SPONSOR: Sen. Marshall & Rep. Oberle
Sens. Bonini, Copeland, Peterson, Sokola; Reps. Hudson, Mulrooney, Valihura, Viola

DELAWARE STATE SENATE

143rd GENERAL ASSEMBLY

SENATE SUBSTITUTE NO. 1

FOR

SENATE BILL NO. 42

AN ACT TO AMEND TITLE 24 OF THE DELAWARE CODE RELATING TO PHARMACY.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

Section 1. Amend Chapter 25, Title 24 of the Delaware Code by striking Chapter 25 in its entirety and by substituting the following in lieu thereof:

"CHAPTER 25. PHARMACY

Subchapter I. Objectives; Definitions; Board of Pharmacy

§2501. Objectives.

The primary objective of the Board of Pharmacy is to promote, preserve, and protect the public health, safety, and welfare. In meeting this objective, the Board shall develop and maintain a registry of drug outlets engaged in the manufacture, production, sale, and distribution of drugs, medications, and such other materials as may be used in the diagnosis and prevention of illness and disease and in the treatment of injury, and shall monitor the outlets to insure safe practices. The secondary objective of the Board is to maintain minimum standards of professional competency in the practice of pharmacy.

In meeting its objectives, the Board shall develop standards assuring professional competence; shall monitor complaints brought against pharmacists regulated by the Board; shall adjudicate at formal complaint hearings; shall promulgate rules and regulations; and shall impose sanctions, where necessary, against pharmacists. This chapter must be liberally construed to carry out these objectives.

§2502. Definitions.

The following words, terms, and phrases when used in this chapter have the meanings ascribed to them in this section, except where the context clearly indicates a different meaning.

(1) 'Board,' 'Board of Pharmacy,' or 'State Board of Pharmacy' means the Delaware State Board of Pharmacy.

(2) 'Certified pharmacy technician' means a person who is certified by the Pharmacy Technician Certification Board (PTCB) or other entity approved by the Board of Pharmacy. A certified pharmacy technician may perform services authorized in the rules and regulations of the Board of Pharmacy only while under the direct supervision of a pharmacist licensed in this State. A certified pharmacy technician shall register biennially with the Board.

(3) 'Direct supervision' means oversight and control by a licensed pharmacist who remains on the premises and is responsible for the work performed by a subordinate.

(4) 'Dispense' means to furnish or deliver a drug to an ultimate user by or pursuant to the lawful prescription of a practitioner. Dispense includes the preparation, packaging, labeling, or compounding necessary to prepare a drug for furnishing or delivery.

(5) 'Division' means the Division of Professional Regulation.

(6) 'Drug' means (i) a substance recognized as a drug in the Official United States Pharmacopoeia/National Formulary; (ii) a substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of any illness, condition, or disease in humans or animals; (iii) a substance, other than food, intended to affect the structure or any function of the body of a human or an animal; or (iv) a substance intended for use as a component of any substance specified in (i), (ii), or (iii) of this definition. 'Drug' does not include devices or their components, parts, or accessories.

(7) 'Drug outlet' means a pharmacy, an in-state or out-of-state drug wholesaler, a drug manufacturer, a drug distributor, or a non-pharmacy veterinary drug seller.

(8) 'Executive Secretary' means the executive secretary of the Delaware State Board of Pharmacy.

(9) 'Federal Food and Drug Administration (FDA) Approved Drug Products with Therapeutic Equivalence Evaluations' means the publication with that title containing a list of prescription drugs by generic name.

(10) 'Intern' means a person who is registered by the Board of Pharmacy and supervised by an approved preceptor and who is completing the practical experience requirement of the Board prior to his or her licensure as a pharmacist.

(11) 'Internship' or 'externship' means a period of practical experience established by Board of Pharmacy regulation that must be completed by an applicant for a license to practice pharmacy in this State.

(12) 'Manufacturer' means a person who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a drug, but does not include a person who is engaged in the preparation and dispensing of a drug pursuant to a prescription.

(13) 'Over-the-counter product' or 'OTC' means a substance which may be sold without a prescription and which is packaged for use by the consumer and labeled in accordance with the requirements of State and federal statutes and regulations.

(14) 'Person' means a natural person or an entity.

(15) 'Pharmacist' or 'licensee' means an individual licensed by the State pursuant to this chapter to engage in the practice of pharmacy.

(16) 'Pharmacy' means a place where drugs are compounded or dispensed.

(17) 'Pharmacy technician' means an individual who is not registered as an intern or a certified pharmacy technician with the Board of Pharmacy, but who may perform specified tasks as authorized in the Board's rules and regulations only while under the direct supervision of a pharmacist licensed in this State.

(18) 'Practice of pharmacy' means the interpreting, evaluating, and dispensing of a practitioner's or prescriber's order. The practice of pharmacy includes, but is not limited to, the proper compounding, labeling, packaging, and dispensing of a drug to a patient or the patient's agent, and administering a drug to a patient. The practice of pharmacy includes the application of the pharmacist's knowledge of pharmaceutics, pharmacology, pharmacokinetics, drug and food interactions, drug product selection, and patient counseling. It also includes: (i) participation in drug utilization and/or drug regimen reviews; (ii) participation in therapeutic drug selection and substitution of therapeutically equivalent drug products; (iii) advising practitioners and other health care professionals, as well as patients, regarding the total scope of drug therapy, so as to deliver the best care possible; (iv) monitoring drug therapy; (v) performing and interpreting capillary blood tests to screen and monitor disease risk factors or facilitate patient education, the results of which must be reported to the patient's health care practitioner; (vi) conducting or managing a pharmacy or other business establishment where drugs are compounded or dispensed; and (vii) administering of injectables, biologicals, and adult immunizations pursuant to a valid prescription or physician-approved protocol limited to the physician's patients, except that a prescription or protocol is not required for administering an influenza or pneumococcus vaccine. Regulations applicable to paragraph (viii) of this subsection must be established by the Pharmacy Regulatory Council of the Board of Medical Practice which consists of one public member, four pharmacists appointed by the Board of Pharmacy, and two physicians appointed by the Board of Medical Practice. One of the physicians serves as the chairperson of the Council.

(19) 'Practitioner' or 'prescriber' means an individual who is authorized by law to prescribe drugs in the course of professional practice or research in any state.

(20) 'Preceptor' means a licensed pharmacist who is approved by the Board to supervise an intern.

(21) 'Prescription drug' or 'legend drug' means a drug required by federal or State law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients, subject to §503(b) of the Federal Food, Drug and Cosmetic Act [21 U.S.C. §353(b)].

(22) 'Prescription drug order' or 'prescription' means the lawful written or verbal order of a practitioner for a drug.

(23) 'State' means the State of Delaware.

(24) 'Therapeutically equivalent drug' means a drug which contains the same active ingredient(s) and is identical in strength or concentration, dosage form, and route of administration and which is classified as being therapeutically equivalent to another drug in the latest edition or supplement of the Federal Food and Drug Administration (FDA) Approved Drug Products with Therapeutic Equivalence Evaluations, sometimes referred to as the Orange Book.

