

Regulatory Analysis Form

This space for use by IRRC

(1) Agency

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

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

16A-5420

IRRC Number: 2663

(3) Short Title

Pharmacist Breaks

(4) PA Code Cite

49 Pa. Code §§ 27.11 and 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

Final Order Adopting Regulation

Policy Statement

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

No

Yes: By the Attorney General

Yes: By the Governor

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

The proposed regulation will amend § 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) State the statutory authority for the regulation and any relevant state or federal court decisions.

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).

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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?

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.

(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. 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.

(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 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.

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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.)

Approximately 18,426 pharmacists and 3,264 pharmacies apply for licenses and permits biennially.

(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.

There are no costs and/or savings associated with compliance with the proposed regulation.

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(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:	\$N/A	\$N/A	\$N/A	\$N/A	\$N/A	\$N/A
Regulated Community						
Local Government						
State Government						
Total Costs						
REVENUE LOSSES:	\$N/A	\$N/A	\$N/A	\$N/A	\$N/A	\$N/A
Regulated Community						
Local Government						
State Government						
Total Revenue Losses						

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

There are no costs or savings associated with the proposed rulemaking.

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.

(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 permit a sole pharmacist on duty to take a break while allowing the pharmacy to remain open.

(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 the regulations is the only way to permit a sole pharmacist on duty to take a break while allowing the pharmacy to remain open.

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

(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.

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: Angus M. Elliott
(DEPUTY ATTORNEY GENERAL)

DEC 19 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-5420

DATE OF ADOPTION: _____

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

TITLE: Chairman
(EXECUTIVE OFFICER, CHAIRMAN OR SE

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

BY: Andrew C. Clark

DEC 3 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.

NOTICE OF PROPOSED 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) 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 pharmacist 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 must 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 must 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 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 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 regulation will have no fiscal impact on the Board or the regulated community.

Paperwork Requirements

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

Sunset Date

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

Regulatory Review

Under Section 5(a) of the Regulatory Review Act (71 P.S. §745.5(a)), on 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 Regulatory Review Act, IRRC may convey any comments, recommendations or objections regarding the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections must specify the regulatory review criteria that have not been met. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the rulemaking, by the Board, the General Assembly, and the Governor of comments, recommendations or objections raised.

Public Comment

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

Edward J. Bechtel, R.Ph.
Chairperson

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 27. STATE BOARD OF PHARMACY

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).

* * * * *



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

January 9, 2008

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


Re: Proposed Regulation
State Board of Pharmacy
16A-5420: Pharmacist Breaks

Dear Chairman Coccodrilli:

Enclosed is a copy of a proposed 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,


for Michael A. Podgurski, R.Ph., 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-5420
SUBJECT: PHARMACIST BREAKS
AGENCY: DEPARTMENT OF STATE
STATE BOARD OF PHARMACY

TYPE OF REGULATION

- X Proposed Regulation
Final Regulation
Final Regulation with Notice of Proposed Rulemaking Omitted
120-day Emergency Certification of the Attorney General
120-day Emergency Certification of the Governor
Delivery of Tolled Regulation
a. With Revisions b. Without Revisions

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
<u>1-9-08</u>	<u></u>	HOUSE COMMITTEE ON PROFESSIONAL LICENSURE MAJORITY CHAIRMAN <u>Sturla</u>
<u>1/9/08</u>	<u>Mary Walmer</u>	SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE MAJORITY CHAIRMAN <u>Tomlinson</u>
<u>1/9/08</u>	<u>St. Belmont</u>	INDEPENDENT REGULATORY REVIEW COMMISSION ATTORNEY GENERAL (for Final Omitted only)
<u>1/9/08</u>	<u>C. Lu B...</u>	LEGISLATIVE REFERENCE BUREAU (for Proposed only)