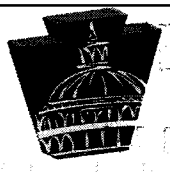
# Regulatory Analysis Form

(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: **16A**

Identification Number: **5416**

IRRC Number: 2640

(3) Short Title:

**General Revisions**

(4) PA Code Cite:

**49 Pa. Code §§ 27.1, 27.2, 27.3, 27.12, 27.17, 27.18, 27.19, 27.21, 27.25, 27.31**

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

Primary Contact: **Carole L. Clarke, Board Counsel, Department of State; (717)783-7200; P.O. Box 2649, Harrisburg, PA 17105-2649; (717)787-0251; caclarke@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**The Board undertook a wholesale review of its regulations to determine what provisions were outdated.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.**

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

| | |
|---|---|
| A. The date by which the agency must receive public comments: | October 29, 2007 |
| 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: | by October 29, 2009 |
| D. The expected effective date of the final-form regulation: | upon publication 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) and 6(k) of the Pharmacy Act (act) (63 P.S. §§ 390-4(j) and 390-6(k)).**

(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.

**There is a compelling public interest in revising and updating regulations on a periodic basis. The Board reviewed its regulations and chose to amend certain regulations to reflect current practice. The profession as a whole benefits from having updated regulations to govern the profession.**

(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 20,328 pharmacists and 3,256 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.

| | 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) | FY –2 (FY 06-07) | FY –1 (FY 07-08) | Current FY (FY 08-09) |
|---|---|---|---|---|
| Pa. State Board of Pharmacy | **$1,434,730** | **$1,683,729** | **projected $1,751,209** | **budget $1,889,000** |

(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 revise the regulations.**

(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 than any federal requirements.**

## Regulatory Analysis Form

(25) How does this regulation compare with those of other states? How will this affect Pennsylvania's ability to compete with other states?

**There are numerous provisions that were amended and all compare favorably with the 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. The regulation supplements some Department of Health regulations regarding controlled substance prescriptions, where the Department of Health regulations were silent. The regulation may impact the Department of Public Welfare's reimbursement regulations. However, reimbursement is a separate issue from regulating the practice of pharmacy.**

(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.**

(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.**

(2) Prepare worksheets, proposals or other presentations for funeral services.

(3) Engage in discussions or other communications with customers regarding the actual selection of funeral services and merchandise incidental to the services.

(4) Make financial arrangements for the rendering of funeral services and merchandise incidental to the services.

(5) Offer to or enter into a preneed funeral contract with any customer on behalf of the funeral director or funeral entity.

(6) Engage in any activity that would cause a customer to believe that the unlicensed employee is skilled in the knowledge, science or practice of funeral directing.

(7) Engage in any activity that constitutes the practice of funeral directing under the act.

(d) Nothing in this section shall be construed to alter the scope of practice of a licensed insurance agent acting under licensure from the Insurance Department, so long as the insurance agent is not acting as a funeral director or practicing funeral directing.

[Pa.B. Doc. No. 07-1793. Filed for public inspection September 28, 2007, 9:00 a.m.]

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# STATE BOARD OF PHARMACY

## [ 49 PA. CODE CH. 27 ]

## Revisions Regarding Current Pharmacy Practice

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 to read as set forth in Annex A.

*Effective Date*

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

*Statutory Authority*

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

*§ 27.12 (relating to practice of pharmacy and delegation of duties)*

The Board proposes to amend § 27.12 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.

*§ 27.17 (relating to security for Schedule II controlled substances)*

The Board proposes to amend § 27.17 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 in 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 manner 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.

*§ 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, 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 salable quantity, usually one tablet or salable 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.

*§ 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.

*§ 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 rulemaking will require all internship affidavits to be submitted to the Board before the applicant is authorized to take the exam.

*§ 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.

*§ 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 rulemaking will not impose any adverse fiscal impact on the Commonwealth, its political subdivisions, the public or the regulated community.

