Regulatory Analysis Form

(1) Agency **Department of State, Bureau of Professional and Occupational Affairs, State Board of Pharmacy**	This space for use by IRRC RECEIVED 2007 SEP 19 AM 11: 52 INDEPENDENT REGULATORY REVIEW COMMISSION
(2) I.D. Number (Governor's Office Use) **16A-5416**	**IRRC Number:** 2640

(3) Short Title
General Revisions

(4) PA Code Cite **49 Pa. Code, §§ 27.1 - 27.3, 27.12, 27.17 - 27.19, 27.21, 27.25, and 27.31**	(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) **_X_ Proposed Rulemaking** **___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 Board proposes to amend § 27.1 to change the definition of "ACPE" to reflect a recent name-change and to add a definition for "licensed person." In § 27.2 the Board proposes to replace the outdated "BNDD" with "DEA" to reflect the current name for the Federal drug enforcement agency. The Board proposes to delete § 27.3 (relating to location of office). The Board proposes to amend § 27.12 to allow pharmacy interns to accept and transcribe oral orders and telephone prescriptions. The Board proposes to amend § 27.17 to update the language regarding storage of Schedule II controlled substances to make it consistent with § 27.16(b)(3) and with regulations of the Department of Health. The Board also proposes to amend § 27.18 to bring the regulation up to date with current practices in the industry by confirming that an image of a prescription can serve as the original prescription, prescriptions may be refilled for up to 1 year from the date of the prescription, prescriptions for Schedule II controlled substances may not be filled more than 6 months from the date of the prescription, a broader class of drugs may be filled through mail order, pharmacy interns may take oral orders and prescriptions, the promotion of the sale of any controlled substances is prohibited, and other advertising requirements are updated. The Board proposes to amend § 27.19 to require a PDR for a new prescription or drug order, except when a physician dispenses a drug to a patient being treated in the emergency room. The proposed regulation would require PDRs for inpatients of an institution. The Board proposes to amend

§ 27.21 to reflect the current practice of the Board that internship experience should be filed with the Board before the applicant is authorized to take the exam. The Board proposes to amend § 27.25 to reflect that the Multistate Pharmacy Jurisprudence Examination is the current law examination administered by the test administrator. Finally, the Board proposes to amend § 27.31 to reflect the current Board practice of online license renewal.

(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)).

(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?

Outdated regulations hinder the practice of pharmacy. Pharmacists and the public benefit by the enactment of regulations that reflect the current practice of pharmacy and the current practices of the Board.

(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 general public and regulated practitioners will benefit from updated regulations reflecting current pharmacy practice standards.

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 groups 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.)

Approximately 18,426 pharmacists and 3,264 pharmacies apply for licenses and permits biennially. All will be required to comply with the amendments.

(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 considered input from the attendees at its monthly Board meetings. The Board also sent an exposure draft to stakeholders requesting input and comments. The Board received comments from the Pennsylvania Society of Health-System Pharmacists and the Pennsylvania Pharmacists Association.

(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.

No legal, accounting or consulting costs and/or savings are anticipated as a result of the regulation.

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.

No legal, accounting or consulting costs and/or savings to state government are anticipated as a result of the 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:	$ 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.

Not applicable.

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 because existing regulations needed to be amended.

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

No other regulatory schemes were considered.

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.

No.

(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 will not put Pennsylvania at a competitive disadvantage. As regulations differ from state to state it is difficult to summarize how the regulation package as a whole compares with surrounding states. But given that this regulation removes outdated provisions and brings the regulations up to date with the standards in the industry the regulations should be comparable with other states.

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

This regulation should not affect the regulations of other state agencies.

(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, to the extent that paperwork requirements are addressed in the regulation they are only intended to bring the regulation up to date with the current practice in the industry or of the Board.

(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.

(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-form publication in the Pennsylvania Bulletin.

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

The Board reviews the effectiveness of its regulation on an ongoing basis, generally as part of its annual review of its operations.

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: Amy M. Elliott
(DEPUTY ATTORNEY GENERAL)

SEP 04 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-5416

DATE OF ADOPTION: _____

BY: 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

JUL 20 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, CHAPTER 27
GENERAL REVISIONS

The State Board of Pharmacy (Board) proposes to amend §§ 27.1, 27.2, 27.12, 27.17 - 27.19, 27.21, 27.25 and 27.31, and to delete § 27.3 (relating to location of office), to read as set forth in Annex A.

