SPONSOR: Sen. Poore & Rep. Kamela Smith
Sens. Brown, Buckson, Cruce, Hansen, Hocker, Hoffner, Huxtable, Lawson, Lockman, Mantzavinos, Paradee, Pettyjohn, Pinkney, Richardson, Seigfried, Sokola, Sturgeon, Townsend, Walsh, Wilson

DELAWARE STATE SENATE
153rd GENERAL ASSEMBLY

SENATE BILL NO. 180
AS AMENDED BY
SENATE AMENDMENT NO. 1

AN ACT TO AMEND CHAPTER 25, TITLE 24 OF THE DELAWARE CODE RELATING TO THE BOARD OF 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 making deletions as shown by strike through and insertions as shown by underline as follows:

§ 2501. Objectives <u>of the Board</u>.

~~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.~~

<u>(a) The primary objective of the Board of Pharmacy, to which all other objectives and purposes are secondary, is to protect the general public, specifically those individuals who are the direct recipients of services regulated by this chapter, from unsafe practices and from occupational practices which reduce competition or fix the price of services rendered.</u>

<u>(b) The secondary objectives of the Board are to maintain minimum standards of licensee competency and to maintain certain standards in the delivery of services to the public. In meeting these objectives, the Board shall do all of the following:</u>

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(1) Develop standards assuring professional competence.

(2) Monitor complaints brought against licensees regulated by the Board.

(3) Adjudicate at formal hearings.

(4) Promulgate rules and regulations.

(5) Impose sanctions where necessary.

§ 2502. Definitions.

For purposes of this chapter:

(1) "Administer" means the direct application of a prescription drug, whether by injection, inhalation, ingestion, or any other means, to the body of a patient by any of the following:

a. An individual authorized by law to administer the drug, including a practitioner or an authorized agent under a practitioner's supervision.

b. The patient at the direction of a practitioner.

(2) "Biological product" means a biological product as defined in ~~§ 351 of the Public Health Service Act (42 U.S.C. § 262)~~ 42 U.S.C. § 262.

~~(2)~~ (3) "Board~~," "Board of Pharmacy," or "State Board of Pharmacy~~" means the Delaware ~~State~~ Board of Pharmacy.

~~(3)~~ (4) "Certified pharmacy technician" means ~~a person~~ an individual who is certified by the Pharmacy Technician Certification Board (PTCB) or other entity approved by the Board ~~of Pharmacy~~.

~~(4)~~ (5) "Collaborative pharmacy practice" means the practice of pharmacy whereby 1 or more pharmacists provides patient care and drug therapy management services not otherwise permitted to be performed by a pharmacist to patients under a collaborative pharmacy practice ~~agreement(s)~~ agreement with 1 or more practitioners which defines the nature, scope, conditions, and limitations of the services to be provided by the ~~pharmacist(s)~~ pharmacist.

~~(5)~~ (6) "Collaborative pharmacy practice agreement" means a written and signed agreement between 1 or more pharmacists and 1 or more practitioners that provides for collaborative pharmacy practice.

(7) "Compounding" means the preparation, assembling, packaging, or labeling of a drug as the result of a practitioner's prescription or initiative based on the relationship of the practitioner or patient with the pharmacist in the course of professional practice or for the purpose of, or incident to, research, teaching, or chemical analysis and not for sale or dispensing. Compounding also includes the preparation of drugs in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns. All compounding must comply with applicable United States

Pharmacopeia ("USP") standards. Nothing in this title is meant to limit a prescriber's ability under pre-existing law to order a compounded medication for use in the prescriber's practice, as permitted by State and federal law.

(8) "Controlled substance" means any drug designated as such under the Uniform Controlled Substances Act, Chapter 47, Title 16 of the Delaware Code and 21 Code of Federal Regulations, Part 1308.

(9) "Deliver" or "deliver" means the actual, constructive, or attempted transfer of a drug from one person to another, whether or not for consideration.

~~(6)~~ (10) "Direct supervision" means oversight and control by a licensed pharmacist who remains ~~on the premises~~ in the licensed establishment where the pharmacy department is located and is responsible for the work performed by ~~a subordinate~~ support personnel.

~~(7)~~ (11) "Dispense" or "dispensing" means the procedure involving the interpretation of a practitioner's prescription order for a drug or biological, and pursuant to that order the proper selection, measuring, compounding, labeling, and packaging in a proper container for subsequent administration to, or use by, a patient ~~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~~.

~~(8)~~ (12) "Division" means the Division of Professional Regulation.

~~(9)~~ (13) "Drug" means any of the following:

a. A substance recognized as a drug in the Official United States Pharmacopoeia/National ~~Formulary;~~ Formulary.

b. A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of any illness, condition, or disease in humans or ~~animals;~~ animals.

c. A substance, other than food, intended to affect the structure or any function of the body of a human or an ~~animal; or~~ animal.

d. A substance intended for use as a component of any substance specified in paragraph ~~(8)a., b. or c.se~~ paragraph a., b., or c., of this ~~section~~ subsection.

"Drug" does not include devices or their components, parts, or accessories.

~~(10) "Drug outlet" means a pharmacy, an in-state or out-of-state drug wholesaler, a drug manufacturer, a drug distributor, or a nonpharmacy veterinary drug seller.~~

~~(11)~~ (14) "Executive Secretary" means the executive secretary of the ~~Delaware State Board of Pharmacy~~ Board, who ~~shall~~ must be a pharmacist.

~~(12)~~ (15) "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.~~ that identifies drug products approved on the basis of safety and effectiveness by the FDA under the Federal Food, Drug, and Cosmetic Act. This is sometimes referred to as the "Orange Book."

~~(13)~~ (16) "Interchangeable" means a biological product licensed by the Federal Food and Drug Administration pursuant to 42 U.S.C. § ~~262(k)(4)~~ 262.

~~(14)~~ (17) "Intern" means ~~a person~~ an individual who is r~~egisterewd~~ licensed by the Board ~~of Pharmacy~~ and supervised by an approved preceptor and who is completing the practical experience requirement of the Board prior to that person's licensure as a pharmacist.

~~(15)~~ (18) "Internship" or "externship" means a period of practical experience established by ~~Board of Pharmacy~~ the Board's rules and regulations ~~regulation~~ that must be completed by an applicant for a license to practice pharmacy in this State.

(19) "Key personnel" means the designated representative or most senior individual responsible for facility operations, purchasing, and inventory control, the supervisor of such individual, and, if the establishment is not a publicly held company, all principals and owners who directly or indirectly own more than 10% interest in the establishment.

(20) "Label" means written, printed, or graphic matter on the immediate container of a drug.

(21) "Labeling" means the process of affixing a label, including all information required by federal and state statutes or rules and regulations, to a drug container. The term does not include any of the following:

a. The labeling by a manufacturer or distributor of a nonprescription drug or commercially packaged prescription drug.

b. Unit dose packaging.

~~(16)~~ (22) "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.

(23) "Manufacturing" means the production, preparation, propagation, conversion, or processing of a drug, either directly or indirectly, by extraction from a substance of natural origin or independently by a chemical or biological synthesis. The term includes packaging or repackaging a substance or labeling or relabeling a container and promoting and marketing the drug and preparing and promoting a commercially available product from a bulk compound for resale by a person, including a pharmacy or practitioner. The term does not include compounding.

~~(17)~~ (24) "Monitoring drug therapy" means interpreting and analyzing information needed to evaluate the safety and efficacy of drug therapy.

(25) "NABP" means the National Association of Boards of Pharmacy or its successor.

(26) "Outsourcing facility" means a facility that meets all of the following:

a. Is located within the United States of America at one address that is engaged in the compounding of sterile drugs or nonsterile drugs.

b. Has registered as an outsourcing facility with the Food and Drug Administration under § 503B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 353b).

c. Is doing business within or into Delaware.

d. Is licensed with the Board as a wholesaler prior to applying to the Board to become an outsourcing facility.

e. Is licensed with the Board as an outsourcing facility.

~~(18)~~ (27) "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.