*Paperwork Requirements*

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

*Sunset Date*

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

*Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on 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, 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-5416. 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 ] 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 Drug Enforcement Administration (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 a manner that obstructs 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 ] must** 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) **[ [ Reserved ] ] 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 ] 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 ] A** registered pharmacist may **not** 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 ] apply** to the advertisement and sale of drugs:

* * * * *

(2) No person may promote to the public the sale of **[ Schedule II ] any** 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).

* * * * *

[Pa.B. Doc. No. 07-1794. Filed for public inspection September 28, 2007, 9:00 a.m.]

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# STATE BOARD OF SOCIAL WORKERS, MARRIAGE AND FAMILY THERAPISTS AND PROFESSIONAL COUNSELORS

## [ 49 PA. CODE CH. 47 ]

## Biennial Renewal Fees

The State Board of Social Workers, Marriage and Family Therapists and Professional Counselors (Board) proposes to amend § 47.4 (relating to licensure fees), to read as set forth in Annex A. The proposed rulemaking would increase the biennial license renewal fee for licensed social workers, clinical social workers, marriage and family therapists and professional counselors from $45 to $75.

*Effective Date*

The amendment will be effective upon publication of the final-form rulemaking in the *Pennsylvania Bulletin*. The increased fees will be effective for the biennial renewal period beginning March 1, 2009.

*Statutory Authority*

Section 18(c) of the Social Workers, Marriage and Family Therapists and Professional Counselors Act (act) (63 P. S. § 1918(c)) requires the Board to increase fees by regulation to meet or exceed projected expenditures if the revenues raised by fees, fines and civil penalties are not sufficient to meet Board expenditures.

*Background and Purpose*

The Board's current biennial license renewal fees for licensed social workers were established on December 1, 1990. (See 20 Pa.B. 5937 (December 1, 1990).) The Board's current biennial license renewal fees for the newer licensee classifications of licensed clinical social workers, marriage and family therapists and professional counselors were originally established at 32 Pa.B. 5885 (November 27, 2002) and were set at that time at the same level as those in effect for licensed social workers ($45). Under section 18(c) of the act (63 P. S. § 1918(c)), the Board is required by law to support its operations from the revenue it generates from fees, fines and civil penalties. In addition, the act provides that the Board must increase fees if the revenue raised by fees, fines and civil penalties is not sufficient to meet expenditures over a 2-year period. The Board raises virtually all of its revenue through biennial renewal fees.

At its Board meeting on February 13, 2007, the Department of State's Offices of Revenue and Budget presented a summary of the Board's revenue and expenses for Fiscal Years (FY) 2004-2005 and 2005-2006 and projected revenue and expenses through 2016-2017. The Offices of Revenue and Budget project a deficit of $67,350.37 in FY 2008-2009, a deficit of $416,350.37 in FY 2010-2011, a deficit of $338,350.37 in FY 2011-2012, a deficit of $841,350.37 in FY 2012-2013, a deficit of $827,350.37 in FY 2013-2014, a deficit of $1,397,350.37 in FY 2014-2015, a deficit of $1,453,350.37 in FY 2015-2016 and a deficit of $2,097,350.37 in FY 2016-2017. The major reason for the projected deficits is that the renewal fees for social workers have not been increased since 1990 and the renewal fees for licensed clinical social workers, marriage and family therapists and professional counselors have not been increased since their inception in 2002. Those fees have carried the Board for almost 17 years for social workers and 5 years for the other newer licensee categories. As a result of the projected deficits, the Offices of Revenue and Budget recommended that the Board raise fees to meet or exceed projected expenditures, in compliance with section 18(c) of the act. The Budget Office anticipates that the proposed new biennial renewal fees will enable the Board to meet its estimated expenditures for at least 9 years.

