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THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 874 Session of 1997

INTRODUCED BY RHOADES, AFFLERBACH, GREENLEAF, TOMLINSON, LAVALLE, KUKOVICH, COSTA, ROBBINS, MADIGAN, MUSTO, STOUT, HELFRICK, WOZNIAK, PUNT, CORMAN, BRIGHTBILL, KASUNIC, WILLIAMS AND WHITE, APRIL 2, 1997

REFERRED TO CONSUMER PROTECTION AND PROFESSIONAL LICENSURE, APRIL 2, 1997

AN ACT

Relating to the regulation of the practice of pharmacy; and making repeals.

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The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

CHAPTER 1

PRELIMINARY PROVISIONS

Section 101. Short title.

This act shall be known and may be cited as the Pharmacy Practice Act.

Section 102. Legislative declaration.

It is declared to be a matter of public interest and concern that the practice of pharmacy, as defined in this act, merit and receive the confidence of the public. It is further declared that only qualified persons be permitted to engage in the practice of pharmacy in the Commonwealth of Pennsylvania.

Section 103. Statement of purpose.

It is the purpose of this act to promote, preserve and protect the public health, safety and welfare by the effective control and regulation of the practice of pharmacy through:

(1) The licensure of pharmacists.

(2) The licensure of pharmacist interns.

(3) The registration of technicians.

(4) The licensure, control and regulation of all sites or persons who are required to obtain a license or permit

from the board, whether located in or out of the Commonwealth, that deliver, dispense, administer, distribute, manufacture, promote or sell drugs within this Commonwealth.

Section 104. Definitions.

The following words and phrases when used in this act shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"Administer." The direct introduction of or the application of a drug into or on the body of a patient or research subject by injection, inhalation, ingestion or any other means.

"Beyond-use date." A date determined by a pharmacist and placed on a prescription label at the time dispensing that is intended to indicate to the patient or caregiver a time beyond which the contents of that prescription are not recommended for use.

"Board." The Pennsylvania State Board of Pharmacy.

"Collaborative care agreement." A written agreement or protocol between a licensed prescriber and a pharmacist authorizing that pharmacist to:

(1) Initiate, modify, monitor, continue or discontinue drug therapy.

(2) Administer medications.

(3) Order and perform laboratory or other diagnostic tests in accordance with regulations adopted by the Pennsylvania State Board of Pharmacy.

"Collaborative pharmacy practice." The practice of pharmacy whereby a pharmacist has jointly agreed to work in conjunction with one or more licensed prescribers under a protocol whereby the pharmacist may perform certain patient care functions authorized by the practitioner or practitioners under certain

specified conditions or limitations, including, but not limited to, the initiating, continuing or discontinuing of drug therapy; the administration of drugs; and the ordering and/or the performing of laboratory tests which may be necessarily incident to the treatment.

"Compounding." The preparation, mixing, assembling, packaging or labeling of a drug pursuant to or in anticipation of a valid prescription drug order, including, but not limited to, packaging, intravenous admixture or manual combination of drug ingredients.

"Confidential information." Information relevant to a patient's health care which is acquired by the pharmacist incident to a professional relationship. Confidential information is privileged and may be released only to the patient, or to a third party upon the authorization of the patient, or where such release is necessary to protect the patient's health and well-being, or to such other persons or government agencies authorized by law to receive that information.

"Controlled substance." Any drug designated as such under the provisions of the act of April 14, 1972 (P.L.233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act.

"Deliver" or "delivery." The actual, constructive or attempted transfer of a drug or device from one person to another, whether or not for consideration.

"Device." An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component part or accessory, which is required under Federal or State law to be prescribed by

a health practitioner and dispensed by a pharmacist.

"Disease state management." A comprehensive, integrated approach to patient care based upon the natural course of disease which emphasizes treatments designed to address an illness with maximum efficiency.

"Dispense" or "dispensing." The procedure entailing the interpretation of a health practitioner's medical order or a prescription drug order for a drug or device and pursuant to that order, the proper selection, measuring, labeling and packaging of a drug or device in a proper container for subsequent administration to or use by a patient.

"Distribute." The delivery of a drug or device other than by administering or dispensing.

"Drug."

(1) Articles, including radioactive substances, recognized as drugs in any official compendium, or supplement thereto, or designated from time to time by the Pennsylvania State Board of Pharmacy for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals.

(2) Articles, other than food, intended to affect the structure or any function of the body of humans or other animals.

(3) Articles intended for use as a component of any articles specified in paragraphs (1) and (2), but not including devices or their component parts or accessories.

"Drug regimen review." Any retrospective, concurrent and prospective review by a pharmacist of a patient's drug-related therapy, including, but not limited to, evaluation of any or all of the following areas:

(1) Known allergies.

(2) Rational therapy-contraindications.

(3) Appropriate dose and route of administration.

(4) Appropriate directions for use.

(5) Duplicative therapies.

(6) Potential misuse or abuse.

(7) Drug-drug, drug-food, drug-disease and drug-clinical laboratory interactions.

(8) Adverse drug reactions.

(9) Drug utilization review and optimal therapeutic outcomes.

"Electronic data transmission." The transmission of information in electronic form or the transmission of the exact visual image of a document by way of electronic equipment.

"Emergency refill prescription." A refill of a prescription which is essential to the continuation of therapy for which that refill has not been authorized and for which the pharmacist notifies the prescriber within 72 hours, of dispensing that prescription that an emergency refill prescription has been dispensed.

"Federal act." The Federal Food, Drug and Cosmetic Act (52 Stat. 1040, 21 U.S.C. § 301 et seq.)

"Health care provider" or "health practitioner." An individual licensed by the Commonwealth to provide patient care under the authority of a professional practice act, and includes licensed prescribers and health care providers or health practitioners.

"Home infusion pharmacy." A pharmacy which compounds solutions for direct administration to a patient in a private residence, long-term care facility, hospice or similar setting

by means of parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion.

"Immediate supervision." A level of control which assures that the pharmacist has the ultimate responsibility for the accuracy, safety and patient outcomes with respect to the actions of pharmacy technicians and pharmacist interns and the use of automation in all practice settings.

"Impaired professional support group." A peer assistance group whose goals are to direct an impaired colleague into treatment.

"Labeling." The process of preparing and affixing a label to any drug container, which label shall include all information required by Federal and State law, rule or regulation.

"Licensed prescriber." A physician, dentist, veterinarian, podiatrist, or other individual duly authorized and licensed by law to independently prescribe drugs, including prescription drugs.

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

"Managing drug therapy." Adjusting a drug regimen; changing the duration of therapy; adjusting drug strength, frequency of administration and/or route; and the initiation or discontinuation of therapy, including the administration of drugs.

"Manufacturer." Any person, except a pharmacist compounding in the normal course of professional practice within this Commonwealth, engaged in the commercial production, preparation, propagation, compounding, conversion, or processing of a drug, either directly or indirectly, by extraction from substances of

natural origin or independently by means of chemical synthesis, or both, and includes any packaging or repackaging of a drug or the labeling or relabeling of the drug container.

"Medical order." A lawful order by a specifically identified health practitioner for a specifically identified patient.

"Nonprescription drug." A drug which may be sold without prescription and which is labeled for use by the consumer in accordance with the requirements of the laws and rules of the Federal Government and this Commonwealth.

"Nonresident pharmacy." A pharmacy located outside this Commonwealth.

"Patient counseling." The process of the communication of information between the pharmacist and the patient, including, but not limited to, both verbal and written information as defined in the rules of the Pennsylvania State Board of Pharmacy in order to promote the proper use of any drug and to enhance drug therapy.

"Person." An individual, corporation, partnership, association, or any other legal entity including government.

"Pharmacist." A health care provider or practitioner currently licensed by the Pennsylvania State Board of Pharmacy to engage in the practice of pharmacy.

"Pharmacist care" or "pharmaceutical care" or "pharmacy care." The provision, by a pharmacist, of drug therapy and other patient care services to achieve patient outcomes which improve the patient's quality of life as it is related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process.

"Pharmacist intern." An individual licensed by the Pennsylvania State Board of Pharmacy to engage in the practice

of pharmacy under the immediate supervision of a licensed pharmacist and who makes satisfactory progress toward meeting the requirements for licensure as a pharmacist.

"Pharmacy." Any place within this Commonwealth which is properly issued a permit by the Pennsylvania State Board of Pharmacy where drugs, devices, radiopharmaceuticals and diagnostic agents for human or animal consumption are stored, dispensed or compounded, or any place outside this Commonwealth where drugs, devices, radiopharmaceuticals and diagnostic agents for human and animal consumption are dispensed to residents of this Commonwealth. The term "pharmacy" shall not include the operation of a manufacturer or distributor as defined in the Act of April 14, 1972 (P.L.233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act. Within an institution the term "pharmacy" refers to all organized pharmacy service within that institution.