(28) "Patient counseling" means communication by a pharmacist, or registered intern or pharmacy student under direct supervision, of pertinent drug information, as specified by the Board's rules and regulations, to a patient or caregiver to improve therapy.

~~(19) "Person" means a natural person or an entity.~~

(29) "Person" means as defined in § 302 of Title 1.

~~(20)~~ (30) "Pharmacist" or "licensee" means an individual licensed by the State pursuant to this chapter to engage in the practice of pharmacy.

~~(21)~~ (31) "Pharmacy" means a place where ~~drugs are compounded or dispensed~~ the practice of pharmacy occurs.

~~(22)~~ (32) "Pharmacy technician" means an individual ~~who is not registered as an intern with the Board of Pharmacy or a certified pharmacy technician~~ working in a pharmacy practice site who, under the immediate supervision of a pharmacist, assists in pharmacy activities, as permitted by the rules and regulations of the Board, that do not require the professional judgment of a pharmacist.

~~(23)~~ (33) "Practice of pharmacy" means the interpreting, evaluating, and dispensing of a practitioner's or prescriber's order. The "practice of pharmacy" includes 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. The "practice of pharmacy" also includes all of the following:

a. Participation in drug utilization ~~and/or~~ or drug regimen reviews.

b. Participation in therapeutic drug selection, substitution of therapeutically equivalent ~~drugproducts~~ drug products.

c. 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.

d. Monitoring drug therapy.

e. 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; screening~~ practitioner. Screening results ~~to~~ must be reported only if outside normal limits.

f. Conducting or managing a pharmacy or other business establishment where drugs are compounded or dispensed.

g. [Repealed.]

h. Administration of injectable medications, biologicals, and immunizations pursuant to a valid prescription from a practitioner or practitioner-approved protocol approved by a physician duly licensed in the State under subchapter III of Chapter 17 of this title or a nurse duly licensed in the State under Chapter 19 of this title. Upon request, a copy of the protocol will be made available to the designated prescriber or prescribers without cost. All vaccine administrations shall be reported to DelVAX within 72 hours of administration. This report to DelVAX shall include the patient's name, the name of the immunization, inoculations, or vaccinations administered, site of injection, lot and expiration, the facility that provided vaccination, and the date of administration, and shall be submitted electronically. Pharmacists, pharmacy interns, and nationally-certified pharmacy technicians who have completed an accredited training program, are currently trained in CPR, and have notified the Delaware Board of Pharmacy, may administer immunizations via a prescriber's order or protocol for patients 3 years of age and older.

i. Dispensing contraceptives or dispensing and administering injectable hormonal contraceptives under Chapter 30O of Title 16.

j. Ordering, performing, and interpreting tests authorized by the Food and Drug Administration, and waived under the federal Clinical Laboratory Improvement Amendments of 1988 [42 U.S.C. § 263a].

k. Initiating drug therapy for health conditions in accordance with § 2525 of this title.

l. Collaborative pharmacy practice in accordance with a collaborative pharmacy practice agreement.

m. Initiating, dispensing, or administering medications for human immunodeficiency virus (HIV) pre-exposure prophylaxis and HIV post-exposure prophylaxis under § 2525A of this title, which includes administering laboratory tests, conducting assessments and consultations, and providing referrals.

~~(24)~~ (34) "Practitioner" or "prescriber" means an individual who is authorized by law to prescribe drugs in the course of professional practice or by collaborative pharmacy practice agreement or research in any state.

~~(25)~~ (35) "Practitioner-dispensed topical medication" means a drug that is all of the following:

a. Dispensed by a practitioner to a patient.

b. A topical antibiotic, anti-inflammatory, dilation, or glaucoma drop or ointment.

c. On stand-by or retrieved from a dispensing system for a specified patient for use during a procedure or visit with the practitioner.

~~(26)~~ (36) "Preceptor" means ~~a licensed pharmacist who is approved by the Board to supervise an intern~~ an individual who is a pharmacist, meets the qualifications under the rules and regulations of the Board, and participates in the instructional training of pharmacy interns and externs.

~~(27)~~ (37) "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)~~ 503B of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 353(b)).

~~(28)~~ (38) "Prescription drug order" or "prescription" means the lawful ~~written or verbal order of a practitioner for a drug~~ authorization for a drug by a licensed practitioner in written, verbal, electronic, or fax format and must include the information set forth in the Board's rules and regulations.

~~(29)~~ (39) "Reference product" means a product as defined by the Federal Food and Drug Administration pursuant to 42 U.S.C. § 262.

~~(30)~~ (40) "State" means the State of Delaware.

~~(31)~~ (41) "Substantially related" means the nature of the criminal conduct, for which the person was convicted, has a direct bearing on the fitness or ability to perform 1 or more of the duties or responsibilities necessarily related to the practice of pharmacy.

~~(32)~~ (42) "Substitution" or "substitute" ~~means~~ means a pharmacist's selection of prescriber authorized generic or therapeutically equivalent prescription medications or, in the case of biologicals, ~~pharmacist~~ a pharmacist's selection of an interchangeable biological product in place of the prescribed product. Generic ~~substitution~~ substitute means a drug that is the same active ingredient, equivalent in strength to the strength written on the ~~prescription~~ prescription, 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~~."

~~(33)~~ (43) "Therapeutically equivalent drug" means a drug which contains the same active ingredient or ingredients 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~~, Evaluations, sometimes referred to as the Orange Book~~.

~~(34) "Use or abuse of drugs" means:~~

~~a. The use of illegal drugs;~~

~~b. The use of prescription drugs without a prescription; or~~

~~c. The excessive use or abuse of alcoholic beverage or drugs to the extent that it impairs a pharmacist's ability to perform the work of a pharmacist.~~

~~(35)~~ (44) "Wholesale distribution" means the distribution of drugs in compliance with federal laws and regulations, including the Drug Supply Chain Security Act, to a person other than a consumer or ~~patient. Wholesale distribution~~ patient but does not include any of the following:

a. The distribution of drugs within a healthcare group-purchasing ~~organization;~~ organization.

b. The transfer of prescription drugs by a pharmacy to another pharmacy to alleviate a temporary ~~shortage;~~ shortage.

c. The dispensing of a drug pursuant to a ~~prescription; or~~ prescription.

d. The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug under any of the following circumstances:

1. By a charitable organization described in § 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. § 501(c)(3)) to a nonprofit affiliate of the charitable organization to the extent permitted by ~~law;~~ law.

2. Among hospitals or other health care entities which are under common ~~control;~~ control.

3. For emergency medical reasons.

~~(36)~~ (45) ~~"Wholesale distributor"~~ "Wholesaler" 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 9 members who are appointed by the ~~Governor and~~ Governor, who are residents of the ~~State.~~ State, and who are comprised as follows:

(1) Six members are pharmacists who have been engaged in the practice of pharmacy in Delaware for at least 5 years and who are representative of the various practice settings in the field of pharmacy.

(2) Three members are public members~~, 1 from each county~~. A public ~~member~~ member:

a. ~~may~~ May not be, nor ever have been, a pharmacist or a member of the immediate family of a ~~pharmacist;~~ pharmacist.

b. ~~may~~ May not be, nor ever have been, employed by a ~~pharmacy;~~ pharmacy.

c. ~~may~~ May not have a material interest in the providing of goods or services to a ~~pharmacy;~~ pharmacy. ~~and may~~

d. May not be, nor ever have been, engaged in an activity directly related to the practice of pharmacy. ~~A public member must~~

e. 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 3 years, and may succeed oneself for 1 additional term; provided, however, that where a member was initially appointed to fill a vacancy, the member may succeed oneself for only 1 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 3 members expire in any 1 year. A person who is a member of the Board on July 24, 2007, may complete that person's own term.~~ Each member is appointed for a term of 3 years and may serve 2 additional, successive terms. Each term of office expires on the date specified in the appointment; however, a member remains eligible to participate in Board proceedings until the Governor replaces that member.

(d) A person who has never served on the Board may be appointed to the Board ~~for 2~~ for 3 consecutive terms; but that person is thereafter ineligible to serve for 2 consecutive appointments. ~~A person who has been twice appointed to the Board or who has served on the Board for 6 years within any 9-year period may not again be appointed to the Board until an interim period of at least 1 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 3 consecutive regular business meetings or who fails to attend at least $^1/_2$ of all regular business meetings during any calendar year is guilty of neglect of duty.