(25) 'Use or abuse of drugs' means: (i) the use of illegal drugs; (ii) the use of prescription drugs without a prescription; (iii) the excessive use of legally prescribed drugs; or (iv) the abuse of alcoholic beverage or drugs to the extent that it impairs a pharmacist's ability to perform the work of a pharmacist.

(26) 'Wholesale distribution' means the distribution of drugs to a person other than a consumer or patient. Wholesale distribution does not include:

(a) the distribution of drugs within a healthcare group-purchasing organization;

(b) the transfer of prescription drugs by a pharmacy to another pharmacy to alleviate a temporary shortage;

(c) the dispensing of a drug pursuant to a prescription; or

(d) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug:

(i) by a charitable organization described in §501(c)(3) of the Internal Revenue Code of 1854 [26 U.S.C. §501(c)(3)] to a nonprofit affiliate of the charitable organization to the extent permitted by law;

(ii) among hospitals or other health care entities which are under common control;

(iii) for emergency medical reasons.

(27) 'Wholesale distributor' means a person engaged in the wholesale distribution of drugs, including, but not limited to, a manufacturer's or distributor's warehouse, a chain drug warehouse or wholesale drug warehouse, an independent wholesale drug trader, and a pharmacy that engages in the wholesale distribution of drugs.

§2503. Board of Pharmacy; appointments; composition; qualifications; terms; vacancies; suspension or removal; unexcused absences; compensation.

(a) The Delaware State Board of Pharmacy shall administer and enforce this chapter.

(b) The Board consists of nine members who are appointed by the Governor and who are residents of the State. Six members are pharmacists who have been engaged in the practice of pharmacy in Delaware for at least five years and who are representative of the various practice settings in the field of pharmacy. Three members are public members, one from each county**.**

A public member may not be, nor ever have been, a pharmacist or a member of the immediate family of a pharmacist; may not be, nor ever have been, employed by a pharmacy; may not have a material interest in the providing of goods or services to a pharmacy; and may not be, nor ever have been, engaged in an activity directly related to the practice of pharmacy. A public member must be accessible to inquiries, comments, and suggestions from the general public.

(c) Except as provided in subsection (d) of this section, each Board member serves a term of three years, and may succeed himself or herself for one additional term; provided, however, that where a member was initially appointed to fill a vacancy, the member may succeed himself or herself for only one additional full term. A person appointed to fill a vacancy on the Board holds office for the remainder of the unexpired term of the vacating member. Each term of office expires on the date specified in the appointment; however, a Board member whose appointment has expired remains eligible to participate in Board proceedings unless or until replaced by the Governor. Members must be appointed so that the terms of no more than three members expire in any one year. A person who is a member of the Board on the effective date of this chapter may complete his or her term.

(d) A person who has never served on the Board may be appointed to the Board for two consecutive terms; but that person is thereafter ineligible to serve for two consecutive appointments. A person who has been twice appointed to the Board or who has served on the Board for six years within any nine-year period may not again be appointed to the Board until an interim period of at least one term has expired since the person last served.

(e) An act or vote on Board business by a person appointed to the Board in violation of this section is invalid.

(f) The Governor shall suspend or remove a member of the Board for the member's misfeasance, nonfeasance, malfeasance, misconduct, incompetency, or neglect of duty. A member subject to a disciplinary hearing must be disqualified from Board business until the charge is adjudicated or the matter is otherwise concluded. A Board member may appeal to the Superior Court a suspension or removal initiated pursuant to this subsection.

(g) A member of the Board, while serving on the Board, may not hold elective office in any professional association of pharmacists or serve as an officer of a professional association’s political action committee (PAC).

(h) The provisions of the State Employees', Officers' and Officials' Code of Conduct set forth in Chapter 58 of Title 29 apply to the members of the Board.

(i) A member who is absent without adequate reason for three consecutive regular business meetings or who fails to attend at least half of all regular business meetings during any calendar year is guilty of neglect of duty.

(j) The Division shall reimburse Board members for expenses involved in each meeting, including travel, according to Division policy. A member may not receive more than $50 for each meeting attended, and not more than $500 in any calendar year. After attending 10 meetings, a member may not be compensated for any subsequent meetings attended in that year.

§2504. Organization; meetings; officers; quorum; Executive Secretary.

(a) The Board shall hold regularly scheduled business meetings at least six times in a calendar year, and at other times as the president of the Board considers necessary, and at the request of a majority of the Board members.

(b) The Board shall elect annually a president and other officers as it considers appropriate and necessary to conduct business. Each term of office is for one year. An officer may not serve for more than three consecutive terms in the same office.

(c) The Director of the Office of Narcotics and Dangerous Drugs serves as the Executive Secretary of the Board and as an ex officio member without a vote. The Executive Secretary is responsible for the performance of the regular administrative functions of the Board and other duties as the Board may direct. If the Memorandum of Understanding between the Department of Administrative Services and the Department of Health and Social Services relating to the responsibilities of the Office of Narcotics and Dangerous Drugs and the Board of Pharmacy terminates, the Director of the Office of Narcotics and Dangerous Drugs will cease being the Executive Secretary of the Board of Pharmacy, and the Division of Professional Regulation shall be responsible for replacing the Executive Secretary.

(d) A majority of the members of the Board constitutes a quorum for the purpose of transacting business; however, no disciplinary action may be taken without the affirmative vote of at least five members.

(e) Minutes of all meetings must be recorded. The Executive Secretary shall maintain copies of the recorded minutes. At any hearing where evidence is presented, a record from which a verbatim transcript can be prepared must be made. The person requesting a transcript incurs the expense of preparing the transcript.

§2505. Records.

The Executive Secretary shall keep complete records relating to meetings of the Board, examinations, rosters of licensees and permit holders, changes and additions to the Board's rules and regulations, complaints, hearings, and other matters as the Board determines. Records kept in accord with this section are prima facie evidence of the proceedings of the Board.

§2506. Authority of the Board.

(a) The Board of Pharmacy has the authority to:

(1) promulgate rules and regulations in accordance with the procedures specified in the Administrative Procedures Act of this Code;

(2) designate the application form to be used by all applicants and to process all applications pursuant to this chapter;

(3) designate the national standardized examinations in pharmacy and jurisprudence as approved by the National Association of Boards of Pharmacy, or its successor, to be taken by a person applying for a license to practice pharmacy;

(4) evaluate the credentials of each person applying for a license to practice pharmacy in order to determine whether the person meets the qualifications set forth in this chapter;

(5) grant a license to and renew the license of each person who qualifies for a license to practice pharmacy; and grant or renew a license with restrictions, if appropriate, as a reasonable accommodation to an applicant with a disability;

(6) establish by regulation continuing education standards required for license renewal;

(7) evaluate certified records, including criminal history records, to determine whether an applicant for licensure who previously has been licensed, certified, or registered in another jurisdiction to practice pharmacy has engaged in any act or offense that would be grounds for disciplinary action under this chapter and whether there are disciplinary proceedings or unresolved complaints pending against the applicant for such acts or offenses;

(8) maintain a registry of interns and certified pharmacy technicians;

