

PROPOSED RULEMAKING

STATE BOARD OF FUNERAL DIRECTORS

[49 PA. CODE CH. 13]

Preneed Activities of Unlicensed Employee

The State Board of Funeral Directors (Board) proposes to amend § 13.1 (relating to definitions) and to add § 13.206a (relating to utilization of unlicensed employees by a funeral entity), to read as set forth in Annex A.

Effective date

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

The amendments are authorized under sections 11, 13, 15 and 16(a) of the Funeral Director Law (act) (63 P. S. §§ 479.11, 479.13, 479.15 and 479.16(a)).

Background and Need for the Amendment

Section 13(c) of the act (63 P. S. § 479.13(c)) provides, "No person other than a licensed funeral director shall, directly or indirectly, or through an agent, offer to or enter into a contract with a living person to render funeral services to such person when needed." In *Ferguson v. State Bd. of Funeral Directors*, 768 A.2d 393, 400 (Pa. Cmwlth. 2001), appeal denied, 566 Pa. 670, 782 A.2d 549, the court affirmed the Board's conclusion that an insurance agent who identified herself as working with a funeral director and, equipped with the funeral director's price lists and other literature, counseled the preneed selection of funeral goods and services, even though the funeral director later met with each customer and had the customer sign a statement of funeral goods and services prepared by the funeral director on the basis of the insurance agent's worksheets, offered to enter into a contract with the insured for funeral goods and services when needed without being licensed to practice funeral directing (in violation of section 13(c) of the act). The court also held that by doing so the insurance agent made arrangements for funeral services and sold funeral merchandise to the public incidental to the funeral services and therefore engaged in the practice of funeral directing without a license (in violation of section 13(a) of the act). Id. at 399-400. By doing that and entering into a life insurance contract to fund the preneed arrangements, which the funeral director had already agreed to accept as payment in full, the insurance agent also made financial arrangements for the rendering of funeral services and sale of merchandise incidental to the services and therefore engaged in the practice of funeral directing without a license (in violation of section 13(a) of the act). Id. However, in *Walker v. Flitton*, 364 F.Supp.2d 503 (U.S.D.C. M.D. Pa. 2005), a case involving commercial free speech rights under the First Amendment of the Federal constitution, the court ordered that the Board "shall not prohibit agents or employees of specific licensed funeral directors from providing accurate information to consumers regarding the sale of preneed funeral plans and services. This interaction shall include, but shall not necessarily be limited to, the distribution of accurate price lists to consumers, but under no circumstances may unlicensed individuals contract with consumers for the sale of preneed funerals, nor may they act as a 'funeral director' as defined in [the act]." The court indicated that

it did not intend to alter the Pennsylvania substantive law set forth in *Ferguson*. Id. at 513.

The Board has determined that its regulations need to address what unlicensed employees of a funeral establishment may do concerning preneed sales. See, *Walker* at 525-26 ("as a result of the [Board's] considered failure to enact a clarification of [its] interpretation of [the act], both consumers and the funeral industry in Pennsylvania have been forced to speculate as to precisely what conduct by unlicensed individuals is permissible"). The court "strongly urge[d] the Board members to fulfill their mandate by giving prompt attention to the goal of resolving all of the unclarity which has attended the sale and marketing of preneed funerals and life insurance policies to fund them in Pennsylvania." Id. at 529. The Board intends in this proposed rulemaking to be responsive to the court's mandate while remaining true to the act as previously construed.

This proposed rulemaking addresses only preneed activities and not actions after a death has occurred. In the event the licensed funeral director is temporarily absent, an unlicensed member of the funeral home staff may make tentative funeral arrangements after a death has occurred. See section 13(d) of the act (63 P. S. § 479.13(d)). Making tentative arrangements does not include offering to enter into a contract with a living person to render funeral services to the person when needed, and does not include making arrangements for funeral services and selling merchandise incidental to the service and does not include making financial arrangements for the rendering of funeral services and sale of merchandise incidental to the services. See 49 Pa. Code § 13.205 (relating to tentative agreements) tentative arrangements means contacting a licensed funeral director for the embalming operation, obtaining and placing obituary notices, setting a service time with the clergyperson and cemetery official and making an appointment for the family with a licensed funeral director for the selection of merchandise.

Description of the Proposed Amendments

In § 13.1 (relating to definitions), the term "preneed activity" would be defined as activity concerning the provision of funeral merchandise and services upon the death of a specifically identified person living at the time of the activity, and the term "preneed funeral contract" would be defined as an agreement under which a funeral entity promises or agrees to provide funeral merchandise and render services upon the death of a person living at the time the contract is made. These definitions are consistent with section 13(c) of the act.

