Regulatory Analysis Form

(Completed by Promulgating Agency)

IRRC

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-5420

IRRC Number: 2663

RECEIVED
2009 SEP 28 P 1:37
INDEPENDENT REGULATORY REVIEW COMMISSION

(3) Short Title:

Pharmacist breaks

(4) PA Code Cite:

49 Pa. Code §§ 27.11, 27.16

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

Primary Contact: **Thomas A. Blackburn, Regulatory unit counsel, Department of State; (717)783-7200; P.O. Box 2649, Harrisburg, PA 17105-2649; (717)787-0251; tblackburn@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 amends § 27.11 (relating to pharmacy permit and pharmacist manager) to allow a sole pharmacist on duty to take up to a 30-minute break while remaining in the immediate building. "Immediate building" is defined as the physical structure (or individual store) containing the pharmacy. The pharmacist shall be available for emergencies or for counseling. The pharmacy may remain open during the break period for patient related services including receipt of new written prescriptions, preparation of prescription for final verification by the pharmacist and delivery of prescription medications that have been verified by the pharmacist.

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

A. The date by which the agency must receive public comments: Feb. 18, 2008

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: N/A

D. The expected effective date of the final-form regulation: 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), 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.

(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.

Currently there is disparity between traditional pharmacies where the entire building is licensed as the pharmacy and bigger "box" and grocery stores. In the latter type of store only the area containing the pharmacy is licensed. Therefore the pharmacy must close if the pharmacist wishes to take a break and the break or restroom is located in a different part of the store. Closing the pharmacy for the pharmacist to take a break creates a hardship for patients who must wait for the break to be over before either dropping off or picking up a prescription. It is in the public interest to have the pharmacy remain open so patients can receive pharmacy services while the pharmacist takes a short break. The public is still protected because the activities performed while the pharmacist is away are limited to accepting new prescriptions, preparing prescriptions for pharmacist verification and only delivering those prescriptions that have already been verified by the pharmacist.

Nonregulation of pharmacists and pharmacies increases the risk of substandard pharmacy care, which may adversely affect public health. Pharmacists must be allowed to take break otherwise their work performance could suffer. However requiring the pharmacy to close during the course of the day while the pharmacist is on break inconveniences the patient. Both pharmacists and patients are better served by this regulation. The public will benefit from pharmacies remaining open while a pharmacist is on break thereby allowing prescriptions to be picked up and dropped off. The regulated community benefits because a sole pharmacist on duty may take a break while the pharmacy remains open to provide service to patients.

(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.

The rulemaking is not based on any scientific data, studies, or references.

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

The Board does not foresee any persons being 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 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.

(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.

There are no 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.

There are no 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.

Regulatory Analysis Form

	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**

Regulatory Analysis Form

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

Because there are no costs or other adverse effects associated with the rulemaking, the identified benefits outweigh any costs.

(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.

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

No alternative regulatory approaches were considered. Amending the regulations is the only way to permit a sole pharmacist on duty to take a break while allowing the pharmacy to remain open.

(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?

The regulatory provisions for pharmacist breaks are comparable to those in surrounding states. 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.

This rulemaking will not affect other regulations of the Board 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 not require any additional recordkeeping or other paperwork.

Regulatory Analysis Form

(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-5420

_____
DATE OF ADOPTION:

BY: Michael A. Podgurski
Michael A. Podgurski, RPh

TITLE: Chairperson
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

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

BY: Andrew C. Clark

AUG - 7 2009
DATE OF APPROVAL

(Deputy General Counsel
(~~Chief Counsel~~,
~~Independent Agency~~
(~~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 §§ 27.11, 27.16
PHARMACIST BREAKS

The State Board of Pharmacy (Board) amends §§ 27.11 and 27.16 (relating to pharmacy permit and pharmacist manager; and construction and equipment requirements) to read as set forth in Annex A.

Description and Need for the Rulemaking

Currently, the Board does not have regulations pertaining to when and how a sole pharmacist on duty may take a break while the pharmacy remains open. The Board's regulations only state that a pharmacy may not be open without a licensed pharmacist present and on duty. This has created a disparity among different types of pharmacies. In traditional "drug stores" the entire building is licensed as a pharmacy, therefore a pharmacist may take a break anywhere in the store and still be in the pharmacy. However, in large retail establishments only the area containing the pharmacy is licensed. Retail establishments include large wholesale stores, grocery stores and retail stores. Because the regulation mandates that the pharmacy must be closed when the pharmacist is not present in the pharmacy, the pharmacy must close if the pharmacist leaves the pharmacy to take a break in another area of the retail store. This has put retail establishments at a disparity with the more traditional drug stores.