(9) refer all complaints from licensees and the public concerning persons licensed under this chapter, or concerning the practices of the Board or the profession, to the Division for investigation pursuant to §8807 of Title 29 and assign a member of the Board to assist the Division in an advisory capacity with the investigation for the technical aspects of the complaint; provided, however, that the Secretary of the Department of Administrative Services is not precluded from entering into a memorandum of understanding with the Secretary of the Department of Health and Social Services for the purpose of allowing employees of the Department of Health and Social Services to function as inspectors, investigators, and administrative support for the Board of Pharmacy;

(10) issue subpoenas to require the attendance of persons and the production of books and papers for the purpose of conducting investigations preliminary to hearings and for the purpose of eliciting testimony at hearings. A person who is subpoenaed may be required to testify in any and all matters within the jurisdiction of the Board. Subpoenas may be issued only by the president or the Executive Secretary of the Board and are enforceable by the Superior Court;

(11) conduct hearings and issue orders in accordance with the procedures established in the Administrative Procedures Act in Chapter 101 of Title 29;

(12) designate and impose an appropriate sanction or penalty, if it has been determined after a hearing that a sanction or penalty should be imposed;

(13) evaluate applications and issue permits to pharmacies or other establishments, as provided under this chapter;

(14) join professional organizations and associations organized exclusively to promote the improvement of the standards of the practice of pharmacy for the protection of the health, safety, and welfare of the public and whose activities assist and facilitate the work of the Board, and pay annual dues to the organizations and associations joined;

(15) regulate the sale and dispensing of drugs and other materials, including the right to seize any drugs and other materials found by the Board to be detrimental to the public health, safety, or welfare, in accordance with Chapter 33 of Title 16;

(16) Regulate the purity and quality of drugs and other materials within the practice of pharmacy;

(17) promulgate rules and regulations to implement the law relating to pure drugs, pursuant to §3315 of Title 16.

(b) The Board shall submit a written report to the Governor within 3 months after the conclusion of each fiscal year and shall make the report available to anyone requesting a copy.

## Subchapter II. Licensure

### §2507. License required.

(a) A person may not, in this State, engage in the practice of pharmacy or hold himself or herself out to the public as being qualified to practice pharmacy, or use in connection with his or her name, or otherwise assume or use, a title or description conveying or tending to convey the impression that he or she is qualified to practice pharmacy, except as provided in this chapter.

(b) Only a person who is licensed to practice pharmacy in this State, or who is a pharmacy intern, or who is a pharmacy student participating in an approved college of pharmacy coordinated practical experience program under the direct supervision of a licensed pharmacist may certify a prescription, perform drug utilization reviews, provide drug information requiring clinical or technical knowledge, counsel patients, receive new verbal prescription orders without recorded backup, or contact a practitioner concerning a prescription drug order interpretation or therapy modification.

(c) It is unlawful for a person to practice pharmacy in this State if the person's license to practice pharmacy expires, is placed on inactive status, or is suspended or revoked.

(d) The penalty for a violation of this section is, for a first conviction, a fine of not less than five hundred dollars ($500) nor more that one thousand dollars ($1000), and for a second or subsequent conviction, a fine of not less than one thousand dollars ($1000) nor more than two thousand dollars ($2000).

### §2508. Qualifications of applicant; judicial review; report to Attorney General.

(a) An applicant for a license to practice pharmacy must submit evidence, verified by oath or affirmation and satisfactory to the Board, that he or she has completed the requirements for graduation from a school or college of pharmacy accredited by the

American Council on Pharmaceutical Education; or, if the applicant is a graduate of a foreign school or college of pharmacy, that he or she graduated and received a pharmacy degree from a pharmacy degree program which has been approved by the Board.

(b) An applicant for a license to practice pharmacy must obtain practical experience in the practice of pharmacy during and/or after attendance at a school or college of pharmacy, under such terms and conditions as the Board determines. The Board shall also determine the necessary qualifications for preceptors used in internships or other programs.

(c) An applicant for a license to practice pharmacy must have good moral character.

(d) The Board shall determine whether an applicant whose conduct or status is described in one or more of the following paragraphs of this subsection is qualified to engage in the practice of pharmacy. In making this determination, the Board shall consider whether the applicant's conduct is or is not related to the practice of pharmacy and whether licensure of the applicant will or will not present a risk to public health, safety, or welfare.

(1) The applicant received an administrative penalty regarding the practice of pharmacy, including but not limited to fines, formal reprimands, license suspension or revocation (except for license revocation for nonpayment of license renewal fees), probationary limitations, or entry into a consent agreement which contains conditions placed by a Board on the applicant's professional conduct and practice, including the voluntary surrender of the applicant's license to practice pharmacy.

(2) The applicant has an impairment related to drugs, alcohol, or mental competence.

(3) The applicant was convicted of a felony.

(4) The applicant has a criminal conviction record or a pending criminal charge related to an incident, the circumstances of which relate to the practice of pharmacy.

(e) An applicant shall cause his or her entire criminal history record to be submitted to the Board by both the State Bureau of Identification and the Federal Bureau of Investigation. If the applicant does not have a criminal history record, the applicant shall cause to be submitted statements from each agency that the agency has no record of criminal history information relating to the applicant. The State Bureau of Identification is the intermediary for the purpose of this subsection and the Board, or its designee, is the screening point for the receipt of the federal criminal history record. The applicant is responsible for the required fee, if any, for obtaining the records.

(f) If the Board finds that false information has been intentionally provided to the Board, it shall report its finding to the Attorney General's Office for further action.

(g) If the Board refuses to accept, or rejects, an application and the applicant believes that the Board acted without justification, or imposed higher or different standards for the applicant than for other applicants, or in some other unlawful manner contributed to or caused the refusal or rejection of the application, the applicant may appeal to the Superior Court.

§2509. Examination.

(a) The Board shall adopt the administration, grading procedures, and passing score of the North American Pharmacist Licensure Examination (NAPLEX) and the Multistate Pharmacy Jurisprudence Examination (MPJE) or of comparable alternative national examinations.

(b) The Board shall determine in its rules and regulations the frequency and conditions under which a candidate may retest after a failure.

§2510. Reciprocity.

(a) The Board shall grant a license to practice pharmacy to a reciprocal applicant who pays the appropriate fee, submits a completed application on forms provided by the Board and which completed application is accepted by the Board, and who otherwise qualifies pursuant to subsection (b) of this section and sends proof to the Board that:

(1) the reciprocal applicant's current licensure is in good standing in another state, the District of Columbia, or a territory of the United States;

(2) the reciprocal applicant passed the NAPLEX and MPJE or a comparable alternative national examination adopted by the Board for this State; and

(3) the reciprocal applicant passed the examination of the Foreign Pharmacy Graduate Examination Committee (FPGEC) of the National Association of Boards of Pharmacy Foundation (NABP), if the applicant is a graduate of a foreign school of pharmacy.

