Regulatory Analysis Form

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INDEPENDENT REGULATORY REVIEW COMMISSION

(1) Agency

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

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

16A-5415

IRRC Number: 2593

(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)

___Proposed Rulemaking
_X_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 regulation will amend §27.14 by deleting the list of supplies pharmacies are required to maintain. The 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.

The regulation also amends §27.16 by deleting the specific measurement requirement of the pharmacy sink.

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

The 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).

Regulatory Analysis Form

(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The regulation deletes outdated supplies and equipment requirements.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 regulation will allow pharmacies to maintain only that equipment that is necessary for their scope of practice. The 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 since 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.

Regulatory Analysis Form

(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 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. No public comments were received during the 30-day public comment period. HPLC submitted two comments. The Board addressed one of HPLC's comments by amending the final-form regulation and addressed the second comment in the Preamble.

(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.

Regulatory Analysis Form

(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	$1,532,884.94	$1, 433,964.55	$1,652,516.51	$1,862,000.00

(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.

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.

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 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. 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 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)

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INDEPENDENT REGULATORY
REVIEW COMMISSION

#2593

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-5415

DATE OF ADOPTION: _____

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

TITLE: Chairperson
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

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

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

BY: Andrew C. Clark

JUN 9 2008
DATE OF APPROVAL

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

[ ] 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, CHAPTER 27
SUPPLIES AND EQUIPMENT

The State Board of Pharmacy (Board) hereby amends §§ 27.14 and 27.16 (relating to supplies; and construction and equipment requirements) to read as set forth in Annex A. The final rulemaking deletes references to specific supplies that a pharmacy must maintain and instead allows pharmacies to maintain equipment to enable them to prepare and dispense prescriptions properly within their scope of practice. The final rulemaking also deletes the reference to the specific measurement of a pharmacy sink.

Notice of Proposed Rulemaking was published at 37 Pa.B. 1036 (March 3, 2007). Publication was followed by a 30-day public comment period. The Board received no public comments, however the Pennsylvania Pharmacists Association has indicated its support of these amendments in correspondence with the Independent Regulatory Review Commission (IRRC). The House Professional Licensure Committee (HPLC) submitted two comments to the proposed rulemaking on April 18, 2007. The Senate Consumer Protection and Professional Licensure Committee made no comments. IRRC submitted no comments to the proposed rulemaking.

Summary of Comments and Responses to Proposed Rulemaking

The HPLC noted that the proposed rulemaking deleted the requirement that the refrigerator be kept within the prescription area and asked if it was the Board's intent to remove that requirement. The Board did not intend to remove that requirement, but notes that the definition of prescription area includes the area of the pharmacy used for legend drug storage. As the refrigerator is to be used solely for drugs requiring refrigeration it would necessarily have to be kept in the prescription area. However, the Board understands that one could interpret the change in the regulation to mean that the refrigerator no longer has to be located in the prescription area. To avoid any confusion, the Board has amended § 27.14(c)(1) to require the refrigerator to be kept in the prescription area.

The HPLC next asked what criteria the Board's inspectors will use for performing inspections. In many states where the regulations are similar to these amendments, inspectors still use a checklist to guide them during a pharmacy inspection. The Bureau of Enforcement and Investigation anticipates that it will develop inspection guidelines, with input from the Board, based on different pharmacy practice settings. Inspection for supplies is only a small part of what the inspectors look for during an inspection. Inspectors also look at items such as filing of prescriptions, labels, cleanliness of the pharmacy, outdated drugs, posting of the pharmacy permit, and technician protocols.

In the final-form rulemaking, the Board also reinserted the language that was added by the Board's "Technology and Automation" rulemaking in 2006. See 36 Pa.B. 2518 (May 27, 2006). This language was inadvertently left out of the proposed annex and was deleted from the proposed rulemaking by the Legislative Reference Bureau. The Board did not intend for this language to be deleted and has amended the final rulemaking package to reinsert the language as intended.

Statutory Authority

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

Fiscal Impact and Paperwork Requirements

The amendments would have not a fiscal impact on the Commonwealth, its political subdivisions, the public or the regulated community. The amendments will require the Board to revise the inspection forms. There will be no additional paperwork requirements imposed on the regulated community.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on February 21, 2007, the Board submitted a copy of the notice of proposed rulemaking, published at 37 Pa.B. 1036 (March 3, 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 _____, 2008, the final-form rulemaking was approved by the HPLC. On _____, 2008, the final-form rulemaking was deemed approved by the SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on _____, 2008, 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. 1036 (March 3, 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.