(j) Each member of the Board shall be reimbursed for all expenses involved in each meeting, including travel, and in addition shall receive compensation per meeting attended in an amount determined by the Division in accordance with Del. Const. art. III, § 9.

~~(k) The Pharmacy Regulatory Council shall fall under the authority of the Board of Medical Licensure and Discipline and shall consist of 4 pharmacists and 1 member of the public appointed by the Board of Pharmacy, and 2 physicians appointed by the Board of Medical Licensure and Discipline. One of the physicians shall serve as chairperson of the Council. Regulations applicable to activities described in § 2502(21)h. of this title must be approved by the Council.~~

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

(a) The Board shall elect annually from its membership a President and a Vice President. Each officer serves for 1 year and may not succeed oneself for more than 2 consecutive terms.

(b) The Board shall hold regularly scheduled business meetings at least 6 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 1 year. An officer may not serve for more than 3 consecutive terms in the same office.~~

(c) The Executive Secretary, who is an ex officio member of the Board without a vote, is responsible for the performance of the regular administrative functions of the Board and other duties as the Board may direct.

(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 5 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~~ Division ~~shall~~ must 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.~~ Powers and duties.

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

(1) Promulgate rules and regulations not inconsistent with § 2501(a) of this title in accordance with the procedures specified in the Administrative Procedures Act ~~[Chapter 101 of Title 29];~~ in Chapter 101 of Title 29.

(2) ~~Designate the application form to be used by all applicants and to process~~ Process all applications pursuant to this ~~chapter;~~ 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~~ an individual applying for a license to practice ~~pharmacy;~~ pharmacy.

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

(5) Grant a license to ~~and renew the license of~~ each ~~person~~ individual 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;~~ licensure and renew licenses as appropriate.

(6) Evaluate applications and issue licenses to pharmacies and other establishments that meet the qualifications set forth in this chapter.

~~(6)~~ (7) Establish by regulation continuing education standards required for license ~~renewal;~~ renewal.

(8) Perform random audits of continuing education credits submitted by licensees for license renewal.

~~(7)~~ (9) 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;~~ chapter.

~~(8) Maintain a registry of interns;~~

~~(9)~~ (10) 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 § 8735 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;~~ complaint.

~~(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 by the Director of the Division of Professional Regulation 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;~~ 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;~~ imposed.

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

~~(14)~~ (13) 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;~~ joined.

~~(15)~~ (14) Regulate the sale and dispensing of drugs and other materials, including the right to seize any drugs and other materials found by the Executive Secretary or other agent of the Board to be detrimental to the public health, safety, or welfare, in accordance with ~~Chapter 33 of Title 16;~~ § 3315 of Title 16.

~~(16)~~ (15) Regulate the purity and quality of drugs and other materials within the practice of ~~pharmacy;~~ pharmacy.

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

~~(18) Appoint public members and pharmacists to the Pharmacy Regulatory Council of the Board of Medical Licensure and Discipline.~~

(17) Seize any drugs found by the Board or Executive Secretary to constitute an imminent danger to the public health and welfare.

(18) Establish by rule and regulation minimum specifications for record keeping, prescription and patient profile record maintenance, monitoring of drug therapy, and pharmacy practice sites including the physical premises, technical equipment, environment, supplies, personnel, and procedures for the storage, compounding, and dispensing of drugs.

(19) Inspect any pharmacy for the purpose of determining if any provision of the laws governing the legal distribution of drugs or the practice of pharmacy are being violated.

(20) Appoint advisory committees as the Board determines to be appropriate.

(21) Promulgate a Code of Ethics by rule and regulation.

(b) The Board of Pharmacy shall promulgate regulations specifically identifying those ~~crimes,~~ crimes which are substantially related to the practice of pharmacy.

~~(c) 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 of pharmacists and interns

§ 2507. License required.

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

(b) No ~~person~~ individual who has not been issued a certificate as a pharmacist or who is not a pharmacy intern, or a pharmacy student participating in an approved College of Pharmacy coordinated practical experience program under the direct supervision of a licensed pharmacist, within the meaning of this chapter, ~~shall~~ 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 prescriber concerning prescription drug order interpretation or therapy modification. Other responsibilities may be delegated to a certified pharmacy technician or pharmacy technicians who are under the direct supervision of a pharmacist.

(c) It is unlawful for ~~a person~~ an individual to practice pharmacy in this State if the ~~person's~~ individual'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 $500 nor more than $1000, and for a second or subsequent conviction, a fine of not less than $1000 nor more than $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 the applicant 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 the applicant 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) The Board shall determine whether an applicant whose conduct or status is described in 1 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, and shall conduct its analysis of criminal history records consistent with the provisions of § 8735(x) of Title 29.~~

~~(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 has a criminal conviction record or a pending criminal charge related to a crime that is substantially related to the practice of pharmacy. However, after a hearing or review of documentation and consideration of the factors set forth in § 8735(x)(3) of Title 29, the Board by an affirmative vote of a majority of the quorum, shall waive this paragraph (c)(3), if it finds that granting a waiver would not create an unreasonable risk to public safety.~~

~~a.-d. [Repealed.]~~

(a) An applicant who is applying for licensure as a pharmacist under this chapter shall submit evidence, verified by oath and satisfactory to the Board, that the applicant meets all of the following requirements:

(1) 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 was educated outside of the United States or its territories, has met the education requirements set forth in the Board's rules and regulations.

(2) Has obtained practical experience as an intern in the practice of pharmacy during or after attendance at a school or college of pharmacy, under such terms and conditions as set forth in the Board's rules and regulations.

(3) Has received a passing score on the North American Pharmacist Licensure Examination (NAPLEX) as developed and approved by NABP or its successor.

(4) Has received a passing score on a jurisprudence examination as set forth in the Board's rules and regulations.

(5) Has not receive an administrative penalty regarding the practice of pharmacy, including 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. The Board may, after a hearing or review of documentation, determine whether such administrative penalty is grounds to deny licensure.

(6) Does not have a current condition that impairs the applicant's judgment or adversely affects the applicant's ability to practice safely and in a competent, ethical, and professional manner.

(7) The applicant does not have a criminal conviction record or a pending criminal charge related to a crime that is substantially related to the practice of pharmacy. However, after a hearing or review of documentation and consideration of the factors set forth in § 8735(x)(3) of Title 29, the Board by an affirmative vote of a majority of the quorum, may waive this paragraph if it finds that granting a waiver would not create an unreasonable risk to public safety.

(b) An applicant for licensure as an intern must meet the following requirements:

(1) The applicant must submit an "Application for Registration of Internship" after entering the first professional year at a school or college of pharmacy accredited by the American Council on Pharmaceutical Education. The application must include an "Affidavit of Class Standing" form and an "Affidavit of Preceptor" form. The application and requisite forms are set forth by the Board or the Division.

(2) If the applicant was educated outside of the United States or its territories, the applicant must meet the education requirements set forth in the Board's rules and regulations.

(3) The applicant has not received an administrative penalty regarding the practice of pharmacy, including 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. The Board may, after a hearing or review of documentation, determine whether such administrative penalty is grounds to deny licensure.

(4) Does not have a current condition that impairs the applicant's judgment or adversely affects the applicant's ability to practice safely and in a competent, ethical, and professional manner.

(5) The applicant does not have a criminal conviction record or a pending criminal charge related to a crime that is substantially related to the practice of pharmacy. However, after a hearing or review of documentation and consideration of the factors set forth in § 8735(x)(3) of Title 29, the Board by an affirmative vote of a majority of the quorum, may waive this paragraph if it finds that granting a waiver would not create an unreasonable risk to public safety.