(b) The provisions of §2508(c), (d), (e), (f), and (g) of this chapter apply to reciprocal applicants. If a disciplinary proceeding or unresolved complaint is pending against a reciprocal applicant, the reciprocal applicant may not be licensed in this State until the proceeding or complaint has been resolved to the satisfaction of the Board. A reciprocal applicant for licensure in this State is deemed to have given consent to the release of information regarding disciplinary proceedings and unresolved complaints and to have waived all objections to the admissibility of the information as evidence at any hearing or other proceeding to which the reciprocal applicant may be subjected.

(c) A reciprocal applicant is not required to obtain practical experience pursuant to §2508(b) of this subchapter.

§2511. Fees.

The amount charged by the Division for each fee imposed under this chapter must approximate and reasonably reflect the cost necessary to defray the expenses of the Board as well as the proportional expenses incurred by the Division in its services or

activities on behalf of the Board. A separate fee may be charged for each service or activity. At the beginning of each licensure biennium, the Division, or a State agency acting on its behalf, shall compute and set the fee for the licensure biennium.

§2512. Issuance and renewal of license.

(a) The Board shall issue a license to each applicant who meets the requirements of this chapter for licensure to practice pharmacy and who pays the fee established under §2511 of this chapter.

(b) A license to practice pharmacy must be renewed biennially, in a manner determined by the Division. License renewal must include the completion and submission of a renewal form provided by the Division, payment of the appropriate fee, and proof that the licensee has met the continuing education requirements established by the Board.

(c) The Board, in its rules and regulations, shall determine the period of time within which a licensee may renew his or her license, notwithstanding the fact that the licensee failed to renew his or her license on or before the designated renewal date; provided, however, that the period of time may not exceed one year beyond the designated renewal date.

(d) A licensee, upon the licensee's written request, may be placed on inactive status for no more than 4 years. A licensee on inactive status who desires to reactivate his or her license shall complete and submit an application form approved by the Board, submit the renewal fee set by the Division, and submit proof of fulfillment of the continuing education requirements established by the Board.

(e) If a licensee is on inactive status for more than 4 years, he or she may be re-licensed, but only by following the re-entry process established by the Board in its rules and regulations.

§2513. Temporary license.

The Executive Secretary, jointly with the president of the Board, may issue a temporary, 90-day license to practice pharmacy to a person who has made application for a permanent license and whose application is pending. In issuing a temporary, 90-day license, the Board may impose conditions as it considers appropriate, including, but not limited to, restrictions on the practice of pharmacy. The Board may grant one 90-day extension of a temporary license.

§2514. Complaints.

(a) All complaints received by the Division must be investigated in accordance with 29 Del. C. §8807 or with any authorized memorandum of understanding between the Division and the Department of Health and Human Services.

(b) If the Board determines that a person is engaging in or has engaged in the practice of pharmacy or is using the title "pharmacist" and is not licensed to practice pharmacy pursuant to §2507 of this chapter, the Board shall request that the Office of the Attorney General issue a cease and desist order.

§2515. Grounds for discipline.

(a) A pharmacist licensed under this chapter is subject to disciplinary sanctions set forth in §2516 of this chapter if, after a hearing, the Board finds that the pharmacist:

(1) has employed or knowingly cooperated in fraud or material deception in order to acquire a license to practice pharmacy, has impersonated another person holding a license, has allowed another person to use the pharmacist's license, or has aided or abetted a person not licensed to practice pharmacy to represent himself or herself as a pharmacist;

(2) has illegally, incompetently, or negligently practiced pharmacy;

(3) has been convicted of a felony, or has been convicted of any offense, the circumstances of which substantially relate to the practice of pharmacy. A copy of the record of conviction certified by the clerk of the court entering the conviction is conclusive evidence of conviction;

(4) has used or abused drugs, as defined in §2502(25) of this chapter, in the past two years;

(5) has engaged in an act of consumer fraud or deception, engaged in the restrain of competition, or participated in price-fixing activities;

(6) has violated a lawful provision of this chapter or any lawful regulation established hereunder;

(7) has had his or her license to practice pharmacy suspended or revoked or has been subjected to other disciplinary action taken by the appropriate licensing authority in another jurisdiction; provided, however, that the underlying grounds for the suspension, revocation, or other action in another jurisdiction have been presented to the Board by certified record and the Board has determined that the facts found by the appropriate licensing authority in the other jurisdiction constitute one or more of the acts listed in this subsection. Every person licensed to practice pharmacy in this State is deemed to have given consent to the release of information regarding license suspension or revocation or other disciplinary action by the Board of Pharmacy or by other comparable agencies in other jurisdictions and to have waived all objections to the admissibility of previously adjudicated evidence of the acts or offenses which underlie license suspension or revocation or other disciplinary action;

(8) has failed to notify the Board that his or her license to practice pharmacy in another jurisdiction has been subject to discipline, or has been surrendered, suspended, or revoked. A certified copy of the record of disciplinary action, or of the surrender, suspension, or revocation of the license is conclusive evidence thereof; or

(9) has a physical or mental impairment that prevents the pharmacist from engaging in the practice of pharmacy with reasonable skill, competence, and safety to the public.

(b) Subject to the provisions of this chapter and Subchapter IV of Chapter 101 of Title 29, the Board shall not restrict, suspend, or revoke a license to practice pharmacy or limit a licensee's right to engage in the practice of pharmacy until the Board gives to the licensee proper notice and opportunity to be heard.

§2516. Disciplinary sanctions.

(a) The Board may impose any of the following sanctions, singly or in combination, when it determines that a person licensed to practice pharmacy has violated a ground for discipline set forth in §2515 of this chapter:

(1) issue a letter of reprimand to the licensee;

(2) censure the licensee;

(3) place the licensee on probationary status and require the licensee to:

a. report regularly to the Board upon the matters that are the basis of the probation; and/or

b. limit all practice and professional activities to those areas prescribed by the Board;

(4) suspend the license of the licensee;

(5) revoke the license of the licensee;

(6) impose an administrative penalty, not to exceed $500 for each violation.

(b) The Board may withdraw or reduce conditions of probation imposed pursuant to subsection (a)(3) of this section, if it finds that the deficiencies that required the conditions of probation to be imposed have been remedied.

(c) If the Board suspends a license to practice pharmacy due to an impairment of the licensee, the Board may reinstate the license if, after a hearing, the Board is satisfied that the licensee is able to practice pharmacy with reasonable skill, competence, and safety to the public.

§2517. Hearing procedures.

(a) If a complaint alleging a violation of §2515 of this chapter is filed with the Board pursuant to 29 Del. C. §8807(h), the Board shall set a time and place to conduct a hearing on the complaint. The Board shall give notice of the hearing and shall conduct the hearing in accordance with the Administrative Procedures Act, Chapter 101 of Title 29.

(b) A hearing pursuant to this section is informal, without the use of the Rules of Evidence. If the Board decides by a majority vote of all members that the complaint has merit, the Board may take any action permitted under this chapter that the Board considers necessary. The Board's decision must be in writing and must include the reasons for the decision. The Board shall immediately mail its decision to the licensee or personally serve the licensee with the decision.