Proposed § 13.206a would address the use of unlicensed employees of the funeral entity concerning preneed activity. Proposed § 13.206a(a) would set forth standards for the relationship between the funeral director or entity and the unlicensed employee. Proposed § 13.206a(a)(1) would make clear that the funeral director and funeral entity are professionally responsible for the actions of the unlicensed employee. See, *Walker* at 515 (funeral director is exposed to sanction by Board for improper action of unlicensed employee). Proposed § 13.206a(a)(2) would require the funeral director to closely supervise the unlicensed employee. See, *Walker* at 527 (Board may require close supervision by funeral director of unlicensed employees interacting with customers concerning preneed sales). Proposed § 13.206a(a)(3)

would prohibit the funeral director from paying any commission to the unlicensed employee for soliciting business. See, section 11(a)(8) of the act (63 P.S. § 479.11(a)(8)) (Board may take disciplinary action against a funeral director who "solicit[s] patronage . . . by paying a commission or agreeing to pay a commission to any person or persons for soliciting or for business secured, or paying any gratuity to any person with the intent to have such person aid in securing business"). By prohibiting the unlicensed employee from being paid based upon how much preneed business the employee brings into the funeral home, this provision is intended to reduce the employee's incentive to persuade a customer to select funeral services and merchandise whether or not that selection would be in the customer's interest. Proposed § 13.206a(a)(4) would require the funeral director to meet face-to-face with the customer before entering into the contract, and proposed § 13.206a(a)(5) would require that any document presented to a customer by the unlicensed employee must include a notice that the document will not be binding and that a licensed funeral director must meet with the customer before entering into any contract. See, *Walker* at 527 (unlicensed individual may not contract with customer, and Board may require licensed funeral director to consult face-to-face with preneed customer before the customer's proposed contract is signed by the funeral director).

In *Walker*, supra, at pages 526-27, the court noted the responsibility of the Board to delineate with precision what conduct by unlicensed persons is permissible. Proposed § 13.206a(b) and (c) would set forth those actions of unlicensed employees that would be permitted or prohibited, respectively. Proposed § 13.206a(b)(1) would specifically authorize an unlicensed employee to distribute general price lists of the employing funeral entity, and proposed § 13.206a(b)(2) would authorize an unlicensed employee to provide general assistance to the employing funeral entity by engaging in activities not otherwise prohibited. These provisions are intended to allow funeral entities enough latitude to be responsive in allowing unlicensed employees to communicate with consumers with regard to preneed activity without violating the act, while being responsive to the mandate of the court in *Walker*.

Proposed § 13.206a(c) would prohibit an unlicensed employee from engaging in certain actions concerning preneed activities. Proposed § 13.206a(c)(1) would prohibit an unlicensed employee from being associated with any other funeral entity. See, *Walker* at 506, n. 17 at 520 (court need not address unlicensed person not trained by and acting on behalf of specified funeral director, because plaintiffs are fulltime employees of funeral home trained and supervised by licensed funeral director). Being restricted to a single funeral entity, the unlicensed employee would be acting only on behalf of the funeral director and funeral entity responsible for the unlicensed employee's actions who also have presumably trained the unlicensed employee. Additionally, if an unlicensed employee were to work for more than one funeral entity, the various funeral directors may be less likely to closely supervise the unlicensed employee, because each funeral director might tacitly assume that all work away from that funeral entity would be supervised by the funeral directors at other funeral entities, and the unlicensed employee might not be closely supervised at all.

Because the Board cannot authorize unlicensed employees of a funeral entity to practice funeral directing, proposed § 13.206a(c)(2) and (3) would prohibit an unlicensed employee from preparing worksheets, proposals or

other presentations for funeral services or to engage in discussions or other communications with customers regarding the actual selection of funeral services and merchandise incidental to those services. See, *Ferguson* at 400 (counseling selection of preneed funeral services is making arrangements for funeral service and selling funeral merchandise incidental to the services and is therefore engaging in the practice of funeral directing). Similarly, proposed § 13.206a(c)(4) would prohibit an unlicensed employee from making financial arrangements for the rendering of funeral services and merchandise incidental to such services. See, *Walker* at 527 (under no circumstances may unlicensed individual act as a funeral director as defined in section 2(1) of the act); section 2(1) of the act (term "funeral director" includes "a person who makes arrangements for funeral service and who sells funeral merchandise to the public incidental to such service or who makes financial arrangements for the rendering of such services and the sale of such merchandise"); see also, *Ferguson* at 400 (entering into contract for life insurance to fund funeral and effectuating the assignment of the policy to the funeral director as previously agreed constitutes making financial arrangements for funeral services and merchandise). Because these actions by the unlicensed person constituted the unlicensed practice of funeral directing in *Ferguson*, the Board must make clear that an unlicensed person cannot practice funeral directing by engaging in these actions.

