Regulatory Analysis Form

(Completed by Promulgating Agency)

IRRC

Independent Regulatory Review Commission

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INDEPENDENT REGULATORY REVIEW COMMISSION

SECTION I: PROFILE

(1) Agency:

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

(2) Agency Number:

Identification Number:

16A-5418

IRRC Number: 2625

(3) Short Title:

Sales of hypodermic syringes and needles

(4) PA Code Cite:

49 Pa. Code § 27.18(s)

(5) Agency Contacts (List Telephone Number, Address, Fax Number and Email Address):

Primary Contact: **Carole L. Clarke, Board Counsel, Department of State; (717)783-7200; P.O. Box 2649, Harrisburg, PA 17105-2649; (717)787-0251; caclarke@state.pa.us**

Secondary Contact: **Joyce McKeever, Deputy Chief Counsel, Department of State (717)783-7200; P.O. Box 2649, Harrisburg, PA 17105-2649; (717)787-0251; jmckeever@state.pa.us**

(6) Primary Contact for Public Comments (List Telephone Number, Address, Fax Number and Email Address) – Complete if different from #5: **State Board of Pharmacy (717)783-7156; P.O. Box 2649, Harrisburg, PA 17105-2649; (717)787-7769; st-pharmacy@state.pa.us**

(All Comments will appear on IRRC'S website)

(7) Type of Rulemaking (check applicable box):

- ☐ Proposed Regulation
- X Final Regulation
- ☐ Final Omitted Regulation
- ☐ Emergency Certification Regulation;
  - ☐ Certification by the Governor
  - ☐ Certification by the Attorney General

Regulatory Analysis Form

(8) Briefly explain the regulation in clear and nontechnical language. (100 words or less)

The rulemaking will amend the Board's regulations to allow pharmacists to dispense hypodermic needles and syringes without a prescription. The rulemaking also removes outdated reporting requirements and duplicative standards of unprofessional conduct.

(9) Include a schedule for review of the regulation including:

A. The date by which the agency must receive public comments: Sept. 24, 2007

B. The date or dates on which public meetings or hearings will be held: N/A

C. The expected date of promulgation of the proposed regulation as a final-form regulation: by September 24, 2009

D. The expected effective date of the final-form regulation: upon publ. as final

E. The date by which compliance with the final-form regulation will be required: effective date

F. The date by which required permits, licenses or other approvals must be obtained: N/A

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

The Board continually reviews the efficacy of its regulations, as part of its annual review process under Executive Order 1996-1. The Board reviews its regulatory proposals at regularly scheduled public meetings, generally the third Tuesday of each month. More information can be found on the Board's website (www.dos.state.pa.us/pharmacy).

SECTION II: STATEMENT OF NEED

(11) State the statutory authority for the regulation. Include specific statutory citation.

This rulemaking is authorized by sections 4(j), and 6(k)(1) and 6(k)(9) of the Pharmacy Act (act) (63 P.S. §§ 390-4(j), 390-6(k)(1) and 390-6(k)(9)).

(12) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.

The rulemaking is not mandated by any federal or state law or court order or federal regulation. There are no relevant state or federal court decisions.

(13) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

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 three states that still prohibit 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 hypodermic needles and syringes without a prescription.

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

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

(14) If scientific data, studies, references are used to justify this regulation, please submit material with the regulatory package. Please provide full citation and/or links to internet source.

As noted in the proposed preamble the following materials support this regulation: 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). As this information is voluminous copies will be provided upon request. Information on studies used to support this regulation can be found at http://www.dogwoodcenter.org/science/20science.html.

(15) Describe who and how many will be adversely affected by the regulation. How are they affected?

The Board does not anticipate that any groups will be adversely affected by the rulemaking.

(16) 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 pharmacists and pharmacies that dispense hypodermic needles and syringes will be required to comply with the rulemaking. The Board licenses approximately 18,426 pharmacists and 3,364 pharmacies.

SECTION III: COST AND IMPACT ANALYSIS

(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. Explain how the dollar estimates were derived.

There are no costs or savings to the regulated community associated with compliance with the rulemaking.

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. Explain how the dollar estimates were derived.

The rulemaking should result in an unquantifiable savings to health-care programs by reducing the spread of hepatitis C and HIV. There are no other costs or savings to local governments associated with compliance with the rulemaking.

(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. Explain how the dollar estimates were derived.

The rulemaking should result in an unquantifiable savings to health-care programs by reducing the spread of hepatitis C and HIV. There are no other costs or savings to state government associated with compliance with the rulemaking.