(c) If a licensee is in disagreement with the decision of the Board, the licensee may appeal the Board's decision to the Superior Court within 30 days of the postmarked date of the copy of the decision mailed to him or her, or within 30 days of service. Upon appeal, the Court shall hear the evidence on the record. A stay pending review may be granted by the Court in accordance with 29 Del. C. §10144.

§2518. Reinstatement of a suspended license; removal from probationary status.

(a) As a condition of reinstatement of a suspended license or the issuance of another license after revocation, the Board may impose any condition or conditions that are authorized under this chapter. Before reinstating a suspended license or removing a licensee from probationary status, the Board shall, without a hearing, make a determination as to whether the licensee has taken the required corrective actions and has satisfied all of the conditions imposed pursuant to the license suspension and/or the probation period. A licensee who disagrees with a determination made by the Board under this subsection may request a hearing before the Board.

(b) A licensee seeking reinstatement or removal from probationary status must pay the appropriate fees and submit the evidence required by the Board to show that all the conditions imposed pursuant to the license suspension and/or the probation period have been met. Proof that the licensee has met his or her continuing education requirements may also be required.

§2519. Emergency suspension.

By a decision of five or more members, the Board may order the suspension of a license to practice pharmacy prior to a hearing or simultaneously with the scheduling of a hearing if it finds that the licensee, by continuing in the practice of pharmacy, poses an imminent danger to public health, safety or welfare. An emergency license suspension pursuant to this section continues in effect until the conclusion of the proceedings, including judicial review, if any, unless the suspension is withdrawn by the Board or modified by the Superior Court. If a license is suspended pursuant to this section, the hearing must be held no later than 30 days from the date of service of the suspension order unless the hearing is continued at the request of the licensee.

§2520. Counseling of pharmacists.

(a) If the Executive Secretary and the president of the Board jointly find after an investigation that a pharmacist has violated a provision of this chapter or a regulation enacted pursuant to this chapter, but that the violation can be reasonably resolved without a formal disciplinary sanction under §2516 of this chapter, the Executive Secretary may counsel the pharmacist regarding the violation. The Executive Secretary shall notify the pharmacist in writing of the finding and of the decision not to proceed with formal disciplinary sanctioning. The notification must explain the finding and request the presence of the pharmacist at a

counseling session. During the counseling session, the Executive Secretary shall discuss with the pharmacist the violation, and establish a plan of correction, if necessary.

(b) Counseling pursuant to subsection (a) of this section is voluntary. However, if the pharmacist fails to attend the counseling session or fails to comply with the necessary plan of correction specified by the Executive Secretary, the violation must be handled in the same manner as a violation of §2515 of this chapter is handled.

(c) The counseling of a pharmacist under this section is not considered disciplinary action if the pharmacist attends the counseling session and complies with any necessary plan of correction required by the Executive Secretary. Counseling pursuant to this section may not be used in considering disciplinary sanctions in a future hearing unrelated to the incident for which the pharmacist was counseled unless the future incident involves the same or similar allegations as those for which the pharmacist was counseled.

§2521. Impaired pharmacist.

(a) An 'impaired pharmacist' is a pharmacist whose use or abuse of drugs or alcohol affects his or her ability to practice pharmacy. An impaired pharmacist may be eligible to enter an approved treatment program pursuant to an agreement with the Executive Secretary and the Board president.

(b) Disciplinary action will not be taken against a pharmacist who enters into and successfully completes an approved treatment program pursuant to subsection (a) of this section as long as a complaint has not been filed against the pharmacist and as long as the pharmacist has not been convicted of, or has not pleaded guilty or *nolo contendere* to a felony or a drug offense. Records related to a treatment program under this section are not public records, and may be used in a subsequent related disciplinary matter before the Board only if the pharmacist was, or could have been, disciplined.

(c) A pharmacist who does not qualify under subsection (b) of this section may, nevertheless, enter into an agreement with the Executive Secretary and the Board president to participate in an approved treatment program. Action on a disciplinary complaint may be deferred and ultimately dismissed if the pharmacist successfully completes the treatment program.

(d) An agreement pursuant to this section that permits an impaired pharmacist to enter into an approved treatment program must contain at least the following provisions:

(1) The pharmacist must agree not to engage in the practice of pharmacy for the duration of the treatment program.

(2) The pharmacist must sign a release so that records of treatment and progress are released to the Executive Secretary and the Board president.

(3) If the pharmacist does not make satisfactory progress in the program, the agreement is void and an investigation and disciplinary proceedings may be pursued.

(4) The pharmacist must agree to submit to random drug and alcohol screening at a specified laboratory or health care facility.

(5) The pharmacist must agree to be personally responsible for all cost related to the program.

(e) A pharmacist who successfully completes an approved treatment program may return to the practice of pharmacy if the Executive Secretary and the Board president determine that the pharmacist's return to practice will not endanger the public health, safety, or welfare. The Executive Secretary and the president may require the pharmacist to agree to specific conditions of practice to protect the public.

Subchapter III. Miscellaneous provisions.

§2522. Prescription labeling.

(a) A practitioner prescribing a drug to be prepared and dispensed by a pharmacist in this State for the use of a patient or any third person must, as part of the prescription, include directions describing the exact method by which the drug must be taken or administered. A prescription without specific directions, or a prescription bearing the notation “as directed” without specific directions, may not be prepared or dispensed.

(b) A pharmacist shall affix to every container in which a drug is dispensed a label containing the following information:

(1) prescription number;

(2) the date the prescription is dispensed;

(3) patient’s full name;

(4) brand or established name and strength of the drug to the extent that it can be measured;

(5) practitioner’s directions as found on the prescription;

(6) practitioner’s name;

(7) name and address of the dispensing pharmacy or practitioner.

(c) A practitioner who sells or dispenses drugs directly to a patient shall label the container in accordance with this section, with the exception of a prescription number.

§2523. Exemptions.

Nothing in this chapter may be construed to prevent:

(a) a student or graduate of an accredited school of pharmacy from receiving practical training pursuant to an internship or other approved program under the supervision of a pharmacist in this State;

(b) a pharmacy technician or certified pharmacy technician from performing under the direct supervision of a pharmacist the functions permitted under the rules and regulations of the Board and not inconsistent with this chapter;

(c) a practitioner licensed under the laws of this State to practice within the scope of his or her license;

(d) the selling at retail of over-the-counter products;

(e) a business not licensed as a pharmacy to sell gases that are used for medicinal purposes and which require a prescription, provided that:

(1) the business is registered with the Board;

(2) the sale is authorized by a written order or by a verbal order reduced to writing from a practitioner;

(3) the record of the written order or of the verbal order reduced to writing is maintained on the premises of the business for at least two years; and

(4) the gas product is stored and dispensed according to requirements established by the Board.

(f) the sale of non-controlled prescription drugs designated for veterinary use by a business not licensed as a pharmacy, provided that the business is registered with the Board and the sale is authorized by a written order or by a verbal order reduced to writing from a licensed veterinarian.

(g) a pharmacist in this State from dispensing a valid non-controlled prescription drug pursuant to a prescription received via electronic transmission from a practitioner's office to the prescription department of the dispensing pharmacy.

