

CHAPTER 27. STATE BOARD OF PHARMACY

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Authority

The provisions of this Chapter 27 issued under section 506 of The Administrative Code of 1929 (71 P. S. § 186); and the Pharmacy Act (63 P. S. §§ 390-1—390-13), unless otherwise noted.

Source

The provisions of this Chapter 27 adopted June 1, 1973, effective June 2, 1973, 3 Pa.B. 1051, unless otherwise noted.

Cross References

This chapter cited in 28 Pa. Code § 501.4 (relating to regulations); 28 Pa. Code § 551.52 (relating to ASF responsibilities); 28 Pa. Code § 561.1 (relating to drugs and biologicals); 28 Pa. Code § 601.3 (relating to requirements for home health care agencies); 49 Pa. Code § 41.26 (relating to professional corporations); and 49 Pa. Code § 47.21 (relating to professional corporations).

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 Accreditation Council for Pharmacy Education.

Act—The Pharmacy Act (63 P. S. §§ 390-1—390-13).

Automated medication system—

(i) A process that performs operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing and distribution of medications, and which collects, controls and maintains all transaction information.

(ii) The term does not include an automatic counting device or unit-based dispensing cabinet.

Automatic counting device—A device used in a pharmacy to automatically count medication for dispensing.

Board—The State Board of Pharmacy.

Bureau—The Bureau of Professional and Occupational Affairs of the Department.

CEU—*Continuing education units*—The unit of measuring contact hours of continuing education provided by ACPE accredited providers. Ten contact hours are equivalent to 1.0 CEU.

Central fill pharmacy—A pharmacy engaging in centralized prescription processing by filling and refilling prescriptions, which includes the preparation and packaging of the medication. A central fill pharmacy may also be the originating or delivering pharmacy.

Central processing center—A pharmacy operated under the direction of a pharmacist that processes information related to the practice of pharmacy and that engages solely in centralized prescription processing but from which drugs are not dispensed.

Centralized prescription processing—The processing, under the direction of a pharmacist, of a request to fill or refill a prescription, to perform functions such as refill authorizations, interventions or other matters related to the practice of pharmacy for subsequent delivery to the delivering pharmacy.

Commissioner—The Commissioner of Professional and Occupational Affairs in the Department.

Contact hours—Continuing education units of measure equivalent to 50 to 60 minutes of participation in an approved organized learning experience, including home study with approved educational materials.

Continuing education—Professional education obtained to maintain, improve or expand current skills or knowledge, or to develop new skills or knowledge.

DEA—The Federal Drug Enforcement Administration.

Delivering pharmacy—The pharmacy that receives the processed prescription or the filled or refilled prescription for delivering to the patient or the patient's authorized representative. A delivering pharmacy may also be an originating or central fill pharmacy.

Department—The Department of State of the Commonwealth.

Drug order—

(i) An oral or written order issued by a medical practitioner which is either written on or entered by computer into the medical record of a patient in an institution for the dispensing of a drug or device for administration to the patient.

(ii) The term does not include an order for a drug for a patient in an institution which the patient will self-administer which will be considered a prescription.

FDA—The United States Food and Drug Administration, a division of the United States Department of Health and Human Services.

FDLE—Federal Drug Law Examination.

Institution—A health care facility as defined in section 103 of the Health Care Facilities Act (35 P. S. § 448.103) which offers care and medical treatment to patients who require food, board and overnight sleeping facilities.

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

Long-term care facility—A nursing home, retirement care, mental care or other institution that provides extended health care to resident patients.

MJPE—Multistate Pharmacy Jurisprudence Examination.

Management of drug therapy—

(i) Any of the following processes performed under a written protocol as set forth in section 9.1 of the act (63 P. S. § 390-9.1) or under a collaborative agreement as set forth in section 9.3 of the act (63 P. S. § 390-9.3):

(A) Adjusting a drug regimen.

(B) Adjusting drug strength, frequency of administration or route.

(C) Administration of drugs.

(D) Ordering laboratory tests and ordering and performing other diagnostic tests necessary in the management of drug therapy.

(E) Monitoring the patient's vital signs.

(F) Providing education and training to the patient that is related to the management of the drug therapy.

(ii) The term excludes medication therapy management services in the practice of pharmacy provided under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. No. 108-173, 117 Stat. 2066).

Medical practitioner—A physician, dentist, veterinarian or other individual authorized and licensed by law to prescribe drugs.

Non-institutional setting—A setting other than an institution as defined in the act and this section.

Nonproprietary drug—A drug containing any quantity of a controlled substance or a drug which is required by an applicable Federal or state law to be dispensed only by prescription.

Order—Any directive from a medical practitioner.

Originating pharmacy—

(i) The pharmacy that receives the patient's or prescribing practitioner's request to fill or refill a prescription and performs functions such as the prospective drug review.

(ii) The term includes a central processing center or a central fill pharmacy if the prescription was transmitted by the prescriber directly to the central processing center or central fill pharmacy or if the patient requested the refill from that pharmacy.

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.

Pharmacist manager—The pharmacist named in the permit to operate a pharmacy who is in charge of a pharmacy and responsible for operations involving the practice of pharmacy under section 4 of the act (63 P. S. § 390-4).

Pharmacy—The place licensed by the Board where the practice of pharmacy is conducted.

Pharmacy intern—A person registered by the Board as a pharmacy intern under section 3(e) of the act (63 P. S. § 390-3(e)) and § 27.26 (relating to pharmacy internship).

Pharmacy technician—

(i) An unlicensed person working in a pharmacy to assist a pharmacist in the practice of pharmacy in accordance with § 27.12 (relating to practice of pharmacy and delegation of duties).

(ii) The term does not include a pharmacy intern, or clerical or house-keeping personnel.

Practice of pharmacy—

(i) The provision of health care services by a pharmacist, which includes:

- (A) The interpretation, evaluation and implementation of medical orders for the provision of pharmacy services or prescription drug orders.
- (B) The delivery, dispensing or distribution of prescription drugs.
- (C) Participation in drug and device selection.
- (D) Drug administration.
- (E) Drug regimen review.
- (F) Drug or drug-related research.
- (G) Compounding.
- (H) Proper and safe storage of drugs and devices.
- (I) Management of drug therapy under a written collaborative agreement as set forth in section 9.3 of the act or, if in an institutional setting, consistent with the institution's assignment of clinical duties under a written protocol as set forth in section 9.1 of the act.
- (J) Maintaining proper records.
- (K) Patient counseling.
- (L) Acts, services, operations or transactions necessary or incident to the provision of these health care services.
- (M) Drug therapy management, including services provided under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

(ii) The term does not include the operations of a manufacturer or distributor as defined in The Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. §§ 780-101—780.144).

Prescription—A written, electronic or oral order issued by a licensed medical practitioner in the course of professional practice for a controlled substance, other drug or device, or medication which is dispensed for use by a consumer.

Prescription area—

- (i) That area of the pharmacy used for compounding, legend drug storage and other activities necessary to the practice of pharmacy.
- (ii) The term does not include waiting counters or display space attached to the waiting counters.

Proprietary drug—A nonprescription, nonnarcotic medicine or drug which may be sold without a prescription and which is prepackaged for use by the consumer and labeled in accordance with the requirements of Federal and State statutes and regulations.

Satellite pharmacy—

- (i) A pharmacy in an institution which provides specialized services for the patients of the institution and which is dependent upon the centrally located pharmacy for administrative control, staffing and drug procurement.
- (ii) The term does not include a pharmacy serving the public on the premises of an institution nor does it include a pharmacy located off prem-

ises from the centrally located pharmacy of the institution regardless of whether the pharmacy is owned by the same person or entity which owns the institution.

USP—The United States Pharmacopeia—A compendium of drug information published by the United States Pharmacopeial Convention.

Authority

The provisions of this § 27.1 amended under sections 4(j), 6(k)(1) and (9) and 9.3 of the Pharmacy Act (63 P. S. §§ 390-4(j), 390-6(k)(1) and (9) and 390-9.3).

Source

The provisions of this § 27.1 amended December 19, 1986, effective December 20, 1986, 16 Pa.B. 4883; amended June 20, 1997, effective June 21, 1997, 27 Pa.B. 2931; amended September 4, 1998, effective September 5, 1998, 28 Pa.B. 4532; amended May 26, 2006, effective May 27, 2006, 36 Pa.B. 2518; amended June 30, 2006, effective July 1, 2006, 36 Pa.B. 3237; amended December 24, 2009, effective December 26, 2009, 39 Pa.B. 7205; amended February 12, 2010, effective February 13, 2010, 40 Pa.B. 842; corrected October 7, 2011, effective May 27, 2006, 41 Pa.B. 5365; amended August 21, 2015, effective August 22, 2015, 45 Pa.B. 4911; amended June 21, 2019, effective June 22, 2019, 49 Pa.B. 3210. Immediately preceding text appears at serial pages (378260) to (378264).

Cross References

This section cited in 6 Pa. Code § 22.62 (relating to conditions of provider participation); 49 Pa. Code § 27.11 (relating to pharmacy permit and pharmacist manager); and 49 Pa. Code § 27.12 (relating to practice of pharmacy and delegation of duties).

§ 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 the DEA or the Secretary of the Department of Health.

Source

The provisions of this § 27.2 amended December 24, 2009, effective December 26, 2009, 39 Pa.B. 7205. Immediately preceding text appears at serial page (320543).

Cross References

This section cited in 6 Pa. Code § 22.62 (relating to conditions of provider participation).

§ 27.3. [Reserved].

Source

The provisions of this § 27.3 reserved December 24, 2009, effective December 26, 2009, 39 Pa.B. 7205. Immediately preceding text appears at serial page (320543).

Cross References

This section cited in 6 Pa. Code § 22.62 (relating to conditions of provider participation).

§ 27.4. Filing of addresses.

A licensed pharmacist and pharmacy in this Commonwealth shall file a current mailing address with the Board at its office and shall notify the Board of changes in the mailing address within 10 days of the changes.

Cross References

This section cited in 6 Pa. Code § 22.62 (relating to conditions of provider participation).

STANDARDS**§ 27.11. Pharmacy permit and pharmacist manager.**

(a) A permit to conduct a pharmacy issued under section 4 of the act (63 P. S. § 390-4) shall show the name and address of the pharmacy, the name of the current owner and the name of the current pharmacist manager.

(b) A pharmacy may not display, advertise or use any name other than the name in which it is registered.

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

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

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

- (i) The receipt of new written prescriptions.
- (ii) The preparation of prescriptions for final verification by the pharmacist.
- (iii) The delivery of prescription medications that have been verified by the pharmacist.

(d) A change in name or ownership or controlling interest of the pharmacy shall require a new permit. Applications for new permits shall be filed within 30 days of the change in name, ownership or controlling interest.

(e) A person or entity holding a certificate, license, permit or registration as a licensed pharmacist or pharmacy may not post or display in public view a current certificate, license, permit, registration or renewal of a person not lawfully employed by the licensee.

(f) A pharmacy which closes or otherwise ceases operation shall immediately return to the Board its current permit and shall immediately inform the Board of the disposition of the prescription files and nonproprietary drugs. After 30 days, neither prescription files nor nonproprietary drugs may be sold, transferred or disposed of without prior permission from the Board. When a pharmacy closes or ceases operation, signs, symbols or other indications of a pharmacy shall immediately be removed from both the interior and exterior of the premises.

(g) If the pharmacist manager ceases to hold that position, the pharmacy permit holder shall inform the Board in writing of this fact and of the new pharmacist manager not more than 15 days later. If the Board does not object within 30 days of notification, the new pharmacist manager may be deemed approved. If the permit holder is unable to replace the pharmacist manager within those 15 days, the permit holder may request in writing an extension of up to 30 additional days to obtain a replacement. A pharmacy may not operate without a pharmacist manager for more than 15 days unless the pharmacy first obtains from the Board an extension of time for obtaining a replacement.

(h) A pharmacist may not serve as the pharmacist manager of more than one pharmacy at any given time. The holder of a permit to operate a pharmacy which has lost the services of a pharmacist manager and cannot obtain a suitable replacement may apply in writing to the Board for a temporary waiver of this subsection. The Board may grant a waiver which would authorize a pharmacist manager to serve as pharmacist manager of more than one pharmacy for up to 60 days after the initial 15 days permitted under subsection (g).

(i) Each pharmacy in this Commonwealth will require a separate permit regardless of ownership unless the pharmacy is a satellite pharmacy as defined in § 27.1 (relating to definitions).

Authority

The provisions of this § 27.11 amended under sections 4(2) and 6(k)(1) and (9) of the Pharmacy Act (63 P. S. §§ 390-4(j), 390-6(k)(1) and (9)).

Source

The provisions of this § 27.11 amended September 4, 1998, effective September 5, 1998, 28 Pa.B. 4532; amended December 11, 2009, effective December 12, 2009, 39 Pa.B. 7005. Immediately preceding text appears at serial pages (342123) to (342124).

Cross References

This section cited in 6 Pa. Code § 22.62 (relating to conditions of provider participation); 49 Pa. Code § 27.16 (relating to construction and equipment requirements); and 49 Pa. Code § 43b.7 (relating to schedule of civil penalties—pharmacists and pharmacies).

§ 27.12. Practice of pharmacy and delegation of duties.

(a) *General.* It is unlawful for a person not licensed as a pharmacist by the Board to engage or allow another person to engage in the practice of pharmacy as defined in § 27.1 (relating to definitions) and section 2 of the act (63 P. S. § 390-2) except in accordance with this section.

(b) *Delegation.* A pharmacist may delegate aspects of the practice of pharmacy to a pharmacy intern or pharmacy technician, as defined in § 27.1, subject to the following conditions:

(1) The pharmacist shall review every prescription or drug order prior to its being dispensed to determine the name of the drug, strength, dosage, quantity, permissible refills and other information required under § 27.18(b) (relating to standards of practice) to verify the accuracy of the preparation.

(2) The pharmacist shall provide direct, immediate and personal supervision to pharmacy interns and pharmacy technicians working with the pharmacist. Direct, immediate and personal supervision means that the supervising pharmacist has reviewed the prescription or drug order prior to its being dispensed, has verified the final product and is immediately available on the premises to direct the work of interns and technicians and respond to questions or problems.

(3) The pharmacist shall ensure that the label of the container in which a nonproprietary drug is dispensed or sold pursuant to a prescription complies with the labeling requirements of § 27.18(d).

(c) *Pharmacy interns.*

(1) A pharmacy intern may work only under the direct, immediate, personal supervision of a pharmacist in accordance with subsection (b)(2).

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

(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.

(d) *Pharmacy technicians.*

(1) A pharmacy technician may work only under the direct, immediate, personal supervision of a pharmacist in accordance with subsection (b)(2).

(2) The following are examples of the types of activities which a pharmacy technician may perform:

- (i) Carry containers of drugs in and around the pharmacy.
- (ii) Count pills, tablets and capsules and put them in a container.
- (iii) Type or print, or both, labels.
- (iv) Maintain records which are related to the practice of pharmacy.

(v) Assist the pharmacist in preparing and reconstituting parenteral products and other medications. After the parenteral product or other medication has been prepared, the supervising pharmacist shall initial the label of the product or medication to document his final inspection and to accept total responsibility for its preparation.

(vi) Enter prescription, drug order or patient information in a patient profile.

(vii) Assist the pharmacist in the compounding of drug products, as permitted by the written protocol created and maintained in accordance with paragraph (4).

(3) A pharmacy technician may not:

(i) Accept or transcribe an oral order or telephone prescription.

(ii) Enter or be in a pharmacy if a pharmacist is not on duty.

(iii) Perform any act within the practice of pharmacy that involves discretion or independent professional judgment.

(iv) Perform a duty until the technician has been trained and the duty has been specified in a written protocol.

(4) The pharmacist manager shall create and maintain a written protocol for each pharmacy technician employed in the pharmacy. The protocol shall specify each duty which the pharmacy technician may perform. The pharmacist manager and the pharmacy technician shall date and sign the protocol and each amendment to the protocol. The pharmacist manager shall make the protocol available to agents of the Board upon demand.