The Board proposed to amend § 27.11(c) to state that the prescription area of a pharmacy may not be open without a licensed pharmacist on duty at all times. This would clarify that the retail area in a traditional drug store where the whole building is licensed as a pharmacy may still be open when the prescription area is closed. The prescription area is already defined in § 27.1 (relating to definitions) as the area of the pharmacy used for compounding, legend drug storage and other activities necessary to the practice of pharmacy. The term "prescription area" does not include waiting counters or display space attached to the waiting counters.

The Board also proposed to amend § 27.11(c) to allow a sole pharmacist on duty in a pharmacy to take up to a 30-minute break. The proposed amendment would not affect multiple pharmacists on duty taking staggered breaks. If only one pharmacist is on duty the pharmacist must remain in the building containing the pharmacy during the break. For pharmacies where the entire building is licensed this would not change current practice. However for pharmacies located in large retail establishments and institutions, the pharmacist must remain in the immediate building. The term "immediate building" is defined as the physical structure that contains the pharmacy. For example in a large retail, wholesale or grocery store, the pharmacist must remain in that store. In an institution, the pharmacist must remain in the building containing the pharmacy, so that in institutions on a campus with multiple buildings, the pharmacist could not go to another building during his break. Pharmacies located in malls are not included in the class of pharmacies that only have a portion of the store licensed, as those pharmacies are typically the traditional retail pharmacy where the entire store is licensed. If a large retail establishment with a pharmacy inside is attached to a mall then the restriction that the pharmacist must remain in the retail establishment applies. The pharmacist should not leave the store to go into the mall while the pharmacy remains open. The Board proposed to add § 27.11(c)(2) to allow a pharmacy to remain open during a sole pharmacist's break to receive new written prescriptions, prepare prescriptions for final verification by the pharmacist and to deliver prescription medications that have already been verified by the pharmacist.

Finally, the Board proposed to amend § 27.16(b)(2)(iii) to cross reference §27.11(c)(1) and add and define the term "immediate building."

With the implementation of these standards the Board intends to allow pharmacists to take breaks as needed while still being available for counseling or other emergencies. The public is protected because while the pharmacist is away from the pharmacy, no prescriptions could be delivered to a patient that were not first verified by the pharmacist; however new written prescriptions could be accepted and pharmacy technicians and pharmacy interns may prepare prescriptions for final verification.

Summary of Comments and Responses to Proposed Rulemaking

The Board published notice of proposed rulemaking at 38 Pa.B. 351 (January 19, 2008) with a 30-day public comment period. The Board received comments from the Pennsylvania Pharmacists Association (PPA), but from no other members of the public. The Board received comments from the House Professional Licensure Committee (HPLC) and the Independent Regulatory Review Commission (IRRC) as part of their review of proposed rulemaking under the Regulatory Review Act (71 P.S. §§ 745.1-745.12). The Board did not receive any comments from the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC).

The PPA supported the proposed rulemaking.

The HPLC first questioned whether a break of 30 minutes is consistent with labor law and policies of the large pharmacies. The HPLC, joined by IRRC, also questioned whether the break was a single break or whether multiple breaks totaling up to 30 minutes throughout the entire shift. This rulemaking does not set standards for how often or for how long a pharmacy may or must permit a pharmacist to go on break; rather it provides the opportunity for a pharmacy to remain open when the sole pharmacist on duty is on a break of 30 minutes or less. Therefore, the amendment will not conflict with labor laws or policies.

The HPLC also questioned what protocol should be followed for requested counseling during a pharmacist's break. Would a customer seeking counseling form a pharmacist be expected to wait until the pharmacist returned from break, or would the pharmacist have to cut the break short. Proposed § 27.11(c)(1) provides that the pharmacist "shall be accessible for emergencies or for counseling, if requested." The implication of this provision is that the pharmacist would return to the prescription area as needed during this period.

The Board has not found a need to revise its rulemaking in response to the comments. However, in the course of reviewing these comments, the Board noticed that the phrase "while working in a pharmacy" in § 27.11(c) was not consistent with the language of the general rule of that section. Accordingly, the Board has replaced this phrase with "while the pharmacy is open."

Fiscal Impact and Paperwork Requirements

The final-form rulemaking will have no adverse fiscal impact on the Commonwealth or its

political subdivisions and will impose no additional paperwork requirements upon the Commonwealth, political subdivisions or the private sector.