§2524. Miscellaneous fees.

The Division shall set fees to defray registration costs, costs for maintaining registries required under this chapter, and the costs of replacing lost or destroyed licenses and permits.

## Subchapter IV. Pharmacies

§2526. Permit required for each pharmacy.

(a) A person may not operate a pharmacy within the State without first having obtained a permit to operate a pharmacy from the Board. A person who desires to operate more than one pharmacy must make a separate permit application for each

pharmacy. However, separate permits are not required for sites designated as pharmacies within the same institution at one general location, provided that each site is approved by the Board.

(b) The Board shall issue a separate permit for each qualifying pharmacy. A permit to operate a pharmacy granted by the Board may not be assigned or otherwise transferred to another person except upon such conditions as the Board specifically designates, and then only pursuant to the written consent of the Board or its designee. A permit must be available on site for inspection by authorized persons.

§2527. Application fees for permits.

The application for a permit to operate a pharmacy must be made on a form furnished by the Board and must be accompanied by the application fee and/or permit fee established pursuant to §2511 of this chapter.

§2528. Requirements for and issuance of permit.

(a) In determining if a permit to operate a pharmacy should be issued, the Board shall consider, but is not limited to considering, the probability that:

(1) the pharmacy will be operated in full compliance with the law and with the rules and regulations of the Board;

(2) the pharmacy will be managed by a pharmacist-in-charge who is licensed to practice pharmacy in the State and who will serve as a pharmacist-in-charge in only that pharmacy;

(3) the location and appointments of the pharmacy are such that it can be operated without endangering public health, safety, or welfare. In determining a danger to public health, safety, or welfare, the Board shall consider, but is not limited to considering, the following factors:

a. whether an applicant, permit holder, principal, or a person having ownership interest in the pharmacy has a conviction for deceptive business practices or for a violation of drug laws under federal law or any state's law;

b. whether an applicant, permit holder, principal, or a person having controlling ownership interest in the pharmacy has been or is the subject of an action by a regulatory agency for a violation of the agency's statutes or regulations;

(4) the pharmacist-in-charge, whose name is on the application, will comply with pharmacy, controlled substance, and other applicable statutes and regulations;

(5) the pharmacy will provide conspicuous notice to consumers that dispensing errors may be reported to the Board of Pharmacy, as provided in the rules and regulations.

(b) A permit to operate a pharmacy may not be issued or renewed unless the pharmacy is equipped with proper reference materials and professional and technical equipment as provided in the Board's rules and regulations.

(c) The Executive Secretary, jointly with the Board president, may issue a temporary, 60-day permit to operate a pharmacy to an otherwise qualified pharmacy while the application for a permanent permit is pending. The Board may grant one 60-day extension of a temporary permit.

§2529. Renewal of permit.

(a) A permit to operate a pharmacy must be renewed biennially in a manner determined by the Division, including the payment of the renewal fee established pursuant to §2511 of this chapter.

(b) The Board, in its rules and regulations, shall determine the period within which a permit holder may renew the permit to operate a pharmacy, notwithstanding the fact that the permit holder failed to renew on or before the designated renewal date; provided, however, that the period of time may not exceed one year beyond the designated renewal date.

(c) A permit to operate a pharmacy terminates automatically upon a transfer of the controlling interest in the pharmacy, upon the termination of the legal existence of the pharmacy, or upon the discontinuance of business or professional practice.

(d) The closing of a pharmacy must be in compliance with the rules and regulations of the Board. If the closing is to be permanent, the Board must be notified 14 days prior to the closing. If the closing is to be for more than 7 consecutive business days, the Board must be notified 5 days prior to the temporary closing.

§2530. Revocation or suspension of permit.

(a) The Board may suspend or revoke a permit to operate a pharmacy when examination or inspection of the pharmacy discloses that the pharmacy is not being operated according to law or is being operated in a manner which endangers public health, safety, or welfare.

(b) The Board may suspend or revoke a permit to operate a pharmacy if the pharmacy's prescription department is closed for more than 14 consecutive days, unless the closing of the prescription department was due to a cause which the Board finds reasonable.

(c) In determining if a pharmacy is being operated in a manner which endangers the public health, safety, or welfare pursuant to subsection (a) of this section, the Board shall consider, but is not limited to considering, the following factors:

(1) compliance by the permit holder with the law and with the rules and regulations of the Board;

(2) a conviction of the permit holder, a principal, or a person having controlling ownership interest in the pharmacy for a violation of federal law or of any state's law other than a violation of a minor traffic offense;

(3) an action by a regulatory agency against the permit holder for a violation of the agency's statutes or regulations.

§2531. Hearings on actions involving permits.

(a) If the Board intends not to issue a permit or intends to suspend or revoke a permit, the Board shall give written notice to the applicant or permit holder of the intended action and the reasons therefor. The applicant or permit holder has at least ten days from the date of notice to request a hearing. Notice of the hearing must be given and the hearing must be conducted in accordance with the Administrative Procedures Act, Chapter 101 of Title 29.

(b) A hearing pursuant to subsection (a) of this section is informal, without the use of the Rules of Evidence. The Board's decision must be in writing and must include the reasons for the decision. The Board's decision must be mailed immediately to or personally served upon the applicant or permit holder.

(c) If an applicant or permit holder is in disagreement with the decision of the Board, the applicant or permit holder may appeal the Board's decision to the Superior Court within 30 days of the postmarked date of the copy of a mailed decision or within 30 days of the date of service of the decision. Upon appeal, the Court shall hear the evidence on the record. A stay pending review may be granted by the Court in accordance with 29 Del. C. §10144.

§2532. Pharmacy records.

A suitable book or file in which the original of every prescription compounded or dispensed at the pharmacy must be preserved for a period of not less than 3 years. The book or file of original prescriptions must at all times be open to inspection by authorized agents of the Board and/or of the Department of Health and Social Services.

§2533. Prescription department.

(a) A pharmacy must contain a secure room or area with a door that can be locked when the pharmacy is without the attendance and supervision of a pharmacist. The secure room or area, known as the prescription department, must contain the entire stock of prescription drugs, chemicals, and preparations used in compounding and preparing prescriptions.

(b) Only a pharmacist is authorized to unlock and lock the prescription department of a pharmacy.

(c) A sign giving the name of the pharmacist-on-duty must at all times be posted in the vicinity of the prescription department of a pharmacy.

(d) During the absence of a pharmacist, the prescription department of a pharmacy must be locked until the pharmacist returns to duty. However, the merchandising section of the pharmacy may remain open.

(e) A prescription department must have at least 250 square feet of floor space. The counter inside the prescription department must be at least 18 inches wide and must have 4 linear feet for each pharmacist working concurrently on dispensing and compounding prescriptions. The counter must be kept clear and free of all merchandise and other materials not currently in use in dispensing and compounding prescriptions. The aisle behind the counter must be at least 30 inches wide and must be kept free of obstruction at all times. A prescription department which existed on February 11, 1992, is exempt from the requirements of this subsection unless the department is remodeled or relocated.

§2534. Inspections.

