27.18(u), provides that a violation of The Controlled Substance, Drug, Device and Cosmetic Act or the rules and regulations promulgated thereunder constitutes a violation of the Board's regulations and the act.

The Department of Health recommended that the Board also require pharmacies to distribute information on safe needle disposal. The Board declined to include this in the proposed rulemaking, but will work with the Department of Health to alert pharmacies of available literature and safe needle disposal practices.

Fiscal Impact

The proposed regulation will have no fiscal impact on the Board or the regulated community.

Paperwork Requirements

The proposed regulation will impose no paperwork requirements on the Board or the regulated community.

Sunset Date

The Board monitors its regulations on an ongoing basis. Therefore, no sunset date has been assigned.

Regulatory Review

Under Section 5(a) of the Regulatory Review Act (71 P.S. §745.5(a)), on August 15, 2007, the Board submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the Senate Consumer Protection and Professional Licensure Committee and the House Professional Licensure Committee. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey any comments, recommendations or objections regarding the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections must specify the regulatory review criteria that have not been met. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the rulemaking, by the Board, the General Assembly, and the Governor of comments, recommendations or objections raised.

Public Comment

Interested persons are invited to submit written comments, recommendations or objections regarding this proposed rulemaking to Melanie Zimmerman, Executive Secretary, State Board of Pharmacy, P.O. Box 2649, Harrisburg, Pennsylvania 17105-2649, within 30 days following publication of this proposed rulemaking in the Pennsylvania Bulletin.

Edward J. Bechtel, R.Ph.
Chairperson

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 27. STATE BOARD OF PHARMACY

STANDARDS

* * * * *

§ 27.18. Standards of practice.

* * * * *

(s) [The following provisions are applicable to paraphernalia and accessories:

(1) Sale of accessories, such as empty capsules, quinine, sugar of milk or a similar product found in illegal traffic when sold in unusually large quantities shall be immediately reported to the Board. A pharmacist who sells, gives away or otherwise disposes of accessories, chemicals or proprietary products when the pharmacist knows or has reason to know of their intended use for illegal purposes shall be guilty of unprofessional conduct and in violation of this chapter.

(2) Sales of needles and syringes shall be made by the pharmacist only to persons showing a prescription issued by a licensed practitioner. The prescription shall be in force for a maximum of 1 year from date of its issuance. This subsection shall take effect 3 months after the other provisions of this chapter take effect in order to give the public ample notice.]

Sales of hypodermic needles and syringes shall be made by a pharmacist or under the direct supervision of a pharmacist in accordance with the following:

(1) Up to 30 hypodermic needles and syringes may be sold to persons 18 years of age or older without a prescription.

(2) Sales of over 30 hypodermic needles and syringes shall be made only to persons presenting a prescription issued by a licensed practitioner.

(3) Sales of hypodermic needles and syringes may not be made to persons under 18 years of age without a prescription.

(4) All hypodermic needles and syringes must be kept in the prescription area of the pharmacy, as defined in § 27.1 (relating to definitions), and must be accessible only by pharmacists and pharmacy personnel authorized to be in the prescription area of the pharmacy while the pharmacy is open.

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF PHARMACY
Post Office Box 2649
Harrisburg, Pennsylvania 17105-2649
(717) 783-7156

August 15, 2007

The Honorable Arthur Coccodrilli, Chairman
INDEPENDENT REGULATORY REVIEW COMMISSION
14th Floor, Harristown 2, 333 Market Street
Harrisburg, Pennsylvania 17101

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

Dear Chairman Coccodrilli:

Enclosed is a copy of a proposed rulemaking package of the State Board of Pharmacy pertaining to the sale of hypodermic needles and syringes.

The Board will be pleased to provide whatever information the Commission may require during the course of its review of the rulemaking.

Sincerely,

Edward J. Bechtel, R.Ph., Chairperson
State Board of Pharmacy

EJB/CLC:klh
Enclosure
cc: Basil L. Merenda, Commissioner
Bureau of Professional and Occupational Affairs
Albert H. Masland, Chief Counsel
Department of State
Joyce McKeever, Deputy Chief Counsel
Department of State
Cynthia Montgomery, Regulatory Counsel
Department of State
Gerald S. Smith, Senior Counsel in Charge
Department of State
Carole L. Clarke, Counsel
State Board of Pharmacy
State Board of Pharmacy

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER:	16A-5418
SUBJECT:	SALES OF HYPODERMIC NEEDLES AND SYRINGES
AGENCY:	DEPARTMENT OF STATE STATE BOARD OF PHARMACY

TYPE OF REGULATION

X Proposed Regulation

Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

Delivery of Tolled Regulation
a. With Revisions b. Without Revisions

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
8/13/07		HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
		SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
8/15/07		INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
8/15/07		LEGISLATIVE REFERENCE BUREAU (for Proposed only)