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) ~~[~~ Except for a pharmacy operating as a central processing center, a ~~]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.]

A refrigerator, used solely for the storage of drugs requiring refrigeration, equipped with a thermometer or a temperature monitoring device. THE REFRIGERATOR SHALL BE KEPT IN THE PRESCRIPTION AREA.

[(11)] (2) * * *

[(12)] (3) * * *

[(13)] (4) * * *

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

[(14)] (6) * * *

* * * * *

§ 27.16. Construction and equipment requirements.

* * * * *

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

* * * * *

(5) *Sanitary facilities.* [Except for pharmacies operating as central processing centers, pharmacies] ~~Pharmacies~~ shall be equipped with a sink within the prescription area to be used solely for pharmaceutical purposes. [The sink must measure at least 200 square inches exclusive of drainboard area.] The sink must 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.

* * * * *

course must pay the fee required by § 21.253. That section, however, did not set the fee.

Section 11.2(a) and (d) of the act requires the Board to set fees by regulation so that revenues meet or exceed expenditures over a biennial period. General operating expenses for enforcement of the act are funded through biennial license renewal fees. The various licensing boards of the Bureau of Professional and Occupational Affairs (Bureau) attempt to recover expenses regarding services which are provided directly to individuals, such as applications, verification of licensure or provision of required review and approval, directly through fees in which the actual cost of providing the service forms the basis for the fee. Actual cost calculations are based upon the product of the average time necessary to perform the function and the pay rate for the classification of the personnel performing the function, together with a proportionate share of administrative overhead.

The Board now proposes to implement the fee necessary for an application for approval of CRNP continuing education courses offered by providers that are not on the preapproved provider list. In this proposed rulemaking, the fee for the service provided would be implemented to allocate costs to those who use the service or application.

Description of Proposed Amendment

Based on estimates provided by the Bureau's Revenue Office, the Board proposes a fee of $100 for approval of a CRNP continuing education course. The fee was calculated based on an estimate of the Board staff and resources that will be expended to review and approve a CRNP continuing education course.

Fiscal Impact and Paperwork Requirements

The proposed rulemaking will have no adverse fiscal impact on the Commonwealth or its political subdivisions. The fees will have a modest fiscal impact on members of the private sector who apply for services from the Board. The proposed rulemaking will impose no additional paperwork requirements upon the Commonwealth, political subdivisions or the private sector.

Sunset Date

The Board continuously monitors the cost effectiveness of its regulations. 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 February 21, 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 to 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 which 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 Ann Steffanic, Board Administrator, State Board of Nursing, P. O. Box 2649, Harrisburg, PA 17105-2649 within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*. Reference No. 16A-5128 (CRNP CE course approval fee) when submitting comments.

MARY E. BOWEN, R. N., CRNP,
Chairperson

Fiscal Note: 16A-5128. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 21. STATE BOARD OF NURSING

Subchapter C. CERTIFIED REGISTERED NURSE PRACTITIONERS

GENERAL PROVISIONS

§ 21.253. Fees.

The following fees are charged by the Board:

* * * * *

Application for approval of CRNP continuing education course..... $100

[Pa.B. Doc. No. 07-350. Filed for public inspection March 2, 2007, 9:00 a.m.]

STATE BOARD OF PHARMACY

[49 PA. CODE CH. 27]

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 rulemaking would delete references to specific supplies that a pharmacy must maintain and instead allow pharmacies to maintain equipment to enable them to prepare and dispense prescriptions properly within their scope of practice. The proposed rulemaking would also delete the reference to the specific measurement of a pharmacy sink.

Effective Date

The proposed rulemaking will be effective upon final-form publication in the *Pennsylvania Bulletin*.

Statutory Authority

The proposed rulemaking 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)).

Background and Need for Amendments

Section 27.14(c) currently lists specific supplies and equipment that pharmacies must maintain (except phar-

macies 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 deleting 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. These supplies 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) 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 would delete the specific list of supplies and equipment in subsection (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 deletes the specific measurements for the pharmacy sink.

Fiscal Impact

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

Paperwork Requirements

The proposed rulemaking 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)), on February 21, 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 to 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 which 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, PA 17105-26409 within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*.

EDWARD J. BECHTEL, R.Ph.,
Chairperson

Fiscal Note: 16A-5415. No fiscal impact; (8) recommends adoption.

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) **[Except for a pharmacy operating as a central processing center, a]** 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 1/2 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.]

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

[(11)] (2) * * *

[(12)] (3) * * *

[(13)] (4) * * *

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

[(14)] (6) * * *

* * * * *

§ 27.16. Construction and equipment requirements.