Effective date

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

Statutory Authority

The final rulemaking is authorized under sections 4(j), 6(k)(1) and 6(k)(9) of the act (63 P.S. §§ 390-4(j), 390-6(k)(1) and 390-6(k)(9)).

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on January 9, 2008, the Board submitted a copy of the notice of proposed rulemaking, published at 38 Pa.B. 351, to IRRC and the chairpersons of the HPLC and the 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 received 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 _____ ___, 2009, the final-form rulemaking was approved by the HPLC. On _____ ___, 2009, the final-form rulemaking was deemed approved by the SCP/PLC. Under section 5(g) of the Regulatory Review Act, IRRC was deemed to have approved the final-form rulemaking.

Additional Information

Persons who require additional information about the final-form rulemaking should submit inquiries to Regulatory Unit Counsel, Department of State, by mail to P.O. Box 2649, Harrisburg, PA 17105-2649, by telephone at (717) 783-7156, or by e-mail at st-pharmacy@state.pa.us.

Findings

The Board finds that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) and regulations promulgated thereunder, 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) The amendments to this final-form rulemaking do not enlarge the scope of proposed rulemaking published at 38 Pa.B. 351.

(4) The final-form rulemaking adopted by this order is necessary and appropriate for the administration of the Pharmacy Act.

Order

The Board, acting under its authorizing statute, orders that:

(a) The regulations of the Board at 49 Pa. Code Chapter 27 are amended, by amending §§ 27.11 and 27.16, to read as set forth in Annex A.

(b) The Board shall submit this order and 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 A and deposit them with the Legislative Reference Bureau as required by law.

(d) The final-form rulemaking shall take effect upon publication in the *Pennsylvania Bulletin*.

Michael A. Podgurski, RPh, Chairperson
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

GENERAL PROVISIONS

* * * * *

§ 27.11. Pharmacy permit and pharmacist manager.

* * * * *

(c) [A] The prescription area of a pharmacy may not be open without a licensed pharmacist on duty at all times. A sole pharmacist on duty may take up to a 30-minute break ~~while working in a pharmacy~~ WHILE THE PHARMACY REMAINS OPEN consistent with the following:

(1) The pharmacist shall remain in the pharmacy or, in the case of a pharmacy located within a retail establishment or institution, in the immediate building containing the pharmacy, and shall be accessible for emergencies or for counseling, if requested. For purposes of this paragraph, the term "immediate building" means the physical structure that contains the pharmacy. A pharmacy located at a complex consisting of multiple retail and other business establishments, such as a mall, is not considered to be "located within a retail establishment." In that case, the entire store containing the pharmacy is licensed, and the pharmacist shall remain in the store during a break.

(2) The pharmacy may remain open during the pharmacist's break for patient-related services, including:

(i) The receipt of new written prescriptions.

(ii) The preparation of prescriptions for final verification by the pharmacist.

(iii) The delivery of prescription medications that have been verified by the pharmacist.

* * * * *

§ 27.16. Construction and equipment requirements.

* * * * *

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

* * * * *

(2) *Pharmacies in retail establishments.* Pharmacies located within retail establishments whose business hours differ shall adhere to the following standards:

* * * * *

(iii) The pharmacy shall be closed whenever a licensed pharmacist is not present in the immediate building and on duty. For purposes of this section, the term "immediate building" has the same meaning given to it in § 27.11(c)(1) (relating to pharmacy permit and pharmacist manager).

* * * * *

Sunset Date

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

Regulatory Review

Under section 5(a) of the Regulatory Review Act (act) (71 P. S. § 745.5(a)), on January 9, 2008, 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 act, IRRC may convey any comments, recommendations or objections regarding the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections must specify the regulatory review criteria that have not been met. The 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 17105-2649, within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*.

EDWARD J. BECHTEL, R.Ph.,
Chairperson

Fiscal Note: 16A-5417. 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

GENERAL PROVISIONS

§ 27.1. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

ACPE—The **[American Council of Pharmaceutical Education] Accreditation Council for Pharmacy Education**.

* * * * *

RENEWAL OF PHARMACIST LICENSE AND PHARMACY PERMIT

§ 27.32. Continuing education.