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

The Board undertook a wholesale review of its regulations to determine what provisions were outdated. Through careful review and with input from stakeholders, the Board decided to delete certain regulations and to update others to reflect current pharmacy practice.

Description of Proposed Amendments

General Changes

In § 27.1 (relating to definitions), the Board's proposal would update the definition of "ACPE" to reflect the organization's current name – the Accreditation Council for Pharmacy Education. The Board also proposes to define "licensed person" to clarify that as used throughout Chapter 27, the term refers only to persons licensed by the Board and not to persons licensed by other boards under the Bureau of Professional and Occupational Affairs.

The Board proposes to amend § 27.2 (relating to other definitions) to replace the outdated acronym "BNDD," which previously stood for Bureau of Narcotics and Dangerous Drugs, with the defined term "DEA," which is the federal agency responsible for enforcing the federal drug laws. The Board also proposes to delete § 27.3 (relating to location of office), because the address provided has been long outdated. The Board chose not to replace it because the Board's current address is subject to change and is readily available on the Board's website.

Section 27.12 (relating to practice of pharmacy and delegation of duties)

The Board proposes to amend this section to delete the prohibition on pharmacy interns accepting and transcribing oral orders and telephone prescriptions. The purpose of a pharmacy internship is to prepare a pharmacy student to function as a pharmacist. One of the pharmacist's duties is to receive telephone prescriptions and other oral orders. Pharmacy interns are well prepared to assume this responsibility and, with direct supervision by a pharmacist required for all pharmacy interns, there is no increased risk to the public.

Section 27.17 (relating to security for Schedule II controlled substances)

The Board proposes to amend this section to remove the requirement that Schedule II controlled substances be stored in a separate, secure area in the pharmacy. The Board had previously amended § 27.16(b)(3) (relating to construction and equipment requirements) to conform to Department of Health regulations at 28 Pa. Code § 25.63 (relating to security controls for practitioners and research personnel), to allow controlled substances to be dispersed throughout the stock of the pharmacy in a matter that obstructs theft or diversion of controlled substances. Section 27.17, however, was not amended and has resulted in confusion over how Schedule II controlled substances must be stored. With the proposed revision, § 27.17 will be consistent with the Department of Health regulations and with previously amended regulations of the Board.

Section 27.18 (relating to standards of practice)

The Board proposes to amend § 27.18(b)(4) to clarify that readily retrievable images of prescriptions may serve as the original prescriptions. This change was already effected by amendments to §§ 27.14 and 27.201 (relating to supplies; and electronically transmitted prescriptions). The proposed change merely serves to conform this section to those recent amendments. The Board also proposes to add § 27.18(i) to codify the standard practice that prescriptions may be refilled for a period up to 1 year from the date of the prescription.

In addition, the Board proposes to amend § 27.18(j) to prohibit the filling of Schedule II prescriptions after 6 months have passed from the date of the prescription. Currently, there is no time limit as to how long a prescription for a Schedule II controlled substance is valid. The Board believes there should be a limit and proposes 6 months as a reasonable time during which a Schedule II controlled substance prescription may be filled. The Board believes that this requirement will bring the time restriction in line with the restriction for filling of Schedule III, IV and V substances.

The Board also proposes to amend § 27.18(l)(3) to allow mailing of prescriptions subject to significant deterioration of the original content due to heat, cold fermentation or prolonged agitation, if the shipping is done in a manner that would preserve the integrity of the drug. Shipping is now possible in insulated containers with temperature control devices and other sensors that would alert the patient if the integrity of the drug were compromised.

The Board proposes to amend § 27.18(n) and (o) to conform with the proposed amendments to § 27.12 (relating to practice of pharmacy and delegation of duties), to allow pharmacy interns to accept and transcribe oral or telephone prescriptions or orders. The Board also proposes to amend § 27.18(r)(2) to extend the current prohibition of advertising the sale of Schedule II controlled substances to all controlled substances.