Although the $30 fee increase is significant, it is not surprising. As already stated, the fees for licensed social workers have not been increased since 1990 and the fees for licensed clinical social workers, marriage and family therapists and professional counselors have not been increased since they were originally established in 2002. Also, in spite of the proposed increase, the Board's new renewal fee of $75 every 2 years will still be lower than a majority of the surrounding States. For example, in New York, social workers and clinical social workers pay $155 every 3 years. In New Jersey, social workers pay $120 every 2 years and clinical social workers pay $160 every 2 years. In Delaware, clinical social workers pay $102 every 2 years. In Ohio, social workers pay $60 every 2 years. In

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE

**DATE:** **August 28, 2009**

**SUBJECT:** **Final Rulemaking:**
**State Board of Pharmacy**
**General Revisions (16A-5416)**

**TO:** **Andrew C. Clark, Deputy General Counsel**
**Office of General Counsel**

**FROM:** **Carole L. Clarke, Board Counsel** CLC
**Department of State**

There are no significant legal and policy issues presented by this amendment to the regulations of the State Board of Pharmacy concerning continuing education.

I certify that I have reviewed this regulation for form and legality, that I have discussed any legal and policy issues with the administrative officers responsible for the program, and that all information contained in the Preamble and Annex is correct and accurate.

CLC

**LIST OF COMMENTATORS 16A-5416**

1. **JERRY MUSHENO, J.D., R.Ph.**
   **ADJUNCT ASSISTANT PROFESSOR**
   **PHARMACY LAW**
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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-5416

_____
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

OCT 2 2008
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 §§ 27.1, 27.2, 27.3, 27.12, 27.17, 27.18, 27.19, 27.21, 27.25, 27.31
## REVISIONS REGARDING CURRENT PHARMACY PRACTICE

The State Board of Pharmacy (Board) hereby deletes § 27.3 (relating to location of office) and amends §§ 27.1, 27.2, 27.12, 27.17—27.19, 27.21, 27.25 and 27.31 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 Purpose

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.

Summary of Comments and Responses to Proposed Rulemaking

The Board published notice of proposed rulemaking at 37 Pa.B. 5260 (September 29, 2007), with a 30-day public comment period. The Board received comments from Patricia Clancy Kienle and Jerry Mucheno, J.D., R.Ph. who wrote on behalf of the P-3 class of Wilkes University Nesbitt School of Pharmacy. 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).

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

With regard to § 27.12, one commenter commented that they supported the change that allows pharmacy interns to accept and transcribe oral orders. The commenter and IRRC suggested that the Board affirmatively add that duty to § 27.12(c)(3) in the list of procedures that pharmacy interns are allowed to perform. That list pertains specifically to processing ingredients. The Board believes that with the removal of the prohibition in § 27.12(c)(2), the intent is clear and declines to add this to the list. The Board does not want to go down the road of listing each specific task that a pharmacy intern may perform. Pharmacists may delegate many aspects of the practice of pharmacy to pharmacy interns; therefore so long as an action is not prohibited the intern may perform it.

IRRC asked whether the Board considered adding a specific penalty provision to § 27.12 for the failure of a pharmacist to appropriately supervise a pharmacy intern. Under section 5(a)(6) of the act, 63 P.S. § 390-5(a)(6), the Board has the authority to discipline a pharmacist who has "violated or knowingly permitted the violation of any provision of this act or regulation of the board." Therefore, the Board does not intend to include a specific penalty provision in § 27.12 for failure to supervise a pharmacy intern. Any disciplinary matter for failure to supervise a pharmacy intern would be treated as any other violation of a regulation and evaluated on a case-by-case basis.

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

One commenter commented that proposed § 27.17(a) does not allow properly trained pharmacy technicians to access or transport controlled substances. The Board notes, as indicated by the brackets, that this language in the current regulation is being removed. The change that was proposed, and remains unchanged in the final-form regulation, is to remove the specific prohibitions on who can have access to controlled substances.

IRRC noted that the changes to § 27.17 appear to be contradictory, first requiring Schedule II controlled substances to be secured in locked cabinets and then permitting them to be dispersed throughout the stock of noncontrolled substances. Another commenter also suggested a change in the wording of § 27.17(a) with regard to storing Schedule II controlled substances to enhance clarity. The Board intended to be consistent with the Drug Enforcement Administration's (DEA) regulations at 21 C.F.R. § 1301.75 (b) (relating to physical security controls for practitioners) and the Department of Health's regulations at 28 Pa. Code § 25.63 (relating to security controls for practitioners and research personnel), both of which have been in place for over 30 years, to allow for dispersal as another method of obstructing the theft or diversion of controlled substances. In 1998, the Board had amended § 27.16(b)(3) (relating to construction and equipment requirements) to adopt this change, however, no similar amendment was made to § 27.17 at that time, or anytime since. Therefore, the amendments being made at this time are intended to promote internal consistency within the Board's regulations, not to change a substantive rule. The language has not been amended in response to these comments in order to be consistent with the regulations of the DEA and the Department of Health relating to security for controlled substances, both of which use nearly identical language to that being adopted by the Board.