Authority

The provisions of this § 27.12 amended under sections 4(j) and 6(k)(1) and (9) of the Pharmacy Act (63 P.S. §§ 390-4(j) and 390-6(k)(1) and (9)).

Source

The provisions of this § 27.12 amended September 4, 1998, effective September 5, 1998, 28 Pa.B. 4532; amended December 24, 2009, effective December 26, 2009, 39 Pa.B. 7205; amended June 21, 2019, effective June 22, 2019, 49 Pa.B. 3210. Immediately preceding text appears at serial pages (347398) to (347399).

Cross References

This section cited in 6 Pa. Code § 22.62 (relating to conditions of provider participation); and 49 Pa. Code § 27.1 (relating to definitions).

§ 27.13. Inspection reports.

A person to whom a pharmacy or pharmacist certificate, license, permit or registration has been issued shall retain copies of reports or notices issued by inspectors or by the Board, and shall maintain the reports and notices on the licensed

premises in such a manner as to make them readily available upon request of the Board or its agents for a period of 2 years from date of issuance of the inspection reports or notices.

Cross References

This section cited in 6 Pa. Code § 22.62 (relating to conditions of provider participation).

§ 27.14. Supplies.

(a) A pharmacy shall maintain a supply of drugs and devices adequate to meet the needs of the health professions and the patients it is intended to serve. The applicant for a pharmacy permit shall show proof by affidavit that the applicant has ordered or possesses and shall continue to maintain an inventory of nonproprietary drugs, devices and equipment appropriate to the practice of that pharmacy. The inventory must include at least \$5,000 worth of nonproprietary drugs and devices, at cost, from a licensed wholesaler or manufacturer. The inventory may not go below this figure at any time. A central processing center is not required to maintain \$5,000 worth of nonproprietary drugs and devices under § 27.203(b) (relating to centralized prescription processing).

(b) Drugs which must be removed from active stock shall be removed in accordance with the following provisions:

(1) The pharmacist manager is responsible for removing from the active stock of the pharmacy and disposing of the following:

- (i) A drug whose expiration date has passed.
- (ii) A drug which does not meet legal standards of strength and purity.
- (iii) A drug which varies from the strength and purity indicated on the label of the commercial container.
- (iv) A drug which has been improperly stored.
- (v) A drug which has deteriorated.
- (vi) A drug which is unfit, misbranded or adulterated under Federal or State statutes.

(2) Drugs which have been removed from active stock in accordance with this subsection may not be sold or given away. The drugs shall be returned to the wholesaler or manufacturer for disposal or disposed of by the pharmacy according to Federal or State statutes or regulations.

(3) A pharmacy desiring to or required to dispose of a controlled substance shall contact the nearest DEA office for authority and instructions to dispose of the substance.

(4) The pharmacist manager shall be responsible for keeping proper records of controlled substances which have been disposed of. These records must include the name of the substance, the number of units or the volume of the substance or the number of commercial containers and the date and manner of disposal.

(c) Except for a pharmacy operating as a central processing center, a pharmacy shall maintain at least the following equipment and supplies:

(1) A refrigerator, used solely for the storage of drugs requiring refrigeration, equipped with a thermometer or a temperature monitoring device. The refrigerator shall be kept in the prescription area.

(2) Prescription files for keeping prescriptions of nonproprietary drugs in accordance with the act and, for controlled substance prescriptions, State and Federal laws and regulations. The original prescription or image of the original prescription shall be retained for 2 years from the date of the most recent filling. A pharmacy may make use of a computerized recordkeeping system for keeping track of telephone prescriptions, refills, counseling, and the like in accordance with § 27.202 (relating to computerized recordkeeping systems).

(3) Current copies of the act and this chapter.

(4) Federal and Commonwealth statutes and regulations pertaining to the practice of pharmacy.

(5) Additional equipment and supplies necessary to enable the pharmacy to properly prepare and dispense prescriptions consistent with its scope of practice.

(6) An adequate reference library which meets the following standards:

(i) Enables a pharmacy to prepare and dispense prescriptions properly, consistent with its scope of practice.

(ii) Includes reference sources appropriate to the type of pharmacy practice at that particular location. A pharmacy shall include in the pharmacy's library current material regarding the technical, clinical and professional aspects of practice with emphasis in the area in which the pharmacy specializes.

(iii) Enables the pharmacist to compound medications in a safe and effective manner consistent with accepted standards of pharmacy practice.

(iv) Lists the possible drug interactions and possible adverse effects of medications dispensed by the pharmacy.

(v) Lists the therapeutic equivalents for medications.

(vi) Lists the therapeutic usage and dosages of medications dispensed by the pharmacy.

(vii) Provides guidelines for the counseling of patients.

(viii) A pharmacy that specializes in nuclear or parenteral prescriptions may limit the library it maintains under subparagraph (ii) relating to the pharmacy's own specialization.

(ix) Maintains the latest editions including current supplements of each of its reference sources.

(d) A pharmacy operating as a central processing center shall maintain equipment, supplies and access to a reference library recognized by the pharmacy community in this Commonwealth as meeting minimum standards of practice as a central processing center.

Authority

The provisions of this § 27.14 amended under sections 4(j) and 6(k)(1) and (9) of the Pharmacy Act (63 P. S. §§ 390-4(j) and 390-6(k)(1) and (9)); amended under sections 4(j) and 6(k)(1) of the Pharmacy Act (63 P. S. §§ 390-(4)(j) and 309-6(k)(1)).

Source

The provisions of this § 27.14 adopted June 1, 1973, effective June 2, 1973, 3 Pa.B. 1051; amended June 14, 1991, effective June 15, 1991, 21 Pa.B. 2710; amended September 4, 1998, effective September 5, 1998, 28 Pa.B. 4532; amended March 1, 2002, effective March 2, 2002, 32 Pa.B. 1194; amended May 26, 2006, effective May 27, 2006, 36 Pa.B. 2518; amended September 5, 2008, effective September 6, 2008, 38 Pa.B. 4895. Immediately preceding text appears at serial pages (319638) to (319640).

Cross References

This section cited in 6 Pa. Code § 22.62 (relating to conditions of provider participation); 28 Pa. Code § 113.12 (relating to supplies); 28 Pa. Code § 561.12 (relating to supplies); and 49 Pa. Code § 43b.7 (relating to schedule of civil penalties—pharmacists and pharmacies).

§ 27.15. Sanitary standards.

- (a) The pharmacy and equipment shall be maintained in a clean and orderly condition and in good repair.
- (b) The pharmacy shall comply with the health and sanitation statutes of the Commonwealth and of the municipality and county in which the pharmacy is located.
- (c) Waste material may not be permitted to collect upon the floor, counter or other area of the pharmacy. The pharmacy shall have a waste removal system adequate to maintain clean and sanitary conditions.
- (d) The prescription area shall be dry and well ventilated, free from rodents, insects, dirt and foreign material, and well lighted.
- (e) Plumbing shall be in good repair and working order.
- (f) The prescription area shall contain only appliances, instruments, equipment, materials, drugs, medicines, chemicals and supplies necessary for the practice of pharmacy, as set forth in section 2(11) of the act (63 P. S. § 390-2(11)), and other equipment and supplies deemed reasonable for the operation and management of a pharmacy as established by the Board.
- (g) Persons working in the prescription area shall be required to keep themselves and their apparel in a clean, sanitary and professional manner.

Source

The provisions of this § 27.15 amended September 4, 1998, effective September 5, 1998, 28 Pa.B. 4532. Immediately preceding text appears at serial pages (201796) and (238307).

Cross References

This section cited in 6 Pa. Code § 22.62 (relating to conditions of provider participation); 28 Pa. Code § 113.14 (relating to space); 28 Pa. Code § 561.14 (relating to space); and 49 Pa. Code § 43b.7 (relating to schedule of civil penalties—pharmacists and pharmacies).

§ 27.16. Construction and equipment requirements.

(a) *Approval of plans.* The following requirements are applicable to approval of plans:

(1) *New pharmacy or change-of-location.* Plans for construction of a new pharmacy or new location for an existing pharmacy may be submitted to the Board for approval prior to proceeding with construction. Within 90 days of receiving the plans, the Board will notify the applicant of its approval of the planned pharmacy or of its disapproval and the reasons for disapproval. The plans, including dimensions, must demonstrate compliance with applicable regulations and show the layout and fixtures for the prescription area and the immediately adjacent area.

(2) *Alterations.* The practice of pharmacy shall cease while substantial alterations in the layout or fixtures of an approved pharmacy are being made unless:

(i) The pharmacy makes the alterations and takes adequate precautions so that the health and safety of professionals, employees and the public is protected during the continuing operation of the pharmacy.

(ii) The plans for the alterations and a description of the precautions are submitted to the Board at least 30 days before the beginning of alteration work. If the Board raises no objection during that time, the pharmacy is authorized to proceed with the alterations as planned.

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

(1) *Minimum size.*

(i) The minimum size of the prescription area must be at least 250 square feet, and must be large enough, considering the level of activity, to carry on the practice of pharmacy in a manner that protects the health and safety of professionals, employees and the public. Within the prescription area, there must be a prescription working counter of at least 10 linear feet in length and 2 linear feet in width. If more than two pharmacists are on duty simultaneously, the minimum counter length shall be increased by 5 linear feet for an additional pharmacist. Institutions with special considerations may apply to the Board for a waiver.

(ii) A pharmacy operating as a central processing center need not conform to the minimum space requirements in subparagraph (i).

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

(i) The pharmacy can be securely sealed off from the remainder of the retail establishment.

(ii) The barrier devices which seal off the pharmacy must be capable of providing security for the pharmacy. The barrier devices must reach from

floor to ceiling, shall be impenetrable by hand or the use of a reach extender, and be securely locked whenever a licensed pharmacist is not present and on duty.

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

(iv) Safes, electrical equipment or other facilities of the retail establishment may not be located in or approached through the pharmacy unless a pharmacist is on duty whenever staff from the retail establishment need access to these facilities.

(v) The hours of the pharmacy shall be posted at all points of public access.

(vi) Protocols for access to the pharmacy when it is closed by nonpharmacist staff for bona fide emergencies, such as fires, natural disasters or police matters, must include notification to the pharmacist manager.

(3) *Locked compartment.* Space shall be provided in the prescription area for a substantially constructed cabinet or safe to contain controlled substances unless the pharmacy disperses controlled substances throughout the stock of noncontrolled substances in a manner that obstructs the theft of controlled substances. If the pharmacy stocks Schedule I controlled substances, these substances shall be stored in a securely locked, substantially constructed cabinet or safe.

(4) *Telephone.* At least one telephone shall be accessible in the prescription area, and the telephone number must be the telephone number printed on the prescription label.

(5) *Sanitary facilities.* Except for pharmacies operating as central processing centers, pharmacies shall be equipped with a sink within the prescription area to be used solely for pharmaceutical purposes. The sink must be connected properly to supply hot and cold water. Restroom facilities for employees of the pharmacy shall be provided reasonably close to, but outside of the prescription area.

(6) *Lighting and ventilation.* The pharmacy must be well lighted and ventilated.

(7) *Television set.* A television set may not be placed within the prescription area or so situated in the pharmacy that its viewing screen may be seen when looking at it from within the prescription area.

(8) *Physical arrangement.* The prescription area must be arranged so that prescription drugs and devices are inaccessible to an unlicensed or unauthorized person. The prescription area may not be used for storage of merchandise or other items other than those used in the preparation, dispensing or delivery of drugs. Animals may not be allowed in a prescription area except for security reasons.

(9) *Existing pharmacies.* Existing pharmacies licensed by the Board prior to the effective date of this chapter may continue if they reasonably conform, or are made to reasonably conform, to the intent of this chapter. The Board will determine what constitutes reasonable conformity consonant with the public interest, health, safety and welfare.

Authority

The provisions of this § 27.16 amended under sections 4(j) and 6(k)(1) and (9) of the Pharmacy Act (63 P. S. §§ 390-4(j) and 390-6(k)(1) and (9)).

Source

The provisions of this § 27.16 amended November 28, 1997, effective November 29, 1997, 27 Pa.B. 6218; amended September 4, 1998, effective September 5, 1998, 28 Pa.B. 4532; amended May 26, 2006, effective May 27, 2006, 36 Pa.B. 2518; amended September 5, 2008, effective September 6, 2008, 38 Pa.B. 4895; amended December 11, 2009, effective December 12, 2009, 39 Pa.B. 7005. Immediately preceding text appears at serial pages (342126), (336893) to (336894) and (342127).

Cross References

This section cited in 6 Pa. Code § 22.62 (relating to conditions of provider participation); 28 Pa. Code § 113.14 (relating to space); 28 Pa. Code § 113.15 (relating to locked storage); 28 Pa. Code § 561.14 (relating to space); 28 Pa. Code § 561.15 (relating to locked storage); 49 Pa. Code § 27.203 (relating to centralized prescription processing); and 49 Pa. Code § 43b.7 (relating to schedule of civil penalties—pharmacists and pharmacies).

§ 27.17. Security for Schedule II controlled substances.

(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.

(b) The occasional entry of authorized personnel into an area where the controlled substances are accessible to clean, deliver or perform other necessary functions shall be allowed only when a licensed pharmacist is present and supervising.

(c) The pharmacist manager shall be responsible for assuring that licensed persons, 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.

Source

The provisions of this § 27.17 amended December 24, 2009, effective December 26, 2009, 39 Pa.B. 7205. Immediately preceding text appears at serial page (346638).

Cross References

This section cited in 6 Pa. Code § 22.62 (relating to conditions of provider participation); 28 Pa. Code § 113.15 (relating to locked storage); and 28 Pa. Code § 561.15 (relating to locked storage).

§ 27.18. Standards of practice.

(a) A pharmacist shall dispense a new prescription in a new and clean container or in the manufacturer's original container. In refilling a prescription, the pharmacist may reuse the original container of that prescription if the container is clean and reusable. The refill requires a new label containing the information specified in subsection (d). Pharmacies and pharmacists shall comply with the Poison Prevention Packaging Act of 1970 (15 U.S.C.A. §§ 1471—1476) which includes the use of child resistant containers.

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

(1) Prescriptions on file must show the name and address of the patient; the name and address or other identifier of the prescriber; the date the prescription was issued, if the prescription is for a controlled substance or if it was written with a PRN or ad lib refill designation; the name and quantity of the drug prescribed; directions for its use; cautions communicated to the ultimate consumer by means of auxiliary labels or other means when dispensed to the ultimate consumer; the date the prescription was compounded and dispensed; and the name or initials of the dispensing pharmacist.

(2) Prescriptions for controlled substances must show the DEA number of the prescriber. Prescriptions for Schedule II controlled substances must be written with ink, indelible pencil, typewriter, word processor, computer printer or by electronic means and shall be manually signed by the prescriber, except that prescriptions written by electronic means shall be electronically signed by the prescriber. Electronic prescriptions of Schedule II controlled substances must comply with § 27.201(b) (relating to electronically transmitted prescriptions). The pharmacist is responsible for compounding and dispensing nonproprietary drugs consistent with the Federal Controlled Substances Act (21 U.S.C.A. §§ 801—904), The Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. §§ 780-101—780-144) and the regulations promulgated under these acts.

(3) If a prescription for a nonproprietary drug is refilled, a record of the refill must show the date of the refill, the name or initials of the dispensing pharmacist and the quantity dispensed. If the pharmacist dispenses a quantity different from that of the original prescription, the pharmacist shall indicate the changes on the back of the original prescription or must enter the changes in the computerized files of the pharmacy.

(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.

(5) In an institution, Schedule II controlled substances which the pharmacy dispensed and which were ultimately received by the patient shall be recorded and the record kept for 2 years.

(c) A pharmacist may decline to fill or refill a prescription if the pharmacist knows or has reason to know that it is false, fraudulent or unlawful, or that it is

tendered by a patient served by a public or private third-party payor who will not reimburse the pharmacist for that prescription. A pharmacist may not knowingly fill or refill a prescription for a controlled substance or nonproprietary drug or device if the pharmacist knows or has reason to know it is for use by a person other than the one for whom the prescription was written, or will be otherwise diverted, abused or misused. In addition, a pharmacist may decline to fill or refill a prescription if, in the pharmacist's professional judgment exercised in the interest of the safety of the patient, the pharmacist believes the prescription should not be filled or refilled. The pharmacist shall explain the decision to the patient. If necessary the pharmacist shall attempt to discuss the decision with the prescriber.