(a) The Board will renew the license of a pharmacist who has completed a minimum of 30 contact hours (3 CEU) of continuing education during the preceding biennial renewal period. **Beginning with the license period commencing on _____ (*Editor's Note:* The blank refers to the date of the first biennial renewal that occurs at least 2 years from the effective date of adoption of this proposed rulemaking.), 2 of the required 30 contact hours shall be completed in courses from the ACPE topic designator "Patient Safety." [For] In addition, for** licensees with authority to administer injectable medications, biologicals and immunizations in accordance with section 9.2 of the act (63 P. S. § 390-9.2) and **[§ 27.301] § 27.401** (relating to qualifications for authority), at least 2 of the required 30 hours **[shall] must** concern the administration of injectable medications, biologicals and immunizations, including, **but not limited to,** disease epidemiology, vaccine characteristics, injection technique, emergency response to adverse events **[,]** and related topics. **[Programs offered by providers accredited by the ACPE are approved by the Board.] Except as provided in subsection (h), only continuing education programs offered by ACPE-accredited providers of continuing pharmaceutical education targeted toward pharmacists are acceptable to the Board.**

(b) A pharmacist shall prove compliance with **[the requirements of]** subsection (a) by completing and submitting a form provided to the pharmacist by the Board for that purpose with the renewal application. The certificates provided upon completion of an approved program shall be retained by a pharmacist for 2 years after renewal, and shall be produced upon demand by the Board or its auditing agents. The Board will utilize a random audit of 5% of renewals to determine compliance with **[the requirements of]** subsection (a), and may expand the audit if rates of noncompliance at 20% or more of the sample are revealed by the initial audit. Individuals selected for the audit will be required to produce certificates proving the information they provided to the Board on the form submitted with the renewal application. **Notwithstanding any disciplinary action taken under subsection (i), a pharmacist found to be in noncompliance with the continuing education requirements shall make up the delinquent contact hours within 6 months of the notice of deficiency from the Board.**

* * * * *

(h) Continuing education program providers which are not ACPE **[approved]-accredited** may apply to the Board for approval, and shall make a showing of program accreditation substantially similar to ACPE accreditation standards. **Requests for approval shall be submitted to the Board at least 60 days prior to the start date of the program. Retroactive requests for approval will not be considered.** The Board will maintain a list of programs approved under this subsection.

* * * * *

[Pa.B. Doc. No. 08-92. Filed for public inspection January 18, 2008, 9:00 a.m.]

[49 PA. CODE CH. 27]

Pharmacist Breaks

The State Board of Pharmacy (Board) proposes to amend §§ 27.11 and 27.16 (relating to pharmacy permit and pharmacist manager; and construction and equipment requirements) to read as set forth in Annex A. The proposed rulemaking would set standards for a pharma-

cist to take a 30-minute break, but still be available for emergencies or counseling if needed.

Effective Date

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

Statutory Authority

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

Background and Need for Amendment

Currently, the Board does not have regulations pertaining to when and how a sole pharmacist on duty may take a break while the pharmacy remains open. The Board's regulations only state that a pharmacy may not be open without a licensed pharmacist present and on duty. This has created a disparity among different types of pharmacies. In traditional "drug stores" the entire building is licensed as a pharmacy, therefore a pharmacist may take a break anywhere in the store and still be in the pharmacy. However, in large retail establishments only the area containing the pharmacy is licensed. Retail establishments include large wholesale stores, grocery stores and retail stores. Because the regulation mandates that the pharmacy must be closed when the pharmacist is not present in the pharmacy, the pharmacy must close if the pharmacist leaves the pharmacy to take a break in another area of the retail store. This has put retail establishments at a disparity with the more traditional drug stores.

Description of Proposed Amendments

The Board proposes to amend § 27.11(c) to state that the prescription area of a pharmacy may not be open without a licensed pharmacist on duty at all times. This is to clarify that the retail area in a traditional drug store where the whole building is licensed as a pharmacy may still be open when the prescription area is closed. The prescription area is already defined in § 27.1 (relating to definitions) as the area of the pharmacy used for compounding, legend drug storage and other activities necessary to the practice of pharmacy. The term prescription area does not include waiting counters or display space attached to the waiting counters. The Board also proposes to amend § 27.11(c) to allow a sole pharmacist on duty in a pharmacy to take up to a 30-minute break. The proposed amendment does not affect multiple pharmacists on duty taking staggered breaks. If only one pharmacist is on duty, the pharmacist shall remain in the building containing the pharmacy during the break. For pharmacies where the entire building is licensed this does not change current practice. However for pharmacies located in large retail establishments and institutions, the pharmacist shall remain in the immediate building. The immediate building is defined as the physical structure that contains the pharmacy. For example in a large retail, wholesale or grocery store, the pharmacist shall remain in that store. In an institution, the pharmacist shall remain in the building containing the pharmacy, so that in institutions on a campus with multiple buildings, the pharmacist could not go to another building during a break. Pharmacies located in malls are not included in the class of pharmacies that only have a portion of the store licensed, as those pharmacies are typically the traditional retail pharmacy where the entire store is licensed. If a large retail establishment with a pharmacy inside is attached to a mall, the restriction that the pharmacist shall remain in the retail establishment applies. The pharmacist should not leave the store to go into the mall while the pharmacy remains open.