"Pharmacy practice site." Any place within or outside this Commonwealth where the practice of pharmacy is provided to residents of this Commonwealth.

"Pharmacy technician." An individual who is registered with the board and who may assist in the practice of pharmacy under the immediate supervision of a licensed pharmacist.

"Practice of pharmacy," The provision of health care services by a pharmacist, including, but not limited to:

(1) The interpretation, evaluation and implementation of medical orders.

(2) The delivering, dispensing or distributing of prescription drugs.

(3) Participation in drug and device selection.

(4) Drug administration.

(5) Drug regimen review.

(6) Drug or drug-related research.

(7) The provision of pharmacist care in all areas including primary care.

(8) Compounding.

(9) Proper and safe storage of drugs and devices.

(10) Managing drug therapy.

(11) Participation in collaborative care agreements.

(12) Maintaining proper records.

(13) Patient counseling.

(14) Performing physical assessment.

(15) Ordering and performing laboratory or other diagnostic tests.

(16) Disease state management.

(17) Any other acts, services, operations or transactions necessary or incident to providing pharmacist care.

"Preceptor." An individual who is currently licensed as a pharmacist by the Pennsylvania State Board of Pharmacy, meets the qualifications as a preceptor under the rules of the board, has filed with the board any application or documentation and the board may require and participates in the instructional training of pharmacy interns.

"Prescription drug" or "legend drug" or "nonproprietary drug." Any drug which is required by any applicable Federal or State law or regulation to be dispensed only pursuant to a prescription drug order or which is restricted to use by health practitioners.

"Prescription drug order." A lawful order issued by a duly licensed health practitioner for drugs, drug-related devices or

treatment for a human or animal, including orders issued through collaborative care agreements.

Primary care." A pharmacist's activities in patient education, health promotion, assistance in the selection of and use of over-the-counter drugs and appliances for the treatment of common diseases and injuries; drug selection under protocol; nutrition; and any other activities falling within the pharmacist's statutory or regulatory scope of practice.

"Protocol." A written document that describes the nature and scope of the drug therapy management to be carried out by the pharmacist or other health practitioner.

"Wholesaler." Any person within this Commonwealth who legally buys drugs for resale or distribution to persons other than patients or consumers.

Section 105. Construction of act.

This act shall be liberally construed to carry out these objectives and purposes.

CHAPTER 3

PENNSYLVANIA STATE BOARD OF PHARMACY

Section 301. Pennsylvania State Board of Pharmacy.

The responsibility for enforcement of the provisions of this act is hereby vested in the Pennsylvania State Board of Pharmacy. The board shall have all the powers, duties and authority specifically granted by or necessary for the enforcement of this act, as well as any other powers, duties and authorities that may be granted by law.

Section 302. Membership.

Beginning with any vacancies existing on the effective date of this act, and as terms expire or vacancies occur thereafter, the board shall consist of:

(1) The Commissioner of Professional and Occupational Affairs.

(2) The Director of the Bureau of Consumer Protection in the Office of Attorney General or a designee of the director.

(3) Two persons representing the public at large.

(4) Seven persons who are licensed to practice pharmacy in this Commonwealth. Of the seven appointees under this paragraph:

(i) Two pharmacists shall be appointed from independent retail pharmacies.

(ii) Two pharmacists shall be appointed who are employees of retail chain pharmacies which operate five or more pharmacies licensed within this Commonwealth.

(iii) One pharmacist shall be appointed from an acute care institutional pharmacy.

(iv) Two pharmacists shall be appointed who are each involved in one of the following areas:

(A) Long-term care pharmacy or consulting pharmacy.

(B) Pharmacy education at an accredited school or college of pharmacy, as recognized by the board, within this Commonwealth.

(C) Nuclear pharmacy, home health care practice or any other specialty recognized by the board and not yet represented.

Section 303. Qualification.

Each pharmacist member of the board shall at the time of appointment:

(1) Be a resident of this Commonwealth for not less than one year.

(2) Must have been registered as a pharmacist in this Commonwealth for at least five years immediately preceding appointment.

(3) The public members of the board shall have been residents of this Commonwealth for not less than two years at the time of their appointment, shall have attained the age of majority, and shall not be, nor shall ever have been, a pharmacist, or the spouse of a pharmacist, or a person who has ever had any material financial interest in the provision of pharmacy services or who has engaged in any activity directly related to the practice of pharmacy.

Section 304. Appointment.

Nominations for appointment to the board may be made to the Governor by any individual, any professional pharmacy association within this Commonwealth or any other entity. All professional and public members of the board shall be appointed by the Governor with the advice and consent of a majority of the members elected to the Senate.

Section 305. Terms of office.

(a) Regular term.--Except as provided in subsection (b), the terms of each professional member and each public member of the Board shall be four years, or until a successor has been appointed and qualified, but not longer than six months beyond the four-year period. In the event that any member shall die or resign or otherwise become disqualified during that member's term, a successor shall be appointed in the same way and with the same qualifications as the original member and shall hold office for the unexpired portion of the term.

(b) Terms to be staggered.--The terms of the professional and public members of the board shall be staggered, so that the

terms of no more than three members shall expire in any year. Each member shall serve until a successor is appointed and qualified as provided in subsection (a).

(c) Existing board members.--The present members of the board on the effective date of this act shall serve the balance of their terms.

(d) Reappointment.--No professional or public member of the board shall be eligible for appointment to serve more than three consecutive full terms. The completion of the unexpired portion of a full term shall not constitute a full term for purposes of this subsection. Any present board member appointed initially for a term of less than four years shall be eligible to serve for three additional full terms.

(e) Vacancies.--Any vacancy which occurs in the membership of the board for any reason, shall be filled by the Governor in the manner provided for appointment of board members in section 304.

Section 306. Removal.

(a) Grounds for removal.--A board member may be removed pursuant to the procedure set forth in subsection (b), upon one or more of the following grounds:

(1) The refusal or inability for any reason of a board member to perform the duties as a member of the board in an efficient, responsible, and professional manner.

(2) The misuse of office by a member of the board to obtain personal, pecuniary, or material gain or advantage for that member or another person through such office.

(3) The violation by any member of the board of laws governing the practice of pharmacy or the distribution of drugs and/or devices.

(4) The failure of the board member to attend three consecutive board meetings unless the Commissioner of Professional and Occupational Affairs, upon written request from that member, finds that member should be excused from a meeting because of illness or the death of a family member, or other valid reason.

(5) The failure of a public member to attend two consecutive statutorily mandated training seminars under section 813(e) of the Act of April 9, 1929 (P.L.177, No.175), known as The Administrative Code of 1929, unless the Commissioner of Professional and Occupational Affairs, upon written request from the public member, finds that the public member should be excused from a meeting because of illness or the death of a family member, or other valid reason.

(b) Procedure.--Removal of a member of the board shall be in accordance with 2 Pa.C.S. Ch. 5 Subch. A (relating to practice and procedure of Commonwealth agencies).

Section 307. Organization.

(a) Officers.--The board shall elect from its members a chairperson and any other officers deemed appropriate and necessary to conduct the business of the board. The chair of the board shall preside at all meetings of the board and shall be responsible for the performance of all of the duties and functions of the board required or permitted by this act. Each additional officer elected by the board shall perform those duties normally associated with that position and any other duties assigned by the board.

(b) Terms of office for officers.--Officers elected by the board shall serve terms of one year commencing with the day of their election and ending upon election of their successors, and

shall serve no more than two consecutive full terms in each office to which they are elected.

Section 308. Compensation of board members.

Each member of the board, except the Commissioner of Professional and Occupational Affairs and the Director of the Bureau of Consumer Protection, shall receive $250 per day when actually attending to the work of the board. Members shall also receive timely reimbursement for reasonable traveling, lodging and other necessary expenses incurred in the performance of their duties in accordance with Commonwealth regulations.

Section 309. Meetings.

(a) Regular meetings.--The board shall meet at least once every two months and at any additional times that may be necessary to conduct the business of the board. Any additional meetings may be called by the chairperson of the board or by two-thirds of the members of the board.

(b) Place of meeting.--The board shall meet at such place as it may, from time to time, determine. The place for each meeting shall be determined prior to giving notice of that meeting to each member. The place of a meeting may not be changed after notice is given without adequate prior to all members of the board.