(d) The container in which a prescription drug or device is sold or dispensed to the ultimate consumer shall bear a label which shall be written in ink, typed or computer generated and shall contain the following information:

- (1) The name, address, telephone number and DEA number of the pharmacy.
- (2) The name of the patient.
- (3) Full directions for the use of its contents.
- (4) The name of the prescriber.
- (5) The serial number of the prescription and the date originally filled.
- (6) The trade or brand name of the drug, strength, dosage form and quantity dispensed. If a generic drug is dispensed, the manufacturer's name or suitable abbreviation of the manufacturer's name shall also be shown.
- (7) On controlled substances, the statement: "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."

(e) No pharmacist may enter into an arrangement or agreement with a nonlicensed person whereby prescription orders or prescription drugs and devices may be regularly left with, picked up from, solicited by, accepted by or delivered to the nonlicensed person or whereby a pharmacist pays or has an arrangement or agreement with the nonlicensed person to perform these functions. Nothing in this section shall prohibit a licensee from picking up a prescription or delivering a prescription drug or device, at the request of the patient, at the office or home of the prescriber or patient, at an institution in which a patient is confined, at another place as the patient designates for his safety and convenience, or by means of an employe, the mails or common carrier. Nothing in this section shall prohibit a licensee from delivering naloxone to an identified employee of a Pennsylvania correctional facility, prison, jail or residential drug treatment facility under a prescription and for an identified individual who is pending release or discharge from the correctional facility, prison, jail or residential drug treatment facility.

(f) No pharmacist or pharmacy may dispense, dispose of, or sell a Schedule V cough preparation containing codeine, dilaudid or other narcotic cough prepa-

ration without a prescription, except that this subsection does not apply to a preparation used within an institution.

(g) Sales of Schedule V narcotic preparations are required to have affixed to the bottle or container at the time of sale a label indicating the name and address of the pharmacy and the initials of the pharmacist and the date of sale.

(h) No prescription may be knowingly filled or refilled for a patient which prescription was written for prior use by a prescriber who is deceased or no longer in practice.

(i) Prescriptions for nonproprietary drugs may be refilled for 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 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. A controlled substance in Schedule III, IV or V may not be filled or refilled more than five times in the 6-month period from the date of the prescription.

(k) Prepacking and labeling in convenient quantities for subsequent use shall be done under the direct personal supervision of a registered pharmacist. A container shall have a label containing the name of the drug and, if the name is generic, the name of the manufacturer, its strength, the manufacturer's control number or other code control number and the expiration date, if any. A log shall be kept in the pharmacy stating the name of the drug and, if the name is generic, the name of the manufacturer, its strength, the manufacturer's control number or other code control number, the expiration date, if any, and the date and quantity prepacked.

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

(1) Prescription medication shall be sent only in first class mail or common carrier, except where the purchaser is advised in advance that a slower means of transportation will be used and agrees thereto.

(2) The mailing of antibiotics which have been reconstituted is prohibited.

(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 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.

(m) Prescription drugs, medications and devices which are delivered shall be sent in such containers as are reasonably necessary, considering the nature of the drug, medication or device, to insure its safety and effectiveness for the patient.

(n) A prescription by means of an oral order, telephone or otherwise, shall be received and transcribed 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. 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.

(p) The pharmacist has the responsibility to make his professional service available under the following conditions:

(1) A pharmacist practicing in a hospital, institution or similar place or specialized ambulatory care unit may not be required to extend pharmaceutical services to other than registered patients of that hospital or institution.

(2) A pharmacist shall offer complete pharmaceutical service by compounding or dispensing prescriptions which may reasonably be expected to be compounded or dispensed by pharmacists to meet the needs of persons who would usually attempt to utilize the services.

(3) A pharmacist shall safeguard the storage and distribution of prescription drugs and devices under Commonwealth and Federal statutes, maintaining proper records therefor and shall, upon request, advise concerning contents, therapeutic values and uses of the drugs, devices and articles.

(4) No pharmacy or pharmacist may discriminate against a person on account of race, creed, religion, national origin or sex.

(q) No pharmacist, pharmacy owner or pharmacist manager may be permitted to provide a medical practitioner or a person authorized to prescribe drugs or devices with prescription blanks bearing a pharmacist's name or the name or address of the pharmacy thereon.

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

(1) A person may not advertise the filling or refilling of prescriptions for a consumer or patient in this Commonwealth if that person is not licensed under the act or the prescription is not filled or refilled in a pharmacy licensed by the Board.

(2) A person may not promote to the public the sale of any controlled substances.

- (3) Advertisements of prescription drugs and devices may not be false or misleading, and must be truthful, reasonable, informative and understandable to the public.
- (4) A drug or device misbranded or adulterated in Federal law is misbranded and adulterated in Commonwealth law.
- (5) An advertisement of a prescription must be for a commercially reasonable quantity.
- (6) A person advertising special prices for prescriptions, dangerous drugs or nonproprietary drugs, preparations or products, devices and appliances, if using a 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 percentage prices are derived, so the consumer or patient knows exactly what the retail price is.
- (7) The patient has the right to request a copy of an original prescription. The copy must clearly indicate on its face that it is a copy and may not be used to obtain a new prescription or refill. Before a pharmacist provides a copy of a written prescription to a patient or an authorized agent of the patient, the person requesting the copy shall show the pharmacist acceptable authorization and identification, such as a driver's license. The pharmacist shall record in writing the date, to whom and by whom the copy was given.
- (8) A violation of the Unfair Trade Practices and Consumer Protection Law (73 P. S. §§ 201-1—201-9.2) is a violation of this chapter.
- (s) Sales of hypodermic needles and syringes shall be made by a pharmacist or under the direct, immediate and personal supervision of a pharmacist in accordance with the following:
- (1) Hypodermic needles and syringes may be sold without a prescription.
 - (2) Hypodermic needles and syringes shall be kept in the prescription area of the pharmacy, as defined in § 27.1 (relating to definitions), and be accessible only by pharmacists and pharmacy personnel authorized to be in the prescription area of the pharmacy while the pharmacy is open.
- (t) A pharmacist may only 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.
- (u) A violation by a pharmacist of the Federal Controlled Substances Act (21 U.S.C.A. § 321 et seq.) or The Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. §§ 780-101—780-144) or the rules and regulations promulgated thereunder constitutes a violation of this chapter and of the act.
- (v) A drug order in an institution is not required to conform to the labeling requirements of subsection (d) as long as the drug is dispensed in unit dose. A drug not in unit dose shall be labeled to indicate the patient name, drug name, drug strength, dosing instructions and lot number. The label of a parenteral, enteral or total parenteral nutrition product shall contain the name of the patient; the ingredients, including the name, strength, quantity of each, the diluent and expiration date; and the initials of the pharmacist.

Authority

The provisions of this § 27.18 amended under section 6(k)(9) of the Pharmacy Act (63 P.S. § 390-6(k)(9)).

Source

The provisions of this § 27.18 amended September 4, 1998, effective September 5, 1998, 28 Pa.B. 4532; amended September 11, 2009, effective immediately, 39 Pa.B. 5312; amended December 24, 2009, effective December 26, 2009, 39 Pa.B. 7205; amended August 10, 2012, effective August 11, 2012, 42 Pa.B. 5182; amended November 30, 2018, effective December 1, 2018, 48 Pa.B. 7404. Immediately preceding text appears at serial pages (362964) to (362969).

Notes of Decisions

Revocation of a pharmacist's license for a violation of 49 Pa. Code § 27.18(u) (relating to violations by a pharmacist of the Federal Controlled Substances Act (21 U.S.C. § 321 *et seq.*) or the Pennsylvania Controlled Substances, Drug, Devices and Cosmetic Act (35 P.S. §§ 780-101—780-144)) is not an abuse of discretion. *Rosenthal v. State Board of Pharmacy*, 457 A.2d 243 (Pa. Cmwlth. 1983).

If a pharmacist has been charged only with violations of the Pharmacy Act (63 P.S. §§ 390-1—390-13) and the Board's regulations, the Board's authority to revoke or suspend his license is governed by the provisions of section 5(a)(6) of the Pharmacy Act (63 P.S. § 390-5(a)(6)); the provisions of section 23(b) of the Drug Act (35 P.S. § 780-123(b)) are not applicable, even though the violations may also constitute grounds for a criminal prosecution. *Moeslein v. State Board of Pharmacy*, 432 A.2d 295 (Pa. Cmwlth. 1981).

With regard to the prohibitions of subsection (t), it is irrelevant whether a pharmacist continually fills overlapping prescriptions for the same person, from the same physician, and for the same drug, in the same quantity and dosage, or continually refills a prior prescription; the subsection gives a clear description of what conduct is prohibited such that it satisfies due process requirements. *Goldberg v. State Board of Pharmacy*, 410 A.2d 413 (Pa. Cmwlth. 1980).

Revocation of a pharmacist's license for distributing cocaine and dexedrine without a prescription is not an unduly harsh punishment; the classification of cocaine as a controlled substance is not a denial of equal protection. *Carr v. State Board of Pharmacy*, 409 A.2d 941 (Pa. Cmwlth. 1980).

Since the petitioner pled guilty to four criminal charges under the Drug Act, only one of which was a felony, the Board has the power to revoke his license but is not obligated to do so, and the case will be remanded if it appears that the Board's decision to revoke his license is based in part on the mistaken belief that a plea of guilty to any offense in connection with the practice of pharmacy is sufficient to revoke a license. *Intrieri v. Commissioner of Professional and Occupational Affairs*, 396 A.2d 927 (Pa. Cmwlth. 1979).

Cross References

This section cited in 6 Pa. Code § 11.142 (relating to labeling of medications); 6 Pa. Code § 22.62 (relating to conditions of provider participation); 6 Pa. Code § 22.63 (relating to other provisions for providing services by mail); 28 Pa. Code § 113.25 (relating to drug distribution systems); 49 Pa. Code § 27.12 (relating to practice of pharmacy and delegation of duties); 49 Pa. Code § 27.101 (relating to radiopharmaceutical prescriptions—statement of policy); 49 Pa. Code § 27.201 (relating to electronically transmitted prescriptions); 49 Pa. Code § 27.202 (relating to computerized recordkeeping systems); 49 Pa. Code § 43b.7 (relating to schedule of civil penalties—pharmacists and pharmacies); 49 Pa. Code § 27.605 (relating to label information required); and 49 Pa. Code § 27.606 (relating to compounding records).

§ 27.19. Prospective drug review and patient counseling.

(a) *PDR Required.* A pharmacist shall perform a PDR before filling, delivering or sending a new 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 (f) prior to dispensing the medication to the patient or caregiver.

(b) *Purpose.* The purpose of the PDR is to help assure that a drug dispensed under a prescription is not likely to have an adverse medical result. The PDR accomplishes this 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.

(c) *Scope.*

(1) The PDR is required for prescriptions and drug orders.

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

(i) A patient visits a physician in the physician's office and receives a prescription. The patient has the prescription filled in a retail pharmacy.

(ii) A pharmacist fills a prescription for a patient who lives in a personal care home.

(iii) A pharmacist in a hospital pharmacy fills an outpatient prescription for a hospital employee.

(iv) A patient is treated on a nonemergency basis in an outpatient clinic of a hospital and is given a prescription. The patient has the prescription filled either in the hospital pharmacy or in a retail pharmacy.

(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 physician dispenses a drug to a patient being treated in the emergency room.

(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.

(v) A pharmacist delivers naloxone to an identified employee of a Pennsylvania correctional facility, prison, jail or residential drug treatment facility under a prescription and for an identified individual who is pending release or discharge from the correctional facility, prison, jail or residential drug treatment facility.

(d) *Offer to counsel.*

(1) An offer to counsel shall be made to each patient or caregiver when the pharmacist fills, delivers or sends a new retail or outpatient prescription.

(2) The pharmacist or designee of the pharmacist shall orally make the offer in person if a patient or caregiver comes to the pharmacy. If the pharmacist in the exercise of professional judgment in the interest of a patient believes

that an oral offer would be less effective than a written offer, the pharmacist may substitute a written offer. The following are examples of situations in which a pharmacist might substitute a written offer:

- (i) The patient or caregiver is hearing impaired.
 - (ii) The patient or caregiver is not an English speaker.
- (3) If neither the patient nor caregiver comes to the pharmacy, the offer to counsel shall be made in one of the following ways:
- (i) The pharmacist or designee may telephone the patient or caregiver.
 - (ii) The pharmacy delivery person may orally make the offer to the patient or caregiver.
 - (iii) The pharmacist may send a written offer to counsel together with the filled prescription which is delivered or sent to the patient.
- (4) A written offer to counsel must include the telephone number of the pharmacy.
- (5) A pharmacy shall provide toll-free telephone service if its primary patient population is beyond the local or toll-free exchange.
- (6) A mail order pharmacy shall make the offer to counsel either by telephone or by sending a written offer together with the filled prescription. The written offer must include a toll-free telephone number of the pharmacy which a patient or caregiver may use to obtain counselling.
- (7) The obligation to make an offer to counsel will be fulfilled by making one offer in accordance with this subsection.
- (e) *Counselling.*
- (1) Only a pharmacist may counsel.
 - (2) If a patient or caregiver who comes to the pharmacy indicates that he wants counselling, the pharmacist shall counsel the patient or caregiver in person, or, at the discretion of the patient or caregiver, by telephone.
 - (3) If the filled prescription is sent or delivered to the patient or caregiver, counselling shall be by telephone.
 - (4) The following are examples of matters which a pharmacist in the exercise of professional judgment might deem significant and discuss with the patient or caregiver:
 - (i) The name and description of the medication.
 - (ii) The route of administration, dosage form and duration of drug therapy.
 - (iii) Special directions and precautions for preparation, administration and use by the patient.
 - (iv) Common severe side effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.
 - (v) Techniques for self-monitoring drug therapy.
 - (vi) Proper storage.
 - (vii) Prescription refill information.

(viii) Action to be taken in the event of a missed dose.

(5) If a pharmacist discovers a specific problem with a medication during the course of a PDR, the pharmacist shall intervene to attempt to resolve the problem.

(f) *Patient profile.*

(1) The pharmacist or designee of the pharmacist shall make a reasonable effort to obtain, record and maintain the following information about each patient:

(i) The name, address, telephone number, date of birth (or age) and gender.

(ii) Individual history, if significant, including known allergies and drug reactions, and a list of medications and relevant devices, as provided by the patient or caregiver.

(iii) Pharmacist comments relative to the individual's drug therapy.

(2) The patient profile may be maintained electronically or manually.

(3) The pharmacist or designee of the pharmacist shall begin a patient profile when the pharmacist fills a prescription for a new patient or for a current patient for whom a profile had not previously been maintained.

(4) The patient profile shall be maintained for at least 2 years after the last entry.

(5) The Board will consider a single request for information for a patient profile made to a patient or caregiver a reasonable effort to obtain the information outlined in this subsection.

(g) *Refusal to accept counselling or to provide information.*

(1) A pharmacist is not required to provide counselling or obtain information for the patient profile if the patient or caregiver refuses the offer to counsel or refuses to divulge information for the patient profile. If a patient or caregiver fails to respond to an offer to counsel or a request for information, the failure to respond will be deemed a refusal.

(2) The pharmacist or designee shall document the refusal of a patient or caregiver to accept counselling or provide information. The documentation must include the name or initials of the pharmacist or designee noting the refusal. The following kinds of documentation are acceptable:

(i) A notation made by the pharmacist or designee on the prescription or patient profile or the electronic records of the pharmacy.

(ii) A writing signed by the patient or caregiver.

(h) *Confidentiality.*

(1) Information gained by a pharmacist, pharmacy or employee of a pharmacy about a patient under this section shall be regarded as confidential. The information shall be maintained in accordance with section 8(10) of the act (63 P. S. § 390-8(10)).

