

<h1>Regulatory Analysis Form</h1>		This space for use by IRRC RECEIVED 2007 FEB 21 AM 11:21 INDEPENDENT REGULATORY REVIEW COMMISSION
(1) Agency Department of State, Bureau of Professional and Occupational Affairs, State Board of Pharmacy		IRRC Number: 2593
(2) I.D. Number (Governor's Office Use) 16A-5415		
(3) Short Title Supplies and Equipment		
(4) PA Code Cite 49 Pa. Code, §§ 27.14, 27.16	(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) <input checked="" type="checkbox"/> Proposed Rulemaking <input type="checkbox"/> Final Order Adopting Regulation <input type="checkbox"/> Policy Statement	(7) Is a 120-Day Emergency Certification Attached? <input checked="" type="checkbox"/> No Yes: By the Attorney General Yes: By the Governor	
(8) Briefly explain the regulation in clear and nontechnical language. <p>The proposed regulation will amend §27.14 by deleting the list of supplies pharmacies are required to maintain. The proposed regulation keeps the requirement to have a refrigerator, but amends the language to clearly state that the refrigerator is for storing drugs only. The amendment proposes to replace the list of supplies with language that allows a pharmacy to maintain equipment consistent with its scope of practice.</p> <p>The proposed regulation also amends §27.16 by deleting the specific measurement requirement of the pharmacy sink.</p>		
(9) State the statutory authority for the regulation and any relevant state or federal court decisions. <p>The proposed regulation is authorized by sections 4(j) and 6(k)(1) and (9) of the Pharmacy Act, 63 P.S. §§ 390-4(j) and 390-6(k)(1) and (9).</p>		

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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?

The proposed regulation deletes outdated supplies and equipment requirements. Today many pharmacies have specialized practice areas and do not need all the supplies and equipment currently required by the regulations. The proposed regulation will allow pharmacies to maintain only that equipment that is necessary for their scope of practice. The proposed regulation also deletes the requirement that the pharmacy sink be a certain size. Considering the purposes that the sink is used for, such as hand washing and cleaning compounding equipment, it is unnecessary to specify that the sink be a certain size when a much smaller sink would suffice.

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

Nonregulation of pharmacists and pharmacies increases the risk of substandard pharmacy care, which may adversely affect public health.

(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 regulated community will benefit from not having to purchase and maintain unnecessary and unused supplies and equipment.

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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 people or groups of people who will be adversely affected by the proposed regulation.

(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.)

The approximately 3,160 licensed pharmacies in the Commonwealth 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.

In developing and drafting the regulation, the Board obtained input from stakeholders by written correspondence and open work sessions.

(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.

Pharmacies will no longer have to purchase supplies and equipment that go unused, therefore it is anticipated that there will be a 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.

There is no cost/savings to the Board associated with implementation of this regulation.

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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:						
Regulated Community						
Local Government						
State Government						
Total Revenue Losses						

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

There are no costs associated with this regulation. There may, however, be some savings. Currently a pharmacy must maintain the required supplies and equipment whether or not they are actually used. The regulated community may actually save money because a pharmacy will not be mandated to purchase and maintain unused required supplies and equipment. However, those savings, if any, are not known at this time.

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	\$1,619,513.81	\$1, 532,000.53	\$1,423,782.19	\$1,788,000.00

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

There are no adverse effects and costs associated with this regulation. Pharmacies will benefit because they will no longer be required to maintain supplies and equipment that they do not use, thus resulting in a possible savings.

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

No nonregulatory approaches were considered. Amending the regulations is the only way to delete the specific list of supplies and equipment.

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

No alternative regulatory schemes were considered. Amending these specific regulations is the only way to delete the specific list of supplies and equipment.

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(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.

There are no federal standards that apply.

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

The proposed regulations are comparable to those of surrounding states; there should be no competitive disadvantage.

Delaware, Maryland, Ohio and West Virginia have equipment regulations similar to the Board's proposed language. Delaware, New Jersey, and New York have regulations that list specific supplies and equipment.

(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 regulation amends current §§ 27.14 and 27.16. No other agency's regulations are affected.