The Board further proposes to amend § 27.18(r)(5) to remove an outdated requirement that the price of the smallest salable quantity be shown in close proximity to an advertisement for a commercially reasonable quantity. This language can cause advertisements to be misleading when the smallest saleable quantity, usually one tablet or capsule, is used. In addition, the Board is proposing to amend § 27.18(r)(6) to clarify and correct the word choice in the existing regulation. Finally, the Board proposes to amend § 27.18(t) to replace the term "renew" with the more widely used term "refill" when referring to prescriptions.

Section 27.19 (relating to prospective drug review and patient counseling)

The Board proposes to amend § 27.19 to require pharmacists to perform a prospective drug review (PDR) prior to dispensing any prescription or drug order, except when a physician dispenses a drug to a patient being treated in the emergency room. The Board would expand the PDR to drug orders in institutions because the Board believes it is in the interest of public protection to check for drug interactions for both prescriptions and drug orders. Many institutions commonly perform a PDR for drug orders, even though it is not currently mandated.

Section 27.21 (relating to application for examination and licensure)

The Board proposes to amend § 27.21 to reflect the current practice of the Board. With the advent of computerized testing, the applicant now schedules the exam and there are no longer only one or two exam dates per year. Therefore, it is no longer feasible to allow applicants to submit internship affidavits up to the exam date because the Board does not know the date the applicant took the exam until the score is forwarded to the Board. The proposed revision will require all internship affidavits to be submitted to the Board before the applicant is authorized to take the exam.

Section 27.25 (relating to licensure by reciprocity)

The Board proposes to revise this section to reflect the fact that the Multistate Pharmacy Jurisprudence Examination (MPJE) is now the law exam administered to applicants applying by reciprocity. On January 26, 1983, the Federal Drug Law Examination (FDLE) became a requirement for licensure in this Commonwealth; however, that exam has since been replaced by the MPJE. Section 27.24 (relating to examinations and passing scores) was previously amended to reflect this change, but § 27.25 was not. The revised § 27.25 will recognize that some applicants for licensure by reciprocity can demonstrate they took the FDLE, while other applicants can demonstrate that they took the MPJE.

Section 27.31 (relating to biennial renewal)

The Board proposes to amend this section to reflect the current practice of mailing a reminder card about the upcoming renewal. The card encourages renewal of the license online, however pharmacists may request that the hard-copy form be mailed to them. For the 2006 renewal, 88% of pharmacists renewed online.

Fiscal Impact

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

Paperwork Requirements

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

Sunset Date

The Board reviews the effectiveness of its regulations on an ongoing basis. Therefore, no sunset date has been assigned.

Regulatory Review

Under Section 5(a) of the Regulatory Review Act (71 P.S. §745.5(a)), on September 19, 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 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 and 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.

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.

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

Licensed person – A person holding a license issued by the Board.

* * * * *

§ 27.2. Other definitions.

The definitions contained in the act and also in The Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. §§ 780-101 – 780-144), including the term "controlled substances" and the schedules thereof, apply to this chapter. A requirement contained in this chapter for a controlled substance applies to the lowest schedule of a controlled substance now or subsequently classified as a controlled substance by either [BNDD] the DEA or the Secretary of the Department of Health.

* * * * *

§ 27.3. [Location of office] (Reserved).

[The principal office of the Board is located at 617 Transportation and Safety Building, Harrisburg, Pennsylvania 17120.]

* * * * *

STANDARDS

* * * * *

§ 27.12. Practice of pharmacy and delegation of duties.

* * * * *

(c) *Pharmacy interns.*

* * * * *

(2) [A pharmacy intern may neither accept nor transcribe an oral order or telephone prescription.

(3)] A pharmacy intern may neither enter nor be in a pharmacy if a pharmacist is not on duty.

([4]3) A pharmacy intern working under the direct, immediate, personal supervision of a pharmacist may perform procedures which require professional skill and training. Examples of these procedures include: verifying ingredients, weighing ingredients, compounding ingredients and other similar processing of ingredients.

* * * * *

§ 27.17. Security for Schedule II controlled substances.

(a) [From the time that a Schedule II controlled substance is received for storage in the prescription area until the time that controlled substance has been prepared and compounded into an individual prescription, no person except a licensed pharmacist or a licensed pharmacist intern or, in an institution, a licensed physician or registered nurse, may have access to the controlled substances or work in an area where open containers of

the controlled substances are shelved or stored. The Board will consider the following measures as adequately controlling access to the controlled substances:

(1) A safe, vault or other storage facility in compliance with storage requirements for BNDD Schedule II drugs.