Proposed § 13.206a(c)(5) would prohibit an unlicensed employee from offering to or entering into a preneed funeral contract with any customer on behalf of the funeral entity. See, *Walker* at 527 (under no circumstances may unlicensed individual contract with consumer for sale of preneed funeral). Section 13(c) of the act, as construed in *Ferguson*, makes it clear that only a licensed funeral director may enter into a preneed contract. This proposed provision is necessary to maintain that limitation. Proposed § 13.206a(c)(6) and (7) would prohibit an unlicensed employee from engaging 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 or to engage in any activity that constitutes the practice of funeral directing under the act. See, *Walker* at 527 (under no circumstances may unlicensed individuals act as a funeral director as defined in section 2(1) of the act); section 15(1) of the act (person is deemed to be practicing as a funeral director under the act if he "holds himself out to the public in any manner as one who is skilled in the knowledge, science and practice of funeral directing, embalming or undertaking"). These prohibitions of proposed § 13.206a(c) are intended to protect the public by clearly defining what an unlicensed employee of a funeral entity may not do in regard to preneed activity consistent with the act as construed in *Ferguson* and in accordance with the judicial mandate in *Walker*.

Finally, proposed § 13.206a(d) would make clear that the Board's rulemaking is not intended to affect the scope of practice of insurance agents licensed by the Insurance Department.

In November, 2005, the Board solicited input from and provided an exposure draft of this proposed rulemaking to funeral directors and organizations as required. The Board held a public hearing on the exposure draft on December 12, 2005. At a public meeting in March 2006, a committee of the Board discussed the various comments and prepared a revised draft of this proposed rulemaking, which the Board subsequently approved. The Board prepared an alternate version of this proposed rulemaking,

which would permit unlicensed employees to engage in a greater range of activities. In January 2007, the Board provided to interested parties this alternative exposure draft and solicited comments. In response to extensive comments from the regulated community, the Board determined that it should proceed with the proposed rulemaking in substantially the same form as previously approved. In addition, the Board considered the impact the rulemaking would have on the regulated community and on public health, safety and welfare.

Fiscal Impact and Paperwork Requirements

The proposed rulemaking will have no adverse fiscal impact on the Commonwealth or its political subdivisions. The rulemaking will impose no additional paperwork requirements upon the Commonwealth, its political subdivisions or the private sector.

Sunset Date

The Board continuously monitors the cost effectiveness of its regulations. Therefore, no sunset date has been assigned.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on 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 shall specify the regulatory review criteria which have not been met. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the rulemaking, by the Board, the General Assembly and the Governor of comments, recommendations or objections raised.

Public Comment

Interested persons are invited to submit written comments, suggestions or objections regarding this proposed rulemaking to Michelle T. Smey, Administrative Officer, State Board of Funeral Directors, P. O. Box 2649, Harrisburg, PA 17105-2649, within 30 days of publication of this proposed rulemaking in the *Pennsylvania Bulletin*. Please reference No. 16A-4816 (Preneed activities of unlicensed employees), when submitting comments.

ANTHONY SCARANTINO,
Chairperson

Fiscal Note: 16A-4816. 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 13. STATE BOARD OF FUNERAL DIRECTORS

GENERAL PROVISIONS

§ 13.1. Definitions.

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

* * * * *

Preneed activity—Any activity on behalf of a funeral entity concerning the provision of funeral service or merchandise upon the death of a specifically identified person living at the time of the activity.

Preneed funeral contract—An agreement under which a funeral entity promises or agrees to provide funeral merchandise or render services upon the death of a person living at the time the contract is made, whether or not the funeral entity receives preneed funeral funds.

* * * * *

§ 13.206a. Utilization of unlicensed employees by a funeral entity.

(a) A licensed funeral director or funeral entity may permit an unlicensed employee of the funeral entity to interact with customers concerning preneed activity in accordance with this section.

(1) The funeral director or funeral entity utilizing an unlicensed employee shall be professionally responsible for the actions of the unlicensed employee.

(2) The unlicensed employee shall operate only under the close supervision of a licensed funeral director.

(3) The funeral director or funeral entity may not pay or agree to pay a commission to the unlicensed employee for soliciting business or for business secured by the unlicensed employee.

(4) A licensed funeral director of the funeral entity employing an unlicensed employee in this capacity shall consult face-to-face with each customer before entering into or offering to enter into a preneed funeral contract.