~~(d)~~ (c) An applicant shall submit fingerprints and other necessary information in order to obtain a report of the individual's entire criminal history record from the State Bureau of Identification and from the Federal Bureau of Investigation pursuant to Federal Bureau of Investigation appropriation of Title II of Public Law 92-544 (28 U.S.C § 534). If the applicant does not have a criminal history record, the applicant shall cause to be submitted a statement from each agency that the agency has no record of criminal history information relating to the applicant. The State Bureau of Identification ~~shall be~~ is the intermediary for the purpose of this subsection and the Board, or its designee, ~~shall be~~ 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.

~~(e)~~ (d) 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.

~~(f)~~ (e) If the Board refuses to accept, or rejects, an application and the applicant believes that the Board acted without ~~justification,~~ 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 or license transfer.

~~(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:~~

(a) Upon payment of the appropriate fee and submission of an application, the Board shall grant a license to each applicant who presents proof of current licensure, in good standing, in another state, the District of Columbia, or territory of the United States and who, in addition:

~~(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;~~

(1) Meets the criteria for licensure in good standing as defined in § 2508(a)(5)-(7) in all states in which the applicant is or was licensed.

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

(3) Has received a passing score on a jurisprudence examination as set forth in the Board's rules and regulations.

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

(5) Has submitted fingerprints and other necessary information in order to obtain a report of the individual's entire criminal history record from the State Bureau of Identification and from the Federal Bureau of Investigation pursuant to Federal Bureau of Investigation appropriation of Title II of Public Law 92-544 (28 U.S.C § 534). If the applicant does not have a criminal history record, the applicant shall cause to be submitted a statement 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.

~~(b) The provisions of § 2508(c), (d), (e), and (f) of this title 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)~~ (b) A reciprocal applicant is not required to obtain the practical experience ~~pursuant to § 2508(b)~~ required under § 2508(a) of this title.

§ 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; reinstatement; inactive status.

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

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

(c) A licensee who has allowed that licensee's license to lapse for more than 1 year but for less than 4 years may renew such lapsed license upon completion of all of the following:

(1) Payment of a late fee established by the Division.

(2) Providing proof that the licensee has met any continuing education requirements established by the Board.

(3) Submission of fingerprints and other necessary information in order to obtain a report of the individual's entire criminal history record from the State Bureau of Identification and from the Federal Bureau of Investigation.

(4) Review of NABP clearinghouse for discipline in other jurisdictions.

(d) A licensee who has allowed that licensee's license to lapse for longer than 4 years may reinstate such license upon completion of all of the following:

(1) Payment of a late fee established by the Division.

(2) Providing proof that the licensee has met any continuing education requirements established by the Board.

(3) Submission of fingerprints and other necessary information in order to obtain a report of the individual's entire criminal history record from the State Bureau of Identification and from the Federal Bureau of Investigation.

(4) Review of NABP clearinghouse for discipline in other jurisdictions.

(5) Proof of re-taking and passing the MPJE.

(e) Any licensee, upon written request, may be placed in an inactive status for up to 4 years, and the licensee may reactivate the license after meeting all of the following criteria:

(1) Providing the Board with written notification that the licensee intends to reactivate the license.

(2) Satisfying all the continuing education requirements set forth in the Board's rules and regulations.

(3) Paying the appropriate renewal fee.

(4) Submitting fingerprints and other necessary information in order to obtain a report of the individual's entire criminal history record from the State Bureau of Identification and from the Federal Bureau of Investigation.

(5) Review by the Division or the Board of the NABP clearinghouse for discipline in other jurisdictions.

(f) If a licensee who has been placed on inactive status under subsection (e) of this section fails to reactivate that license within 4 years of being placed on inactive status under subsection (e) of this section, the individual must reapply for licensure and re-take and pass the MPJE.

~~(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 shall not renew any license to any applicant unless and until the applicant has offered proof that the applicant has completed continuing professional education relating to:~~

~~(1) The distribution, dispensing or delivery of controlled substances, as defined in this chapter; or~~

~~(2) The detection and recognition of symptoms, patterns of behavior, or other characteristic of impairment and dependency resulting from the abusive or illegal use of controlled substances; and~~

~~(3) Other topics as the Board deems appropriate.~~

~~(d) The Board, in its rules and regulations, shall determine the period of time within which a licensee may renew that licensee's own license, notwithstanding the fact that the licensee failed to renew that licensee's own license on or before the designated renewal date; provided, however, that the period of time may not exceed 1 year beyond the designated renewal date.~~

~~(e) 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 that licensee's own 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.~~

~~(f) If a licensee is on inactive status for more than 4 years, that licensee may be relicensed, but only by following the reentry process established by the Board in its rules and regulations.~~

§ 2513. ~~Temporary license.~~

~~The Executive Secretary 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 1 90-day extension of a temporary license.~~

[REPEALED]

§ 2514. Complaints.

(a) All complaints received by the Division must be investigated in accordance with § 8735 of Title 29.

(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 title~~ this Chapter, the Board shall request that ~~the Office of~~ the Attorney General issue a cease and desist order and take any other further appropriate action.

§ 2515. Grounds for discipline.

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

(1) ~~Has employed~~ Engaged in 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 be represented as a ~~pharmacist;~~ pharmacist.

(2) ~~Has illegally~~ Illegally, incompetently, or negligently practiced ~~pharmacy;~~ pharmacy.

(3) ~~Has been convicted~~ Was convicted of a crime that is substantially related 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;~~ conviction.

(4) ~~Has used or abused drugs, as defined in § 2502(32) of this title, in the past 2 years;~~ Has a current condition that impairs the pharmacist's judgment or adversely affects the pharmacist's ability to practice safely and in a competent, ethical, and professional manner.

(5) ~~Has engaged~~ Engaged in an act of consumer fraud or deception, engaged in the ~~restrain~~ restraint of competition, or participated in price-fixing ~~activities;~~ activities.

(6) ~~Has violated~~ Violated a lawful provision of this chapter or any lawful regulation established ~~hereunder;~~ hereunder.

(7) ~~Has had~~ Had that pharmacist's own license to practice pharmacy suspended or revoked or ~~has been~~ was 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 1 or more of the acts listed in this subsection. Every person licensed to practice pharmacy in this State ~~is deemed to have given consent~~ consents 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~~ waives all objections to the admissibility of previously adjudicated evidence of the acts or offenses which underlie license suspension or revocation or other disciplinary ~~action;~~ action.

(8) ~~Has failed~~ Failed to notify the Board that the pharmacist's license to practice pharmacy in another jurisdiction ~~has been~~ was subject to discipline, or ~~has been~~ was surrendered, suspended, or revoked; or that the licensee has been convicted of a crime that is substantially related to the practice of pharmacy. A certified copy of the record of disciplinary action, or of the surrender, suspension, or revocation of the license is conclusive evidence thereof. A copy of the record of conviction certified by the clerk of the court entering the conviction is conclusive evidence of ~~conviction; or~~ conviction.

(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.

(10) Violated the Board's Code of Ethics as adopted in the Board's rules and regulations.

(b) Subject to the provisions of this chapter and subchapter IV of Chapter 101 of Title 29, the Board ~~shall~~ may not ~~restrict, suspend, or revoke~~ discipline 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 title:

(1) Issue a letter of ~~reprimand to the licensee;~~ reprimand.

~~(2) Censure the licensee;~~

~~(3)~~ (2) Place the licensee on probationary status and require the licensee to do any of the following:

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

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

~~(4)~~ (3) Suspend the license of the ~~licensee;~~ licensee.

~~(5)~~ ~~(4)~~ ~~Revoke~~ Permanently revoke the license of the ~~licensee;~~ licensee.

~~(6)~~ (5) Impose an administrative penalty, not to exceed ~~$500~~ $10,000 for ~~each~~ a first-time violation. Any subsequent violations may be subject to an administrative penalty, not to exceed $50,000 for each such violation.

(b) The Board may withdraw or reduce conditions of probation imposed ~~pursuant to~~ under paragraph ~~(a)(3)~~ (a)(2) of this ~~section,~~ 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 title is filed with the Board ~~pursuant to~~ under § 8735(h) of Title 29, ~~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~~ the hearing must be noticed and conducted 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)~~ (b) 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 is mailed to that licensee~~, 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 § 10144 of Title 29.