The HPLC asked for the Board's reasoning for the safety measure of including controlled substances distributed throughout the stock of noncontrolled substances and noted that it did not appear to be an adequate safety measure. As noted above, many pharmacies have dispersed their controlled substances throughout the stock of noncontrolled substances for years as the DEA and the Department of Health have had this language in their regulations for over 30 years and because similar language has been in § 27.16(b)(3) since 1998. See 28 Pa.B. 4532. Dispersing controlled substances throughout the stock is considered to be more secure, as they are not easily identifiable as controlled substances when mixed in with the other stock of the pharmacy. If anyone illegally entered the pharmacy to procure controlled substances they would have to search throughout the stock of the pharmacy to find the controlled substances. Conversely, if all controlled substances were located in one area of the pharmacy, it would be easier to locate them and to illegally procure large quantities of controlled substances in a short period of time.

IRRC further commented that the Board should clarify what a "substantially constructed cabinet" is. The Board notes that this language has been in effect for over 30 years in the DEA's and the Department of Health's regulations mentioned above, as well as similar language in the Board's existing regulation at § 27.16(b)(3). The Board has not received any inquiries from licensees or inspectors about what would be considered a substantially constructed cabinet. The Board believes the term is clear and is understood by the regulated community. For this reason, the Board has made no amendment to the final rulemaking in response to these comments.

IRRC asked how the Board would enforce these storage provisions. The Board will continue to enforce these provisions through routine inspections and investigating complaints. IRRC next asked whether the Board has considered specifying which categories of medical professionals can access Schedule II controlled substances in facilities under the jurisdiction of the Board. The Board discussed this in drafting the proposed regulation and decided to delete the language in § 27.17 that prohibited anyone except a licensed pharmacist or pharmacy intern or, in an institution, a licensed physician or registered nurse from having access to controlled substances. The Board declines to specify who can access Schedule II controlled substances and instead will leave it up to the pharmacy and pharmacist to determine who is authorized to be present in the pharmacy. In a typical retail pharmacy, the only people in the prescription area would normally be the pharmacist, pharmacy technicians and interns and any authorized staff people. In an institution, that list of people would include other medical professionals who are part of the health care team. The Board is comfortable leaving that decision to the discretion of the pharmacist who must still be present and supervising when other authorized personnel are in the pharmacy.

A commenter also commented that "other persons" in § 27.17(b) should be clarified. The Board has changed the regulation to specify, "authorized personnel." The commenter also suggested that the Board affirmatively express the ability of a pharmacy technician to assist in the processing of Schedule II prescription in this section. The Board declines to affirmatively state that pharmacy technicians may be in an area where controlled substances are stored. As controlled substances may be stored throughout the pharmacy, the Board feels it is unnecessary to make this change. Also, this section applies to more than just pharmacy technicians.

*Section 27.18 (relating to standards of practice).*

A commenter commented on § 27.18(j), which the Board has amended to provide that prescriptions for Schedule II controlled substances may not be filled more than 6 months from the date of the prescription. The commenter asked the Board to verify that this change is within its purview. The Board feels confident that it is, having previously adopted similar regulations regarding how long prescriptions for Schedule III, IV and V substances are valid. IRRC asked what the Board's statutory authority is for amending § 27.18(j). The Board's authority to regulate the distribution of drugs and devices and the practice of pharmacy is found in section 6(k)(9) of the Pharmacy Act, 63 P.S. §390-6(k)(9). IRRC also asked how the Board determined that 6 months is an appropriate timeframe in which to honor this type of prescription. Similarly, the HPLC asked what the Board's rationale for permitting Schedule II controlled substances to be filled no more than 6 months after the date of the prescription. The Board notes that currently there is no law or regulation

that prescribes how long a prescription for a Schedule II controlled substance is valid. Six months is a timeframe that other states use, for example Virginia and Arkansas both say that a Schedule II prescription is valid for 6 months. See Code Ark. R. § 07-04-0004 (relating to time limit on a new Schedule II prescription); and 18 V.A.C. 110-20-290 (relating to dispensing of Schedule II drugs). The Board believes that 6 months is a reasonable timeframe during which the Schedule II prescription may be valid.