(2) The pharmacist or pharmacy may reveal the information if one of the following circumstances occurs:

- (i) The patient consents to the disclosure.
- (ii) The Board or its authorized agents require the information for any proceeding under the act.
- (iii) State or Federal law or regulations require or authorize the disclosure.
- (iv) A court orders the disclosure.

Authority

The provisions of this § 27.19 amended under section 6(k)(9) of the Pharmacy Act (63 P.S. § 390-6(k)(9)).

Source

The provisions of this § 27.19 adopted March 4, 1994, effective March 5, 1994, 24 Pa.B. 1180; amended December 24, 2009, effective December 26, 2009, 39 Pa.B. 7205; amended November 30, 2018, effective December 1, 2018, 48 Pa.B. 7404. Immediately preceding text appears at serial pages (362969) to (362970) and (347413) to (347415).

Cross References

This section cited in 49 Pa. Code § 27.203 (relating to centralized prescription processing).

§ 27.20. Facsimile machines.

(a) *Schedule II controlled substances.*

(1) A pharmacist may fill a prescription for a Schedule II controlled substance which was received on a facsimile machine if the original prescription signed by the medical practitioner is presented to the pharmacist for review prior to the actual dispensing of the controlled substance. The original prescription shall be maintained as the original pharmacy record.

(2) There are three exceptions to the requirement that the pharmacist review the original of the prescription received on a facsimile machine before dispensing a Schedule II controlled substance. A pharmacist may fill and dispense a prescription for a Schedule II controlled substance which was received on a facsimile machine and may use the facsimile as the original pharmacy record of the following:

- (i) A prescription for a Schedule II controlled narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion in the patient's home.
- (ii) A prescription for a Schedule II controlled substance for a resident of a long-term care facility.
- (iii) A prescription for a Schedule II controlled narcotic substance for a patient enrolled in a hospice care program.

(b) *Schedule III, IV and V controlled substances and other nonproprietary drugs.* A pharmacist may fill and dispense a prescription signed by a medical practitioner for a Schedule III, IV or V controlled substance or other nonpropri-

etary drug which was received on a facsimile machine. The pharmacist may use the facsimile as the original pharmacy record.

(c) *General.*

(1) A pharmacist shall exercise professional judgment regarding the accuracy and authenticity of the facsimile copy of a prescription.

(2) Unless the original prescription will be maintained as the original pharmacy record, the quality of paper on which a facsimile copy of a prescription is printed shall be of a type that the facsimile copy can be maintained as a record for at least 2 years, as required under section 4(a)(3) of the act (63 P. S. § 390-4(a)(3)).

(3) A pharmacist or pharmacy may not contribute in any way to the installation of a facsimile machine in the office of a medical practitioner or in an institution.

(4) For purposes of this section, a prescription does not include an order for medication which is dispensed for immediate administration to a patient in an institution.

Source

The provisions of this § 27.20 adopted June 20, 1997, effective June 21, 1997, 27 Pa.B. 2931; amended March 1, 2002, effective March 2, 2002, 32 Pa.B. 1194. Immediately preceding text appears at serial pages (247942) and (248955).

PHARMACISTS

§ 27.21. Application for examination and licensure.

(a) A candidate for licensure to practice pharmacy by examination applying to take the North American Pharmacist Licensure Examination (NAPLEX) and the Multistate Pharmacy Jurisprudence Examination (MPJE) shall obtain an application for licensure from the Board, complete the application and file the application with the Board.

(b) The applicant shall include in the application proof of graduation with a B.S. or advanced degree in pharmacy granted by an ACPE accredited school or college; affidavits of all internship experience gained prior to submitting the application; and the application fee.

(c) The applicant shall also complete and submit the examination fees and examination registration forms to the test administrator.

(d) Affidavits of internship experience shall be filed before authorization to take the exam is given.

Authority

The provisions of this § 27.21 amended under section 812.1 of The Administrative Code of 1929 (71 P. S. § 279.3a); and sections 3, 4(j), 6(k) and 8.2 of the Pharmacy Act (63 P. S. §§ 390-3, 390-4(j), 390-6(k) and 8.2).

Source

The provisions of this § 27.21 amended May 23, 1997, effective May 24, 1997, 27 Pa.B. 2545; amended October 16, 1998, effective October 17, 1998, 28 Pa.B. 5241; amended December 24, 2009, effective December 26, 2009, 39 Pa.B. 7205. Immediately preceding text appears at serial pages (287433) to (287434).

Cross References

This section cited in 49 Pa. Code § 27.52 (relating to graduates of foreign schools and noncitizens).

§ 27.22. Application after expulsion from examination.

An applicant for an examination and registration as a licensed pharmacist who has been expelled from an examination room for cribbing, cheating or other dishonest conduct may not be permitted to file a new application for examination within 1 year thereafter, and shall petition the Board specially for permission to take a subsequent examination.

Cross References

This section cited in 49 Pa. Code § 27.52 (relating to graduates of foreign schools and noncitizens).

§ 27.23. Time and place for holding examination.

Examinations shall be held at times and places and determined by the Board in conjunction with the test administrator.

Source

The provisions of this § 27.23 amended May 23, 1997, effective May 24, 1997, 27 Pa.B. 2545. Immediately preceding text appears at serial page (201810).

Cross References

This section cited in 49 Pa. Code § 27.52 (relating to graduates of foreign schools and noncitizens).

§ 27.24. Examinations and passing scores.

On and after March 1, 1997, but before November 1, 1998, candidates for licensure by examination are required to pass both the North American Pharmacist Licensure Examination (NAPLEX) and the Federal Drug Law Examination (FDLE), developed and administered by the National Association of Boards of Pharmacy (NABP).

(b) On and after November 1, 1998, candidates for licensure by examination are required to pass both the NAPLEX and the Multistate Pharmacy Jurisprudence Examination (MPJE), developed and administered by the NABP.

(c) The minimum passing score on each examination will be as determined by the NABP.

Authority

The provisions of this § 27.24 amended under section 812.1 of The Administrative Code of 1929 (71 P. S. § 279.3a); and sections 3, 6(k) and 8.2 of the Pharmacy Act (63 P. S. §§ 390-3, 390-6(k) and 390-8.2).

Source

The provisions of this § 27.24 amended September 5, 1986, effective September 6, 1986, 16 Pa.B. 3293; amended June 12, 1992, effective June 13, 1992, 22 Pa.B. 3064; corrected June 20, 1992, effective June 13, 1992, 22 Pa.B. 3064; amended May 23, 1997, effective May 24, 1997, 27 Pa.B. 2545; amended October 16, 1998, effective October 17, 1998, 28 Pa.B. 5241. Immediately preceding text appears at serial pages (247944) to (247945).

Cross References

This section cited in 49 Pa. Code § 27.52 (relating to graduates of foreign schools and noncitizens).

§ 27.25. Licensure by reciprocity.

(a) An applicant for licensure by reciprocity shall comply with section 3(g) of the act (63 P. S. § 390-3(g)).

(b) 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 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.

Source

The provisions of this § 27.25 amended May 23, 1997, effective May 24, 1997, 27 Pa.B. 2545; amended September 4, 1998, effective September 5, 1998, 28 Pa.B. 4532; amended December 24, 2009, effective December 26, 2009, 39 Pa.B. 7205. Immediately preceding text appears at serial page (248957).

Cross References

This section cited in 49 Pa. Code § 27.52 (relating to graduates of foreign schools and noncitizens).

§ 27.26. Pharmacy internship.

(a) Pharmacy internship means the supervised practical experience required for licensure as a registered pharmacist. The purpose of the pharmacy internship program is to provide a registered intern with the knowledge and practical experience necessary for functioning competently and effectively upon licensure.

(b) Registration as a pharmacy intern will be available to an individual of good moral character who has completed at least 2 years of college and is enrolled or accepted as a student of pharmacy in an ACPE-accredited pharmacy degree program. A person desiring to register as a pharmacy intern shall do the following:

(1) Apply to the Board for registration including the fee specified in § 27.91 (relating to schedule of fees) for registering as a pharmacy intern.

(2) Forward to the Board acceptable documentation verifying that the applicant has successfully completed at least 2 years of college and is enrolled or accepted as a student of pharmacy in an ACPE-accredited pharmacy degree program. Acceptable documentation includes a document bearing the school's seal received by the Board directly from the dean or registrar of the ACPE-accredited pharmacy degree program which includes the pharmacy student's name, address, Social Security number, and a statement indicating that the stu-

dent has successfully completed at least 2 years of college and is enrolled or accepted as a student of pharmacy in, or has graduated from, the ACPE-accredited pharmacy degree program.

(c) The Board will register an applicant after it receives a completed application and other items in subsection (b). A pharmacy intern registration is valid for 6 years from the date of issue exclusive of time spent in the military. A pharmacy intern registration will automatically become invalid if the pharmacy intern permanently ceases enrollment in an ACPE-accredited pharmacy degree program prior to graduation. A pharmacy intern whose registration becomes invalid under this subsection shall immediately return to the Board the pharmacy intern registration and preceptor approval documents.

(d) The following applies to internship credit:

- (1) An intern shall serve at least 1,500 hours.
- (2) A maximum of 50 hours may be credited in 1 week.
- (3) An intern shall serve at least 500 of the 1,500 hours in a pharmacy.
- (4) An intern may earn up to 1,000 of the 1,500 hours in an internship program sponsored or approved by an ACPE-accredited pharmacy degree program.

(5) The Board may grant internship credit for hours that an individual served in a pharmacy before the individual registered as an intern only if the individual shows good cause for failing to register in timely fashion.

(6) The Board will not grant internship credit for hours which an individual served in a pharmacy if the supervising pharmacist was not registered as a preceptor. An exception to the requirement that the supervising pharmacist register as a preceptor will be made for internship hours acquired in an internship program sponsored or approved by an ACPE-accredited pharmacy degree program.

(e) The Board will grant internship credit only for activities related to the practice of pharmacy. The following are examples of these activities: scrutinizing prescriptions or drug orders, taking oral orders for prescriptions by telephone or otherwise, compounding medications and filling prescriptions. The Board will not grant internship credit for activities which are not related to the practice of pharmacy.

(f) An intern who wishes to receive credit for internship experience that is not in a pharmacy or sponsored or approved by an APCE-accredited pharmacy degree program shall apply to the Board for approval before beginning an internship experience. Upon receipt of the application, the Board will review and determine how much, if any, credit will be given. Requests for approval shall be submitted at least 90 days before the internship experience begins. Credit given for a nontraditional internship may not be used to satisfy the requirement of subsection (d)(3) pertaining to the minimum amount of time the internship shall be served in a pharmacy.

(g) A person may not be eligible to become a candidate for registration to practice pharmacy unless the person receives instruction in practical pharmacy and pharmaceutical technique from an instructor, professor or faculty member

who is a registered pharmacist or from a faculty member who is a registered pharmacist at an ACPE-accredited pharmacy degree program.

(h) The following requirements are applicable to a pharmacy utilized for intern training:

(1) A pharmacy may not have been or be in violation of Federal, State or municipal statutes and ordinances governing any phase of activity in which it is engaged. A pharmacy may appeal to the Board for a waiver of this provision.

(2) A pharmacy shall be managed so that the emphasis is on activities connected with the distribution of articles and services pertaining to medical care, including drugs, medicines, prescriptions, medical supplies and materials.

(3) A pharmacy shall be kept in a sanitary, orderly and clean condition, and the prescription department shall meet the requirements in the statutes and regulations as they affect prescription departments.

(4) A pharmacy shall compound and dispense a sufficient number of prescriptions including renewals so as to provide the pharmacy intern with ample opportunity to scrutinize prescriptions and to compound and dispense under the supervision of a licensed pharmacist.

(5) A pharmacy shall have in its employ a licensed pharmacist who is registered as a pharmacist preceptor.

(6) A pharmacy which meets the qualifications of this section shall be approved by the Board after proper notification by the owner or manager of willingness to cooperate in the development of the internship program. Whenever a new intern is accepted for training in the pharmacy, the pharmacist preceptor shall notify the Board of the name of the intern and his anticipated period of internship in the pharmacy.

(i) The requirements for registration as a pharmacist preceptor are as follows:

(1) A pharmacist preceptor may not have been convicted of a criminal offense relating to the practice of pharmacy.

(2) An applicant shall hold a license without restriction to practice pharmacy in this Commonwealth and shall be engaged in the active practice of pharmacy in this Commonwealth.

(3) An applicant shall be working on a full-time basis in a pharmacy utilized for intern training.

(4) A pharmacist preceptor may not direct the training of more than two pharmacy interns at any one time, unless the program has been approved by the Board for a greater number.

(5) A pharmacist preceptor shall be willing to cooperate with the Board in developing an intern program and shall apply to the Board signifying the desire to do so.

(6) A pharmacist preceptor shall certify to the commencement and completion of intern training and may make recommendations to the Board concerning the competency of the intern under his supervision.

(7) A pharmacist preceptor shall report to the Board, as required by the Board, on the progress of an intern under the pharmacist's supervision.

(8) A pharmacist preceptor shall be charged with the responsibility for seeing that his intern receives proper pharmaceutical training and experience, always keeping in mind the objections of the practical training program.

(j) Credit will be granted for practical experience gained in pharmacies outside this Commonwealth upon presentation of evidence satisfactory to the Board to indicate that the experience gained is substantially equivalent to that required by this chapter.

(k) The pharmacy internship may not be deemed satisfactorily completed until the intern has filed affidavits with the Board certifying that the intern has obtained a total of 1,500 hours of practical experience since registration as a pharmacy intern.

(l) When a candidate receives his first certificate and identification card to practice as a pharmacist, his registration as an intern terminates.

Source

The provisions of this § 27.26 amended May 30, 1980, effective May 31, 1980, 10 Pa.B. 2162; amended September 4, 1998, effective September 5, 1998, 28 Pa.B. 4532; corrected October 30, 1998, effective September 5, 1998, 28 Pa.B. 5485; amended December 5, 2014, effective December 6, 2014, 44 Pa.B. 7552. Immediately preceding text appears at serial pages (347418) to (347420) and (347731).

Cross References

This section cited in 49 Pa. Code § 27.1 (relating to definitions); and 49 Pa. Code § 27.52 (relating to graduates of foreign schools and noncitizens).

§ 27.27. [Reserved].

Source

The provisions of this § 27.27 adopted August 13, 1982, effective August 14, 1982, 12 Pa.B. 2687; amended August 2, 1985, effective August 3, 1985, 15 Pa.B. 2813; reserved September 30, 1988, effective October 1, 1988, 18 Pa.B. 4416. Immediately preceding text appears at serial pages (114090) to (114091).

RENEWAL OF PHARMACIST LICENSE AND PHARMACY PERMIT

§ 27.31. Biennial renewal.

(a) A holder of a pharmacy permit shall renew the permit every 2 years, in odd-number years. Renewal requires completion of a form mailed to the holder by the Board in advance of the renewal period, and payment of the specified fee.

(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. A pharmacist shall also submit proof of compliance with the continuing education requirements of § 27.32 (relating to continuing education).

(c) A pharmacist or holder of a pharmacy permit who fails to timely renew shall cease practice or operation until the license or permit is renewed. The holder may be subject to disciplinary action, and will be assessed an additional fee of \$5 for each month or part of month after which renewal occurs beyond the date specified by the Board. Notice of lapsed pharmacy permits shall be forwarded to

other Commonwealth agencies, including the Department of Health, the Department of Public Welfare and the Department of Aging.

(d) A pharmacist allowing the license to lapse may so notify the Board on the renewal form. Reasons shall be briefly stated, and the pharmacist's pocket license and display license shall be surrendered to the Board with the renewal form. A pharmacist who has had a lapsed license for 1 year or more, and who then seeks to reactivate the license, will be required to show current proficiency to practice pharmacy. The full-time practice of pharmacy in another state, during the period of lapsed licensure in this Commonwealth, will be evidence of current proficiency. A holder of a lapsed license who engaged in activities outside the profession of pharmacy during the lapsed period shall complete hours of continuing education equivalent to the hours which he would have been required to take had he held an active license.

Source

The provisions of this § 27.31 amended December 19, 1986, effective December 20, 1986, 16 Pa.B. 4883; amended December 24, 2009, effective December 26, 2009, 39 Pa.B. 7205. Immediately preceding text appears at serial pages (250225) and (342131).