(c) Quorum.--A majority of the members of the board serving in accordance with law shall constitute a quorum for the purposes of conducting the business of the board. Except for temporary and automatic suspensions under this act, a member may not be counted as part of a quorum or vote on any issue unless that member is physically in attendance at the meeting.

(d) Open meetings.--All board meetings and hearings shall be open to the public. The board may, in its discretion and

according to law, conduct any portion of its meeting in executive session, closed to the public. Executive sessions may not be utilized during hearings or discussion of current regulations or development of regulations.

Section 310. Executive director.

(a) Selection.--The board shall select and employ, with the approval of the Commissioner of Professional and Occupational Affairs, an executive director who shall be a full-time employee and who shall be a pharmacist licensed in this Commonwealth. The executive director shall be paid such compensation as determined by the board to be commensurate with the level of compensation paid other executive directors to professional licensing boards in this Commonwealth.

(b) Duties.--The executive director shall have the following duties:

(1) Establish guidelines and information, with the concurrence of the board, for training of inspectors within the Department of State who are responsible for inspecting pharmacies.

(2) Assist the board in revising and promulgating regulations.

(3) Review recorded minutes and proceedings of all board meetings and be the custodian of such documents.

(4) Maintain a record of policies set by the board and disseminate that information to all board licensees.

(5) Perform any other duties the board may request.

The executive director shall be provided adequate facilities, staff and pharmacy inspectors to perform the aforesaid functions.

Section 311. Employees.

The board may, in its discretion, employ persons in addition to the executive director in such other positions or capacities as it deems necessary for the proper conduct of board business and to fulfill the board's responsibilities as defined by this act.

Section 312. Rules and regulations.

The board shall, within 180 days of the effective date of this act and at times necessary thereafter promulgate, adopt, amend and repeal rules and/or regulations as deemed necessary by the board for the proper administration and enforcement of this act. Rules and regulations shall be promulgated in accordance with the procedures specified in the act of July 31, 1968 (P.L.769, No.240), referred to as the Commonwealth Documents Law, and the act of June 25, 1982 (P.L.633, No.181), known as the Regulatory Review Act.

Section 313. Powers and responsibilities.

The board shall have sole responsibility for the control and regulation of the practice of pharmacy in this Commonwealth, including, but not limited to, the following:

(1) To determine the nature of examinations for any applicant for a pharmacist license.

(2) To examine, inspect and investigate all applications and all applicants for licensure as pharmacists, pharmacies or pharmacy interns, or registration as pharmacy technicians, and to grant certificates of licensure or registration to all applicants whom it shall judge to be properly qualified.

(3) To renew licenses to engage in the practice of pharmacy and to operate a pharmacy.

(4) To establish and enforce compliance with professional standards of conduct of pharmacists engaged in

the practice of pharmacy.

(5) To determine and issue standards for recognition and approval of degree programs of schools and colleges of pharmacy whose graduates shall be eligible for licensure in this Commonwealth, and to specific and enforce requirements for practical training, including internship.

(6) To enforce those provisions of this act relating to the conduct or competence of pharmacists practicing in this Commonwealth and to suspend, revoke or restrict licenses to engage in the practice of pharmacy.

(7) To prepare position descriptions, to employ a minimum of eight pharmacy inspectors, or more of such inspectors if the board deems necessary, who shall be pharmacists licensed in this Commonwealth.

(8) To retain appropriate consultants to assist it for any purpose which it may deem necessary, subject to the limitation that the board may not delegate any of its final decision making responsibilities to any consultant.

(9) To investigate or cause to be investigated all violations of the provisions of this act and its regulations and to cause prosecutions to be instituted in the courts upon advice from the Office of Attorney General.

(10) To inspect any pharmacy licensed by this Commonwealth at reasonable hours for the purpose of determining if any provisions of the laws governing the legal distribution of drugs or devices for the practice of pharmacy are being violated. The board, its officers, inspectors and representatives shall cooperate with all agencies charged with the enforcement of the laws of the United States, of this Commonwealth and of all other states relating to drugs,

devices and the practice of pharmacy.

(11) To make or order inspections of other places in which drugs or devices are stored, held, compounded, dispensed or sold to a consumer, and to take and analyze any drugs or devices and to seize and condemn any drugs or devices which are adulterated, misbranded, or stored, held, dispensed, distributed, or compounded in violation of the provisions of this act or the provisions of the act of April 14, 1972 (P.L.233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act.

(12) To establish minimum specifications for the physical facilities, technical equipment, environment, supplies, personnel and procedures, for the storage, compounding and/or dispensing of drugs or devices and for the monitoring of drug therapy.

(13) To establish minimum standards for maintaining the integrity and confidentiality of prescription information and other patient care information.

(14) To conduct hearings for the revocation or suspension of licenses, permits or registrations, for which hearings the board shall have the power to subpoena witnesses.

(15) To assist the regularly constituted enforcement agencies of this Commonwealth in enforcing all laws pertaining to drugs, controlled substances and the practice of pharmacy.

(16) To have authority to issue subpoenas, upon application of an attorney responsible for representing the Commonwealth in disciplinary matters before the board, for the purpose of investigating alleged violations of the

disciplinary provisions administered by the board.

(i) The board shall have the power to subpoena witnesses, to administer oaths, to examine witnesses and to take such testimony or compel the production of such books, records, papers and documents as it may deem necessary or proper in, and pertinent to, any proceeding, investigation or hearing held or had by it.

(ii) Patient records may not be subpoenaed without the consent of the patient or without order of a court of competent jurisdiction on a showing that the records are reasonably necessary for the conduct of the investigation.

(iii) The court may impose such limitations on the scope of the subpoena as are necessary to prevent unnecessary intrusion into a patient confidential situation.

(iv) The board is authorized to apply to Commonwealth Court to enforce its subpoenas.

(17) In addition to its appropriation from the Commonwealth, to receive and expend funds from parties other than the Commonwealth, subject to the following restrictions:

(i) The funds are awarded for the pursuit of a specific objective which the board is authorized to accomplish by this act, or which the board is qualified to accomplish by reason of its jurisdiction or professional expertise.

(ii) Activities connected with or occasioned by the expenditure of these funds do not interfere with the performance of the board's duties and responsibilities and do not conflict with the exercise of the board's

powers as specified by this act.

(iii) The funds are kept in a separate special account and periodic reports are made to the Commissioner of Professional and Occupational Affairs concerning the board's receipt and expenditure of such funds.

The powers and duties of the board, as enumerated in this section, shall not be applicable to manufacturers or distributors as defined in the act of April 14, 1972 (P.L.233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act.

Section 314. Communication to licensees.

The board shall at least every six months, and more frequently if necessary, convey relevant information concerning this act, rules or regulations promulgated thereunder, and the practice of pharmacy to all pharmacists and pharmacies registered in this Commonwealth and any nonresident pharmacies licensed by the board.

Section 315. Annual report.

The board shall submit annually a report to the Consumer Protection and Professional Licensure Committee of the Senate and the Professional Licensure Committee of the House of Representatives containing a description of the types of complaints received, the status of cases, any board action which has been taken and the length of time from the initial complaint to final board resolution.

CHAPTER 5

PHARMACISTS AND PHARMACIES

SUBCHAPTER A

PHARMACISTS

Section 501. Declaration.

The practice of pharmacy in this Commonwealth is hereby declared to be a health care professional practice in which the pharmacist is considered a health care provider affecting the public health, safety and welfare, and is subject to regulation and control in the public interest.

Section 502. Licensing of pharmacists.

Except as otherwise provided in this act, it shall be unlawful for any individual to engage in the practice of pharmacy within this Commonwealth unless that individual is currently licensed to practice pharmacy pursuant to the provisions of this act.

Section 503. Prerequisites for pharmacist license.

The board may license as a pharmacist any person who has filed an application therefore, subscribed by the person under oath or affirmation, containing such information as the board may by regulation require, and who:

(1) Has satisfied the board that the applicant is of good moral and professional character, and not unfit or unable to practice pharmacy by reason of the extent or manner of the applicant's use of alcoholic beverages or controlled substances or by reason of a physical or mental disability.

(2) Holds an entry level practice degree in pharmacy granted by a school or college of pharmacy which is accredited by an accrediting body recognized by the board.

(3) Has completed an internship or other equivalent program which has been approved by the board or has demonstrated experience in the practice of pharmacy which meets or exceeds the minimum internship requirements of the board.

(4) Has satisfactorily passed such examinations as

required by the board.

(5) Has paid the fee specified by the board for the examination and any related materials and has paid for the issuance of the license.