A commenter suggested that the Board limit the validity of a prescription for a Schedule II drug to no later than 90 days after it was written. The Board declines to make this change. The Board is aware of the provisions of 21 C.F.R. § 1306.12(b)(1), which permit practitioners to issue multiple prescriptions authorizing a patient to receive a total of up to a 90-day supply of a Schedule II controlled substance, provided certain conditions are met. See 21 C.F.R. § 1306.12(b)(1). The Board is not attempting to override the Federal regulation. The final-form regulation would allow some lag time between the issue date of the prescriptions and the dates when they are actually filled. Given that there was no previous time limit as to how long a Schedule II prescription remained valid, the Board is comfortable with enacting the 6-month limitation. In any case, a pharmacist may refuse to fill a prescription if the pharmacist believes in his professional judgment that in the interest of the safety of the patient the prescription should not be filled. See § 27.18(c).

IRRC commented that amended § 27.18(l)(6) is vague and recommended that more specific language is needed in the final-form regulation. The Board has added examples of various types of shipping that could be used to preserve the integrity of the drug. IRRC also asked how the Board would enforce this provision. The Board will enforce it as it does many of the provisions of the act and regulations through routine inspections and investigating any complaints that are filed.

HPLC commented that the Board's use of "direct supervision" in § 27.18(n) seemed different than other recently proposed regulations. The Board agrees and has changed § 27.18(n) to specify "direct, immediate and personal supervision".

IRRC asked why the Board replaced "pharmacist or pharmacy" with the word "person" in § 27.18(r)(6). The Board changed the wording to be consistent with use of the term "person" in the rest of § 27.18(r). HPLC inquired whether this section would have an impact on physicians offering coupons, specials and samples. This section would have no impact on physicians offering drugs for sale to their own patients. However, advertising to a larger population than just the prescriber's patient population could rise to the level of operating a pharmacy and the Board would be authorized to impose a civil penalty on a practitioner who violates the act.

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

IRRC and another commenter thought that amended § 27.19(d) was confusing with two subsections that gave examples of when a PDR is not required. The Board agrees and has amended this section.

*Section 27.25 (relating to licensure by reciprocity)*

IRRC stated that in § 27.25 there appeared to be abbreviations for licensure exams and asked that the Board define the abbreviations used for the licensure exams. The Board has done so in § 27.1 (relating to definitions).

Other Changes

The Department of Public Welfare (DPW) forwarded comments to the Board after the close of the public comment period. DPW asked the Board to clarify whether a physician is required to date the prescription. The Board's current regulation at § 27.18(b)(1) requires prescriptions on file in the pharmacy to show the date the prescription was issued. The Board only regulates pharmacists and pharmacies and cannot put an affirmative duty on a licensee that it does not regulate. Therefore, so long as the prescription on file in the pharmacy is dated, the Board cannot require that the prescriber must date it. As a practical matter, if a prescription is presented to the pharmacy without a date, the pharmacist may contact the prescriber to confirm the validity of the prescription and enter the date either by hand or a computer-generated label and that becomes the date of the prescription.

DPW also commented that the phrase "authorized by the prescriber" in § 27.18 is ambiguous and suggests that the regulation should be clarified to state when such authorization may or must occur. The Board has amended the final-form regulation to specify that refills may be authorized at any time during the 1-year period during which the prescription is valid.

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.

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 the notice of proposed rulemaking, published at 37 Pa.B. 5260, 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 deleting § 27.3 and by amending §§ 27.1, 27.2, 27.12, 27.17—27.19, 27.21, 27.25 and 27.31, 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, R.Ph., 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**

**§ 27.1. 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] Accreditation Council for Pharmacy Education.

* * * * *

FDLE - FEDERAL DRUG LAW EXAMINATION.