Cross References

This section cited in 49 Pa. Code § 43b.7 (relating to schedule of civil penalties—pharmacists and pharmacies); and 49 Pa. Code § 43b.7a (relating to schedule of civil penalties—pharmacists and pharmacies—statement of policy).

§ 27.32. Continuing education.

(a) The Board will renew the license of a pharmacist who has completed a minimum of 30 contact hours (3 CEU) of continuing education during the preceding biennial renewal period. Beginning with the license period commencing on October 1, 2011, 2 of the required 30 contact hours shall be completed in courses from the ACPE topic designator "Patient Safety." In addition, for licensees with authority to administer injectable medications, biologicals and immunizations in accordance with section 9.2 of the act (63 P. S. § 390-9.2) and § 27.401 (relating to qualifications for authority), at least 2 of the required 30 hours must concern the administration of injectable medications, biologicals and immunizations, including, but not limited to, disease epidemiology, vaccine characteristics, injection technique, emergency response to adverse events and related topics. Except as provided in subsection (h), only continuing education programs offered by ACPE-accredited providers of continuing pharmaceutical education targeted toward pharmacists are acceptable to the Board.

(b) A pharmacist shall prove compliance with subsection (a) by completing and submitting a form provided to the pharmacist by the Board for that purpose with the renewal application. The certificates provided upon completion of an approved program shall be retained by a pharmacist for 2 years after renewal, and shall be produced upon demand by the Board or its agents. The Board will utilize a random audit of 5% of renewals to determine compliance with subsection (a), and may expand the audit if rates of noncompliance at 20% or more of the sample are revealed by the initial audit. Individuals selected for the audit will be required

to produce certificates proving the information they provided to the Board on the form submitted with the renewal application. Notwithstanding any disciplinary action taken under subsection (i), a pharmacist found to be in noncompliance with the continuing education requirements shall make up the delinquent contact hours within 6 months of the notice of deficiency from the Board.

(c) Both live and correspondence courses will be accepted by the Board as long as they are offered by approved providers.

(d) An excess of completed contact hours in one renewal period will not be carried over into the next renewal period.

(e) A newly graduated licensee will be exempt from the requirements in subsection (a) for the license renewal immediately following licensure. A reciprocally licensed pharmacist will be required to show compliance with the requirements in subsection (a), but will have the number of hours required to be completed prorated, on a quarterly basis, from the date of licensure to the next date of renewal. For this purpose, each quarter will consist of 3 months, and will be credited for 3.75 contact hours (.375 CEU). The pharmacist will be required to begin accumulating contact hours at the beginning of the next quarter following licensure.

(f) A pharmacist whose license has been suspended or revoked for disciplinary reasons shall comply with continuing education requirements during the period of suspension or revocation, if the pharmacist wants to resume practice or petition for licensure reinstatement at the conclusion of the disciplinary period.

(g) The Board will consider renewing a license without timely filing of the required hours of continuing education on a case by case basis, upon a showing of incapacity, acute illness or other circumstances which reasonably precluded timely compliance. Pharmacists whose licenses are renewed under this subsection will be required to make up the missing hours of continuing education on a schedule determined by the Board, and to pay applicable fees and fines.

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

(i) A pharmacist who fails to comply with this section, or who submits fraudulent contact hour reports, will be subject to disciplinary action.

Source

The provisions of this § 27.32 adopted December 19, 1986, effective December 20, 1986, 16 Pa.B. 4883; amended June 14, 1991, effective June 15, 1991, 21 Pa.B. 2710; amended June 30, 2006, effective July 1, 2006, 36 Pa.B. 3237; amended February 12, 2010, effective February 13, 2010, 40 Pa.B. 842. Immediately preceding text appears at serial pages (347422) to (347423).

Cross References

This section cited in 49 Pa. Code § 27.31 (relating to biennial renewal).

INSTITUTIONS**§ 27.41. Qualified institutions.**

Only institutions accredited by the Joint Commission on Accreditation of Hospitals or the Commission on Hospital Accreditation of the American Osteopathic Association or meeting the requirements of the "Conditions of Participation for Extended Care Facilities," Federal Health Insurance for the Aged, or licensed by the Department of Welfare or Department of Health, will be considered for an application for a permit to operate a pharmacy. An institution may not be considered for a pharmacy permit unless the pharmacy in that institution is open a minimum of 20 hours per week under the supervision of a registered pharmacist manager.

§ 27.42. Institutional regulation.

Pharmaceutical services in institutions shall always be conducted in accordance with rules and regulations affecting the services which have been or may hereafter be promulgated by the Department of Public Welfare or Department of Health, and the rules and regulations are hereby incorporated automatically. Violation of the rules and regulations constitute a violation of this chapter.

ELIGIBILITY OF NONCITIZENS**§ 27.51. Age.**

A person who has reached his 21st birthday and is a graduate of a college of pharmacy accredited by the American Council of Pharmaceutical Education or a college of pharmacy which meets educational qualifications and requirements of and is approved by the Board, and otherwise meets legal requirements shall be eligible for licensure to practice pharmacy in this Commonwealth.

§ 27.52. Graduates of foreign schools and noncitizens.

(a) Graduates of foreign schools and noncitizens are eligible to become licensed to practice in this Commonwealth if they meet the requirements and qualifications of the act and this chapter.

(b) Graduates of foreign schools and noncitizens are advised that licenses obtained in this Commonwealth may not be accepted by other states under present reciprocal arrangements. The Board recommends that graduates of foreign schools and noncitizens who anticipate practicing in another state in the future should make immediate application to that state.

(c) If a graduate of a foreign college has had experience in the practice of pharmacy and demonstrates knowledge of American pharmacy practices and is proficient generally in his ability to communicate in the English language, the Board may approve a special internship program of less than 1,500 hours, but in no case less than 500 hours. The Board may waive the theoretical examination for a graduate, but he will be required to take the practical examination.

(d) Graduates of foreign colleges are subject to the provisions set forth in §§ 27.21—27.26 (relating to pharmacists).

(e) The Board recognizes those schools or colleges of pharmacy that are accredited by the American Council of Pharmaceutical Education. This body is a national accrediting agency which establishes the standards for colleges of pharmacy and sees that these standards are maintained in the colleges of pharmacy that have been accredited and approved. Since foreign colleges are not accredited by the American Council of Pharmaceutical Education, the Board, with the cooperation and advice of the United States Department of Education and the Pennsylvania Department of Education, may approve foreign colleges of pharmacy and nonaccredited American schools on a case by case basis if they meet the standards and qualifications of the Board. The Board may also, without approving a school, approve individual applications of qualified graduates of schools on a case by case basis.

BRIBERY

§ 27.61. In general.

It shall constitute unprofessional conduct and a violation of this chapter for a licensee of the Board to do the following:

(1) Directly or indirectly to offer or give money or an item of value to an employe of the Commissioner of Professional and Occupational Affairs or any Board or Commission assigned to the administrative jurisdiction of the Commissioner of Professional and Occupational Affairs, except for the payment required by the act and the rules and regulations of the State Board of Professional and Occupational Affairs, in accordance therewith.

(2) To fail to notify in writing the Commissioner at 279 Boas Street, Harrisburg, Pennsylvania 17120 of a demand, solicitation or attempted extortion of money or an item of value by, or on behalf of, an employe of the Commissioner or a board or commission assigned to the administrative jurisdiction of the Commissioner within 5 days thereafter and to furnish the additional information in connection as might reasonably be requested.

MISCELLANEOUS

§ 27.71. Revocation and suspension.

Failure to comply with this chapter shall be grounds for revocation or suspension of licensure under section 5(a)(6) of the act (63 P. S. § 390-5(a)(6)).

Notes of Decisions

Since the petitioner pled guilty to four criminal charges under the Drug Act, only one of which was a felony, the Board has the power to revoke his license but is not obligated to do so, and the case will be remanded if it appears that the Board's decision to revoke his license is based in part on the mis-

taken belief that a plea of guilty to any offense in connection with the practice of pharmacy is sufficient to revoke a license. *Intrieri v. Commissioner of Professional and Occupational Affairs*, 396 A.2d 927 (Pa. Cmwlth. 1979).

APPLICABILITY OF GENERAL RULES

§ 27.81. Applicability of general rules.

Under 1 Pa. Code § 31.1 (relating to scope of part), 1 Pa. Code Part II (relating to general rules of administrative practice and procedure), are applicable to the activities of and proceedings before the Board.

Source

The provisions of this § 27.81 adopted February 7, 1975, effective February 8, 1975, 5 Pa.B. 248.

FEES

§ 27.91. Schedule of fees.

An applicant for a license, certificate, permit or service shall pay the following fees at the time of application:

Application for pharmacy intern certificate	\$35
Application for pharmacist license	\$45
Certification of examination scores or internship hours	\$25
Verification of licensure	\$15
Assistant pharmacist biennial renewal	\$120
Registered pharmacist biennial renewal	\$190
Registered pharmacist late renewal penalty	\$25
New pharmacy permit application	\$125
Reinspection of new pharmacy after failure at first inspection	\$115
Pharmacy permit change without inspection	\$45
Pharmacy permit change when inspection required	\$125
Change in pharmacy ownership or Board of Directors	\$30
Verification of permit	\$15
Biennial renewal of pharmacy permit	\$125
Pharmacy permit late renewal penalty	\$25
Application for approval to administer injectables	\$30
Biennial renewal of approval to administer injectables	\$30

Authority

The provisions of this § 27.91 issued under sections 3, 4(j), 6(k)(1), 8.2 and 9.2(a) of the Pharmacy Act (63 P. S. §§ 390-3, 390-4(j), 390-6(k)(1), 390-8.2 and 390-9.2(a)); amended under section 812.1 of The Administrative Code of 1929 (71 P. S. § 279.3a).

Source

The provisions of this § 27.91 adopted September 30, 1988, effective October 1, 1988, 18 Pa.B. 4416; amended March 16, 1990, effective March 17, 1990, 20 Pa.B. 1501; amended November 8, 1991, effective November 9, 1991, 21 Pa.B. 5258; amended December 8, 1995, effective December 9, 1995, and apply retroactively to examination fees charged on and after September 1, 1995, 25 Pa.B. 5587; amended May 23, 1997, effective May 24, 1997, 27 Pa.B. 2545; amended October 16, 1998, effective October 17, 1998, 28 Pa.B. 5241; amended September 8, 2000, effective September 9, 2000, 30 Pa.B. 4734; amended August 19, 2005, effective August 20, 2005, 35 Pa.B. 4711; amended December 2, 2005, effective December 3, 2005, 35 Pa.B. 6531; amended June 30, 2006, effective July 1, 2006, 36 Pa.B. 3237; amended September 11, 2009, effective immediately, 39 Pa.B. 5309. Immediately preceding text appears at serial pages (320549) to (320550).

Cross References

This section cited in 49 Pa. Code § 27.26 (relating to pharmacy internship); and 49 Pa. Code § 27.402 (relating to application and renewal procedures).

STATEMENT OF POLICY**§ 27.101. Radiopharmaceutical prescriptions—statement of policy.**

(a) *Definition.* The term “radiopharmaceutical” means a pharmaceutical, biological or drug which contains a radioactive entity.

(b) *Unavailable name.* When a pharmacist receives a prescription for a radiopharmaceutical for a patient whose name is unavailable at the time the prescription is received and the pharmacist dispenses the radiopharmaceutical, the pharmacist and pharmacy will be considered to have complied with the provisions of § 27.18(b) and (d) (relating to standards of practice) which require the name of the patient if the pharmacist obtains the name of the patient within 72 hours after dispensing the radiopharmaceutical or, if the radiopharmaceutical is not administered to a patient, marks the prescription “not used.”

Source

The provisions of this § 27.101 adopted April 23, 1993, effective April 24, 1993, 23 Pa.B. 1963.

§ 27.102. Return to stock of undelivered medication—statement of policy.

(a) *Background and purpose.* Section 5(a)(9)(xi) of the act (63 P. S. § 390-5(a)(9)(xi)) prohibits the return to stock of medication once it has left the premises of the pharmacy. However, many prescriptions do not get delivered to patients and, therefore never leave the control of the pharmacy. These prescriptions may be returned to the active stock of the pharmacy. This section sets forth the guidelines that should be considered when returning undelivered medication to the pharmacy’s active stock. This section will insure that the integrity of the drugs is maintained and patient safety is not compromised.

(b) *Guidelines.* The following guidelines should be considered when returning undelivered medications to stock to assure that the quality of medications is maintained:

- (1) Prescriptions that have not been picked up by or delivered to patients should be checked periodically.

(2) Prescriptions not delivered to patients should be assessed by a pharmacist to determine whether they might safely be returned to stock.

(3) Products deemed eligible for redispensing should never be mixed within stock bottles of different lot numbers or with different expiration dates. Manufacturers' stock bottles should never be over-filled. The only safe manner in which drugs can be returned to stock bottles is in those pharmacies in which all medications are tracked by lot numbers and expiration dates.

(4) In those instances in which medication cannot be properly and safely returned to the original stock bottle, the medication may be held in the pharmacy in the container in which it has been repackaged. It is recommended that pharmacies develop an internal manner for so identifying and dating these products.

(5) Medications held for redispensing should be used as soon as possible. Medications held for redispensing, lacking original lot numbers and expiration dates, should only be dispensed to patients up to 6 months from the date the drugs were first prepared for dispensing.

(6) If the manufacturer or the United States Food and Drug Administration orders a recall for a drug product, pharmacists should assume products held in containers without lot numbers are included in the recall and proceed accordingly.

Source

The provisions of this § 27.102 adopted October 17, 2003, effective October 18, 2003, 33 Pa.B. 5202.

§ 27.103. Matters of conscience—statement of policy.

(a) *Background and purpose.* This statement of policy is not intended to supersede relevant laws, rules or regulations. Questions have been raised relating to the professional obligations of licensed pharmacists with respect to providing services to which they may be religiously, morally or ethically opposed. Pharmacists have a professional responsibility to offer complete pharmaceutical service by compounding or dispensing prescriptions which may reasonably be expected to be compounded or dispensed by pharmacists to meet the needs of patients who would usually attempt to utilize the services. However, pharmacists may also decline to fill or refill a prescription if, in the pharmacist's professional judgment exercised in the interest of the safety of the patient, the pharmacist believes the prescription should not be filled or refilled. When a pharmacist recognizes that religious, moral or ethical beliefs will result in the refusal to fill a prescription that is otherwise available in a pharmacy, the pharmacist has a professional obligation to take steps to avoid the possibility of abandoning or neglecting a patient.

(b) *Guidelines.* Pharmacists and pharmacies should consider the following guidelines when a pharmacist has religious, moral or ethical objections to filling certain prescriptions:

(1) When a pharmacist begins practice in a professional setting, the pharmacist should take steps that may include notification to the owner and pharmacist-manager if the pharmacist's beliefs will limit the drug products the pharmacist will dispense.

(2) If a pharmacy employs a pharmacist that has identified circumstances that would preclude the filling of prescriptions for particular products, the owner and pharmacist-manager should devise reasonable accommodations that will respect the pharmacist's choice while assuring delivery of services to patients in need. This may include the scheduling of pharmacists to allow a pharmacist who has a religious, moral or ethical objection to practice simultaneously with another pharmacist who will fill the requested prescription, entering into collaborative arrangements with pharmacies in close proximity, or other accommodations designed to protect the public.

(3) When a pharmacist has a religious, moral or ethical objection to filling a prescription, the pharmacist should not interfere with another pharmacist responding to the professional needs of a patient. The objecting pharmacist should refrain from engaging in nonhealth related judgmental or confrontational activities with the patient.

(4) In the case of a pharmacy staffed by only one licensed pharmacist who conscientiously objects to performing certain pharmacy practices and providing services customarily and ordinarily performed by a licensed pharmacist at a pharmacy, the pharmacist should ensure that protocols are in place that will avoid results that cause harm or potential harm to any patients/customers as a consequence of any action or inaction by the pharmacist based upon any such conscientious objections, including, but not limited to, the denial of access to prescribed medications and disruptions in the continuity of care.