(6) Has not been convicted of any felonious act prohibited by the act of April 14, 1972 (P.L.233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act, or convicted of a felony relating to a controlled substance in a court of law of the United States or any other state, territory or country unless all of the following criteria are satisfied:

(i) At least ten years have elapsed from the date of conviction.

(ii) The applicant satisfactorily demonstrates to the board that the applicant has made significant progress in personal rehabilitation since the conviction such that licensure of that applicant should not be expected to create a substantial risk of harm to the health and safety of patients or the public or a substantial risk of further criminal violations.

(iii) The applicant otherwise satisfies the qualifications contained in or authorized by this act.

An applicant's statement on the application declaring the absence of a conviction shall be deemed satisfactory evidence of the absence of a conviction, unless the board has evidence to the contrary.

Section 504. Examinations.

(a) Schedule of examinations.--The board shall, at least once each year, examine in the practice of pharmacy all applicants who:

(1) Have completed their education requirements.

(2) Make application for examination pursuant to regulations promulgated by the board.

(3) Shall be otherwise eligible for licensure.

(b) Content of examination.--The examination shall be prepared to measure the competence of the applicant to engage in the practice of pharmacy. The board may employ, cooperate with or contract with any organization or consultant or professional testing organization for the preparation, administration and grading of the examination, but the board shall retain the sole discretional responsibility for determining which applicants have successfully passed an examination.

(c) Reexamination.--In case of failure at a first examination, the applicant shall have within two years the privilege of a second and third examination. In case of failure with the third examination, the applicant shall have the privilege of examination only after satisfactorily completing additional preparation as directed and approved by the board.

Section 505. Internship.

(a) Requirement.--To ensure proficiency in the practical aspects of pharmacy, the board shall, by regulation, prescribe internship requirements which must be satisfactorily completed prior to the issuance of a pharmacist license.

(b) Supervision of intern.--To assure adequate practical instruction, pharmacist internship experience as required under this act shall be obtained under the immediate supervision of a pharmacist meeting the requirements established by the board.

(c) Examination to obtain pharmacist license.--Each pharmacist intern applying for examination shall pay to the board an examination fee established by the board through

regulation. Upon passing the required examination and complying with all the rules and regulations of the board and the provisions of this act, the board shall grant the applicant licensure as a pharmacist and issue a license qualifying the applicant to enter into the practice of pharmacy. This license shall not be issued until a fee established by the board through regulation shall be paid to the board.

Section 506. Qualifications for reciprocal license transfer.

(a) Procedure.--The board may, without examination, license as a pharmacist any individual who, at the time of filing an application for licensure, is licensed as a pharmacist in any other state, territory or possession of the United States; provided that that individual shall meet those standards established by the board by regulation and meet all of the following criteria:

(1) Produce evidence satisfactory to the board of having had the required secondary and professional education and training, including internship.

(2) Be of good character and morals as required of applicants for licensure under the provisions of this act.

(3) At the time of initial licensure as a pharmacist have all the qualifications necessary to have been eligible for licensure as a pharmacist in this Commonwealth at the time of licensure in the other state.

(4) Have presented to the board proof of initial licensure by examination and proof that such license is in good standing.

(5) Not be eligible for reciprocal license transfer unless the state in which that individual is licensed shall under similar conditions grant reciprocal licensure as a

pharmacist without examination to pharmacists duly licensed by examination in this Commonwealth.

(b) Fee.--Every application under this subsection shall be accompanied by a fee established by the board through regulation for the application and expense of investigation by the board. A fee established by the board through regulation shall be paid for the license and certificate prior to its approval and issuance by the board.

Section 507. Renewal of licenses.

The board shall provide for, regulate and require all individuals licensed as pharmacists to renew their licenses biennially. The board shall prescribe the form of the renewal application and the information required to be submitted by all applicants, including proof of continuing education. The applicant shall file with the board the renewal application accompanied by a biennial license fee established by the board through regulation. An additional fee established by the board through regulation shall be paid for late licensure renewal of a pharmacist.

Section 508. Continuing pharmacy education.

(a) General rule.--Continuing pharmacy education as the board may require shall be a prerequisite for licensure renewal.

(b) Requirements.--The board shall have authority to:

(1) Define, by regulation, the requirements for continuing education.

(2) Approve programs of continuing education.

(3) Adopt rules and regulations necessary to carry out and enforce this section, which shall include the methods of determining approved programs and any required fees.

Section 509. Reporting multiple licensure.

Any licensed pharmacist of this Commonwealth who is also licensed to practice pharmacy in any other state, territory or country shall report this information to the board on the biennial registration application. Any disciplinary action in any other state, territory and country shall be reported to the board on the biennial renewal application or within 90 days of final disposition, whichever is sooner. Multiple licensure shall be noted by the board on the pharmacist's record, and such state, territory or country shall be notified by the board of any disciplinary actions taken against said pharmacist in this Commonwealth.

SUBCHAPTER C

PHARMACIES

Section 521. Licensing of pharmacies.

(a) General rule.--The board shall issue a permit to any person to conduct a pharmacy:

(1) Who has filed an application to operate a pharmacy.

(2) Who has subscribed the application under oath or affirmation.

(3) Who provides all information the board may require.

(4) Who pays any fee established by the board by regulation.

(5) Whose proposed pharmacy complies with all regulations of the board and with all requirements of this act.

(b) Additional information.--Each applicant for a permit shall provide sufficient evidence to the board that the proposed pharmacy:

(1) Has the necessary reference materials, current supplements to these reference materials and the professional

equipment, technical equipment and other pharmaceutical equipment which such reference materials, supplements and equipment have been determined by the board as necessary to meet the needs of the practice of pharmacy for the area and type of practice to protect the health and welfare of the citizens of this Commonwealth.

(2) Has sufficient physical facilities, including equipment, size, space and sanitation for adequately providing pharmacist care and distributing and dispensing drugs and devices consistent with the protection of the public health, safety and welfare as the board may by regulation establish.

(3) Contains a suitable book or file in which shall be preserved, for a period of not less than two years, every prescription compounded or dispensed therein.

(4) Will be under the immediate supervision of a pharmacist licensed in this Commonwealth at all times that the pharmacy is open for business.

(5) (i) If the applicant is an individual or partnership, that the individual or co-partner, if not a pharmacist, has not previously been found or pleaded guilty or nolo contendere to any crime concerning the practice of pharmacy or involving moral turpitude.

(ii) If the applicant is an individual or partnership and a pharmacist, that that pharmacist is presently licensed by the board.

(iii) If the applicant is an association, that no director or officer has been found or pleaded guilty or nolo contendere to said crimes or had a pharmacy or pharmacist's license revoked or renewal refused for

cause.

(6) If the applicant is a corporation, that no director, officer or person having a beneficial interest of more than ten percent of the stock has been found or pleaded guilty or nolo contendere to said crimes or had a pharmacy or pharmacist's license revoked or renewal refused for cause.

(7) All applicants shall be of good moral and professional character. In determining this qualification, the board may take into consideration, among other things, the conduct and operation of other pharmacies conducted by the applicant.

(c) Supervision.--Every pharmacy shall be under the supervision and management of a pharmacist duly licensed in this Commonwealth.

(d) Display of license.--All licenses and permits issued under the provisions of this act shall be displayed in a conspicuous place in the pharmacy for which they were issued.

(e) Separate applications for each pharmacy.--Separate applications and permits shall be required for each pharmacy. Each permit shall be issued bearing the name of the pharmacist who will be in charge of that pharmacy as defined by regulation and who will be responsible for all operations involving the practice of pharmacy in that pharmacy.

(f) Fees.--All applications for a permit to conduct a pharmacy shall be accompanied by an initial registration fee established by the board by regulation.

(g) Expiration.--All permits granted under this section, unless sooner revoked or suspended, shall expire on the date set forth in the permit. The board may promulgate regulations authorizing the application by a personal representative of a

deceased grantee for an extension of the deceased grantee's permit for a period not to exceed one year from the date of death.

Section 522. Renewal of pharmacy permit.

The board shall renew each permit for the succeeding biennium, unless the board shall have given ten days' previous notice to the applicant for the permit of objections to the renewal based upon a finding or plea of guilty or nolo contendere by the applicant, its partners or officers, to a violation of any of the laws of the United States or of this Commonwealth relating to the practice of pharmacy or to the enforcement of controlled substances or involving moral turpitude, upon payment of a fee established by the board by regulation for each pharmacy. The application for renewal shall be made on or before September 1 of each odd-numbered year.

Section 523. Permit required for operation.

No person shall operate a pharmacy until that person has been granted a pharmacy permit by the board.

Section 524. Display of ownership information.