(a) An agent of the Board or of the Department of Health and Social Services may enter and inspect during business hours any pharmacy or other place in this State where drugs are manufactured, packed, packaged, stocked, distributed, dispensed, or offered for sale.

(b) An agent of the Board or of the Department of Health and Social Services acting pursuant to subsection (a) of this section may inspect and copy records required by this chapter to be kept; may inspect within reasonable limits and in a reasonable manner the premises and all pertinent equipment, finished and unfinished materials, containers, and labeling found therein; may inspect other things therein, including records, files, papers, processes, controls, and facilities relating to a violation of this chapter; and may make an inventory of the stock of drugs therein and obtain samples of drugs and other substances.

§2535. Nonresident pharmacies.

(a) A pharmacy located outside the State which delivers in any manner a prescription drug to a patient in the State is a nonresident pharmacy and must obtain a permit to conduct business in this State. A nonresident pharmacy may not deliver in any manner a prescription drug to a patient in this State unless it has a permit to do so issued by the Board.

(b) If a nonresident pharmacy which has a permit issued pursuant to this section delivers in any manner a prescription drug and the prescription drug is not personally hand delivered to the patient, a written notice must be placed in the shipping container to alert the patient that:

(1) under certain circumstances a prescription drug's effectiveness may be affected by exposure to extremes of heat, cold, or humidity; and

(2) a local or a toll-free telephone service is available to answer questions about the prescription drug.

§2536. Nonresident pharmacies: Service of process; registered agent.

A nonresident pharmacy must designate a registered agent in Delaware for service of process. A nonresident pharmacy that does not designate a registered agent is deemed to have appointed the Secretary of State to be its agent upon whom may be served all legal process in any action or proceeding against the nonresident pharmacy relating to the delivery in any manner of prescription drugs into this State. In any action or proceeding against a nonresident pharmacy, a copy of service of process must be mailed to the nonresident pharmacy by the complaining party by certified mail, return receipt requested, at the address of the nonresident pharmacy, as designated on the nonresident pharmacy's permit application to conduct business in this State. A nonresident pharmacy which does not obtain a permit in this State pursuant to this chapter is deemed to have consented to service of process on the Secretary of State as sufficient service.

§2537. Conditions of nonresident pharmacy's permit to conduct business in this State.

(a) A nonresident pharmacy shall:

(1) provide the location, names, and titles of all principal corporate officers and of all pharmacists who dispense prescription drugs in this State. This information must be provided to the Board upon application for a nonresident pharmacy's permit to conduct business in this State and within 30 days after a change of office location or after the addition or removal of a principal corporate officer or a pharmacist;

(2) certify that it complies with all lawful directions and requests for information from regulatory or licensing agencies of the state in which it is licensed and that it will comply with all such requests made by the Board pursuant to this chapter. The nonresident pharmacy shall maintain at all times a valid license, permit, or registration to operate the pharmacy, which complies with the laws of the state in which it is physically located. The nonresident pharmacy shall maintain patient profiles in compliance with Board regulations, shall comply with the provisions of §2549 of this chapter, and shall provide pertinent patient information. Prior to being issued a permit, the nonresident pharmacy must provide the Board with a copy of its most recent inspection report and, thereafter, must provide the Board with inspection reports within 60 days after receipt from the regulatory licensing agency of the state in which the nonresident pharmacy is physically located;

(3) certify that it maintains its records of prescription drugs dispensed to Delaware patients in a way that the records are readily retrievable from the records of drugs dispensed to other patients;

(4) provide a local or a toll-free telephone service during its regular hours of operation, but not less than 6 days per week for a minimum of 40 hours per week, to facilitate communication between patients in this State and pharmacists at the

nonresident pharmacy who have access to patient records. The toll-free telephone number must appear on the label affixed to each container of prescription drugs dispensed to patients in this State;

(5) pay the permit application or renewal fee for a nonresident pharmacy as set by the Board pursuant to §2511 of this chapter.

(b) The Board shall report any disciplinary action it takes against a nonresident pharmacy to the Board in the state where the pharmacy is physically located.

§2538. Nonresident pharmacies: Violations; penalties.

(a) The Board may suspend or revoke the permit to conduct business in this State of a nonresident pharmacy permit holder who violates federal law or any state's law, any of the conditions of the permit, or any of the rules or regulations adopted by the Board. The Board may impose an administrative penalty of not more than $50 for each day a violation occurs and/or continues.

(b) A person who operates a pharmacy located outside the State and delivers in any manner a prescription drug into the State without having obtained a permit to conduct business in this State pursuant to this chapter commits the offense of operating a nonresident pharmacy without a permit and may be fined not more than $50 for each day that the offense occurs and/or continues.

Subchapter IV. Pharmaceutical Establishments other than Pharmacies

§2540. Requirements for pharmaceutical activities not carried on in a pharmacy.

(a) Drugs, toilet preparations, dentifrices, and cosmetics may not be manufactured, packed, packaged, or distributed within this State unless done so under the personal and immediate supervision of a person approved by the Board after investigation and determination by the Board that the person is qualified by scientific or technical training, education, or experience to perform the duties of supervision that are necessary to protect public health, safety, and welfare.

(b) A person may not operate a pharmaceutical establishment to manufacture, pack, package, or distribute on a wholesale basis to persons other than the ultimate consumer any drugs, toilet preparations, dentifrices, or cosmetics without first obtaining from the Board a permit to operate a pharmaceutical establishment. This subchapter also applies to the activities of a reverse distributor who acts as an agent for a person permitted to operate a pharmaceutical establishment by receiving, inventorying, and managing the disposition of outdated or otherwise nonsalable drugs. A permit issued pursuant to this subchapter must be available for inspection by authorized persons.

(c) A person who has a permit to operate a pharmaceutical establishment is subject to Board rules and regulations with respect to the storage and handling of drugs and to the establishment and maintenance of drug distribution records, and must comply with federal, State, and local law.

(d) A permit to operate a pharmaceutical establishment issued pursuant to this subchapter terminates automatically upon a transfer of the controlling interest in the pharmaceutical establishment, upon the termination of the pharmaceutical establishment's legal existence, or upon the discontinuance of business or professional practice.

(e) Nothing in this subchapter may be construed to apply to pharmacies.

§2541. Application and fee for a permit to operate a pharmaceutical establishment.

The application for a permit to operate a pharmaceutical establishment must be made on a form furnished by the Board and must be accompanied by an application fee and/or permit fee established pursuant to §2511 of this chapter. A separate permit is required for each location. The permit must be available for inspection by authorized persons. The Executive Secretary, jointly with the Board president, may issue a temporary, 60-day permit to operate an otherwise qualified pharmaceutical establishment while the application for a permanent permit is pending. The Board may grant one 60-day extension of a temporary permit.

§2542. Renewal of permit.

A permit to operate a pharmaceutical establishment must be renewed biennially in a manner determined by the Division, including the payment of the renewal fee established pursuant to §2511 of this chapter.

§2543. Hearings and appeals to Superior Court.

A person aggrieved by a Board decision made pursuant to this subchapter has the substantive and procedural rights to notice, hearing, and appeal described in §2531 of this chapter.