(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:	$	$	$	$	$	$
Regulated Community						
Local Government						
State Government						
Total Savings	NA	NA	NA	NA	NA	NA
COSTS:						
Regulated Community						
Local Government						
State Government						
Total Costs	NA	NA	NA	NA	NA	NA
REVENUE LOSSES:						
Regulated Community						
Local Government						
State Government						

Total Revenue Losses	**NA**	**NA**	**NA**	**NA**	**NA**	**NA**

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

Program	FY –3 (FY 05-06) actual	FY –2 (FY 06-07) actual	FY –1 (FY 07-08) actual	Current FY (FY 08-09) budget
Pa. State Board of Pharmacy	**$1,434,730**	**$1,683,729**	**$1,751,209**	**$1,889,000**

(21) Explain how the benefits of the regulation outweigh any cost and adverse effects.

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 communications with and input from the public and any advisory council/group in the development and drafting of the regulation. List the specific persons and/or groups who were involved.

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. The Board considered all these comments in preparing the proposed rulemaking.

After publication of the proposed rulemaking, the Board discussed all comments at public meetings of the Board, which are routinely attended by members of the regulated community and their professional associations.

(23) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

The only alternative regulatory scheme considered by the Board was 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 final rulemaking package that has no limit as commentators convinced the Board that the limit served no compelling public health interest.

(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 regulations.

This rulemaking will not be more stringent and will not overlap or conflict with any federal requirements.

(25) How does this regulation compare with those of other states? How will this affect Pennsylvania's ability to compete 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.

This rulemaking will not put Pennsylvania at a competitive disadvantage.

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

The rulemaking should not affect any existing or proposed regulation of this agency or other state agencies.

(27) Submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

This rulemaking 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.

The rulemaking will not otherwise require any additional recordkeeping or other paperwork.

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(28) 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 determined that there are no special needs of any subset of its applicants or licensees for whom special accommodations should be made.

CDL-1

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

DO NOT WRITE IN THIS SPACE

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

BY: _____
(DEPUTY ATTORNEY GENERAL)

_____
DATE OF APPROVAL

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: Michael A. Podgurski
Michael A. Podgurski, R.Ph.

TITLE: Chairperson
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

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

BY: Andrew C. Clark

MAY 13 2009
DATE OF APPROVAL

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

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

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

FINAL RULEMAKING
COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF PHARMACY

49 Pa. Code §27.18
SALES OF HYPODERMIC SYRINGES AND NEEDLES

The State Board of Pharmacy (Board) adopts amendments to § 27.18, (relating to standards of practice) to read as set forth in Annex A. The regulation alters the requirements regarding the sale of hypodermic needles and syringes in pharmacies.

Notice of Proposed Rulemaking was published at 37 Pa.B. 4652 (August 25, 2007). Publication was followed by a 30-day public comment period. The Board received comments from the National Association of Social Workers, the Pennsylvanians for the Deregulation of Syringe Sales, the Pennsylvania Medical Society (PMS), Allegheny General Hospital, Pittsburgh AIDS Task Force (PATF), Prevention Point Pittsburgh, Southwestern Pennsylvania AIDS Planning Coalition (SWPAPC), Montefiore Medical Center, the AIDS Law Project of Pennsylvania, Representative Babette Josephs, Valley Forge Medical Center & Hospital, the University of Pittsburgh Program for Health Care to Underserved Populations, the Student Global AIDS Project of the University of Pittsburgh, the American Civil Liberties Union of Pennsylvania, Reading Risk Reduction, the American Liver Foundation, the Pennsylvania Pharmacists Association and many individual commentators. The House Professional Licensure Committee (HPLC) submitted four comments to the proposed rulemaking on October 3, 2007. The Senate Consumer Protection and Professional Licensure Committee made no comments. The Independent Regulatory Review Commission (IRRC) submitted two comments to the proposed rulemaking on October 24, 2007.

Summary of Comments and Responses to Proposed Rulemaking

Age Requirement

IRRC and several other commentators questioned the need for the provision in the proposed regulation that prohibited the sale of needles and syringes to persons under the age of 18 without a prescription. Upon review of the comments the Board has reconsidered this provision and removed it in the final rulemaking. While some commentators wrote to support the age limitation, the Board ultimately decided that the limitation served no compelling public health interest.

Limitation on Number of Syringes and Needles Dispensed

PATF, Prevention Point Pittsburgh, SWPAPC, and other individual commentators wrote to encourage the Board to consider removing the restriction on the number of syringes that can be purchased at one time. HPLC questioned the provision in the proposed rulemaking that placed a limit of 30 on the number of syringes that could be dispensed without a prescription. HPLC noted that other states have limits of ten syringes and needles. The Board initially chose 30, as they believed that ten was too few to dispense at one time. However upon reading the comments the Board decided to remove the limitation altogether bringing the regulation in line with the majority of states that have no limit on the number of syringes dispensed without a prescription. HPLC also asked for information about whether the 30-syringe limitation would be for a specified time period. Having chosen to remove this limitation this question is now moot.