The full name or names of the proprietor, or if a partnership, the partners, or if an association or corporation, the name of the pharmacist manager, must be conspicuously displayed in the pharmacy along with any corporate association or duly registered fictitious name.

Section 525. Extraterritorial pharmacy permits.

(a) Requirement.--Any person, entity, pharmacy or pharmacist located outside of this Commonwealth who ships, mails, distributes, dispenses or delivers prescription drugs or devices to individuals within this Commonwealth shall be required to obtain a pharmacy permit from the board.

(b) Waiver.--If the person, entity, pharmacy or pharmacist holds a valid pharmacy permit issued by the state in which that pharmacy is operated, the board may waive any requirements imposed upon pharmacies within this Commonwealth if the waiver of these requirements will not endanger the public health, safety or welfare of the citizens of this Commonwealth.

(c) Nonlicensure, no waiver.--If the person or entity does not hold a valid pharmacy permit from the jurisdiction in which the person or entity is operating, then the board shall mandate that all requirements imposed upon pharmacies in this Commonwealth be met by the person or entity desiring to ship, mail, dispense, distribute or deliver prescription drugs or devices within this Commonwealth.

(d) Registered agent.--Each person, entity, pharmacy or pharmacist located outside of this Commonwealth who ships, mails, dispenses, distributes or delivers prescription drugs or devices in this Commonwealth shall designate a registered agent in this Commonwealth for service of process. Any such person, entity, pharmacy or pharmacist who does not so designate a registered agent shall be deemed to have designated the Secretary of State of this Commonwealth to be its true and lawful attorney, upon whom may be served all legal process in any action or proceeding against such person, entity, pharmacy or pharmacist growing out of or arising from such shipping, mailing, dispensing, distributing or delivery. A copy of any such service of process shall be mailed to such person, entity, pharmacy or pharmacist by the board by certified mail, return receipt requested, postage prepaid, at the address designated on the application for licensure in this Commonwealth. If any such person, entity, pharmacy or pharmacist is not licensed by the

board, service on the Secretary of State only shall be sufficient service for legal purposes.

Section 526. Regulatory power over pharmacies.

The board may promulgate regulations designed to insure methods of operation and conduct which protect the public health and welfare.

CHAPTER 7

ENFORCEMENT

Section 701. Refusal to grant, revocation and suspension of licenses and permits.

The board shall have the power to refuse to grant, refuse to renew, suspend, revoke or restrict the license of any pharmacist or pharmacist intern upon one or more of the following grounds:

(1) Unprofessional conduct as that term is defined by the rules of the board.

(2) Unfit to practice pharmacy because of intemperance in the use of alcoholic beverages, controlled substances or any other substance which impairs the intellect and judgment to such an extent as to impair the performance of professional duties.

(3) Unfit or unable to practice pharmacy by reason of a physical or mental disease or disability. In enforcing this paragraph, the board shall, upon probable cause, have authority to compel a pharmacist or a pharmacist intern to submit to a mental or physical examination by physicians or psychologists approved by the board. Failure to submit to such examination when directed by the board, unless such failure is due to circumstances beyond the individual's control, shall constitute an admission of the allegations against him or her, consequent upon which a default and final

order may be entered without the taking of testimony or presentation of evidence. A pharmacist or a pharmacist intern affected under this paragraph shall at reasonable intervals be afforded an opportunity to demonstrate that the pharmacist or pharmacist intern can resume a competent practice of pharmacy with reasonable skill and safety to patients.

(4) Procured a license through fraud, misrepresentation or deceit.

(5) Been found guilty, pleaded guilty, entered a plea of nolo contendere, or received probation without verdict, disposition in lieu of trial or an Accelerated Rehabilitative Disposition in the disposition of one or more of the following:

(i) A felony.

(ii) Any offense involving moral turpitude or gross immorality.

(iii) Violation of the pharmacy or drug laws of this Commonwealth or rules and regulations pertaining thereto; or of pharmacy laws, rules and regulations of the Federal government or of any other state.

(6) Violated or knowingly permitted the violation of any provision of this act or regulation of the board.

(7) Knowingly:

(i) Allowed, aided or abetted an individual to engage in the practice of pharmacy without a license.

(ii) Aided or abetted an individual to assist in the practice of pharmacy without having registered with the board; or falsely used the title of pharmacist or pharmacist intern. Nothing contained in this paragraph shall prohibit pharmacist interns or registered pharmacy

technicians from assisting in the practice of pharmacy under the immediate supervision of a licensed pharmacist provided such assistance is consistent with proper pharmacy practices and with board regulations.

(8) Willfully deceiving or attempting to deceive the board or its agents with respect to any significant matter under investigation by the board.

(9) Advertising of prices for drugs and pharmaceutical services to the public which does not conform with Federal laws or regulations or with the laws or regulations of this Commonwealth, or which is untrue, false, misleading or deceptive.

(10) Public assertion or implication of professional superiority in the practice of pharmacy.

(11) Paying rebates to physicians or other persons, or the entering into of any agreement with a medical practitioner or any other person for the payment or acceptance of compensation in any form for the recommending of the professional services of either party.

(12) Entering into any agreement with a licensed medical practitioner for the compounding or dispensing of secret formula (coded) prescriptions.

(13) Misbranding or adulteration of any drug or device, or the sale, distribution, or dispensing of any misbranded or adulterated drug or device as defined in the Act of April 14, 1972 (P.L. 233, No. 64), known as The Controlled Substance, Drug, Device and Cosmetic Act.

(14) Displaying or permitting the display of his or her certificate of licensure and/or current registration document in a pharmacy of which he or she is not the proprietor or is

not employed.

(15) For any holder of a current pocket registration card to fail, when practicing, to have the card available for inspection by an authorized agent of the board.

(16) The acceptance back and redistribution of any unused drug or part thereof as defined by regulations.

(17) Accept employment as a pharmacist, or share or receive compensation in any form arising out of, or incidental to, his or her professional activities from any person who orders said pharmacist, directly or indirectly, to engage in any aspect of the practice of pharmacy in contravention of any provision of this act or regulation of the board.

(18) Had a license to practice pharmacy suspended, revoked or refused, or received other disciplinary action by the proper pharmacist licensing authority of another state, territory or country.

(19) Acted in such a manner as to present an immediate and clear danger to the public health or safety.

(20) Is guilty of incompetence, gross negligence or other malpractice, or the departure from, or failure to conform to, the standards of acceptable pharmacy practice, in which case actual injury need not be established.

(21) Knowing that a pharmacist or pharmacist intern is incapable of engaging in the practice of pharmacy or that a pharmacy technician is incapable of assisting in the practice of pharmacy, with reasonable skill, competence, and safety to the public, and failing to report any relevant information to the board.

(22) Engaging in any conduct which subverts or attempts

to subvert any licensing examination or the administration of any licensing exam.

(23) Failing to pay the costs assessed in a disciplinary hearing.

Section 702. Temporary suspension.

(a) Authorization.--A license duly issued under this act may be temporarily suspended under circumstances as determined by the board to be an immediate and clear danger to the public health and safety. The board shall issue an order to that effect without a hearing, but upon due notice to the licensee concerned at his or her last known address, which shall include a written statement of all allegations against the licensee. The case of a temporary suspension pursuant to this section, hearings, appeals from, and rulings resulting therefrom, need not comply with the provisions of 2 Pa.C.S. § 103 (relating to Administrative Agency Law).

(b) Commencement of formal proceedings.--The board shall thereupon commence formal action to suspend, revoke or restrict the license of the person concerned, as otherwise provided for in this act. All actions shall be taken promptly and without delay.

(c) Preliminary hearing.--Within 30 days following the issuance of an order temporarily suspending a license, the board shall conduct or cause to be conducted a preliminary hearing to determine that there is a prima facie case supporting the suspension. The licensee whose license has been temporarily suspended may be present at the preliminary hearing and may be represented by counsel, cross-examine witnesses, inspect physical evidence, call witnesses, offer evidence and testimony and make record of the proceedings. If it is determined that

there is not a prima facie case, the suspended license shall be immediately restored.

(d) Duration of temporary suspension.--The temporary suspension shall remain in effect until vacated by the board, but in no event longer than 180 days.

Section 703. Automatic suspension.

A pharmacist license or a pharmacist intern license issued under this act shall be automatically suspended upon the legal commitment to an institution of a licensee or registrant because of mental incompetency from any cause upon filing with the board a certified copy of such commitment, or upon the conviction of a felony under the Act of April 14, 1972 (P.L.233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act, or conviction of an offense under the laws of another jurisdiction, which if committed in this Commonwealth would be a felony under The Controlled Substance, Drug, Device and Cosmetic Act. Automatic suspension under this section shall not be stayed pending any appeal of conviction. Restoration of such license or registration shall be made as hereinafter provided in the case of revocation or suspension of such license or registration.