(2) A chest or cabinet of sound construction secured to a wall or floor and able to be securely locked.

(3) A wire cage with a door able to be securely locked.

(b) The Board may approve alternative security measures proposed by an applicant upon a showing that a degree of security would be provided equal to or greater than that set forth in subsection (a).] Schedule II controlled substances shall be stored in securely locked, substantially constructed cabinets. However, Schedule II controlled substances may be dispersed throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

([c] b) The occasional entry of other persons into an area where the controlled substances are accessible in order to clean, deliver or perform other necessary functions shall be allowed only when a licensed person is present and supervising.

([d] c) The pharmacist manager shall be responsible for assuring that licensed persons, [employes] employees and others who enter the prescription area know and abide by the standards of security and that the other measures are taken as may be necessary to insure their enforcement.

§ 27.18. Standards of practice.

* * * * *

(b) Prescriptions kept on file in the pharmacy shall meet the following requirements:

* * * * *

(4) Original prescriptions or readily retrievable images of the original prescriptions shall be kept for 2 years from the date of the most recent filling.

* * * * *

(i) Prescriptions for nonproprietary drugs may be refilled for a period of 1 year from the date of the prescription if refills have been authorized by the prescriber. A nonproprietary drug which is refillable by statute on the basis of designation, such as ad lib, PRN or similar instruction, may be refilled for a period of 1 year from the date of the prescription.

(j) Prescriptions for Schedule II controlled substances may not be filled more than 6 months from the date of the prescription. Prescriptions for Schedule II controlled substances may not be refilled. No controlled substance in Schedule III, IV or V may be filled or refilled more than five times in the 6-month period from the date of the prescription. [Other nonproprietary drugs which may be renewed for a longer period of time or for a greater number of refills shall be in specific numbers such as, "may be renewed ten times" and shall be in the original handwriting of the prescriber. A nonproprietary drug which is refillable by statute may not be refilled on the basis of preprinted designations or "ad lib," P.R.N., or similar instructions more than five times in the 6-month period from the date of the prescription.]

(l) Prescriptions sent through the mail to a pharmacy shall be compounded and dispensed in the following manner:

* * * * *

(3) The mailing of a medication or prescription drug or device generally accepted and recognized to be subject to significant deterioration of the original content due to heat, cold fermentation or prolonged agitation [is prohibited] is permissible if it is shipped in a manner which would preserve the integrity of the drug.

* * * * *

(n) A prescription by means of an oral order, telephone or otherwise, shall be received and transcribed [only] by either a registered pharmacist or a pharmacy intern under the direct supervision of a pharmacist.

(o) Except as provided under the definition of order, an oral prescription shall be reduced to writing immediately by the pharmacist or pharmacy intern and shall be filled by, or under the direction of the pharmacist. An order entered on the chart or medical record of a patient in an institution for the diagnostic care and treatment of a patient on an overnight basis, or on the chart or medical record of a patient under emergency treatment in an institution by or on the order of a practitioner authorized by statute to prescribe drugs or devices, shall be considered to be a prescription if the medication is to be furnished directly to the patient for self-administration. It is the responsibility of the prescriber to see that the chart or medical record contains the information required for a prescription and that it is signed by the prescriber himself at the time the drug is given or if he is not present, then on his next visit to the institution. No registered pharmacist may compound, prepare, dispense, fill, sell, or give away a drug or device on the basis of a prescription or order in an institution or hospital unless the prescription or order is an original prescription or order or direct copy thereof issued by the authorized prescriber or practitioner who may be using electronic or computerized equipment.

* * * * *

(r) The following provisions are applicable to the advertisement and sale of drugs:

* * * * *

(2) No person may promote to the public the sale of any [Schedule II] controlled substances [or barbiturates and their compounds].

* * * * *

(5) An advertisement of a prescription shall be for a commercially reasonable quantity. [If the price of a quantity of a prescription drug is advertised, the price of one dosage unit or of the smallest saleable quantity shall be shown in close proximity thereto.]