~~§ 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 that licensee's continuing education requirements may also be required.~~

§ 2519. Temporary suspension pending hearing.

In the event of a formal or informal complaint concerning the activity of a licensee that presents a clear and immediate danger to the public health, safety or welfare, the Board may temporarily suspend the person's license, pending a hearing, upon the written order of the Secretary of State or the Secretary's designee, with the concurrence of the Board chair or the Board chair's designee. An order temporarily suspending a license may not be issued unless the person or the person's attorney received at least 24 hours' written or oral notice before the temporary suspension so that the person or the person's attorney may file a written response to the proposed suspension. The decision as to whether to issue the temporary order of suspension will be decided on the written submissions. An order of temporary suspension pending a hearing may remain in effect for no longer than 60 days from the date of the issuance of the order unless the temporarily suspended person requests a continuance of the hearing date. If the temporarily suspended person requests a continuance, the order of temporary suspension remains in effect until the hearing is convened and a decision is rendered by the Board. A person

whose license has been temporarily suspended pursuant to this section may request an expedited hearing. The Board shall schedule the hearing on an expedited basis, provided that the Board receives the request within 5 calendar days from the date on which the person received notification of the decision to temporarily suspend the person's license.

~~§ 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 title, the Executive Secretary and the president, or his or her designee, 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 and the president, or his or her designee, 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 and the president, or his or her designee, the violation must be handled in the same manner as a violation of § 2515 of this title 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 and the president, or his or her designee. 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 that pharmacist's 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~~ Prescription labeling; exemptions

§ 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~~ must ensure that a label is affixed to every container in which a drug is ~~dispensed a~~ dispensed. The label ~~containing~~ must contain the ~~following information:~~ information required by the Board's rules and regulations.

~~(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) ~~Practitioners who, for good reason, do not wish to reveal the name or strength of the drug prescribed to the patient shall so inform the pharmacist by a notation on the face of the prescription. However, practitioners who sell drugs directly to patients shall label all such drugs in accordance with this section with the exception of a prescription number.~~ Practitioners who sell or dispense drugs directly to patients ~~shall~~ must label all drugs or provide a document ~~including~~ that includes all of the following information:

(1) The patient's full ~~name;~~ name and address.

(2) The date the drugs were dispensed to the ~~patient;~~ patient.

(3) The practitioner's ~~name;~~ name, office phone number, and address.

(4) The practitioner's DEA number in the case of a controlled substance.

(5) Name, strength, dosage form, and quantity (or Stop Date) of drug and route of administration if other than oral form of drug is prescribed.

(6) Renewals authorized.

~~(4)~~ (7) The practitioner's directions.

(d) No pharmacist ~~shall~~ may fail to dispense a prescription because it is not clearly written ~~and/or~~ or lacks information required by this title without first making a reasonable effort to contact the practitioner who issued the prescription to gather the clear and complete information.

§ 2523. Exemptions.

Nothing in this chapter may be construed to prevent any of the following:

(1) 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;~~ State.

(2) A pharmacy intern, or a pharmacy student participating in an approved College of Pharmacy coordinated practical experience program under the direct supervision of a licensed pharmacist, from performing the functions permitted under the rules and regulations of the Board and not inconsistent with this chapter.

~~(2)~~ (3) A pharmacy technician or certified pharmacy technician from performing under the direct supervision of a pharmacist the delegated functions permitted under the rules and regulations of the Board and not inconsistent with this ~~chapter;~~ chapter.

~~(3)~~ (4) A practitioner licensed under the laws of this State to practice within the scope of that practitioner's ~~license;~~ license.

~~(4)~~ (5) The selling at retail of over-the-counter ~~products;~~ products.

~~(5)~~ (6) A business not licensed as a pharmacy to sell gases that are used for medicinal purposes and which require a prescription, provided that:

a. The business is registered with the ~~Board;~~ Board.

b. The sale is authorized by a ~~written~~ written, electronic, or fax order or by a verbal order reduced to writing from a ~~practitioner;~~ licensed practitioner.

c. The record of the ~~written~~ written, electronic, or fax order, or ~~order or of~~ the verbal order reduced to writing is maintained on the premises of the business for at least ~~2 years; and~~ 3 years.

d. The gas product is stored and dispensed according to requirements established by the Board.

~~(6)~~ (7) The sale of noncontrolled 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~~ written, electronic, or fax order or by a verbal order reduced to writing from a licensed veterinarian.

~~(7) A pharmacist in this State from dispensing a valid noncontrolled prescription drug pursuant to a prescription received via electronic transmission from a practitioner's office to the prescription department of the dispensing pharmacy.~~

(8) Pharmacist selection of appropriate dosage forms, concentrations, equivalent strengths or routes of administration of medications.

(9) a. A practitioner from dispensing the unused portion of practitioner-dispensed topical medication to the patient upon discharge or the conclusion of the visit if the practitioner-dispensed topical medication is labeled consistent with the requirements under § 2522 of this title and required for continuing treatment. If the practitioner-dispensed topical medication is used in an operating room or emergency department, the practitioner must counsel the patient on the proper use and administration of the drug.

b. A practitioner who fails to comply with paragraph (9)a. of this section is subject to disciplinary sanction under this title.

~~§ 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.~~

§ 2525. Testing, screening, and treatment of health conditions.

(a) Pursuant to a statewide written protocol approved by the Division of Public Health, a pharmacist may order, test, screen, and treat health conditions that include all of the following:

(1) Influenza.

(2) Group A streptococcus pharyngitis.

(3) SARS-COV-2 or other respiratory illness, condition, or disease.

(4) Lice.

(5) Skin conditions, including ringworm and athlete's foot.

(6) Other emerging and existing public health threats identified by the Division of Public Health if permitted by an order, rule, or regulation.

(b) A pharmacist who orders, tests, screens, or treats health conditions under this section may use any test that may guide clinical decision making that is waived under the federal Clinical Laboratory Improvement Amendments of 1988 [42 U.S.C. § 263a], or the federal rules adopted thereunder, or any established screening procedure that is established via a statewide protocol.

(c) A pharmacist may delegate the administrative and technical tasks of performing a test waived by the federal Clinical Laboratory Improvement Amendments of 1988 to an intern or pharmacy technician acting under the supervision of the pharmacist.

~~(d) Prohibit the denial of reimbursement under health benefit plans for services and procedures performed by a pharmacist that are within the scope of the pharmacist's license and would be covered if the services or procedures were performed by a physician, an advanced practice nurse, or physicians assistant.~~

§ 2525A. Human immunodeficiency virus (HIV) pre-exposure prophylaxis and HIV post-exposure prophylaxis.

(a) Pursuant to a statewide written protocol approved by the Division of Public Health, a pharmacist may initiate, dispense, or administer medications for HIV pre-exposure prophylaxes and for HIV post-exposure prophylaxis, which includes administering laboratory tests, conducting assessments and consultations, and providing referrals,

(b) When initiating therapy for and administering or dispensing HIV pre-exposure prophylaxis or HIV post-exposure prophylaxis under a statewide protocol, a pharmacist must complete a training program approved by the Board within 1 year prior to first-time initiating therapy and administering or dispensing HIV pre-exposure prophylaxis or HIV post-exposure prophylaxis. The training program must include information about all of the following:

(1) Financial assistance programs for HIV pre-exposure prophylaxis and HIV post-exposure prophylaxis.

(2) Relevant federal guidelines regarding HIV pre-exposure prophylaxis or HIV post-exposure prophylaxis.

(c) When initiating therapy for and administering or dispensing HIV pre-exposure prophylaxis or HIV post-exposure prophylaxis to a new patient, a pharmacist may not allow the patient to waive consultation for HIV pre-exposure prophylaxis or HIV post-exposure prophylaxis.