The Board proposes to add § 27.11(c)(2) to allow a pharmacy to remain open during a sole pharmacist's break to receive new written prescriptions, prepare prescriptions for final verification by the pharmacist and to deliver prescription medications that have already been verified by the pharmacist.

Finally, the Board proposes to amend § 27.16(b)(2)(iii) to cross reference § 27.11(c)(1) and add and define the term "immediate building."

With the implementation of these standards, the Board intends to allow pharmacists to take breaks as needed while still being available for counseling or other emergencies. The public is protected because while the pharmacist is away from the pharmacy, no prescriptions could be delivered to a patient that were not first verified by the pharmacist; however new written prescriptions could be accepted and pharmacy technicians and pharmacy interns may prepare prescriptions for final verification.

Fiscal Impact

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

Paperwork Requirements

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

Sunset Date

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

Regulatory Review

Under section 5(a) of the Regulatory Review Act (act) (71 P. S. § 745.5(a)), on January 9, 2008, the Board submitted a copy of these proposed amendments 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 act, IRRC may convey any comments, recommendations or objections regarding the proposed amendments within 30 days of the close of the public comment period. The comments, recommendations or objections must specify the regulatory review criteria that have not been met. The 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 17105-2649, within 30 days following publication of this proposed amendments in the *Pennsylvania Bulletin.*

EDWARD J. BECHTEL, R.Ph.,
Chairperson

Fiscal Note: 16A-5420. 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

GENERAL PROVISIONS

§ 27.11. Pharmacy permit and pharmacist manager.

* * * * *

(c) **[** A **]** **The prescription area of a** pharmacy may not be open without a licensed pharmacist on duty at all times. **A sole pharmacist on duty may take up to a 30-minute break while working in a pharmacy consistent with the following:**

(1) The pharmacist shall remain in the pharmacy or, in the case of a pharmacy located within a retail establishment or institution, in the immediate building containing the pharmacy, and shall be accessible for emergencies or for counseling, if requested. For purposes of this paragraph, the term "immediate building" means the physical structure that contains the pharmacy. A pharmacy located at a complex consisting of multiple retail and other business establishments, such as a mall, is not considered to be "located within a retail establishment." In that case, the entire store containing the pharmacy is licensed, and the pharmacist shall remain in the store during a break.

(2) The pharmacy may remain open during the pharmacist's break for patient-related services, including:

(i) The receipt of new written prescriptions.

(ii) The preparation of prescriptions for final verification by the pharmacist.

(iii) The delivery of prescription medications that have been verified by the pharmacist.

* * * * *

§ 27.16. Construction and equipment requirements.

* * * * *

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

* * * * *

(2) *Pharmacies in retail establishments.* Pharmacies located within retail establishments whose business hours differ shall adhere to the following standards:

* * * * *

(iii) The pharmacy shall be closed whenever a licensed pharmacist is not present **in the immediate building** and on duty. **For purposes of this section, the term "immediate building" has the same meaning given to it in § 27.11(c)(1) (relating to pharmacy permit and pharmacist manager).**

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[Pa.B. Doc. No. 08-93. Filed for public inspection January 18, 2008, 9:00 a.m.]

LIST OF PUBLIC COMMENTATORS

Patricia A. Epple, CAE
Executive Director
Pennsylvania Pharmacists Association
508 North Third Street
Harrisburg, PA 17101-1199
717-234-6151 Ext. 106
Fax 717-236-1618
www.papharmacists.com

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

September 28, 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-5420: Pharmacist Breaks

Dear Chairman Coccodrilli:

Enclosed is a copy of a final rulemaking package of the State Board of Pharmacy pertaining to Pharmacist Breaks.

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/TAB: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
Thomas A. Blackburn, Counsel
State Board of Pharmacy
State Board of Pharmacy

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER:	16A-5420
SUBJECT:	PHARMACIST BREAKS
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

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
9/28/09	Elaine L. Nichols	HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
		MAJORITY CHAIRMAN Michael P. McGeehan
9/28/09	Mary Walmer	SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
		MAJORITY CHAIRMAN Robt. M. Tomlinson
9/28/09	Kathy Cooper	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
		LEGISLATIVE REFERENCE BUREAU (for Proposed only)

August 7, 2009