Source

The provisions of this § 27.103 adopted October 26, 2007, effective October 27, 2007, 37 Pa.B. 5807.

TECHNOLOGY AND AUTOMATION

§ 27.201. Electronically transmitted prescriptions.

(a) For the purposes of this section, an electronically transmitted prescription means the communication of an original prescription or refill authorization by electronic means, to include computer-to-computer, computer-to-facsimile machine or e-mail transmission which contains the same information it contained when the authorized prescriber transmitted it. The term does not include a prescription or refill authorization transmitted by telephone or facsimile machine.

(b) A pharmacist may accept an electronically transmitted prescription from an authorized licensed prescriber or an authorized designated agent which has been sent directly to a pharmacy of the patient's choice if all the following requirements are met:

(1) The prescription must contain the signature or the electronic equivalent of a signature of the prescriber made in accordance with the requirements of the Electronic Transactions Act (73 P. S. §§ 2260.101—2260.5101).

(2) The prescription must include the following information:

- (i) The information that is required to be contained on a prescription under State and Federal law.
 - (ii) The prescriber's telephone number.
 - (iii) The date of the transmission.
 - (iv) The name of the pharmacy intended to receive the transmission.
- (3) The prescription must be electronically encrypted or transmitted by other technological means designed to protect and prevent access, alteration, manipulation or use by any unauthorized person.
- (4) A hard copy or a readily retrievable image of the prescription information that is transmitted shall be stored for at least 2 years from the date of the most recent filling.
- (5) The electronic transmission of a prescription for a Schedule II, III, IV or V controlled substance is considered a written prescription order on a prescription blank and may be accepted by a pharmacist provided that the transmission complies with this chapter and other requirements under Federal or other State laws or regulations, including The Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. §§ 780-101—780-144), Department of Health regulations in 28 Pa. Code §§ 25.1—25.131 and Federal rules established by the United States Drug Enforcement Administration in 21 CFR Part 1311 (relating to requirements for electronic orders and prescriptions).
- (c) An electronically transmitted prescription shall be processed in accordance with the act and this chapter.
- (d) The pharmacist and pharmacy may not provide electronic equipment to a prescriber for the purpose of transmitting prescriptions.

Source

The provisions of this § 27.201 adopted May 26, 2006, effective May 27, 2006, 36 Pa.B. 2518; amended April 10, 2012, effective April 11, 2012, 42 Pa.B. 5182. Immediately preceding text appears at serial pages (347429) to (347430).

Cross References

This section cited in 49 Pa. Code § 18.6a (relating to prescribing, dispensing and administering drugs); and 49 Pa. Code § 27.18 (relating to standards of practice).

§ 27.202. Computerized recordkeeping systems.

- (a) A computerized system used by a pharmacy for recording and maintaining information concerning prescriptions under State and Federal laws must be designed so that it is capable of providing immediate retrieval, by means of monitor, hard-copy printout or other transfer medium, of patient information for all prescriptions filled within the previous 12 months and retrieval within 3 working days of all prescriptions dispensed within the previous 24 months from the last activity date. This information must include the following data:
- (1) The information required to be on prescriptions under § 27.18(b)(1) (relating to standards of practice).
 - (2) Identification of the pharmacist responsible for prescription information entered into the computer system.
- (b) The system must be able to transfer all patient information to hard copy within 3 working days.
- (c) Prescriptions entered into a computer system but not immediately dispensed must meet the following conditions:

- (1) The complete prescription information must be entered in the computer system.
- (2) The information must appear in the patient's profile.
- (3) There must be positive identification, in the computer system or on the hard-copy prescription, of the pharmacist who is responsible for entry of the prescription information into the system.
- (4) The original prescription shall be filed according to § 27.18(b).
- (d) If the computerized recordkeeping system experiences down time, the prescription information shall be entered into the computerized recordkeeping system as soon as it is available for use.
- (e) The system must have adequate safeguards to:
 - (1) Prevent access by any person who is not authorized to obtain information from the system.
 - (2) Identify any modification or manipulation of information concerning a prescription.
 - (3) Prevent accidental erasure of information.

Source

The provisions of this § 27.202 adopted May 26, 2006, effective May 27, 2006, 36 Pa.B. 2518.

§ 27.203. Centralized prescription processing.

- (a) *Centralized prescription processing.* A central fill pharmacy or central processing center may fulfill a request for the processing, filling or refilling of a prescription from either the originating pharmacy or from the patient or the prescriber and may deliver the processed, filled or refilled prescription to a delivering pharmacy if the following requirements are met:
 - (1) The central fill pharmacy or the central processing center that is to process, fill or refill the prescription has a contract with or has the same owner as the originating pharmacy and the delivering pharmacy. Contractual provisions must include confidentiality of patient information.
 - (2) The prescription container:
 - (i) Is clearly labeled with the information required by Federal and State laws and regulations.
 - (ii) Clearly shows the name, address, telephone number and DEA number of the delivering pharmacy.
 - (3) Pharmacies that either utilize or act as central fill pharmacies or central processing centers shall create operating policies and procedures. The policies and procedures must include an audit trail that records and documents the central prescription process and the individuals accountable at each step in the process for complying with Federal and State laws and regulations including recordkeeping.
 - (4) Pharmacies that engage in centralized prescription processing share a common electronic file.
 - (5) Each pharmacy engaging in centralized prescription processing shall be jointly responsible for properly filling the prescription.

(6) The delivering pharmacy is responsible for making the offer to counsel to the patient under § 27.19(e) (relating to prospective drug review and patient counseling).

(b) *Exemptions.* The central processing center is exempt from:

(1) The requirement of maintaining an inventory of at least \$5,000 worth of nonproprietary drugs and devices under § 27.14(a) (relating to supplies).

(2) The minimum size requirements of § 27.16(b)(1) (relating to construction and equipment requirements).

(3) The requirement to have a sink used solely for pharmaceutical purposes under § 27.16(b)(5).

Source

The provisions of this § 27.203 adopted May 26, 2006, effective May 27, 2006, 36 Pa.B. 2518.

§ 27.204. Automated medication systems.

(a) This section establishes standards applicable to licensed pharmacies that utilize automated medication systems which may be used to store, package, dispense or distribute prescriptions.

(b) A pharmacy may use an automated medication system to fill prescriptions or medication orders provided that:

(1) The pharmacist manager, or the pharmacist under contract with a long-term care facility responsible for the dispensing of medications if an automated medication system is utilized at a location which does not have a pharmacy onsite, is responsible for the supervision of the operation of the system.

(2) The automated medication system has been tested and validated by the pharmacy and found to dispense accurately prior to the implementation of the system. The pharmacy shall make the results of the testing available to the Board upon request.

(3) The pharmacy shall make the automated medication system available to the Board for the purpose of inspection, whereby the Board may validate the accuracy of the system.

(4) The automated medication system must electronically record the activity of each pharmacist, technician or other authorized personnel with the time, date and initials or other identifier so that a clear, readily retrievable audit trail is established. A pharmacist will be held responsible for transactions performed by that pharmacist or under the supervision of that pharmacist.

(c) The pharmacist manager or the pharmacist under contract with a long-term care facility responsible for the delivery of medications shall be responsible for the following:

(1) Reviewing and approving all policies and procedures for system operation, safety, security, accuracy, access and patient confidentiality.

(2) Ensuring that medications in the automated medication system are inspected, at least monthly, for expiration date, misbranding and physical integ-

rity, and ensuring that the automated medication system is inspected, at least monthly, for security and accountability.

(3) Assigning, discontinuing or changing personnel access to the automated medication system.

(4) Ensuring that the automated medication system is stocked accurately and an accountability record is maintained in accordance with the written policies and procedures of operation.

(5) Ensuring compliance with the applicable provisions of State and Federal law.

(d) When an automated medication system is used to fill prescriptions or medication orders, it shall be operated according to written policies and procedures of operation created or adopted by the pharmacy. The policies and procedures of operation must:

(1) Include a table of contents.

(2) Include a description of all procedures of operation.

(3) Set forth methods that ensure retention of each amendment, addition, deletion or other change to the policies and procedures of operation for at least 2 years after the change is made. Each change shall be signed or initialed by the registered pharmacist manager and include the date on which the registered pharmacist manager approved the change.

(4) Set forth methods that ensure that a pharmacist currently licensed in the transmitting jurisdiction reviews and approves the transmission of each original or new prescription or medication order to the automated medication system before the transmission is made.

(5) Set forth methods that ensure that access to the records of medications and other medical information of the patients maintained by the pharmacy is limited to licensed practitioners or personnel approved to have access to the records.

(6) Set forth methods that ensure that access to the automated medication system for stocking and removal of medications is limited to licensed pharmacists or the pharmacist's designee acting under the supervision of a licensed pharmacist. An accountability record which documents all transactions relative to stocking and removing medications from the automated medication system must be maintained.

(7) Identify the circumstances under which medications may be removed from the automated medication system by a licensed medical practitioner for distribution to a patient without prior order review by a licensed pharmacist.

(e) A pharmacy that uses an automated medication system to fill prescriptions or medication orders shall, at least annually, review its written policies and procedures of operation and revise them, if necessary.

(f) A copy of the written policies and procedures of operation adopted under this section shall be retained at the pharmacy and at the long-term care facility where the automated medication system is utilized. Upon request, the pharmacy

shall provide to the Board a copy of the written policies and procedures of operation for inspection and review.

(g) The pharmacist manager shall be responsible for ensuring that, prior to performing any services in connection with an automated medication system, all licensed practitioners and supportive personnel are trained in the pharmacy's standard operating procedures with regard to automated medication systems set forth in the written policies and procedures. The training shall be documented and available for inspection.

(h) A pharmacy that uses an automated medication system to fill prescriptions or medication orders shall create and operate according to a written program for quality assurance of the automated medication system which:

- (1) Requires monitoring of the automated medication system.
- (2) Establishes mechanisms and procedures to test the accuracy of the automated medication system at least every 6 months and whenever any upgrade or change is made to the system.
- (3) Requires the pharmacy to maintain all documentation relating to the written program for quality assurance for at least 2 years. Upon reasonable notice from the Board, the pharmacy shall provide information to the Board regarding the quality assurance program for automated medication systems.

(i) A pharmacy that uses an automated medication system to fill prescriptions or medication orders shall maintain a written plan for recovery from a disaster that interrupts the ability of the pharmacy to provide services. The written plan for recovery must include:

- (1) Planning and preparation for a disaster.
- (2) Procedures for response to a disaster.
- (3) Procedures for the maintenance and testing of the written plan for recovery.

(j) A pharmacy that uses an automated medication system to fill prescriptions or medication orders shall maintain a written program for preventative maintenance of the system. Documentation of completion of all maintenance shall be kept on file in the pharmacy for at least 2 years.

Source

The provisions of this § 27.204 adopted May 26, 2006, effective May 27, 2006, 36 Pa.B. 2518.

MANAGEMENT OF DRUG THERAPY

§ 27.301. Written protocol for the management of drug therapy in an institutional setting.

(a) The management of drug therapy under section 9.1 of the act (63 P. S. § 390-9.1) shall be performed under a written protocol consistent with the institution's assignment of clinical duties. Ordering of laboratory tests and ordering

or performing other diagnostic tests necessary in the management of drug therapy shall be consistent with the testing standards of the institution.

(b) The written protocol for management of drug therapy between physicians and pharmacists must contain:

(1) A statement identifying the physician responsible for authorizing management of drug therapy.

(2) A statement identifying the pharmacist authorized to perform management of drug therapy.

(3) A statement requiring that regimens for the management of drug therapy be initiated by a physician for patients referred to a pharmacist for management of drug therapy.

(4) A statement identifying the types of decisions regarding the management of drug therapy that the pharmacist is authorized to make, including a statement of the ailments or diseases involved within the physician's scope of practice, and types of management of drug therapy authorized.

(5) A statement of the functions and tasks the pharmacist shall follow in the course of exercising management of drug therapy, including the method for documenting decisions made and a plan for communication or feedback to the authorizing physician concerning specific decisions made. Documentation of each intervention shall occur as soon as practicable, but no later than 72 hours after the intervention in the patient's medical record and shall also be recorded in the pharmacist's records.

(6) A statement that requires notification to the authorizing physician of any changes in dose, duration or frequency of medication prescribed as soon as practicable but no longer than 72 hours after the change.

(7) A provision for implementation of the written protocol when a physician or pharmacist who is a party to the protocol is temporarily unavailable to participate in its implementation.

(8) A provision for notification of the role of the pharmacist by a physician to each referred patient the management of whose drug therapy may be affected by the written protocol and providing an opportunity for the patient to refuse management of drug therapy by a pharmacist.

(9) The signatures of the physicians and pharmacists who are entering into the written protocol, and the dates signed.

(10) A statement allowing for the termination of the written protocol at the request of any party to it at any time.

(c) The written protocol must be available as follows:

(1) At the practice site of each physician who is a party to the written protocol.

(2) At the practice site of each pharmacist who is a party to the written protocol.

(3) At the institution where a written protocol is in place.

- (4) To any patient the management of whose drug therapy is affected by the written protocol, upon request of the patient.
- (5) Upon request, to representatives of the Bureau and the Department of Health.
- (d) The written protocol shall be filed with the Bureau.
- (e) The written protocol must be effective for a period not to exceed 2 years from the date of execution. At the end of the 2-year period, or sooner, the parties shall review the written protocol and make a determination as to its renewal, necessary modifications or termination.

Authority

The provisions of this § 27.301 amended under sections 6(k)(9) and 9.3 of the Pharmacy Act (63 P. S. §§ 390-6(k)(9) and 390-9.3).

Source

The provisions of this § 27.301 adopted June 30, 2006, effective July 1, 2006, 36 Pa.B. 3237; amended August 21, 2015, effective August 22, 2015, 45 Pa.B. 4911. Immediately preceding text appears at serial pages (347434) and (347735) to (347736).

§ 27.302. Collaborative agreement for management of drug therapy in a non-institutional setting.

- (a) Before practicing the management of drug therapy in a non-institutional setting, a pharmacist shall enter into a written collaborative agreement with a physician authorizing the management of drug therapy for diseases or for conditions or symptoms of diseases.
- (b) The collaborative agreement must be between a physician and a pharmacist.
- (c) A pharmacist may not provide economic or other incentives, inducements or benefits to a physician for the purpose of entering into a collaborative agreement for the management of drug therapy.
- (d) A pharmacist who is employed by a physician under a collaborative agreement for the purpose of management of drug therapy may not engage in retail dispensing while in the health care practice or within the context of employment.
- (e) Participation in a collaborative agreement authorizing the management of drug therapy is voluntary. A physician or pharmacist is not required to participate.
- (f) The collaborative agreement must contain:
 - (1) A statement identifying the physician responsible for authorizing the management of drug therapy.
 - (2) A statement identifying the pharmacist authorized to perform the management of drug therapy.
 - (3) A statement requiring that regimens for the management of drug therapy be initiated by a physician for patients referred to a pharmacist for management of drug therapy.
 - (4) A statement identifying the types of decisions regarding the management of drug therapy that the pharmacist is authorized to make within the physician's scope of practice and types of management of drug therapy authorized.

(5) A statement identifying the terms under which a pharmacist providing the management of drug therapy is permitted to: adjust the drug regimen, the drug strength and the frequency of administration or the route of administration; administer drugs; order laboratory tests; and order and perform other diagnostic tests necessary in the management of drug therapy without prior written or oral consent by the collaborating physician. This paragraph does not provide prescriptive authority to a pharmacist.

(6) A statement of the functions and tasks the pharmacist shall follow in the course of exercising management of drug therapy, including the method for documenting decisions made and a plan for communication or feedback to the authorizing physician concerning specific decisions made. Documentation of each intervention shall occur as soon as practicable, but no later than 72 hours after the intervention, and be recorded in the pharmacist's records.

(7) A statement that requires notification to the authorizing physician of changes in dose, duration or frequency of medication prescribed as soon as practicable but no longer than 72 hours after the change.

(8) A provision for implementation of the collaborative agreement when a physician or pharmacist who is a party to the agreement is temporarily unavailable to participate in its implementation.