Section 704. Impaired licensee.

(a) Board action.--When an impaired pharmacist or pharmacist intern is subject to disciplinary action, the board may defer and ultimately dismiss any of the types of corrective action set forth in this act for an impaired professional so long as the pharmacist or pharmacist intern is progressing satisfactorily in an approved treatment program and in an impaired professional support group recognized by the board.

(b) Information disclosure to board.--If an impaired pharmacist or pharmacist intern enters an approved treatment

program and an impaired professional support group, the approved program provider shall, upon request, disclose to a professional consultant appointed and employed by the board as hereinafter described, such information in his or her possession regarding the impaired pharmacist or pharmacist intern in treatment, when the program provider is not prohibited from disclosing such information by an act of the United States, this Commonwealth or another state.

(c) Agreement by licensee.--An impaired pharmacist or pharmacist intern who enrolls in an approved treatment program shall enter into either:

(1) An agreement with the peer assistance group which will monitor the licensee's progress, monitor compliance with the terms of the agreement and monitor adherence to any limitations on the practice of pharmacy as required by the terms of the agreement so as to protect the public.

(2) An agreement with the board under which the pharmacist's or pharmacist intern's license shall be suspended or revoked, but enforcement of that suspension or revocation shall be stayed for the length of time the impaired pharmacist or pharmacist intern remains in the treatment program and makes satisfactory progress, complies with the terms of the agreement and adheres to any limitations on his or her practice imposed by the board to protect the public.

Failure to enter into one of the agreements shall disqualify the impaired professional from the impaired pharmacist or pharmacist intern program and shall activate an immediate investigation and disciplinary proceeding by the board.

(d) Lack of satisfactory progress.--If, in the opinion of

the professional consultant after consultation with the program provider and/or the peer assistance group, an impaired pharmacist or pharmacist intern who is enrolled in an approved treatment program or the peer assistance program and has entered into an agreement under subsection (a) has not progressed satisfactorily, the professional consultant shall disclose to the board all information in the consultant's possession regarding said pharmacist or pharmacist intern, and the board shall institute proceedings to determine if the stay of the enforcement of the suspension or revocation of the impaired pharmacist's or pharmacist intern's license shall be vacated if the licensee has executed a board agreement. If the licensee has not executed a board agreement but has executed an agreement with the peer assistance program, the board shall immediately institute proceedings to determine if the impaired pharmacist's or pharmacist intern's license should be revoked or suspended.

Section 705. Reinstatement.

(a) Petition.--Any person whose license to practice pharmacy in this Commonwealth has been suspended, revoked or restricted pursuant to this act, whether voluntarily or by action of the board, shall have the right, after any statutorily mandated period of time, or, if no statutory limitation exists, at reasonable intervals, to petition the board for reinstatement of such license.

(b) Forms.--Such petition shall be made in writing and in the form prescribed by the board.

(c) Board procedures.--Upon investigation and hearing, the board may, in its discretion, grant or deny such petition, or it may modify its original findings to reflect any circumstances which have changed sufficiently to warrant such modifications.

The board, also at its discretion, may require such person to pass an examination for reentry into the practice of pharmacy.

(d) Nonreinstatment for revocation.--Unless ordered to do so by Commonwealth Court or an appeal therefrom, the board shall not reinstate the license of a person to the practice of pharmacy pursuant to this act which license has been revoked. Any person whose license has been revoked may apply for reinstatement after a period of five years from the date of revocation, but must meet all of the licensing qualifications of this act for the license applied for, to include the examination requirement.

Section 706. No bar to criminal action.

Nothing herein shall be construed as barring criminal prosecutions for violations of this act.

Section 707. Administrative Agency Law.

All final decisions of the board shall be subject to judicial review pursuant to 2 Pa.C.S. § 103 (relating to Administrative Agency Law).

Section 708. Board action.

When the board finds that the license of any pharmacist or pharmacist intern may be refused, revoked or suspended under the terms of this section, the board may:

(1) Deny the application for a license.

(2) Administer a public reprimand.

(3) Revoke, suspend, limit or otherwise restrict the license as determined by the board.

(4) Require the licensee to submit to the care, counseling or treatment of a physician or a psychologist designated by the board, or enter into an appropriate treatment program as determined by the board.

(5) Suspend enforcement of its findings thereof and place the licensee on probation with the right to vacate the probationary order for noncompliance, unless such suspension is otherwise prohibited by this act.

Section 709. Pharmacy permits.

The board shall have the power to refuse, revoke or suspend the permit of any pharmacy upon proof satisfactory to it that any of the following occurred:

(1) The permit was procured through fraud, misrepresentation or deceit.

(2) The holder or partner or officer thereof has violated any of the provisions of this act, regulations of the board or any provisions of the act of April 14, 1972 (P.L.433, No.64), known as The Controlled Substance, Drug, Device or Cosmetic Act, or the Federal act, or has ordered a pharmacist, pharmacist intern or pharmacy technician in the employ of that pharmacy to engage in any aspect of the practice of pharmacy in contravention of any provisions of the aforesaid acts or regulations.

(3) The holder of the pharmacy permit sold, dispensed or caused or allowed to be sold or dispensed any controlled substance or nonproprietary drug, except by a licensed pharmacist.

(4) Upon the suspension or revocation of a license of a pharmacist or pharmacist intern employed by said pharmacy, it is shown that the illegal acts of the pharmacist or pharmacist intern were within the knowledge or should have been within the knowledge of the permit holder, partner or officer.

(5) The holder of the pharmacy permit, after issuance of

a permit, fails to continue to comply with all requirements of Subchapter C of Chapter 5.

Section 710. Return of license or permit.

Any individual or entity whose license to practice pharmacy or registration to assist in the practice of pharmacy is revoked, suspended or not renewed shall return the license or registration certificate to the offices of the board within ten days after receipt of notice of such action.

Section 711. Hearings.

(a) Notice of determination.--Upon refusal of the board to issue any license or permit, written notices of the grounds supporting such decision shall be given to the applicant, either personally or by registered or certified mail, return receipt requested, and the board shall accord the applicant opportunity of a hearing, upon written request received within 15 days from the date of giving the written notice.

(b) Investigation.--The board may, upon its own motion, and shall, promptly, upon the verified complaint in writing of any person setting forth specifically the wrongful act or acts complained of, investigate any alleged violations of this act by any persons, and shall have the power temporarily to suspend or permanently revoke licenses or permit issued by the board under the provisions of this act at any time when, after due proceedings as provided, it shall find the holder thereof to have been guilty of any violation of the provisions of this act or the rules or regulations of the board.

(c) Conduct of hearings.--Hearings, appeals and rulings resulting therefrom, unless otherwise provided in this act, shall be in accordance with the provisions of the 2 Pa.C.S. § 103 (relating to Administrative Agency Law).

(d) Presence of board member.--A majority of the board shall designate the member or members to be present at each hearing. Subsequent to each hearing, the notes of testimony shall be transcribed and a copy of the transcription shall be given to each member of the board who shall review the same prior to voting thereon. All decisions shall be reached by a majority vote of the entire board. The board shall, by regulation, establish and publish procedural rules concerning the conduct of hearings.

Section 712. Docket and other records.

The board shall maintain in its office a docket or other record of the rulings and decisions upon all complaints filed with it and all investigations instituted by it. The board shall also give immediate written notice of such rulings or decisions to the licensee affected thereby and where the investigation shall have been instituted by complaint filed, to the party or parties by whom the complaint was made. If such ruling shall be to the prejudice or shall injuriously affect the licensee, the board shall also state in the notice the date upon which the ruling shall become effective. If the licensee, at such time, cannot be found, his or her whereabouts being unknown, such notice may be given by the board by advertisement inserted in one issue of a newspaper of general circulation published within the county which was designated by the licensee as his or her mailing address. When any revocation or suspension shall become final, the board shall publish notice thereof in one issue of one or more newspapers of general circulation published within the county in which the licensee was engaged in the practice of pharmacy at the time of such revocation or suspension.

PHARMACIST PRACTICE

Section 901. Practice of pharmacy.

The practice of pharmacy in this Commonwealth is hereby declared a health care professional practice in which the pharmacist is considered a health care provider affecting the public health, safety and welfare and is subject to regulation and control in the public interest. It is declared to be a matter of public interest and concern that the practice of pharmacy, as defined in this act, merit and receive the confidence of the public and that only qualified persons be permitted to engage in the practice of pharmacy in this Commonwealth.