(d) HIV pre-exposure prophylaxis. — (1) Under a statewide protocol, a pharmacist may dispense between a 30-day and 60-day supply of HIV pre-exposure prophylaxis if ~~the~~ all of the following apply:

a. The patient is HIV-negative as documented by a negative HIV test result obtained within the previous 7 days from a test approved by the U.S. Food and Drug Administration.

b. The patient does not report any of the following:

1. Any signs or symptoms of acute HIV infection on a self-reported checklist of acute HIV infection signs and symptoms.

2. Usage of any contraindicated medication.

c. The pharmacist provides counseling to the patient on the ongoing use of HIV pre-exposure prophylaxis, which must include education about all of the following:

1. Side effects.

2. Safety during pregnancy and breastfeeding.

3. Adherence to recommended dosing.

4. The importance of timely testing and treatment for HIV, renal function, hepatitis B, hepatitis C, sexually-transmitted infections, and pregnancy for individuals of childbearing capacity.

5. The requirement for subsequent prescriptions for HIV pre-exposure prophylaxis issued by a primary-care provider.

d. To the extent possible, the pharmacist documents the services provided by the pharmacist in the patient record system shared with the primary-care provider.

(2) If the test results from a test under paragraph (d)(1)a. of this section are not sent directly to the pharmacist, the pharmacist must verify the test results.

(3) If the patient tests positive for HIV infection from a test under paragraph (d)(1)a. of this section, the pharmacist shall do the following and document in the patient's record which of the following was done:

a. If the patient has a primary-care provider, send the result of the test to the patient's primary-care provider after obtaining written permission from the patient to do so.

b. If the patient does not give written permission under paragraph (d)(3)a. of this section or if the patient does not have a primary-care provider, provide a list of providers and clinics in the region that provide care for patients with HIV.

(4) If the patient does not provide evidence of a negative HIV test under paragraph (d)(1)a. of this section, the pharmacist shall initiate and administer an HIV test and interpret the test results prior to initiating any treatment under this subsection.

(e) HIV post-exposure prophylaxis. — (1) Under a statewide protocol, a pharmacist may dispense a course of HIV post-exposure prophylaxis if the pharmacist does all of the following:

a. Screens the patient and determines that the exposure to HIV occurred within the previous 72 hours.

b. Provides HIV testing or determines that the patient is 1 of the following:

1. Willing to undergo HIV testing consistent with federal guidelines.

2. Unwilling to undergo HIV testing but otherwise eligible for HIV post-exposure prophylaxis.

c. Provides counseling to the patient on the ongoing use of HIV post-exposure prophylaxis, which must include education about all of the following:

1. Side effects.

2. Safety during pregnancy and breastfeeding.

3. Adherence to recommended dosing.

4. The importance of timely testing and treatment for HIV, renal function, hepatitis B, hepatitis C, sexually-transmitted infections, and pregnancy for individuals of childbearing capacity.

5. The availability of HIV pre-exposure prophylaxis for a person who is at a substantial risk of acquiring HIV.

d. To the extent possible, documents the services provided by the pharmacist in the patient record system shared with the primary-care provider.

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 1 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 1 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 title.~~

§ 2528. Requirements for and issuance of ~~permit~~ license.

(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:~~ Upon submission of an application, payment of the appropriate fee, and fulfillment of all standards set by the Board by rules and regulations, the Board shall issue a license when the applicant provides evidence, verified by oath, that the pharmacy meets all of the following requirements:

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

(2) The pharmacy will be managed by a pharmacist-in-charge who is licensed to practice pharmacy in the ~~State~~ State. ~~and who will serve as a pharmacist-in-charge in only that pharmacy;~~ Each pharmacy may only have 1 pharmacist-in-charge, and that pharmacist-in-charge may only be a pharmacist-in-charge of 1 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:~~ meet the requirements set forth in the Board's rules and regulations.

~~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~~ must comply with pharmacy, controlled substance, and other applicable statutes and ~~regulations;~~ rules and regulations.

(5) The pharmacy ~~will~~ must provide conspicuous notice to consumers that the Board of Pharmacy is the contact agency for reporting unresolved medication errors.

~~(b)~~ (6) ~~A permit to operate a pharmacy may not be issued or renewed unless the pharmacy is~~ The pharmacy will be equipped with proper reference materials and professional and technical equipment as provided in the Board's rules and regulations.

(7) The pharmacy will be inspected and approved by an agent of the Board prior to opening.

(8) The pharmacy has not obtained a license by misrepresentation or fraud.

(9) The pharmacy has not been disciplined by a regulatory agency.

~~(c) The Executive Secretary 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 1 60-day extension of a temporary permit.~~

(b) As set forth in the Board's rules and regulations, the applicant must designate the specific type of pharmacy license requested.

§ 2529. Renewal of ~~permit~~ license; closing of pharmacy.

(a) A ~~permit~~ license 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 title~~.

(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 1 year beyond the designated renewal date.

(c) ~~A permit~~ As set forth in the Board's rules and regulations, a license to operate a pharmacy terminates automatically upon a ~~transfer of the controlling interest in the pharmacy, upon~~ a change in ownership, the termination of the legal existence of the pharmacy, or ~~upon~~ the discontinuance of business or professional practice.

(d) The temporary or permanent 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~~ Grounds for discipline of a pharmacy license.

~~(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.~~

(a) A license is subject to the disciplinary actions established in § 2531A if, after a hearing, the Board finds that the licensee has done one or more of the following acts:

(1) The pharmacy is not being operated according to the Board's laws or rules and regulations.

~~(b)~~ (2) ~~The Board may suspend or revoke a permit to operate a pharmacy if the~~ 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.

(3) The pharmacy has been disciplined by a regulatory agency.

(4) The pharmacy has obtained a license by misrepresentation or fraud.

(5) The pharmacy has refused access to the pharmacy or pharmacy records to an agent of the Board who seeks access for the purpose of conducting an inspection or investigation.

~~(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~~ licenses.

(a) If the Board intends not to issue a ~~permit~~ license or intends to ~~suspend or revoke~~ discipline a ~~permit~~ license, the Board shall give written notice to the applicant or ~~permit holder~~ licensee of the intended action and the reasons therefor. The applicant or ~~permit holder~~ licensee has at least 10 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)~~ (b) If an applicant or ~~permit holder~~ licensee is in disagreement with the decision of the Board, the applicant or

~~permit holder~~ licensee may appeal the Board's decision to the Superior Court within 30 days of the ~~postmarked~~ date of mailing ~~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 § 10144 of Title 29.

§ 2531A. Disciplinary sanctions.

(a) The Board may impose any of the following sanctions, individually or in combination, when it finds that a pharmacy has violated any condition or committed any violation set forth in § 2530 of this title:

(1) Issue a letter of reprimand.

(2) Place a pharmacy on probationary status and require the pharmacy to:

a. Report regularly to the Board upon the matters which are the basis of the probation.

b. Limit all practice and professional activities as prescribed by the Board.

(3) Suspend any pharmacy's license.

(4) Permanently revoke any pharmacy's license.

(5) Impose a monetary penalty not to exceed $250,000 for each violation and not more than $250,000 for each day of a continuing violation.

§ 2532. Pharmacy records.

(a) ~~A suitable book or file in which the original~~ The pharmacy must maintain a record of every prescription ~~compounded or dispensed~~ dispensed or compounded at the pharmacy ~~must be preserved~~ for a period of not less than 3 years. The ~~book or file of original~~ record of prescriptions must at all times be ~~open to~~ available for inspection by authorized agents of the Board.

(b) Upon request by a person for such person's pharmacy records, a pharmacy shall provide such records~~, in hard copy paper form (unless such person agrees to another form),~~ as soon as is reasonably possible, but by no later than 15 business days after such person has made the request to the pharmacy, unless an emergency or a medical condition dictates that such records should be produced immediately. Nothing herein ~~shall~~ may be construed as limiting or lessening the pharmacy's obligations to maintain confidentiality of such records and the pharmacy ~~shall~~ must follow such pharmacy's standard procedures to ensure maintenance of confidentiality of such records.

§ 2533. Prescription department.

The prescription department must meet the requirements of the Board's rules and regulations.

~~(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 may enter and ~~inspect~~ inspect, during business ~~hours~~ 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 acting pursuant to subsection (a) of this section may do any of the following:

(1) ~~may inspect~~ Inspect and copy records required by this chapter to be ~~kept;~~ kept.