(9) A provision for notification of the role of the pharmacist by a physician to each referred patient the management of whose drug therapy may be affected by the collaborative agreement and providing an opportunity for the patient to refuse management of drug therapy by a pharmacist.

(10) The signatures of the physicians and pharmacists who are entering into the collaborative agreement and the dates signed.

(11) A statement allowing for the termination of the collaborative agreement at the request of a party to it at any time.

(g) The collaborative agreement must be available:

(1) At the practice site of each physician who is a party to the collaborative agreement.

(2) At the practice site of each pharmacist who is a party to the collaborative agreement.

(3) To any patient the management of whose drug therapy is affected by the agreement, upon request of the patient.

(4) Upon request, to representatives of the Bureau and the Department of Health.

(h) The collaborative agreement shall be filed with the Bureau.

(i) The collaborative agreement must be maintained on the premises of the pharmacy for review during inspection by or upon request of representatives of the Bureau and the Department of Health.

(j) The collaborative agreement must be effective for no more than 2 years from the date of execution. At the end of the 2-year period, or sooner, the parties

shall review the collaborative agreement and make a determination as to its renewal, necessary modifications or termination.

(k) A pharmacist who is party to a collaborative agreement authorizing the management of drug therapy shall:

(1) Utilize an area for in-person, telephonic or other approved electronic consultations regarding the management of drug therapy that ensures the confidentiality of the patient information being discussed.

(2) Initiate the management of drug therapy only upon a written referral to the pharmacist from the physician. The written referral must include the minimum frequency in which the pharmacist shall conduct the management of the drug therapy in person.

(3) Confirm that the physician who is a party to the collaborative agreement holds an active and unrestricted license and that the terms of the collaborative agreement are within the scope of the physician's current practice at the time of the execution of the collaborative agreement.

(l) Patient records regarding the management of drug therapy may be maintained in a computerized recordkeeping system which meets the requirements for Federal and State-certified electronic health care records, subject to the following:

(1) The pharmacist who is a party to the collaborative agreement shall have access to the records of the patient who is the recipient of the management of drug therapy.

(2) The physician who is a party to the collaborative agreement shall have access to the pharmacy records of the patient who is the recipient of the management of drug therapy.

(3) The handling of patient records by the pharmacist providing the management of drug therapy shall comply with the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191, 110 Stat. 1936), the Health Information Technology for Economic and Clinical Health Act (Pub. L. No. 111-5, Div. A, Title XIII, Div. B, Title IV, 123 Stat. 226, 467), and associated rules and regulations.

Source

The provisions of this § 27.302 adopted August 21, 2015, effective August 22, 2015, 45 Pa.B. 4911.

PROFESSIONAL LIABILITY INSURANCE

§ 27.311. Certification of professional liability insurance—written protocol.

(a) A licensee who engages in management of drug therapy under a written protocol shall maintain professional liability insurance in the minimum amount of

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\$1 million per occurrence or claims made. The Board will accept from a licensee as satisfactory evidence of insurance coverage any of the following:

- (1) Personally purchased professional liability insurance.
- (2) Professional liability insurance coverage provided by the individual licensee's employer.
- (3) Similar insurance coverage acceptable to the Board.

(b) A licensee who engages in management of drug therapy under a written protocol shall certify compliance with subsection (a) on a form available from the Board. The licensee shall submit the completed certification form to the Board with the written protocol.

(c) A licensee who engages in management of drug therapy under a written protocol shall, upon request, make available to the Board or its agents a certificate of insurance regarding the licensee's maintenance of professional liability insurance.

(d) Failure to maintain insurance coverage as required under the act and this section will subject the licensee to disciplinary action under section 5(a)(6) of the act (63 P. S. § 390-5(a)(6)).

Authority

The provisions of this § 27.311 amended under sections 6(k)(9) and 9.3 of the Pharmacy Act (63 P. S. §§ 390-6(k)(9) and 390-9.3).

Source

The provisions of this § 27.311 adopted June 30, 2006, effective July 1, 2006, 36 Pa.B. 3237; amended August 21, 2015, effective August 22, 2015, 45 Pa.B. 4911. Immediately preceding text appears at serial page (347736).

§ 27.312. Certification of professional liability insurance—collaborative agreement.

(a) A licensee who is a party to a collaborative agreement authorizing the management of drug therapy shall obtain and maintain a level of professional liability insurance coverage in the minimum amount of \$1 million per occurrence or claims made. The Board will accept from a licensee as satisfactory evidence of insurance coverage any of the following:

- (1) Personally purchased liability insurance.
- (2) Professional liability insurance coverage provided by the individual licensee's employer.
- (3) Similar insurance coverage acceptable to the Board.

(b) A licensee who engages in the management of drug therapy under a collaborative agreement shall provide an affidavit to the Board that the licensee has obtained professional liability insurance in accordance with subsection (a) on a form available from the Board. The licensee shall submit the completed affidavit form to the Board with the collaborative agreement.

(c) A licensee who engages in the management of drug therapy under a collaborative agreement shall, upon request, make available to the Board or its agents a certificate of insurance regarding the licensee's maintenance of professional liability insurance.

(d) Failure to maintain insurance coverage as required under the act and this section will subject the licensee to disciplinary action under section 5(a)(6) of the act (63 P. S. § 390-5(a)(6)).

Source

The provisions of this § 27.312 adopted August 21, 2015, effective August 22, 2015, 45 Pa.B. 4911.

**ADMINISTRATION OF INJECTABLE MEDICATIONS,
BIOLOGICALS AND IMMUNIZATIONS**

§ 27.401. Qualifications for authority.

A candidate for authority to administer injectable medications, biologicals and immunizations shall meet the following requirements:

- (1) The pharmacist holds an active license to practice pharmacy in this Commonwealth.
- (2) The pharmacist has completed a course of education and training which meets the requirements of § 27.407 (relating to education requirements).
- (3) The pharmacist holds a current basic cardio-pulmonary resuscitation (CPR) certificate issued by the American Heart Association, American Red Cross or a similar health authority or professional body approved by the Board.

Source

The provisions of this § 27.401 adopted June 30, 2006, effective July 1, 2006, 36 Pa.B. 3237.

Cross References

This section cited in 49 Pa. Code § 27.32 (relating to continuing education).

§ 27.402. Application and renewal procedures.

(a) An applicant for authority to administer injectable medications, biologicals and immunizations shall submit the following to the Board:

- (1) An application obtained from the Board along with the fee required by § 27.91 (relating to schedule of fees).
- (2) Certification that the pharmacist has completed the required education and training in § 27.407 (relating to education requirements).
- (3) Certification that the pharmacist holds an acceptable, current CPR certificate.

(b) A holder of the authority to administer injectable medications, biologicals and immunizations shall renew the authority every 2 years along with the license to practice pharmacy. Renewal requires completion of a form provided to the pharmacist by the Board in advance of the renewal period, payment of the fee specified by § 27.91, certification of completion of 2 hours of continuing education required by section 9.2 of the act (63 P. S. § 390-9.2) and § 27.32 (relating to continuing education), and proof of a current CPR certificate.

Source

The provisions of this § 27.402 adopted June 30, 2006, effective July 1, 2006, 36 Pa.B. 3237.

§ 27.403. Conditions for administration.

(a) A pharmacist who is granted authority may administer injectable medications, biologicals and immunizations to persons who are more than 18 years of age. A person is more than 18 years of age on the day following the person's 18th birthday.

(b) A pharmacist may not delegate the administration of injectable medications, biologicals and immunizations to another person.

(c) A pharmacist shall administer injectable immunizations in accordance with treatment guidelines established by the Centers for Disease Control and Prevention and which have been approved by the Board.

Source

The provisions of this § 27.403 adopted June 30, 2006, effective July 1, 2006, 36 Pa.B. 3237.

§ 27.404. Authority and requirements.

(a) A pharmacist authorized by the Board to administer injectable medications, biologicals and immunizations may only do so under either an order or written protocol.

(b) The order from a licensed prescriber must be written, received electronically or if received orally be reduced to writing, and contain at a minimum the following:

- (1) The identity of the licensed prescriber issuing the order.
- (2) The identity of the patient to receive the injection.

- (3) The identity of the medication, immunization or vaccine, and dose, to be administered.
- (4) The date of the original order and the date or schedule, if any, of each subsequent administration.
- (c) An authorized pharmacist may enter into a written protocol, either approved by a physician or authorized by the medical staff of an institution, governing the administration of injectable medications, biologicals and immunizations for a specific period of time or purpose. The written protocol may be valid for a time period not to exceed 2 years. The protocol must include the following:
 - (1) The identity of the participating pharmacist and physician or institution.
 - (2) The identification of the medication, biological or immunization, which may be administered.
 - (3) The identity of the patient or groups of patients to receive the authorized injectable medication, biological or immunization.
 - (4) The identity of the authorized routes and sites of administration allowed.
 - (5) A provision establishing a course of action the pharmacist shall follow to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions and accidental needle sticks.
 - (6) A provision establishing a length of time the pharmacist shall observe an individual for adverse events following an injection.
 - (7) The identity of the location at which the pharmacist may administer the authorized medication, biological or immunization.
 - (8) Recordkeeping requirements and procedures for notification of administration.
 - (9) A provision that allows for termination of the protocol at the request of any party to it at any time.

Source

The provisions of this § 27.404 adopted June 30, 2006, effective July 1, 2006, 36 Pa.B. 3237.

§ 27.405. Recordkeeping.

- (a) A pharmacist who administers an injectable medication, biological or immunization shall maintain the following records regarding each administration for a minimum of 2 years:
 - (1) The name, address and date of birth of the patient.
 - (2) The date of the administration and site of the injection.
 - (3) The name, dose, manufacturer, lot number and expiration date of the medication, biological or immunization.
 - (4) The name and address of the patient's primary health care provider, as identified by the patient.
 - (5) The name or identifiable initials of the administering pharmacist.

- (6) Documentation of informed consent for administration of injectable medications, biologicals and immunizations.
- (7) The nature of an adverse reaction and who was notified.
- (b) A pharmacist who administers an immunization shall also maintain the following records regarding each administration for a minimum of 2 years:
 - (1) An identification of the Vaccine Information Statement (VIS) that was provided.
 - (2) The date of publication of the VIS.
 - (3) The date and to whom the VIS was provided.
- (c) In an institution, the information required to be maintained in subsections (a) and (b) may be maintained in the patients' medical records.

Source

The provisions of this § 27.405 adopted June 30, 2006, effective July 1, 2006, 36 Pa.B. 3237.

§ 27.406. Notification requirements.

A pharmacist administering injectable medications, biologicals or immunizations shall meet the following notification requirements:

- (1) When administration has occurred under an order, the pharmacist shall notify the ordering prescriber as soon as practicable, but no longer than 72 hours after administration of the following:
 - (i) The identity of the patient.
 - (ii) The identity of the medication, biological or immunization administered.
 - (iii) The route of administration.
 - (iv) The site of the administration.
 - (v) The dose administered.
 - (vi) The date of administration.
- (2) When the administration has occurred under a written protocol, the pharmacist shall notify the participating physician as soon as practicable, but no longer than 72 hours after administration of the following:
 - (i) The identity of the patient.
 - (ii) The identity of the medication, biological or immunization administered.
 - (iii) The site of the administration.
 - (iv) The dose administered.
 - (v) The date of administration.
- (3) In the event of any adverse event or reaction experienced by the patient either under an order or a written protocol, the pharmacist shall notify the patient's physician as soon as is practicable, and in no event later than 24 hours after learning of the adverse event or reaction.

Authority

The provisions of this § 27.406 issued under sections 4(j), 6(k)(1) and (9), 9.1(d)(3) and (e) and 9.2(a) of the Pharmacy Act (63 P. S. §§ 390-4(j), 390-6(k)(1) and (9), 390-9.1(d)(3) and (e) and 390-9.2(a)).

Source

The provisions of this § 27.406 adopted June 30, 2006, effective July 1, 2006, 36 Pa.B. 3237.

§ 27.407. Education requirements.

(a) To apply for the authority to administer injectable medications, biologicals and immunizations, a pharmacist shall meet the following education requirements:

(1) Complete within the 2-year period prior to application an evidence-based course that meets the following criteria:

- (i) Includes study material.
- (ii) Includes hands-on training and techniques for administration.
- (iii) Requires testing with a passing score.
- (iv) Provides a minimum of 10 hours of instruction and experiential training.
- (v) Complies with current guidelines and recommendations by the Centers for Disease Control and Prevention, ACPE or a similar health authority or professional body.

(2) The course must provide instruction on the following topics:

- (i) Basic immunology and the human immune response.
- (ii) Mechanics of immunity, adverse effects, dose and administration schedule of available vaccines.
- (iii) Response to an emergency situation as a result of the administration of an injectable medication, biological or immunization.
- (iv) Administration of subcutaneous, intradermal and intramuscular injections.
- (v) Disease epidemiology.
- (vi) Standards for immunization practices.
- (vii) Vaccine-preventable diseases.
- (viii) Recommended immunization schedules.
- (ix) Vaccine storage and management.
- (x) Biohazard waste disposal and sterile techniques.
- (xi) Informed consent.
- (xii) Authority and recordkeeping requirements as provided in this chapter.

(b) The Board approves courses offered by ACPE-accredited providers and educational institutions that meet the criteria and provide instruction on the topics listed in subsection (a).

Source

The provisions of this § 27.407 adopted June 30, 2006, effective July 1, 2006, 36 Pa.B. 3237.

Cross References

This section cited in 49 Pa. Code § 27.401 (relating to qualifications for authority); and 49 Pa. Code § 27.402 (relating to application and renewal procedures).

CANCER DRUG REPOSITORY PROGRAM**§ 27.501. Purpose.**

This section and §§ 27.502—27.506 establish a Cancer Drug Repository Program under the Cancer Drug Repository Program Act (62 P. S. §§ 2921—2927) through which unused cancer drugs may be redispensed to cancer patients by pharmacies approved by the Board for the purpose of dispensing unused cancer drugs to Pennsylvania residents who are indigent.

Authority

The provisions of this § 27.501 issued under 6(k)(9) of the Pharmacy Act (63 P. S. § 390-6(k)(9)); and sections 3 and 7 of the Cancer Drug Repository Program Act (62 P. S. §§ 2923 and 2927).

Source

The provisions of this § 27.501 adopted November 27, 2013, effective November 30, 2013, 43 Pa.B. 7011.

Cross References

This section cited in 49 Pa. Code § 27.502 (relating to definitions).

§ 27.502. Definitions.

The following words and terms, when used in §§ 27.501 and 27.503—27.506, have the following meanings, unless the context clearly indicates otherwise:

Cancer drug—A prescription drug used to treat:

- (i) Cancer or its side effects.
- (ii) The side effects of a prescription drug used to treat cancer or its side effects.

Original unopened, sealed and tamper-evident unit dose packaging—Single unit dose packaging of a drug product from a manufacturer or a repackager registered with the Federal Food and Drug Administration, or from a licensed Pennsylvania pharmacy, that has been visually inspected by a licensed pharmacist employed by or under contract with the participating pharmacy who has determined that the packaging appears to be unbreached and undamaged, and includes oral medications, injectables, topicals and aerosols.

Authority

The provisions of this § 27.502 issued under 6(k)(9) of the Pharmacy Act (63 P. S. § 390-6(k)(9)); and sections 3 and 7 of the Cancer Drug Repository Program Act (62 P. S. §§ 2923 and 2927).

Source

The provisions of this § 27.502 adopted November 27, 2013, effective November 30, 2013, 43 Pa.B. 7011.

Cross References

This section cited in 49 Pa. Code § 27.501 (relating to purpose).

§ 27.503. Participation in the Cancer Drug Repository Program.

(a) *Participation.* A pharmacy holding a current unrestricted permit may apply for approval to participate in the Cancer Drug Repository Program as an approved cancer drug repository as provided in this chapter.