Section 902. Pharmacy is health care service.

The practice of pharmacy is the provision of health care services by a pharmacist including, but not limited to, the interpretation, evaluation and implementation of medical orders; the delivering, dispensing or distributing of prescription drugs; participation in drug and device selection; drug administration; drug regimen review; drug or drug-related research; provision of pharmacist care in all areas including primary care; compounding; proper and safe storage of drugs and devices; managing drug therapy; participation in collaborative care agreements; maintaining proper records; patient counseling, physical assessment; order and perform laboratory or other diagnostic tests; disease state management; and such acts, services, operations or transactions necessary or incident to providing pharmacist care.

Section 903. Drug regimen review.

In all practice care settings a pharmacist shall:

(1) Perform a drug regimen review prior to dispensing a

prescription.

(2) Maintain a patient history in compliance with regulations of the board for each patient for whom prescriptions are dispensed.

(3) Offer to provide drug information to the patient, caregiver or patient's agent in compliance with regulations of the board.

Section 904. Disease state management.

In all practice care settings a pharmacist who has completed a certified program may perform disease state management through a comprehensive, integrated systems approach to both care and reimbursement based upon natural course of disease which emphasizes treatments designed to address an illness with maximum efficiency.

Section 905. Collaborative care agreements.

(a) Authority to enter.--A pharmacist shall be permitted to enter into a collaborative care agreement with a licensed prescriber. A pharmacist may be permitted to initiate, modify or discontinue prescription drug therapy, administer medications and order or perform laboratory tests as appropriate pursuant to written protocols contained in a collaborative care agreement with a licensed prescriber in this Commonwealth. The collaborative care agreement shall contain a written protocol specifically authorizing the pharmacist to initiate, modify or discontinue drug therapy, to administer medications and to order or perform laboratory tests, all in accordance with regulations adopted by the board.

(b) Licensed prescriber.--The licensed prescriber who is a party to the collaborative care agreement shall be in active practice, and the scope of the agreement shall be within the

scope of the licensed prescriber's current practice.

(c) Content of written protocol.--The protocol required in the collaborative care agreement shall include:

(1) A statement identifying the licensed prescriber and the pharmacist who is a party to the agreement.

(2) A statement of the types of therapeutic decisions that the pharmacist is authorized to make which may include, but are not limited to, a statement of the types of diseases, drugs or drug categories involved and general statement of the procedures, decision criteria or plan the pharmacist is to follow when exercising the licensed prescriber's authority pursuant to the collaborative care agreement.

(3) A statement of the activities the pharmacist is to follow in the course of exercising the authority granted under the collaborative care agreement, including documentation of decisions made and a plan for communication or feedback to the licensed prescriber concerning specific decisions made.

(4) A statement that describes appropriate mechanisms for reporting to the licensed prescriber the monitoring activities of the pharmacist and the results of treatment.

(d) Review.--The collaborative care agreement and protocols contained therein shall be reviewed at least every two years and shall be modified or revised whenever necessary.

(e) Regulatory authority.--The board shall adopt regulations to assure for the protection of the health and welfare of patients treated pursuant to a collaborative care agreement.

Section 906. Compensation.

Pharmacists performing services under sections 903, 904 and 905 shall be compensated for such services.

Section 907. Pharmacy technicians.

(a) Use.--Pharmacy technicians may be utilized to assist pharmacists in the preparation of prescriptions and drug orders in compliance with regulations adopted by the board.

(b) Training.--Technicians may be trained at any licensed pharmacy or trained through educational programs provided by colleges, universities, professional associations, private schools or other entities.

(c) Registration.--Pharmacy technicians must register with the board on a form prescribed by the board and pay a registration fee as determined by the board.

(d) Pharmacist supervision.--Pharmacy technicians shall work only under the immediate supervision of a licensed pharmacist who may supervise no more than three pharmacy technicians in any setting or a higher number of pharmacy technicians if in the best interest of assuring the health and safety of patients and if permitted by the regulations of the board.

(e) Prohibited activities.--Pharmacy technicians shall be prohibited from performing those functions requiring the skill and competence of a licensed pharmacist such as, but not limited to, performing drug regimen reviews, providing drug information and/or patient counseling to patients or caregivers or the monitoring of drug therapy.

Section 908. Prescriptions.

(a) Transmission.--Prescriptions and drug orders may be written by the health practitioner, transmitted by telephone to the pharmacy by the health practitioner or his or her agent, transmitted to the pharmacy by facsimile provided there is no prohibition in Federal or State law prohibiting facsimile transmission of prescription or drug orders for the specific

drug involved or transmitted by electronic data transmission from the health practitioner directly to the pharmacy. The board shall establish regulations governing the use of facsimile or electronic data transmission to assure for the protection of the public health and safety and to provide adequate security to assure confidentiality of such information and data.

(b) Transfer between pharmacies.--A prescription may be transferred between pharmacies in this Commonwealth pursuant to the following requirements and any regulations of the board:

(1) The prescription is for a drug which is lawfully refillable.

(2) The drug is not a Schedule II controlled substance.

(3) An original or new prescription is not required from the prescriber by law.

(4) The pharmacist transferring the prescription cancels the original prescription in his or her records and indicates on the prescription records to whom the prescription was transferred, including the name of the pharmacy, the date of the transfer and the name or initials of the transferring pharmacist.

(5) The pharmacist receiving the transferred prescription:

(i) Notes on the prescription that it is a transferred prescription.

(ii) Records all of the following on the prescription records in addition to other information required by law:

(A) Date of issuance of original prescription.

(B) Date of original filling of prescription and date of last refill.

(C) Original number of refills authorized on prescription.

(D) Number of valid refills remaining.

(iii) Notes the location and file number of the original prescription.

(iv) Notes the name of the pharmacy and pharmacist from whom the prescription was transferred.

(6) A pharmacist may transfer a prescription to another pharmacist employed by the same corporation without regard to the requirements of paragraphs (4) and (5) provided that both pharmacists have access to the same computerized prescription transfer system which contains the prescription refill records and incorporates procedures to prevent unauthorized refills.

Section 909. Emergency refills.

A pharmacist shall be permitted to provide an emergency refill of a prescription that would otherwise not be legally refillable only pursuant to all of the following terms and conditions:

(1) The pharmacist first attempts to obtain an authorization from the authorized prescriber but cannot contact the prescriber.

(2) The drug which is the subject of the refill is essential to the continuation of therapy and, in the pharmacist's professional judgment, the interruption of the therapy might reasonably produce an undesirable health consequence, be detrimental to the patient's welfare or cause physical or mental discomfort.

(3) The drug which is the subject of the refill is not a controlled substance.

(4) The pharmacist enters on the back of the prescription or on another appropriate, uniformly maintained and readily retrievable record, the date and quantity of the refill and the pharmacist must verify the prescription.

(5) The pharmacist provides no more than a 72-hour emergency supply of the medication in conformity with the prescribed directions for use.

(6) Within 72 hours of dispensing the refill, the pharmacist notified the prescriber that an emergency prescription had been dispensed and the quantity of drug provided to the patient.

Section 910. Impaired pharmacist or pharmacist intern.

(a) Board power.--In addition to the provision of section 704, the board, with the approval of the Commissioner of Professional and Occupational Affairs, shall appoint and fix compensation of a professional consultant who is a licensee of the board with education and experience in the identification, treatment and rehabilitation of persons with chemical, physical and mental impairments. Such consultants shall be accountable to the board and shall act as a liaison between the board and treatment programs, such as alcohol and drug treatment programs licensed by the Department of Health, psychological counseling and impaired professional support groups approved by the board and which provide services to licensees under this act.

(b) Required report.--Any hospital or health care facility, peer or colleague who has substantial evidence that a pharmacist or pharmacist intern has an active, addictive disease for which the pharmacist or pharmacist intern is not receiving treatment, is diverting a controlled substance for personal use or is mentally or physically incompetent to carry out the duties of

his or her license or certificate shall make or cause to be made a report to the board except that any person or facility who acts in a treatment capacity to an impaired pharmacist in an approved treatment program is exempt from the mandatory reporting requirements of this subsection. Any person or facility who reports in good faith and without malice shall be immune from any civil or criminal liability resulting from such report. Failure to provide such report within a reasonable time from receipt of such knowledge of impairment shall subject the person or facility to a fine not to exceed $1,000. The board shall levy such penalty only after affording the accused party the opportunity for a hearing, as provided in 2 Pa.C.S. (relating to administrative law and procedure).