Record Keeping

HPLC also questioned what type of record keeping would be used to track the number of syringes dispensed to individuals. The Board is not imposing a record keeping requirement. The

Board does not believe that maintaining a record and requiring individuals to provide their name or other identifying information would advance the public health and safety. In fact such a requirement could act to deter individuals from purchasing needles and syringes in a pharmacy.

Supervision

HPLC commented that the proposed regulation required direct supervision by a pharmacist while the Board's regulation at § 27.12(b)(2) (relating to practice of pharmacy and delegation of duties) requires direct, immediate and personal supervision. HPLC requested clarification of the two different standards. The Board meant to have the same standard as is used for all auxiliary personnel and has changed the language in the final rulemaking package to require direct, immediate and personal supervision by a pharmacist.

Insurance Coverage

PMS suggested a study to determine whether insurers should be mandated to preserve reimbursement for diabetics and people with other medical conditions requiring injected medications. IRRC urged 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. The Board does not have the resources or funds to conduct such a study; moreover, the Board does not regulate or mandate insurance coverage for any prescription items. However, the Board notes that insulin is not a prescription item but is still generally covered by medical insurance.

Miscellaneous

PMS expressed concern regarding the proposed regulation and stated that it could not support the regulation until several qualifications were studied. The first qualification that PMS noted was that the proposed regulations not act to increase the number of IV drug users. As stated in the proposed Preamble several studies clearly indicate no increase in the number of IV drug users following the adoption of similar regulations in other states. No further studies have been published since the proposed rulemaking. Therefore the Board is confident that the change in this regulation will not act to do so in the Commonwealth. PMS next noted that syringe exchange programs should be bolstered to encourage intravenous drug users to become drug free. The Board supports the premise of recovery and rehabilitation for anyone addicted to any kind of drug. However, the Board notes that it does not have purview over syringe exchange programs. PMS next noted that pharmacies should be required to provide materials that educate illicit drug users about the associated risks and encourage drug use withdrawal, and education resources are made available throughout the state. The Board considered this idea when drafting the proposed regulation but chose not to put in a regulatory requirement. Instead the Board is working with the Pennsylvania Department of Health to make available to pharmacies pamphlets on topics such as addiction, HIV/AIDS, and cocaine. Information about how to obtain these materials will be available on the Board's website upon final publication of the regulation. The next qualification PMS noted was that syringes should be kept in the prescription area of the pharmacy. The proposed regulation required that needles and syringes be kept in the prescription area and that requirement has not changed in the final rulemaking.

PMS next noted that drug paraphernalia laws should be reviewed and changed to accommodate the proposal. The Board believes that no change in the laws pertaining to drug paraphernalia is necessary to implement the regulation. Needles and syringes are not per se drug paraphernalia. Drug paraphernalia is defined in the Controlled Substance, Drug, Device and Cosmetic Act (Drug Act), in pertinent part, as, "all equipment, products and materials of any kind which are used, intended for use or designed for use in...injection...or otherwise introducing into the human body a controlled substance in violation of this act. It includes, but is not limited to...(11) Hypodermic syringes, needles and other objects used, intended for use, or designed for use in parenterally injected controlled substances into the human body." Determination of whether an object is drug paraphernalia depends on the intent of the person distributing the object. To be classified as drug paraphernalia the distributor must have the specific intent that the item be used with controlled substances. *Commonwealth v. Lacey*, 344 Pa.Super. 576, 582, 496 A.2d 1256 (1985). "The [Drug] Act includes a specific intent requirement to distinguish innocent transfers of multi-purpose items from illegal transfers of drug paraphernalia." *Id.* Specific intent means that it is not just foreseeable that the material will be used to inject controlled substances in violation of the Drug Act, but that is the purpose, object, plan, or goal of the person distributing the needle or syringe. Needles and syringes have many lawful uses including injecting insulin, allergy serums, fertility drugs, blood thinners, migraine medications, Epinephrine, lawfully prescribed steroids, vitamins and other additives in total parenteral nutrition, and use in home IV therapy. It can be argued that the specific intent of a pharmacist is to distribute syringes to use in conformity with law. Pharmacists cannot be held to reasonably know or believe that anyone purchasing needles and syringes without a prescription is using them to inject controlled substances. PMS also noted that the age limit and number of syringes should be eliminated as restrictions. The Board agrees and has amended the final rulemaking to eliminate those restrictions. Finally, PMS stated that more information be gathered from other states where needles and syringes are available over the counter regarding how they address the above-mentioned issues and their results. The Board has been monitoring this topic going back to 2002. Since the Board first undertook this regulation package Pennsylvania is now one of only three states to still have a prescription requirement. The first states to remove this requirement did so back in the 1990's. The Board has gathered volumes of information about the efficacy of removing the requirement of a prescription to obtain needles and syringes in a pharmacy and is confident that it is prepared to address any issues that may arise with the amendment of the Board's regulations.