(b) *Application.* A pharmacy may apply for approval to participate in the Cancer Drug Repository Program by submitting the following information to the Board, on a form provided by the Board:

- (1) The name, street address and telephone number of the pharmacy.
- (2) Identification and background information of the pharmacy's ownership.
- (3) A description of all pharmacy services provided and the location and manner in which those services are provided.
- (4) A certification by a licensed pharmacist who is employed by or under contract with the pharmacy that the pharmacy meets the eligibility requirements for participation in the Cancer Drug Repository Program under subsection (c).
- (5) The name and telephone number of the licensed pharmacist employed by or under contract with the pharmacy who made the certification required under paragraph (4).

(c) *Eligibility.* A pharmacy is eligible to participate in the Cancer Drug Repository Program if the pharmacy:

- (1) Holds a current unrestricted permit in good standing to operate as a pharmacy in this Commonwealth.
- (2) Delegates to a licensed pharmacist employed by or under contract with the pharmacy the responsibility to receive delivery of donated cancer drugs at the designated delivery area in the pharmacy.
- (3) Agrees to participate in the Cancer Drug Repository Program in accordance with the act, this chapter and the Cancer Drug Repository Program Act (62 P. S. §§ 2921—2927).

(d) *Donations of cancer drugs.*

- (1) A pharmacy, health care facility, drug manufacturer or wholesale drug distributor may donate legally obtained cancer drugs to an approved participating pharmacy if the drugs meet the eligibility requirements under § 27.504

(relating to drugs) as determined by a licensed pharmacist employed by or under contract with an approved participating pharmacy.

(2) To be considered for donation, a cancer drug must be accompanied by a cancer drug repository donor form on a form provided by the Board that:

(i) Is signed by the entity's authorized representative.

(ii) States that to the best of the donor's knowledge the donated drug has been properly stored and that the drug has never been opened, used, tampered with, adulterated or misbranded.

(e) *Changes in approval status.* The Board may refuse, revoke or suspend approval of a pharmacy's participation in the Cancer Drug Repository Program upon proof satisfactory to it that the pharmacy has violated the Cancer Drug Repository Program Act, the act, or any Federal or State law, rule or regulation.

Authority

The provisions of this § 27.503 issued under 6(k)(9) of the Pharmacy Act (63 P. S. § 390-6(k)(9)); and sections 3 and 7 of the Cancer Drug Repository Program Act (62 P. S. §§ 2923 and 2927).

Source

The provisions of this § 27.503 adopted November 27, 2013, effective November 30, 2013, 43 Pa.B. 7011.

Cross References

This section cited in 49 Pa. Code § 27.501 (relating to purpose); and 49 Pa. Code § 27.502 (relating to definitions).

§ 27.504. Drugs.

(a) *Eligible drugs.* Unless otherwise prohibited by Federal or State statute or regulation, a cancer drug may be accepted by a licensed pharmacist at an approved participating pharmacy for dispensing in a Cancer Drug Repository Program if the drug meets one of the following criteria:

(1) The drug is in its original unopened, sealed and tamper-evident unit dose packaging.

(2) The drug is packaged in single unit doses, when the outside original packaging is opened but the single-unit-dose packaging is unopened.

(b) *Ineligible drugs.* A cancer drug may not be accepted by a licensed pharmacist at an approved participating pharmacy for dispensing if the drug meets any one of the following criteria:

(1) The drug bears an expiration date that is earlier than 6 months after the date the drug will be restocked.

(2) The drug shows evidence of having been adulterated or misbranded.

(3) The drug is designated by the Drug Enforcement Agency as a controlled substance under 21 CFR Part 1308 (relating to schedules of controlled substances).

- (4) The drug is subject to restricted distribution by the Food and Drug Administration under 21 CFR 314.520 or 314.610 (relating to approval with restrictions to assure safe use; and approval based on evidence of effectiveness from studies in animals).
- (5) The drug requires refrigeration, freezing or other special temperature requirements beyond controlled room temperature.
- (6) The drug has been previously compounded.
- (c) *Drug categories.* Unless otherwise ineligible under this section, an approved participating pharmacy may accept a cancer drug in any of the categories of the American Hospital Formulary Service Pharmacologic-Therapeutic Classification.
- (d) *Recalls.* An approved participating pharmacy shall handle a recall of any drug in its Cancer Drug Repository Program as if the drug had been delivered directly to the pharmacy by the manufacturer.

Authority

The provisions of this § 27.504 issued under 6(k)(9) of the Pharmacy Act (63 P. S. § 390-6(k)(9)); and sections 3 and 7 of the Cancer Drug Repository Program Act (62 P. S. §§ 2923 and 2927).

Source

The provisions of this § 27.504 adopted November 27, 2013, effective November 30, 2013, 43 Pa.B. 7011.

Cross References

This section cited in 49 Pa. Code § 27.501 (relating to purpose); 49 Pa. Code § 27.502 (relating to definitions); and 49 Pa. Code § 27.503 (relating to participation in the Cancer Drug Repository Program).

§ 27.505. Repositories.

- (a) *Donation site receipt.* An approved participating pharmacy shall designate an area within the pharmacy at which its licensed pharmacist shall personally receive delivery from the donor or its designee, and provide the donor or its designee with written acknowledgement of any donation of a cancer drug.
- (b) *Donation site compliance.* An approved participating pharmacy that accepts donated cancer drugs under the Cancer Drug Repository Program shall comply with all applicable Federal and State laws relating to the storage, distribution, dispensing, disposal and destruction of cancer drugs and visually inspect all cancer drugs prior to dispensing in a manner as to be able to reasonably determine if they are adulterated or misbranded. The cancer drugs shall only be dispensed by a licensed pharmacist according to State law pursuant to a prescription issued by a prescribing practitioner. The cancer drugs may be distributed to another participating physician's office, pharmacy, hospital, health care facility or health clinic for dispensing by a pharmacist as allowed by Federal or State law.

(c) *Disposition.* The approved participating pharmacy repository shall destroy or dispose of donated drugs in a manner in compliance with applicable Federal and State laws if they are not accepted into the Cancer Drug Repository Program for the purpose of dispensing. A record of destruction or disposal of donated drugs that are not accepted or dispensed under the Cancer Drug Repository Program shall be maintained by the participating pharmacy for at least 2 years, and include the following:

- (1) The date of destruction.
- (2) The name, strength and quantity of the cancer drug destroyed.
- (3) The name of the person or firm that destroyed the drug.
- (4) The source of the drugs destroyed.

(d) *Storage.* Drugs received in the Cancer Drug Repository Program shall be stored separately from the rest of the approved participating pharmacy's stock.

(e) *Informed consent.* Prior to dispensing a cancer drug in its Cancer Drug Repository Program, an approved participating pharmacy shall inform the patient that the drug was previously dispensed but was unused and then donated to the approved participating pharmacy in the drug's original unopened, sealed and tamper-evident unit dose packaging to be restocked and redistributed. The approved participating pharmacy may not dispense the drug if the patient does not sign a cancer drug repository informed consent form as supplied by the Board. The informed consent form shall be maintained for at least 2 years after the patient signs it. The form must include the following information:

- (1) The drug being dispensed has been donated and may have been previously dispensed.
- (2) The drug was unused, although previously dispensed.
- (3) The drug was donated to the approved participating pharmacy in the drug's original unopened, sealed and tamper-evident packaging to be restocked and redistributed.
- (4) A visual inspection has been conducted by the pharmacist in a manner as to be able to reasonably determine that the drug has not expired, has not been adulterated or misbranded, and is in its original unopened, sealed and tamper-evident packaging.

(5) The dispensing pharmacist, the prescribing or administering practitioner, the cancer drug repository, the Board and any other participant of the Cancer Drug Repository Program cannot guarantee the safety of the drug being dispensed or administered, and that the pharmacist has determined that the drug appears to be safe to dispense or administer based on the accuracy of the donor's form submitted with the donated drug and the visual inspection required to be performed by the pharmacist before dispensing or administering.

(f) *Recordkeeping.* Drugs used in the Cancer Drug Repository Program must be easily auditable and every dose accounted for by the approved participating pharmacy's maintenance of recordkeeping meeting the following requirements:

- (1) The approved participating pharmacy must record receipt of the drug on a repository donor form as developed by the Board.
- (2) The approved participating pharmacy must record dispensing the drug on a repository dispensing form as developed by the Board.
- (3) The approved participating pharmacy shall record the following information for all cancer drugs received, dispensed and distributed or disposed of or destroyed in the Cancer Drug Repository Program:
 - (i) Name and strength of the cancer drug.
 - (ii) Quantity of the cancer drug.
 - (iii) Expiration date of the cancer drug.
 - (iv) Lot number of the cancer drug.
 - (v) Name of pharmacy that originally dispensed the cancer drug.
 - (vi) Name of the donor of the cancer drug.
 - (vii) Name of the person to whom the cancer drug was originally prescribed.
 - (viii) Name of the person to whom the cancer drug was dispensed.
 - (ix) Date the cancer drug was dispensed.
 - (x) Name of the prescribing practitioner who wrote the prescription for the cancer drug to be dispensed under the Cancer Drug Repository Program.
 - (xi) Date the cancer drug was disposed of or destroyed.
 - (xii) Whether a handling fee was charged and the amount of the fee.
- (4) The approved participating pharmacy shall maintain records required under this section for at least 2 years.
 - (g) *Handling fee.* An approved participating pharmacy may charge a handling fee for distributing or dispensing cancer drugs under the Cancer Drug Repository Program, not to exceed 250% of the Medical Assistance dispensing fee more specifically set forth in the Method of Payment for Pharmaceutical Services provided in 55 Pa. Code Chapter 1121 (relating to pharmaceutical services). (See 55 Pa. Code § 1121.55 (relating to method of payment).) Cancer drugs donated under the Cancer Drug Repository Program may not be resold.
 - (h) *Theft and diversion.* An approved participating pharmacy shall develop, implement and enforce a policy to deter and minimize theft and diversion of cancer drugs it receives in the form of donations made under the Cancer Drug Repository Program.

Authority

The provisions of this § 27.505 issued under 6(k)(9) of the Pharmacy Act (63 P. S. § 390-6(k)(9)); and sections 3 and 7 of the Cancer Drug Repository Program Act (62 P. S. §§ 2923 and 2927).

Source

The provisions of this § 27.505 adopted November 27, 2013, effective November 30, 2013, 43 Pa.B. 7011.

Cross References

This section cited in 49 Pa. Code § 27.501 (relating to purpose); and 49 Pa. Code § 27.502 (relating to definitions).

§ 27.506. Patient eligibility.

(a) *Conditions of eligibility.* To be eligible for the Cancer Drug Repository Program, a patient shall certify that the patient meets the following criteria:

(1) The patient is diagnosed with cancer.

(2) The patient does not possess or has limited prescription drug coverage related to the treatment of the patient's cancer so that the coverage limits prevent the patient from obtaining cancer drugs.

(3) The patient does not meet the eligibility requirements under the State Medical Assistance Program that provides prescription drug coverage related to the treatment of cancer.

(b) *Financial eligibility for the Cancer Drug Repository Program.*

(1) A Pennsylvania resident who meets the eligibility requirements in subsection (a) is financially eligible as an "indigent patient" for the Cancer Drug Repository Program if the resident meets the income standards in this subsection.

(2) The income limits for eligibility for the Cancer Drug Repository Program are based upon the prior year's family income not to exceed 350% of the prior year's Department of Health and Human Services Federal Poverty Income Guidelines for the appropriate family size. The income limits will be published as a notice in the *Pennsylvania Bulletin* and posted on the Board's web site at least once a year as the Federal Poverty Income Guidelines change.

(3) There are no resource limits for determining eligibility under the Cancer Drug Repository Program.

Authority

The provisions of this § 27.506 issued under 6(k)(9) of the Pharmacy Act (63 P. S. § 390-6(k)(9)); and sections 3 and 7 of the Cancer Drug Repository Program Act (62 P. S. §§ 2923 and 2927).

Source

The provisions of this § 27.506 adopted November 27, 2013, effective November 30, 2013, 43 Pa.B. 7011.

Cross References

This section cited in 49 Pa. Code § 27.501 (relating to purpose); and 49 Pa. Code § 27.502 (relating to definitions).

COMPOUNDING**§ 27.601. Compounding of preparations.**

The compounding of sterile and nonsterile preparations shall be done in accordance with section 503a of the Federal Food, Drug, and Cosmetic Act (21

U.S.C.A. § 353a), Federal regulations promulgated thereunder, and the current version of the USP chapters governing compounding.

Authority

The provisions of this § 27.601 issued under sections 4(j) and 6(k)(1) and (9) of the Pharmacy Act (63 P.S. §§ 390-4(j) and 390-6(k)(1) and (9)).

Source

The provisions of this § 27.601 adopted June 21, 2019, effective June 22, 2019, 49 Pa.B. 3210.

§ 27.602. Compounding prohibited.

Pharmacists may not compound any of the following:

(1) Drugs that have been identified by the FDA as withdrawn or removed from the market because the drugs were found to be unsafe or ineffective as set forth in 21 CFR 216.24 (relating to drug products withdrawn or removed from the market for reasons of safety or effectiveness) unless the drug is being used as part of a clinical trial and is approved by an institution's institutional review board.

(2) Drugs that are essentially copies of a commercially available drug product, except as provided in section 503a(b)(1)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. § 353a(b)(1)(D)).

(3) Drugs that have been identified by the FDA in the Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. §§ 301—399h) or the *Code of Federal Regulations* as products which may not be compounded.

Authority

The provisions of this § 27.602 issued under sections 4(j) and 6(k)(1) and (9) of the Pharmacy Act (63 P.S. §§ 390-4(j) and 390-6(k)(1) and (9)).

Source

The provisions of this § 27.602 adopted June 21, 2019, effective June 22, 2019, 49 Pa.B. 3210.

§ 27.603. Pharmacist responsibilities.

(a) As in the dispensing of all prescription drugs, the pharmacist has the responsibility for all of the following:

(1) Inspection and approval or rejection of all components, bulk drug substances (that is, active pharmaceutical ingredients), drug product containers, closures, in-process materials and labeling.

(2) Preparation and review of all compounding records to assure that errors have not occurred in the compounding process.

(3) Proper maintenance, cleanliness and use of all facilities and equipment used in compounding practice.

(b) If errors have occurred, the pharmacist is responsible for conducting a full investigation, and creating and maintaining a record of the investigation which must include conclusions and corrective action.

Authority

The provisions of this § 27.603 issued under sections 4(j) and 6(k)(1) and (9) of the Pharmacy Act (63 P.S. §§ 390-4(j) and 390-6(k)(1) and (9)).

Source

The provisions of this § 27.603 adopted June 21, 2019, effective June 22, 2019, 49 Pa.B. 3210.

§ 27.604. Drug compounding controls.

Accountability for quality control is the responsibility of the compounding pharmacist.

Authority

The provisions of this § 27.604 issued under sections 4(j) and 6(k)(1) and (9) of the Pharmacy Act (63 P.S. §§ 390-4(j) and 390-6(k)(1) and (9)).

Source

The provisions of this § 27.604 adopted June 21, 2019, effective June 22, 2019, 49 Pa.B. 3210.

§ 27.605. Label information required.

The label affixed to or on the dispensing container of a compounded drug product dispensed by a pharmacy pursuant to a prescription or drug order must bear the information as required in § 27.18(d) (relating to standards of practice) and any additional information required by USP provisions pertaining to label information requirements.

Authority

The provisions of this § 27.605 issued under sections 4(j) and 6(k)(1) and (9) of the Pharmacy Act (63 P.S. §§ 390-4(j) and 390-6(k)(1) and (9)).

Source

The provisions of this § 27.605 adopted June 21, 2019, effective June 22, 2019, 49 Pa.B. 3210.

§ 27.606. Compounding records.

Compounding records required by this chapter shall be retained as the original records and shall be readily available at the pharmacy for inspection and photocopying by agents of the Board or other authorized authorities for at least 2 years following the date of the record. Prescriptions for all products compounded at the pharmacy shall be maintained on file at the pharmacy as required under § 27.18(b) (relating to standards of practice).

Authority

The provisions of this § 27.606 issued under sections 4(j) and 6(k)(1) and (9) of the Pharmacy Act (63 P.S. §§ 390-4(j) and 390-6(k)(1) and (9)).

Source

The provisions of this § 27.606 adopted June 21, 2019, effective June 22, 2019, 49 Pa.B. 3210.

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