(2) ~~may inspect~~ Inspect within reasonable limits and in a reasonable manner the premises and all pertinent equipment, finished and unfinished materials, containers, and labeling found ~~therein;~~ therein.

(3) ~~may inspect~~ Inspect other things therein, including records, files, papers, processes, controls, and facilities relating to a violation of this ~~chapter;~~ chapter.

(4) ~~and may make~~ Make an inventory of the stock of drugs therein and obtain samples of drugs and other substances.

(c) All information gathered under this section is to be kept confidential in accordance with all federal and state laws governing privacy.

§ 2535. Nonresident pharmacies.

(a) A pharmacy located ~~outside the State~~ in another state, the District of Columbia, or a territory of the United

States which delivers, dispenses, or distributes ~~in any manner~~ by any method a prescription drug to ~~a patient~~ an ultimate user in the State ~~is a nonresident pharmacy and must obtain a permit to conduct business in this State~~ must obtain a nonresident pharmacy license from the Board. A nonresident pharmacy may not deliver in any manner a prescription drug to ~~a patient~~ an ultimate user in this State unless it has a ~~permit~~ license to do so issued by the Board.

(b) If a nonresident pharmacy which has a ~~permit~~ license issued pursuant to this section delivers in any manner a prescription drug and the prescription drug is not personally hand delivered to the ~~patient~~ ultimate user, a written notice must be placed in theshipping 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~~ humidity.

(2) A local or a toll-free telephone service is available, staffed by a registered pharmacist, to answer questions about the prescription drug.

(c) Upon submission of an application, payment of the appropriate fee, and fulfillment of all standards set forth in the Board's rules and regulations, the Board shall issue a license when the applicant provides evidence, verified by oath, that the pharmacy meets all of the following requirements:

(1) Holds a license in good standing an all states or jurisdictions where the applicant is or was licensed.

(2) Has not obtained a license by misrepresentation or fraud.

(3) Has not been disciplined by a regulatory agency.

(4) Submits the most recent inspection report, that is approved by the Board, and satisfies all of the following requirements:

a. The inspection occurred when the pharmacy was in operation.

b. The inspection addresses all aspects of the pharmacy's business that will be utilized in this State.

c. The inspection was performed by or on behalf of the home state licensing authority, if available.

d. The report is the most recent report available that satisfies the requirements of this paragraph (4).

e. If the home state licensing authority has not conducted an inspection satisfying the requirements of this paragraph (4), the pharmacy must submit an inspection report from NABP's verified pharmacy program or from another qualified entity as determined by the Board.

(5) Submits plans for the pharmacy department as set forth in the Board's rules and regulations.

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

(a) A nonresident pharmacy must designate a registered agent in Delaware for service of process.

(b) A nonresident pharmacy that does not designate a registered agent ~~is deemed to have appointed~~ appoints 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.

(c) 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.

(d) A nonresident pharmacy which does not obtain a permit in this State pursuant to this chapter ~~is deemed to have consented~~ consents 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~~ Grounds for discipline of a nonresident pharmacy.

~~(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 title, 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, staffed by a registered pharmacist, 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 title.~~

(a) A nonresident pharmacy is subject to disciplinary actions established in § 2538 of this title if, after a hearing, the Board finds that the nonresident pharmacy has done one or more of the following acts:

(1) Obtained a license by misrepresentation or fraud.

(2) Failed to operate according to the Board's statutes, laws, and rules and regulations.

(3) Failed to maintain at all times a valid license to operate the pharmacy, which complies with the statutes, laws, and rules and regulations of the state in which it is physically located.

(4) Failed to maintain patient profiles in compliance with Board rules and regulations.

(5) Failed to 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.

(6) Failed to maintain its records of prescription drugs dispensed to Delaware patients in a way that the records are readily retrievable, but no more than 15 days, from the records of drugs dispensed to other patients.

(7) Been disciplined by a regulatory agency.

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

§ 2538. ~~Nonresident pharmacies: violations; penalties~~ Disciplinary sanctions for nonresident pharmacies.

~~(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.~~

(a) The Board may impose any of the following sanctions, individually or in combination, when it finds that a nonresident pharmacy has violated any condition or committed any violation set forth in § 2537 of this title:

(1) Issue a letter of reprimand.

(2) Place a nonresident pharmacy on probationary status, and require the nonresident pharmacy to:

a. Report regularly to the Board upon the matters which are the basis of the probation.

b. Limit all practice and professional activities as prescribed by the Board.

(3) Suspend any nonresident pharmacy's license.

(4) Permanently revoke any nonresident pharmacy's license.

(5) Impose a monetary penalty not to exceed $250,000 for each violation and not more than $250,000 for each day of a continuing violation.

(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~~ license to conduct business in this State pursuant to this chapter commits the offense of operating a nonresident pharmacy without a ~~permit~~ license and may be fined not more than ~~$50~~ $10,000 for each day that the offense occurs ~~and/or~~ or continues.

Subchapter V. Pharmaceutical Establishments Other Than Pharmacies

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

(a) ~~Drugs, toilet preparations, dentifrices, and cosmetics~~ Drugs 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.~~ as set forth in the Board's rules and regulations.

(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~~ license 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~~ license 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~~ As set forth in the Board's rules and regulations, a license to operate a pharmaceutical establishment issued pursuant to this subchapter terminates automatically ~~upon a transfer of the controlling interest in the pharmaceutical establishment,~~ upon a change in ownership, 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.

§ 2540A. Requirements for issuance of license for manufacturers, wholesale distributors, outsourcing facilities, and medical gas distributors.

(a) All applicants under this subchapter must meet all of the following requirements:

(1) The establishment must operate under the personal and immediate supervision of a person who meets state and federal requirements.

(2) The establishment has not been disciplined by a regulatory agency. The Board may, after a hearing or review of documentation, determine whether such discipline is grounds to deny licensure.

(3) No member of the key personnel has done any of the following:

(a) Obtained a license by misrepresentation or fraud.

(b) Attempted to procure, or has procured, a license for any other person by making, or causing to be made, any false representation.

(c) Been convicted of a crime substantially related to the practice of pharmacy. The Board may, after a hearing or review of documentation, determine whether such criminal conviction is grounds to deny licensure.

(d) Been disciplined by a regulatory agency. The Board may, after a hearing or review of documentation, determine whether such discipline is grounds to deny licensure.

(4) All key personnel must submit fingerprints and other necessary information in order to obtain a report of the individual's entire criminal history record from the State Bureau of Identification and from the Federal Bureau of Investigation pursuant to Federal Bureau of Investigation appropriation of Title II of Public Law 92-544 (28 U.S.C. § 534). If such individuals do not have a criminal history record, the applicant shall cause to be submitted a statement from each agency that the agency has no record of criminal history information relating to the individual. The State Bureau of Identification is the intermediary for the purpose of this subsection and the Board, or its designee, shall be 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.

(5) The application for a license to operate a pharmaceutical establishment must be accompanied by any application fee or license fee established by the Division. A separate license is required for each location. The license must be available for inspection by authorized persons.

(6) A license to operate a pharmaceutical establishment issued under this subchapter terminates automatically upon the termination of the pharmaceutical establishment's legal existence or upon the discontinuance of business or professional practice.

(b) Requirements for a manufacturer.

An applicant for licensure as a manufacturer must meet all of the following requirements:

(1) Provide information about ownership and key personnel, including designated representative and supervisor.

(2) Provide recent Good Manufacturing Practice (GMP) inspection report which is acceptable to the Board.

(3) Provide proof of registration pursuant to 21 U.S.C. § 360, where applicable.

(4) Provide proof of licensure or registration by the state in which the manufacturer is physically located, where applicable.

(5) Meet the applicable requirements set forth in the Board's rules and regulations.

(c) Requirements for an outsourcing facility.

An applicant for licensure must meet all of the following requirements:

(1) Provide information about ownership and key personnel, including designated representative and supervisor.

(2) Provide recent Good Manufacturing Practice (GMP) inspection report which is acceptable to the Board.

(3) Provide proof of licensure or registration by the state in which the manufacturer is physically located, where applicable.

(4) Meet the applicable requirements set forth in the Board's rules and regulations.

(d) Requirements for a wholesale distributor.