(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 places of the Board's meetings are available at the Department of State's Website, www.dos.state.pa.us.

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.

No.

(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 pharmacy supplies and equipment.

(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.

There were no commentators for Regulation 16A-5415:Supplies and Equipment.

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INDEPENDENT REGULATORY
REVIEW COMMISSION

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: *Amy M. Elliott*
(DEPUTY ATTORNEY GENERAL)

FEB 09 2007

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-5415

DATE OF ADOPTION:

BY: *Edward J. Bechtel*
Edward J. Bechtel, R.Ph.

TITLE: Chairman
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

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

BY: *Andrew C. Clark*
Andrew C. Clark

JAN 25 2007

DATE OF APPROVAL

(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.

PROPOSED RULEMAKING
COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF PHARMACY
49 PA. CODE, CHAPTER 27.14 and 27.16
Supplies and Equipment

The State Board of Pharmacy (Board) proposes to amend §§27.14 and 27.16 (relating to supplies; and construction and equipment requirements) to read as set forth in Annex A. The proposed regulation would delete references to specific supplies that a pharmacy must maintain and instead allow pharmacies to maintain equipment to enable it to prepare and dispense prescriptions properly within its scope of practice. The proposed regulation would also delete the reference to the specific measurement of a pharmacy sink.

Effective Date

The amendment will be effective upon final 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

Section 27.14(c) (relating to supplies) currently lists specific supplies and equipment that pharmacies must maintain (except pharmacies operating as central processing centers). Certain items on this list are outdated and not used in pharmacies anymore. Other items on the current list are not used in pharmacies that have specific practice areas, such as, compounding pharmacies, nuclear pharmacies, veterinary pharmacies, and so forth. This rulemaking proposes to amend § 27.14(c) by eliminating the specific list of supplies and equipment and replacing it with language that permits a pharmacy to maintain supplies and equipment that are necessary to that pharmacy's area of practice. In addition, there are more advanced balances, scales and weights available than those specified in § 27.14(c)(1) and (2). There are also more advanced measuring tools than the graduates specified in § 27.14(c)(4). The remaining supplies in § 27.14(c)(5), (6), (7), (9), and (10) are outdated and not needed in most pharmacies. They simply sit on the shelves unused. The Board is also deleting § 27.14(c)(9) because it is repetitive with the requirement that pharmacies keep records of prescriptions of controlled substances in accordance with the requirements of the federal Drug Enforcement Administration in 21 CFR 1304.04(h) (relating to maintenance of records and inventories).

Section 27.16(b) (relating to construction and equipment requirements) currently requires that a pharmacy have a sink that measures at least 200 square inches exclusive of drainboard area. The Board proposes to delete the reference to specific measurements of the sink. The Board believes it is unnecessary to specify the size of the sink given the purposes for which it is used, such as hand washing and cleaning compounding equipment.

Description of Proposed Amendments

The proposed amendments to § 27.14 (relating to supplies) would delete the specific list of supplies and equipment in § 27.14(c)(1)-(10). The proposed amendment adds language that requires a refrigerator equipped with a thermometer or a temperature-monitoring device, which is used solely for the storage of drugs requiring refrigeration. This is the only specific equipment that the Board proposes to keep in the regulation but with amended language to make it clear that the refrigerator is not to be used for food storage.

The proposed amendment to §27.16 (relating to construction and equipment requirements) deletes the specific measurements for the pharmacy sink.

Compliance with Executive Order 1996-1

In compliance with Executive Order 1996-1, the Board extended an invitation to boards, associations, and interested licensees and educators to preliminarily review and comment on the Board's draft regulatory proposal. The Board reviewed and considered all comments and suggestions received by these and other interested parties during the regulatory development process.

Fiscal Impact

The proposed amendments would have no fiscal impact on the Commonwealth, its political subdivisions, the public or the regulated community.

Paperwork Requirements

The proposed amendments will not impose any additional paperwork requirements on the Commonwealth or the regulated community.