Several commentators wrote solely to express their support of the proposed regulations. These commentators included medical practitioners and educators. The Board thanks these commentators for their time and efforts in supporting this important regulation.

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), 390-6(k)(1), and (9)).

Fiscal Impact and Paperwork Requirements

The final-form rulemaking will have no fiscal impact on the Board or the regulated community.

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 the notice of proposed rulemaking, published at 37 Pa.B. 4652 (August 25, 2007), to IRRC and the Chairpersons of the House Professional Licensure Committee (HPLC) and the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) for review and comment.

Under section 5(c) of the Regulatory Review Act, IRRC, the HPLC and the SCP/PLC were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Board has considered all comments from IRRC, the HPLC, the SCP/PLC and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P. S. § 745.5a(j.2)), on _____, the final-form rulemaking was approved by the HPLC. On _____, the final-form rulemaking was deemed approved by the SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on _____, and approved the final-form rulemaking.

Additional Information

Individuals who need information about the regulation may contact Melanie Zimmerman, R.Ph., Executive Secretary, State Board of Pharmacy, P.O. Box 2649, Harrisburg, PA 17105-2649.

Findings

The State Board of Pharmacy finds that:

(1) Public notice of intention to adopt a regulation at 49 Pa.Code, Chapter 27, was given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201 and 1202) and the regulations promulgated under those sections at 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law and all comments were considered.

(3) This final rulemaking of the State Board of Pharmacy is necessary and appropriate for the administration of the Pharmacy Act.

(4) The amendments to this final rulemaking do not enlarge the original purpose of the proposed regulation published at 37 Pa.B. 4652 (August 25, 2007).

Order

The Board therefore ORDERS that:

(A) The regulations of the Board, 49 Pa. Code Chapter 27, are amended to read as set forth in Annex A.

(B) The Board shall submit this Order and a copy of Annex A to the Office of Attorney General and the Office of General Counsel for approval as required by law.

(C) The Board shall certify this Order and Annex and shall deposit them with the Legislative Reference Bureau as required by law.

(D) This Order shall take effect upon publication in the Pennsylvania Bulletin.

Michael A. Podgurski, R.Ph.
Chairman, State Board of Pharmacy

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, IMMEDIATE AND PERSONAL supervision of a pharmacist in accordance with the following:

(1) ~~Up to 30 hypodermic~~ 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)~~ Hypodermic needles and syringes shall be kept in the prescription area of the pharmacy, as defined in § 27.1 (relating to definitions), and 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

DATE: **March 6, 2009**

SUBJECT: **Final Rulemaking:**
State Board of Pharmacy
Sales of hypodermic syringes and needles (16A-5418)

TO: **Andrew C. Clark, Deputy General Counsel**
Office of General Counsel

FROM: **Carole L. Clarke, Board Counsel** CLC
State Board of Pharmacy

Other than as discussed in the preamble, there are no significant legal and policy issues presented by this amendment to the regulations of the State Board of Pharmacy concerning sales of hypodermic syringes and needles.

I certify that I have reviewed this regulation for form and legality, that I have discussed any legal and policy issues with the administrative officers responsible for the program, and that all information contained in the Preamble and Annex is correct and accurate.

CLC

Commentators
Reg. 16A-5418

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

June 5, 2009

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

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

Dear Chairman Coccodrilli:

Enclosed is a copy of a final rulemaking package of the State Board of Pharmacy pertaining to 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,

Michael A. Podgurski, R. Ph, Chairperson
State Board of Pharmacy

MAP/CLC:rs
Enclosure
cc: Basil L. Merenda, Commissioner
Bureau of Professional and Occupational Affairs
Peter V. Marks, Executive Deputy Chief Counsel
Department of State
Joyce McKeever, Deputy Chief Counsel
Department of State
Cynthia Montgomery, Regulatory Counsel & Senior Counsel in Charge
Department of State
Carole A. 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 SYRINGES AND NEEDLES
AGENCY:	DEPARTMENT OF STATE STATE BOARD OF PHARMACY

TYPE OF REGULATION

Proposed Regulation

X 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

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INDEPENDENT REGULATORY REVIEW COMMISSION

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
6/5/09	Elaine D. Nichols	HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
		MAJORITY CHAIRMAN Michael P. McGeehan
		SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
6/5/09	M Armstrong	MAJORITY CHAIRMAN Robert M. Tomlinson
6/5/09	Kathy Cooper	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
		LEGISLATIVE REFERENCE BUREAU (for Proposed only)