(1) Provide information about ownership and key personnel, including designated representative and supervisor.

(2) Provide a set of floor plans for the physical location.

(3) Provide the lease or deed for the physical location.

(4) Provide regulatory letter from the Food and Drug Administration (FDA), where applicable.

(5) Provide proof of licensure or registration by the state in which the wholesale distributor is physically located, where applicable.

(6) Meet the applicable requirements set forth in the Board's rules and regulations.

(e) Requirements for a medical gas dispenser.

(1) Provide information about ownership and key personnel, including designated representative and supervisor.

(2) Provide a set of floor plans for the physical location.

(3) Provide proof of licensure or registration by the state in which the medical gas distributor is physically located, where applicable.

(4) Meet the applicable requirements set forth in the Board's rules and regulations.

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

~~(a) 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 title. 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 1 60-day extension of a temporary permit.~~

~~(b) An applicant may not be licensed until its key personnel submit fingerprints and other necessary information in order to obtain a report of the individuals' entire criminal history record from the State Bureau of Identification and from the Federal Bureau of Investigation pursuant to Federal Bureau of Investigation appropriation of Title II of Public Law 92-544 (28 U.S.C § 534). If the applicant's key personnel do not have a criminal history record, the applicant shall cause to be submitted a statement from each agency that the agency has no record of criminal history information relating to the individual. The State Bureau of Identification shall be the intermediary for the purpose of this subsection and the Board of Pharmacy, or its designee, shall be 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.~~

§ 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 title.

§ 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 title~~ the Administrative Procedures Act, Chapter 101 of Title 29.

§ 2544. Inspections.

Inspections of pharmaceutical establishments are conducted in the same manner as inspections of pharmacies

pursuant to § 2534 of this title ~~and, in addition, include the inspection of and activities related to toilet preparations, dentifrices, and cosmetics~~.

§ 2545. ~~Penalties.~~ Grounds for discipline.

~~(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.~~

(a) The Board may discipline a license to operate a pharmaceutical establishment, other than a pharmacy, where:

(1) The establishment is not being operated according to applicable state and federal law and the Board's rules and regulations.

(2) A member of the key personnel has been convicted of a crime substantially related to the practice of pharmacy.

(3) The establishment or a member of the key personnel has been disciplined by a regulatory agency.

(4) The establishment has obtained a license by misrepresentation or fraud.

(5) The establishment has refused access to the pharmacy or pharmacy records to an agent of the Board who seeks access for the purpose of conducting an inspection or investigation.

§ 2546 Disciplinary sanctions.

(a) The Board may impose any of the following sanctions, individually or in combination, when it finds that 1 or more of the conditions or violations set forth in § 2545 of this title applies to a pharmaceutical establishment regulated by this subchapter:

(1) Issue a letter of reprimand.

(2) Place an establishment on probationary status and require the establishment to do any of the following:

a. Report regularly to the Board upon matters which are related to the basis of the probation.

b. Limit all practice and professional activities as prescribed by the Board.

(3) Suspend any establishment's license.

(4) Permanently revoke any establishment's license.

(5) Impose a monetary penalty not to exceed $250,000 for each violation and not more than $250,000 for each day of a continuing violation.

Subchapter VI. Prohibited Acts; Penalties Generally; Enforcement

§ ~~2546~~ 2547. 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.~~ aids," or "apothecary" but only to the extent that the practice of pharmacy is not occurring on the premises.

~~§ 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 title 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 that practitioner's own 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 Chapter 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 1 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.

§ 2549A. Dispensing and substitution of biological products.

(a) A pharmacist may substitute for a prescribed biological product only if:

(1) The practitioner has not expressly prohibited substitution in a manner specified in § 2549 of this title;

(2) The product to be substituted has been designated by the Federal Food and Drug Administration as interchangeable with or therapeutically equivalent to the prescribed product;

(3) The pharmacist informs the patient or the patient's adult representative that an interchangeable biological product has been dispensed; and

(4) The pharmacist indicates on the prescription and on the prescription label the name of the manufacturer of the interchangeable biological product substituted unless the practitioner indicates otherwise.

(b) If a biological product is dispensed, the pharmacist or the pharmacist's designee shall, within a reasonable time but not to exceed 10 days following dispensing, communicate to the practitioner the name and manufacturer of the biological product dispensed, by:

(1) Recording such information in an interoperable electronic health records system shared with the prescribing practitioner, to the extent such a system is in place between a pharmacist and practitioner; or

(2) In the case where electronic health records are not in place between a pharmacist and a practitioner, communicating such information to the practitioner using any prevailing means available. No communication is required under this subsection where there is no interchangeable or therapeutically equivalent biological product for the prescribed biological product, or where a refill prescription is not changed from the biological product originally dispensed.

(c) The pharmacy shall maintain a record of the biological product dispensed as required in § 2532 of this title.

(d) The Board of Pharmacy shall maintain a link on its web site to the current list of all biological products determined by the Federal Food and Drug Administration to be interchangeable with a specific biological product.

(e) Hospital pharmacies shall be exempt from the requirements of subsection (b) of this section.

~~§ 2550. Emergency refills of noncontrolled drugs.~~

~~(a) A pharmacist may dispense an emergency supply of a noncontrolled 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 the prescribing practitioner 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 noncontrolled 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 1 time.~~

~~Subchapter VII. 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.~~

Subchapter VII. Substitution of drugs; emergency refills

§ 2550. 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 that practitioner's own signature on the signature line alongside 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 Chapter 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 1 year, or both a fine and a term of imprisonment.

(c) Every prescription in this State that is reduced to writing 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 such 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.

§ 2551. Dispensing and substitution of biological products.

(a) A pharmacist may substitute for a prescribed biological product only if:

(1) The practitioner has not expressly prohibited substitution in a manner specified in § 2550 of this title.

(2) The product to be substituted has been designated by the Food and Drug Administration (FDA) as interchangeable with or therapeutically equivalent to the prescribed product.

(3) The pharmacist informs the patient or the patient's adult representative that an interchangeable biological product has been dispensed.

(4) The pharmacist indicates on the prescription and on the prescription label the name of the manufacturer of the interchangeable biological product substituted unless the practitioner indicates otherwise.

(b) If a biological product is dispensed, the pharmacist or the pharmacist's designee shall, within a reasonable time but not to exceed 10 days following dispensing, communicate to the practitioner the name and manufacturer of the biological dispensed, by one of the following:

(1) Recording such information in an interoperable electronic health records system shared with the prescribing practitioner, to the extent such a system is in place between a pharmacist and practitioner.

(2) In the case where electronic health records are not in place between a pharmacist and a practitioner, communicating such information to the practitioner using any prevailing means available. No communication is required under this subsection where there is no interchangeable or therapeutically equivalent biological product for the prescribed biological product or where a refill prescription is not changed from the biological product originally dispensed.

(c) The pharmacy must maintain a record of the biological product dispensed as required in § 2532 of this title.

(d) The Board shall maintain a link on its website to the current list of all biological products determined by the U. S. Food and Drug Administration to be interchangeable with a specific biological product.

(e) Hospital pharmacies are exempt from the requirements of subsection (b) of this section.

§ 2552. Emergency refills of noncontrolled drugs.

A pharmacist may dispense an emergency supply of a noncontrolled drug to a patient pursuant to the requirements set forth in the Board's rules and regulations.

Section 2. Amend § 2523, Title 24 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 2523. Exemptions.

Nothing in this chapter may be construed to prevent any of the following:

(10) A pharmacist who is licensed in a jurisdiction or territory of the United States from providing pharmacy services in this State during emergency circumstances, as determined by the Board in coordination with the Secretary of State, or a declared local, jurisdictional, or national disaster. This exemption applies for a period as determined by the Board and the Secretary of State, so long as such person abides by Delaware laws, rules, and regulations relating to pharmacy. In order to be eligible for this exemption, the pharmacist must notify the Board of the pharmacist's intent to practice in this State pursuant to this paragraph.

Section 3. Section 1 of this Act takes effect 1 year after its enactment into law. Section 2 of this Act takes effect upon its enactment into law.