* * * * *

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

* * * * *

MPJE – MULTISTATE PHARMACY JURISPRUDENCE EXAMINATION.

* * * * *

PDR – PROSPECTIVE DRUG REVIEW PERFORMED TO ASSURE THAT A DRUG DISPENSED UNDER A PRESCRIPTION IS NOT LIKELY TO HAVE AN ADVERSE MEDICAL RESULT BY ATTEMPTING TO IDENTIFY POTENTIAL DRUG THERAPY PROBLEMS THAT MIGHT RESULT FROM THERAPEUTIC DUPLICATION, DRUG-DRUG INTERACTIONS, INCORRECT DOSAGE,

INCORRECT DURATION OF DRUG TREATMENT, DRUG-ALLERGY INTERACTIONS, AND CLINICAL ABUSE OR MISUSE.

* * * * *

**§ 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 Drug Enforcement Administration (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~~ AUTHORIZED PERSONNEL 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~~ PHARMACIST 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]must 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) [[Reserved]] 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. REFILLS MAY BE AUTHORIZED AT ANY TIME DURING THE 1-YEAR PERIOD.

(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] permissible if it is shipped in a manner which would preserve the integrity of the drug, SUCH AS COLD PACKS

OR OTHER TEMPERATURE CONTROL DEVICES AND SENSORS THAT WOULD ALERT THE PATIENT IF THE INTEGRITY OF THE DRUG WAS COMPROMISED.

* * * * *

(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, IMMEDIATE AND PERSONAL 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] A registered pharmacist may not 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] apply 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.**

(a) ~~*Definitions.* The following words and terms, when used in this section, have the following meanings, unless the context clearly indicates otherwise:~~

~~*Caregiver* – A person who has assumed responsibility for the care of a patient. The following will be presumed to be caregivers: the spouse, parent, adult child, guardian, legal representative or nurse of the patient.~~

~~*Mail order pharmacy* – A pharmacy whose primary patient population consists of patients who send their prescriptions to the pharmacy through the mail and receive nonproprietary drugs and devices from the pharmacy through the mail, common carrier or express courier service.~~

~~*PDR* – Prospective Drug Review.~~

~~(b) *General.* This section requires a~~ A pharmacist ~~to~~ SHALL 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)~~ (F) 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].

~~(c)~~ (B) * * *

~~(d)~~ (C) *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.

(iii) A MEDICAL PRACTITIONER DISPENSES A DRUG.

(iv) A PHARMACIST DISPENSES A DRUG TO A MEDICAL PRACTITIONER WHICH THE PRACTITIONER WILL ADMINISTER TO A PATIENT.

* * * * *

~~(e)~~ (D) * * *

~~(f)~~ (E) * * *

~~(g)~~ (F) * * *

~~(h)~~ (G) * * *

~~(i)~~ (H) * * *

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## 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.**

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(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

October 6, 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-5416: Revisions Regarding Current Pharmacy Practice

Dear Chairman Coccodrilli:

Enclosed is a copy of a final rulemaking package of the State Board of Pharmacy pertaining to Revisions Regarding Current Pharmacy Practice.

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/CLC: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
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: | REVISIONS REGARDING CURRENT PHARMACY PRACTICE |
| AGENCY: | DEPARTMENT OF STATE<br>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 |
|---|---|---|
| 10/6/09 | Kristin Miller | HOUSE COMMITTEE ON PROFESSIONAL LICENSURE |
| | | MAJORITY CHAIRMAN Michael P. McGeehan |
| 10/6/09 | Mary Weimer | SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE |
| | | MAJORITY CHAIRMAN Robt. M. Tomlinson |
| 10/6/09 | H. Gelnett | INDEPENDENT REGULATORY REVIEW COMMISSION |
| | | ATTORNEY GENERAL (for Final Omitted only) |
| | | LEGISLATIVE REFERENCE BUREAU (for Proposed only) |

October 2, 2009