**[Del. Code tit. 24, §§ 2501 through 2506, 2549 through 2550.]**

## § 2501. Objectives: Pharmacy

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

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

## § 2502. Definitions: Pharmacy

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

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

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

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

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

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

(6) "Distant site" means a site at which a health-care provider legally allowed to practice in the State is located while providing health-care services by means of telemedicine or telehealth.

(7) "Division" means the Division of Professional Regulation.

(8) "Drug" means:

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

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

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

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

(9) "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.

(10) "Executive Secretary" means the executive secretary of the Delaware State Board of Pharmacy who shall be a pharmacist.

(11) "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.

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

(13) "Intern" means a person who is registered by the Board of Pharmacy and supervised by an approved preceptor and who is completing the practical experience requirement of the Board prior to that person's licensure as a pharmacist.

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

(15) "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.

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

(17) "Originating site" means a site in Delaware at which a patient is located at the time health-care services are provided to him or her by means of telemedicine or telehealth, unless the term is otherwise defined with

respect to the provision in which it is used; provided, however, notwithstanding any other provision of law, insurers and providers may agree to alternative siting arrangements deemed appropriate by the parties.

(18) "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.

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

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

(21) "Pharmacy" means a place where drugs are compounded or dispensed.

(22) "Pharmacy technician" means an individual who is not registered as an intern with the Board of Pharmacy or a certified pharmacy technician.

(23) "Practice of pharmacy" means the interpreting, evaluating, and dispensing of a practitioner's or prescriber's order. The practice of pharmacy includes, but is not limited to, the proper compounding, labeling, packaging, and dispensing of a drug to a patient or the patient's agent, and administering a drug to a patient. The practice of pharmacy includes the application of the pharmacist's knowledge of pharmaceutics, pharmacology, pharmacokinetics, drug and food interactions, drug product selection, and patient counseling. It also includes:

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

b. Participation in therapeutic drug selection, substitution of therapeutically equivalent 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 results to be reported only if outside normal limits;

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

g. The use of telemedicine and participation in telehealth in a manner deemed appropriate by regulation; and

h. Administration of injectable medications, biologicals and adult immunizations pursuant to a valid prescription or physician-approved protocol approved by a physician duly licensed in the State under

subchapter III of Chapter 17 of this title. Pharmacists shall request which physician or physicians and notify the physician or physicians as designated by the patient of such administration within 24 hours. The notice shall include the patient's name, the name of the immunizations, inoculations or vaccinations administered, and the date of administration and may be submitted by phone, fax, post or electronically. Upon request a copy of the protocol will be made available to the designated physician or physicians without costs.

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

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

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

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

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

(29) "State" means the State of Delaware.

(30) "Store and forward transfer" means the transmission of a patient's medical information either to or from an originating site or to or from the provider at the distant site, but does not require the patient being present nor must it be in real time.

(31) "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) "Substitution" or "substitute" means pharmacist's selection of prescriber authorized generic or therapeutically equivalent prescription medications or, in the case of biologicals, pharmacist selection of an interchangeable biological product in place of the prescribed product. Generic substitution means a drug that is the same active ingredient, equivalent in strength to the strength written on the 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) "Telehealth" means the use of information and communications technologies consisting of telephones, remote patient monitoring devices or other electronic means which support clinical health care, provider consultation, patient and professional health-related education, public health, health administration, and other services as described in regulation.

(34) "Telemedicine" means a form of telehealth which is the delivery of clinical health-care services by means of real time 2-way audio, visual, or other telecommunications or electronic communications, including the application of secure video conferencing or store and forward transfer technology to provide or support health-care delivery, which facilitate the assessment, diagnosis, consultation, treatment, education, care management and self-management of a patient's health care by a licensee practicing within his or her scope of practice as would be practiced in-person with a patient and with other restrictions as defined in regulation.

(35) "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.

(36) "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.

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

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

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

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

d. The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug:

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;

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

3. For emergency medical reasons.

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

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

(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 who are residents of the State. 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. Three members are public members, 1 from each county. A public member may not be, nor ever have been, a pharmacist or a member of the immediate family of a pharmacist; may not be, nor ever have been, employed by a pharmacy; may not have a material interest in the providing of goods or services to a pharmacy; and may not be, nor ever have been, engaged in an activity directly related to the practice of pharmacy. A public member must be accessible to inquiries, comments, and suggestions from the general public.

(c) Except as provided in subsection (d) of this section, each Board member serves a term of 3 years, and may succeed himself or herself for 1 additional term; provided, however, that where a member was initially appointed to fill a vacancy, the member may succeed himself or herself 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.

(d) A person who has never served on the Board may be appointed to the Board for 2 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(23)h. of this title must be approved by the Council.

## § 2504. Organization; meetings; officers; quorum; Executive Secretary: Pharmacy

(a) 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: Pharmacy

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

## § 2506. Authority of the Board: Pharmacy

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

(1) Promulgate rules and regulations in accordance with the procedures specified in the Administrative Procedures Act [Chapter 101 of Title 29];

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

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

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

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

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

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

(8) Maintain a registry of interns;

(9) Refer all complaints from licensees and the public concerning persons licensed under this chapter, or concerning the practices of the Board or the profession, to the Division for investigation pursuant to § 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;

(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;

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

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

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

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

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

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

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

(b) The Board of Pharmacy shall promulgate regulations specifically identifying those 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.

## § 2549. Substitution of drugs: Pharmacy

(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: Pharmacy

(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: Pharmacy

(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.