(6) [A pharmacist or pharmacy] Any person advertising special prices for prescriptions, dangerous drugs[, proprietary] or nonproprietary drugs, preparations or products, devices and appliances, if using a [percentile] percentage number such as 10% off, 20% off, and the like, as to selected items, shall state or publish a price list from which the [percentile] percentage prices are derived, so the consumer or patient knows exactly what the [cost] retail price is.

* * * * *

(t) A pharmacist may only [renew] refill a prescription at a reasonable time prior to the time when the contents of the prescription shall be consumed according to prescriber's directions.

§ 27.19. Prospective drug review and patient counseling.

* * * * *

(b) *General.* This section requires a pharmacist to perform a PDR before filling, delivering or sending a new [retail or outpatient] prescription or drug order, except when a physician dispenses a drug to a patient being treated in the emergency room. The PDR requires that the pharmacist review a profile of the patient maintained in the pharmacy in accordance with subsection (g) prior to dispensing the medication to the patient or caregiver[and the pharmacist or designee of the pharmacist make an offer to counsel the patient or caregiver].

* * * * *

(d) *Scope.*

(1) The PDR is required for [retail or outpatient] prescriptions and drug orders. The PDR does not extend to the following:

(i) [An order for a drug for an inpatient of an institution, as the term "institution" is defined in this chapter.

(ii)] A drug dispensed in an emergency room.

([iii] ii) A drug dispensed by a medical practitioner.

([iv] iii) A drug dispensed by a pharmacist to a medical practitioner which the practitioner will administer to a patient.

(2) The following are examples of situations in which a PDR is required:

* * * * *

(v) A pharmacist fills a prescription for a patient in a nursing home.

(vi) A pharmacist in a hospital dispenses a drug which will be administered to a patient in the hospital.

(3) The following are examples of situations in which a PDR is not required:

(i) [A pharmacist fills a prescription for a patient in a nursing home.

(ii)A pharmacist in a hospital dispenses a drug which will be administered to a patient in the hospital.

(iii)] A physician dispenses a drug to a patient being treated in the emergency room.

([iv] ii) A pharmacist dispenses a radiopharmaceutical to a physician who will administer it to a patient.

* * * * *

PHARMACISTS

§ 27.21. Application for examination and licensure.

* * * * *

(c) The applicant shall also complete and submit [to the Board with the completed application] the examination fees and examination registration forms [provided by] to the test administrator.

(d) Affidavits of internship experience [gained after the filing of the application shall be filed before the examination date] shall be filed before authorization to take the exam is given.

* * * * *

§ 27.25. Licensure by reciprocity.

* * * * *

(b) [An] Except as provided in subsection (c), an applicant for licensure by reciprocity who received a license to practice pharmacy in any other state, territory or

possession of the United States, after January 26, 1983, shall be required to demonstrate that [he] the applicant passed the FDLE.

(c) If an applicant licensed after January 26, 1983, cannot demonstrate that the applicant passed the FDLE, the applicant shall be required to demonstrate that the applicant passed the Pennsylvania MPJE.

RENEWAL OF PHARMACIST LICENSE AND PHARMACY PERMIT

§ 27.31. Biennial renewal.

* * * * *

(b) A licensed pharmacist shall renew the license every 2 years, in even-numbered years. Renewal requires completion of a form mailed to the pharmacist by the Board in advance of the renewal period or completion of an online electronic form, and payment of the specified fee. [Beginning with 1988 renewals, a] A pharmacist shall also submit proof of compliance with the continuing education requirements of § 27.32 (relating to continuing education).

* * * * *

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 19, 2007

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

Re: Proposed Regulation
State Board of Pharmacy
16A-5416: General Revisions

Dear Chairman Coccodrilli:

Enclosed is a copy of a proposed rulemaking package of the State Board of Pharmacy pertaining to general revisions.

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

Sincerely,

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

EJB/CLC/kmh
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-5416
SUBJECT:	GENERAL REVISIONS
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
9/19/07	J. M. Power	HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
		MAJORITY CHAIRMAN Sturla
9/19/07	Mary Wolmer	SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
		MAJORITY CHAIRMAN
9/19/07	H. Gelwicks	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
9/19/07	Maya Sarar	LEGISLATIVE REFERENCE BUREAU (for Proposed only)