Sunset Date

The Board reviews the effectiveness of 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)), the Board submitted a copy of this proposed regulation on February 21, 2007 to the Independent Regulatory Review Commission (IRRC), the Senate Consumer Protection and Professional Licensure Committee and the House Professional Licensure Committee. In addition to submitting the proposed regulation, the Board has provided IRRC and the committees with a copy of a detailed Regulatory Analysis Form prepared by the Board. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act (71 P.S. §745.5(g)), if IRRC has comments, recommendations or objections regarding any portion of the proposed rulemaking, it will notify the Board within 30 days after the close of the public comment period. The notification will specify the regulatory review criteria that have not been met. The Regulatory Review Act specifies detailed procedures for review of comments, recommendations and objections by the Board, the General Assembly, and the Governor prior to publication of the regulations.

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.

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

§ 27.14. Supplies.

* * * * *

(c) A pharmacy shall maintain at least the following equipment and supplies:

[(1) A Class A prescription balance or other scale with a no-load sensitivity of 6 milligrams or less.

(2) Both an apothecary set of weights from ½ grain to 1 ounce and a set of metric weights from 10 milligrams to 50 grams.

(3) A mechanical refrigerator having the appropriate temperature control for the storage of the drugs, vaccines, biologicals or medicaments which require specific temperatures for their stability. The refrigerator shall be kept within the prescription area.

(4) At least four graduates assorted to measure 1 ml to 500 ml.

(5) At least two mortars and pestals, glass or wedgewood.

(6) At least three spatulas of assorted sizes, metallic-rust resistant and rubber or nonmetallic composition.

(7) At least two funnels, one 120 ml and the other 480 ml.

(8) One glass or tile slab or specially treated paper for use in compounding ointments.

(9) A book to record sales and transfers of Schedule V controlled substances and poisons. This paragraph does not apply to an institutional pharmacy servicing only inpatients.

(10) An adequate supply of filter paper and powder papers and an adequate supply of empty capsules, prescription containers, prescription and poison and other applicable identification labels used in dispensing of prescription drugs and medication.]

(1) A refrigerator, used solely for the storage of drugs requiring refrigeration, equipped with a thermometer or a temperature monitoring device.

[(11)] (2) Prescription files for keeping prescriptions of nonproprietary drugs in accordance with the act and, for controlled substance prescriptions, the regulations of the DEA in 21 CFR 1304.04(h) (relating to maintenance of records and inventories). The original prescription shall be retained for 2 years. A pharmacy may make use of a computerized recordkeeping system for keeping track of telephone prescriptions, refills, counseling, and the like, if the system has safeguards to prevent accidental erasure and the information can be transferred to hard copy within 72 hours.

[(12)] (3) Current copies of the act and this chapter.

[(13)] (4) Federal and Commonwealth statutes and regulations pertaining to the practice of pharmacy.

(5) Additional equipment and supplies necessary to enable the pharmacy to properly prepare and dispense prescriptions consistent with its scope of practice.

[(14)] (6) An adequate reference library which meets the following standards:

* * * * *

§ 27.16. Construction and equipment requirements.

* * * * *

(b) *Building standards.* The following apply to building standards:

* * * * *

(5) *Sanitary facilities.* Pharmacies shall be equipped with a sink within the prescription area to be used solely for pharmaceutical purposes. [The sink shall measure at least 200 square inches exclusive of drainboard area.] The sink shall be connected properly to supply hot and cold water. Restroom facilities for employees of the pharmacy shall be provided reasonably close to, but outside of the prescription area.

* * * * *



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

February 21, 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-5415: Supplies and Equipment

Dear Chairman Coccodrilli:

Enclosed is a copy of a proposed rulemaking package of the State Board of Pharmacy pertaining to supplies and equipment.

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

Sincerely,

A handwritten signature in black ink, appearing to read "Edward J. Bechtel".

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

EJB/CLC:ara

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 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-5415

SUBJECT: SUPPLIES AND EQUIPMENT

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

INDEPENDENT REGULATORY
REVIEW COMMISSION

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FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
2/21/07		HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
2/21/07	Mary Walmer	SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
2/21/07	Kathy Cooper	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
2/21/07	C. Lee Brown	LEGISLATIVE REFERENCE BUREAU (for Proposed only)

February 13, 2007