* * * * *

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

* * * * *

(5) *Sanitary facilities.* **[Except for pharmacies operating as central processing centers, pharmacies] Pharmacies** shall be equipped with a sink within the prescription area to be used solely for pharmaceutical purposes. **[The sink must measure at least 200 square inches exclusive of drainboard area.]** The sink must 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.

* * * * *

[Pa.B. Doc. No. 07-351. Filed for public inspection March 2, 2007, 9:00 a.m.]

STATE BOARD OF VETERINARY MEDICINE

[49 PA. CODE CH. 31]

Professional Conduct

The State Board of Veterinary Medicine (Board) proposes to amend § 31.21 (relating to Rules of Professional Conduct for Veterinarians) to read as set forth in Annex A. The amendments to Principle 1 (relating to competency) would mandate that a veterinarian report to the Board certain conduct regarding issues of professional competency of another veterinarian. Amendments to Principle 3 (relating to professional behavior) would state more comprehensively conduct that is unprofessional. In addition, the Board proposes to amend Principle 7 (relating to veterinarian/client relationships) to specify limits on refusal or discontinuation of treatment.

Effective Date

The proposed rulemaking would become effective upon final-form publication in the *Pennsylvania Bulletin.*

Statutory Authority

Section 5(1) of the Veterinary Medicine Practice Act (act) (63 P. S. § 485.5(1)) authorizes the Board "[a]dopt reasonable rules and regulations governing the practice of veterinary medicine as are necessary to enable it to carry out and make effective the purpose and intent of this statutory law." Section 5(2) of the act authorizes the Board to "[a]dopt rules and regulations of professional conduct appropriate to establish and maintain a high standard of integrity, skills and practice in the profession of veterinary medicine."

Background and Need for Amendment

The Board's proposed amendments arise from the Board's ongoing review and commitment to keeping its regulations consistent with current standards of veterinary medicine practice, from disciplinary matters that have come before the Board and from input from the public regarding the need to regulate in particular areas of professional conduct.

Description of Proposed Rulemaking

The Board proposes to amend Principles 1, 3 and 7 as follows:

Proposed Amendment to Principle 1

Subsections (a)—(c) concern the duty of veterinarians to maintain the aspirational goals of competency in the veterinarian's individual practice. Current subsection (d) concerns a veterinarian's responsibility concerning issues regarding the professional competency of another veterinarian.

The Board proposes to amend subsection (d) to make mandatory a veterinarian's duty to report to the Board when a veterinarian has been unable to informally resolve with another veterinarian an issue of gross professional incompetence. The Board's current regulation is aspirational. The Board proposes to make the duty to inform the Board mandatory. In a related amendment, the Board proposes to amend Principle 3 by adding subsection (k) to provide that unprofessional conduct includes failing to report a matter described in Principle 1(d) to the Board.

Proposed Amendments to Principle 3

The Board proposes to maintain Principle 3(a)—(d) and add subsections (e)—(l). The Board has amended Principle 3 to clarify that a licensee may be disciplined for unprofessional conduct under section 21 of the act (63 P. S. § 485.21). Specifically, a licensee may be disciplined under section 21(1) of the act for willful or repeated violations of any of the rules and regulations of the Board. A licensee may be disciplined under section 21(20) of the act for professional incompetence. This proposed rulemaking clarifies this statutory term. Some of the examples of incompetent, unprofessional or immoral conduct may also subject a licensee to discipline under other subsections of section 21 of the act. For example, the Board believes that fraudulently issuing a health certificate is immoral conduct. This conduct may also be disciplined under section 21(6) of the act.

Proposed subsection (e) would prohibit a veterinarian from attempting to induce or attempting to influence,

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

June 13, 2008

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-5415: Supplies and Equipment

Dear Chairman Coccodrilli:

Enclosed is a copy of a final 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,

Michael A. Podgurski, Chairperson
State Board of Pharmacy

MAP/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-5415
SUBJECT:	SUPPLIES AND EQUIPMENT
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

RECEIVED
2008 JUN 13 AM 10: 23
INDEPENDENT REGULATORY REVIEW COMMISSION

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
6/13/08	J. M. Lum	HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
		MAJORITY CHAIRMAN Mike Sturla
6/13/08	Mary Walmer	SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
		MAJORITY CHAIRMAN Robert M. Tomlinson
6/13/08	Kathy Cooper	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
		LEGISLATIVE REFERENCE BUREAU (for Proposed only)

June 9, 2008