(5) Any document presented by the unlicensed employee to the customer for signature or acknowledgment must bear in 20-point or larger print the following notice completed with the name of the funeral entity:

THIS DOCUMENT DOES NOT CONSTITUTE A CONTRACT OR AN OFFER TO CONTRACT. THIS DOCUMENT IS NOT BINDING ON YOU (THE CUSTOMER) OR [name of funeral entity], BUT IS MERELY FOR INFORMATION PURPOSES TO INFORM YOU OF THE SERVICES AND MERCHANDISE AVAILABLE AND THE COST THEREOF, AS WELL AS FUNDING OPTIONS. ANY NEGOTIATIONS WITH A VIEW TO ENTERING INTO A CONTRACT WITH [name of funeral entity] MUST TAKE PLACE IN A FACE-TO-FACE MEETING WITH A LICENSED FUNERAL DIRECTOR OF [name of funeral entity].

(b) An employee not licensed under the act acting in accordance with this section may:

(1) Distribute general price lists of the employing funeral entity only.

(2) Provide general assistance to the employing funeral entity by engaging in activities, including communications with customers, not otherwise prohibited by the act or this chapter.

(c) An employee not licensed under the act who engages in the activity described in this section may not:

(1) Be associated with any other funeral entity.

(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.]

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 Pharmaceuti- cal] Accreditation Council for Pharmacy Education.

* * * * *

Licensed person—A person holding a license is- sued 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 En- forcement 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, Harris- burg, 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 ingredi- ents and other similar processing of ingredients.

* * * * *

§ 27.17. Security for Schedule II controlled sub- stances.

(a) [From the time that a Schedule II controlled substance is received for storage in the prescrip- tion area until the time that controlled substance has been prepared and compounded into an indi- vidual 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 ad- equately controlling access to the controlled sub- stances:

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

(2) A chest or cabinet of sound construction se- cured 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 respon- sible 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 im- ages of the original prescriptions shall be kept for 2 years from the date of the most recent filling.

* * * * *

(i) [[Reserved]] Prescriptions for nonpropri- etary 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 nonpro- prietary 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 sub- stances 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 pre- scriber. 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 simi- lar 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.

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

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(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.

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(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.

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§ 27.19. Prospective drug review and patient counseling.

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(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.

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(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).

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

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

West Virginia, social workers and clinical social workers pay \$65 every 2 years. Finally, in Maryland, social workers and clinical social workers pay \$200 every 2 years. None of the surrounding states have separate licensee categories for marriage and family therapists or professional counselors.

Description of Proposed Amendments

Based upon the expense and revenue estimates provided to the Board, the Board proposes to amend § 47.4 to increase the fee for biennial renewal of licensed social workers, clinical social workers, marriage and family therapists and professional counselors from \$45 to \$75.

Fiscal Impact

The proposed amendment will increase the biennial renewal fee for licensed social workers, clinical social workers, marriage and family therapists and professional counselors. The proposed amendment should have no other fiscal impact on the private sector, the general public or political subdivisions.

Paperwork Requirements

The proposed amendment will require the Board to alter some of its forms to reflect the new biennial renewal fees; however, the proposed amendment should not create additional paperwork for the private sector.

Sunset Date

The act requires that the Board monitor its revenue and costs on a fiscal year and biennial 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 amendment 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. Comments, recommendations or objections shall specify the regulatory review criteria which have not been met. The Regulatory

Review Act specifies detailed procedures for review, prior to final publication of the rulemaking, by the Board, the General Assembly, and the Governor of comments, recommendations or objections raised.

Public Comment

Interested persons are invited to submit written comments, suggestions or objections regarding this proposed rulemaking to Beth Michlovitz, Counsel, State Board of Social Workers, Marriage and Family Therapists and Professional Counselors, P. O. Box 2649, Harrisburg, PA 17105-2649, within 30 days of publication of this proposed rulemaking in the *Pennsylvania Bulletin*. Please reference No. 16A-6915, Biennial Renewal Fees, when submitting comments.

MICHAEL J. DESTEFANO,
Chairperson

Fiscal Note: 16A-6915. 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 47. STATE BOARD OF SOCIAL WORKERS, MARRIAGE AND FAMILY THERAPISTS AND PROFESSIONAL COUNSELORS

GENERAL PROVISIONS

§ 47.4. Licensure fees.

(a) The fee schedule for licensure as a licensed social worker, provisional license, licensed clinical social worker, licensed marriage and family therapist or licensed professional counselor shall be as follows:

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(2) Biennial renewal for a licensed social worker, clinical social worker, marriage and family therapist or professional counselor\$[45] 75

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[Pa.B. Doc. No. 07-1795. Filed for public inspection September 28, 2007, 9:00 a.m.]