§2544. Inspections.

Inspections of pharmaceutical establishments are conducted in the same manner as inspections of pharmacies pursuant to §2534 of this chapter and, in addition, include the inspection of and activities related to toilet preparations, dentifrices, and cosmetics.

§2545. Penalties.

(a) The Board may suspend or revoke a permit to operate a pharmaceutical establishment if the permit holder violates federal law or any state's law, any of the conditions of the permit, or any of the rules or regulations adopted by the Board relating to the operation of a pharmaceutical establishment. The Board may impose an administrative penalty of not more than $50 for each day a violation occurs and/or continues to occur.

(b) A person who commits the offense of operating a pharmaceutical establishment without a permit may be fined not more than $50 for each day that the offense occurs and/or continues to occur.

## Subchapter V. Prohibited Acts; Penalties Generally; Enforcement

§2546. Use of certain descriptive titles.

Nothing in this chapter may be construed to prohibit the use of the phrase 'proprietary medicine store,' 'patent medicine store,' or 'health and beauty aids.'

§2547. Entry and inspection; penalty.

A person who commits the offense of hindering in any manner an entry or inspection under§2534 or §2544 of this chapter may be fined not more than $500 for each incident.

§2548. Jurisdiction.

Justices of the Peace have jurisdiction over violations of this chapter.

§2549. Substitution of drugs.

(a) When a pharmacist receives a prescription drug order from a practitioner for a brand or trade name drug, the pharmacist may dispense a therapeutically equivalent drug if the following conditions are met:

(1) the practitioner, in the case of a written prescription, places his or her signature on the signature line along side or above the words 'substitution permitted' pursuant to subsection (c) of this section; or, in the case of a verbal prescription or a verbal prescription reduced to writing, the practitioner states that the substitution may be made; or, in the case of an order written in an institution licensed by the Department of Health and Social Services pursuant to Chapter 10 or 11 of Title 16, the practitioner has given written authorization to fill all prescription drug orders with therapeutically equivalent drugs unless otherwise indicated;

(2) the pharmacist informs the patient or the patient’s adult representative that a therapeutically equivalent drug has been dispensed;

(3) the pharmacist indicates on the prescription and on the prescription label the name of the manufacturer or distributor of the therapeutically equivalent drug substituted unless the practitioner indicates otherwise.

(b) Unauthorized dispensing of a therapeutically equivalent drug in violation of this section is punishable by a fine of not less than $500 nor more than $1,000 or by a term of imprisonment of not less than 30 days nor more than one year, or both a fine and a term of imprisonment.

(c) Every prescription written in this State by a practitioner must be on a prescription form containing a line for the practitioner's signature. Alongside or beneath the signature line the words 'Substitution Permitted' must be clearly printed. Beneath the signature line the following statement must be clearly printed: 'In order for a brand name product to be dispensed, the prescriber must handwrite "Brand Necessary" or "Brand Medically Necessary" in the space below.' A second line to accommodate the above-

mentioned wording must be provided beneath the statement. Prescription forms containing the appropriate signature line and statement must be used by every practitioner in this State who prescribes drugs.

§2550. Emergency refills of non-controlled drugs.

(a) A pharmacist may dispense an emergency supply of a non-controlled drug to a patient whose refill authorization has expired if:

(1) the supply dispensed is the minimum needed for the emergency period;

(2) the pharmacist has attempted to reach the prescribing practitioner and has determined that he or she is not available;

(3) the medication is, in the pharmacist's professional judgment, essential for the continuation of therapy for a chronic condition; and

(4) the prescription was originally dispensed at the pharmacy.

(b) If a pharmacist dispenses an emergency supply of a non-controlled drug pursuant to subsection (a) of this section:

(1) the refill date, quantity dispensed, and pharmacist's initials must appear on the patient profile; and

(2) the prescribing practitioner must be notified either in writing or verbally about the pharmacist's action, and the date of the notification must be documented on the patient profile.

(c) A prescription may be refilled with an emergency supply pursuant to this section only one time.

Subchapter VI. Pharmacy Peer Review.

§2551. Immunity of officials reviewing prescription records and pharmacists' work.

The members of the Board and pharmacists who are members of pharmacy peer review committees whose functions are to review prescription records and pharmacists' work with the view to the validity, quality, and appropriateness of service are jointly and severally immune from liability for any claim or cause of action, civil and criminal, arising from an act or omission if the act or omission complained of was done in good faith and without gross or wanton negligence by any member or members acting individually or jointly in carrying out the responsibilities, authority, duties, powers, and privileges of the offices conferred by law upon them under this chapter or under any other provision of law or under rules and regulations of the Board or committees, with good faith being presumed until proven otherwise and with gross or wanton negligence required to be shown by the complainant.".

Section 2. Rules and regulations adopted pursuant to Chapter 25 of Title 24 which are in effect on the date of the enactment of this Act remain valid to the extent that they are consistent with the provisions of this Act.

Section 3. If any provision of this Act or the application thereof to any person or circumstance is held invalid, such invalidity does not affect other provisions or applications of the Act which can be given effect without the invalid provision or application, and, to that end, the provisions of this Act are declared to be severable.

Section 4. Persons who are members of the Board of Pharmacy on the date of the enactment of this Act may complete their terms of office unless replaced by the Governor.

SYNOPSIS

This bill replaces and updates the current pharmacy chapter of Title 24, including provisions relating to objectives, licensure, examination, reciprocity, complaints, grounds for discipline, hearings, and sanctions. The provision for a counseling option for pharmacists impaired by drug or alcohol use or abuse is maintained, but the section has been amended to provide that if the pharmacist does not agree with the alleged facts, the matter proceeds with a complaint and an opportunity for a hearing.

The bill provides for an inactive license for up to four years and a reentry process for a former licensee who has a longer period of inactivity. Applicants for a license to practice pharmacy must now provide criminal background histories. Because this can be a prolonged process, there is a new provision for a temporary license. There are also provisions for temporary permits for pharmacies and pharmaceutical establishments to expedite the processing of applications.

The bill defines a certified pharmacy technician and a pharmacy technician as supportive personnel who may work only under the direct supervision of a pharmacist. The bill defines "direct supervision"; the rules and regulations of the Board define the activities permitted for both levels of supportive personnel within the statutory parameters. For example, neither a certified pharmacy technician nor a pharmacy technician may ever certify a prescription, perform drug utilization review, counsel patients, or perform other designated activities, because those activities are statutorily limited to being performed only by pharmacists, interns, and certain pharmacy students.

A registration fee is required for any registry maintained by the Board. The Board shall establish in it rules and regulations the method by which a pharmacy must notify consumers that dispensing errors and other complaints can be reported to the Board of Pharmacy. An exemption is added for prescription gases, such as oxygen, to allow the sale by a business that is not a pharmacy under certain conditions. The bill also provides that pharmacies, including nonresident pharmacies and other drug outlets, obtain permits that are renewed biennially. These establishments can be sanctioned by the Board with permit suspension or revocation or with a daily monetary penalty.

Author: Senator Marshall