(c) Report by provider.--An approved program provider who makes disclosure to the board pursuant to the requirements of this act shall not be subject to civil liability for such disclosure or its consequences.

CHAPTER 11

UNLAWFUL ACTIVITIES

Section 1101. Unlawful acts.

It shall be unlawful for:

(1) Any person to procure or attempt to procure a license, permit or certificate for himself or herself or for any other person by making or causing to be made any false representations.

(2) Any person not duly licensed as a pharmacist pursuant to this act to engage in the practice of pharmacy, except a pharmacy intern or such other authorized personnel under the immediate personal supervision of a pharmacist, provided that nothing herein shall be construed to prevent a

duly licensed medical practitioner from administering any drug to his or her own patients after diagnosis or treatment of the patient, nor shall anything herein prevent any person from selling or distributing at retail household remedies or proprietary medicines when the same are offered for sale or sold in the original manufacturer's package which was prepared for sale to consumers.

(3) Any unlicensed person to operate or conduct, or to have charge or to supervise any pharmacy. For violation of this section, the owner of the pharmacy shall be equally liable as principle.

(4) Any person to represent that person to be licensed under this act when in fact that person is not licensed.

(5) Any person to knowingly prevent or refuse to permit any member of the board or its duly authorized agents to enter a pharmacy or any other place where drugs or devices are kept, stored, dispensed or distributed to a patient or consumer for the purpose of lawful inspection or other purposes in accordance with the provisions of this act and regulations pursuant thereto.

(6) Any person whose license, permit or certification has been revoked, suspended or refused renewal to fail to deliver the license, permit or certificate to the board within ten days after receipt of notice of such action.

(7) Any person to sell at auction drugs or devices in bulk or in open or unopened packages, unless such sale has been approved in advance by the board and unless such sale shall be under the personal supervision of a licensed pharmacist appointed by the board and whose fee shall be paid by the seller.

(8) Any person, firm or corporation to use the title "pharmacist," "pharmacist care," "pharmacy care," "pharmaceutical care," "assistant pharmacist," "druggist," "apothecary" or similar terms except a person duly licensed as a pharmacist in this Commonwealth or any person to conduct or transact business under a name which contains as part thereof the words "drug store," "pharmacy," "drugs," "medicine store," "medicines," "drug shop," "apothecary," "pharmaceutical" or any term having a similar meaning, or in any manner by advertisement, display or show globes or otherwise describe or refer to the place of the conducted business or person unless the place is a pharmacy duly issued a permit by the board.

(9) Any person who buys, sells or causes to be sold or offers for sale any drug or device which bears or which package bears, or originally did bear, the inscription "sample" or "not for resale" or "for investigational or experimental use only" or other similar words, except where a cost is incurred in the bona fide acquisition of an investigational or experimental drug.

(10) Any person using to that person's own advantage or revealing to anyone other than the board, its duly authorized representatives or to the courts when relevant to any judicial proceeding under this act, any information acquired under authority of this act or concerning any method or process which is a trade secret.

(11) Any pharmacist or owner of a pharmacy advertising or promoting prices for drugs and pharmaceutical services to the public which do not conform to Federal and State laws and regulations.

(12) Any person who knowingly and willfully forges or counterfeits upon any goods, wares or merchandise the private stamps or labels of any mechanic or manufacturer with intent to defraud the purchasers or manufacturers of any goods, wares or merchandise, or keeps in possession or conceals any goods, wares or merchandise or keeps in control, custody or possession any punch plate, stone or other thing in the likeness of any punch plate or stone designated for the printing or imprinting of the private stamps or labels of any mechanic or manufacturer, or who vends any goods, wares or merchandise having thereon any forged or counterfeited stamps or labels purporting to be the stamps or labels of any mechanic or manufacturer, knowing the same to be forged or counterfeited.

(13) Any person by himself or herself or through another to procure or attempt to procure for himself or herself or another any drug:

(i) By fraud, deceit, misrepresentation or subterfuge.

(ii) By the forgery or alteration of a prescription or any written order.

(iii) By the concealment of material facts.

(iv) By the use of a false statement and a prescription order or report.

(14) Any person to deliver a prescription medication by mail or otherwise to a patient within this Commonwealth unless the prescription is filled or refilled in a pharmacy licensed by the board.

(15) One or more licensed prescribers to have a proprietary or beneficial interest in a pharmacy sufficient

to permit them to exercise supervision or control over a pharmacist working in the pharmacy in his or her professional responsibilities and duties.

Section 1102. Criminal penalties.

Any person who violates any of the provisions of section 1101 shall be guilty of a misdemeanor and shall, upon conviction, be sentenced to pay a fine of not more than $5,000, or to imprisonment for not more than one year, or both and for each subsequent offense, shall be sentenced to pay a fine of not more than $15,000, or to imprisonment for not more than three years, or both.

Section 1103. Additional civil penalty.

In addition to any other civil remedy or criminal penalty provided for in this act, the board may levy a civil penalty of up $1,000 on any current licensee who violates any provision of this act or on any person who practices pharmacy without being properly licensed to do so under this act. The board shall levy such penalty only after affording the accused party the opportunity for a hearing, as provided in 2 Pa.C.S. (relating to administrative law and procedure).

CHAPTER 13

FISCAL AFFAIRS

Section 1301. Setting of Fees

(a) General rule.--All fees required under this act shall be fixed by the board by regulation and shall be subject to the act of June 25, 1982 (P.L.633, No.181), known as the Regulatory Review Act. If the revenues raised by fees, fines and civil penalties imposed under this act are not sufficient to meet expenditures over a two-year period, the board shall increase those fees by regulation, so that the projected revenues will

meet or exceed projected expenditures.

(b) Increases in fees.--If the Bureau of Professional and Occupational Affairs determines that the fees, fines and civil penalties established by the board under subsection (a) are inadequate to meet the minimum enforcement efforts required by this act, then the bureau, after consultation with the board and subject to the Regulatory Review Act, shall increase the fees by regulation in an amount such that adequate revenues are raised to meet the required enforcement effort.

Section 1302. Account and fees disposition.

The Commissioner of Professional and Occupational Affairs shall establish a Pharmacy Professional Development Account and all fees, fines and civil penalties imposed in accordance with this act shall be paid into the Pharmacy Professional Development Account. The funds shall be used by the board for professional development and for enforcement efforts mandated by this act.

Section 1303. Annual submissions.

(a) Estimate to department.--The board shall submit annually to the Department of State an estimate of the financial requirements of the board for its administrative, investigative, legal and miscellaneous expenses.

(b) Report to General Assembly.--The board shall submit annually to the and Appropriations Committee of the Senate and the Appropriations Committee of the House of Representatives, 15 days after the Governor has submitted the budget to the General Assembly, a copy of the budget request for the upcoming fiscal year which the board previously submitted to the Department of State.

Section 1304. Hiring of pharmacy inspectors.

The board shall employ a minimum of eight pharmacy inspectors who shall be licensed pharmacists in this Commonwealth. If the board determines that additional pharmacy inspectors are necessary to protect the health and safety of the citizens of this Commonwealth, the board shall hire such additional inspectors. Inspectors shall inspect all licensed locations. All pharmacy inspectors shall be under the authority of the board and shall report to the executive director.

CHAPTER 15

MISCELLANEOUS PROVISIONS

Section 1501. Board members.

Members of the board appropriately confirmed as of the effective date of this act shall continue to serve as members of the board until their present terms expire or until a successor has been appointed and qualified, but no longer than six months after present terms have expired.

Section 1502. Rules and regulations.

Each rule and regulation of the board in effect on the effective date of this act, not inconsistent with this act, shall remain in effect until repealed or amended by the board. Each fee of the board in effect on the effective date of this act, and not inconsistent with this act, shall remain in effect until repealed or amended in accordance with the provisions of this act.

Section 1503. Current licensees.

Any person who holds a valid license issued by the board on the effective date of this act shall, on and after the effective date of this act, be deemed to be licensed by the board as provided for in this act.

Section 1504. Severability.

The provisions of this act are severable. If any provision of this act or its application to any person or circumstance is held invalid, the invalidity shall not affect other provisions or applications of this act which can be given effect without the invalid provision or application.

Section 1505. Repeals.

(a) Absolute.--The act of September 27, 1961 (P.L.1700, No.699), known as the Pharmacy Act, is repealed.

(b) Inconsistent.--The act of April 9, 1929 (P.L.177, No.175), known as The Administrative Code of 1929, is repealed insofar as it is inconsistent with this act.

(c) General.--All other acts and parts of acts are repealed insofar as they are inconsistent with this act.

Section 1506. Effective date.

This act shall take effect January 1, 1998.