OCCUPATIONS CODE

TITLE 3. HEALTH PROFESSIONS

SUBTITLE J. PHARMACY AND PHARMACISTS

CHAPTER 551. GENERAL PROVISIONS

Sec. 551.001. SHORT TITLE. This subtitle may be cited as the Texas Pharmacy Act.

Acts 1999, 76th Leg., ch. 388, Sec. 1, eff. Sept. 1, 1999.

Amended by:

Acts 2013, 83rd Leg., R.S., Ch. 583 (S.B. 869), Sec. 2, eff. June 14, 2013.

Sec. 551.002. LEGISLATIVE DECLARATION; PURPOSE. (a) This subtitle shall be liberally construed to regulate in the public interest the practice of pharmacy in this state as a professional practice that affects the public health, safety, and welfare.

(b) It is a matter of public interest and concern that the practice of pharmacy merits and receives the confidence of the public and that only qualified persons be permitted to engage in the practice of pharmacy in this state.

(c) The purpose of this subtitle is to promote, preserve, and protect the public health, safety, and welfare through:

(1) effectively controlling and regulating the practice of pharmacy; and

(2) licensing pharmacies engaged in the sale, delivery, or distribution of prescription drugs and devices used in diagnosing and treating injury, illness, and disease.

Acts 1999, 76th Leg., ch. 388, Sec. 1, eff. Sept. 1, 1999.

Sec. 551.003. DEFINITIONS. In Chapters 551-566:

(1) "Administer" means to directly apply a prescription drug to the body of a patient by any means, including injection, inhalation, or ingestion, by:

(A) a person authorized by law to administer the drug, including a practitioner or an authorized agent under a practitioner's supervision; or

(B) the patient at the direction of a

practitioner.

(2) "Board" means the Texas State Board of Pharmacy.

(3) "Class A pharmacy license" or "community pharmacy license" means a license described by Section 560.051.

(4) "Class B pharmacy license" or "nuclear pharmacy license" means a license described by Section 560.051.

(5) "Class C pharmacy license" or "institutional pharmacy license" means a license described by Section 560.051.

(6) "Class D pharmacy license" or "clinic pharmacy license" means a license described by Section 560.051.

(7) "Class E pharmacy license" or "nonresident pharmacy license" means a license described by Section 560.051.

(8) "College of pharmacy" means a school, university, or college of pharmacy that:

(A) satisfies the accreditation standards of the American Council on Pharmaceutical Education as adopted by the board; or

(B) has degree requirements that meet the standards of accreditation set by the board.

(9) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device:

(A) as the result of a practitioner's prescription drug order based on the practitioner-patient-pharmacist relationship in the course of professional practice;

(B) for administration to a patient by a practitioner as the result of a practitioner's initiative based on the practitioner-patient-pharmacist relationship in the course of professional practice;

(C) in anticipation of a prescription drug order based on a routine, regularly observed prescribing pattern; or

(D) for or as an incident to research, teaching, or chemical analysis and not for selling or dispensing, except as allowed under Section 562.154 or Chapter 563.

(10) "Confidential record" means a health-related record, including a patient medication record, prescription drug order, or medication order, that:

(A) contains information that identifies an individual; and

(B) is maintained by a pharmacy or pharmacist.

(11) "Controlled substance" means a substance, including a drug:

(A) listed in Schedule I, II, III, IV, or V, as established by the commissioner of public health under Chapter 481, Health and Safety Code, or in Penalty Group 1, 1-A, 2, 3, or 4, Chapter 481; or

(B) included in Schedule I, II, III, IV, or V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. Section 801 et seq.).

(12) "Dangerous drug" means a drug or device that:

(A) is not included in Penalty Group 1, 2, 3, or 4, Chapter 481, Health and Safety Code, and is unsafe for self-medication; or

(B) bears or is required to bear the legend:

(i) "Caution: federal law prohibits dispensing without prescription" or "Rx only" or another legend that complies with federal law; or

(ii) "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian."

(13) "Deliver" or "delivery" means the actual, constructive, or attempted transfer of a prescription drug or device or controlled substance from one person to another, with or without consideration.

(14) "Designated agent" means:

(A) an individual, including a licensed nurse, physician assistant, or pharmacist:

(i) who is designated by a practitioner and authorized to communicate a prescription drug order to a pharmacist; and

(ii) for whom the practitioner assumes legal responsibility;

(B) a licensed nurse, physician assistant, or pharmacist employed in a health care facility to whom a practitioner communicates a prescription drug order; or

(C) a registered nurse or physician assistant authorized by a practitioner to administer a prescription drug order for a dangerous drug under Subchapter B, Chapter 157.

(15) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory, that is required under federal or state law to be ordered or prescribed by a practitioner.

(15-a) "Direct supervision" means supervision by a pharmacist who directs the activities of a pharmacist-intern, pharmacy technician, or pharmacy technician trainee to a sufficient degree to ensure the activities are performed accurately, safely, and without risk of harm to patients, as specified by board rule.

(16) "Dispense" means to prepare, package, compound, or label, in the course of professional practice, a prescription drug or device for delivery to an ultimate user or the user's agent under a practitioner's lawful order.

(17) "Distribute" means to deliver a prescription drug or device other than by administering or dispensing.

(18) "Drug" means:

(A) a substance recognized as a drug in a drug compendium, including the current official United States Pharmacopoeia, official National Formulary, or official Homeopathic Pharmacopoeia, or in a supplement to a drug compendium;

(B) a substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in a human or another animal;

(C) a substance, other than food, intended to affect the structure or a function of the body of a human or another animal;

(D) a substance intended for use as a component of a substance specified in Paragraph (A), (B), or (C);

(E) a dangerous drug; or

(F) a controlled substance.

(19) "Drug regimen review" includes evaluation of prescription drug or medication orders and a patient medication record for:

(A) a known allergy;

(B) a rational therapy-contraindication;

(C) a reasonable dose and route of administration;

(D) reasonable directions for use;

(E) duplication of therapy;

(F) a drug-drug interaction;

(G) drug-food interaction;

(H) drug-disease interaction;

(I) adverse drug reaction; and

(J) proper use, including overuse or underuse.

(20) "Internship" means a practical experience program that is approved by the board.

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

(22) "Labeling" means the process of affixing a label, including all information required by federal and state statute or regulation, to a drug or device container. The term does not include:

(A) the labeling by a manufacturer, packer, or distributor of a nonprescription drug or commercially packaged prescription drug or device; or

(B) unit dose packaging.

(23) "Manufacturing" means the production, preparation, propagation, conversion, or processing of a drug or device, 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 or device 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.

(24) "Medication order" means an order from a practitioner or a practitioner's designated agent for administration of a drug or device.

(25) "Nonprescription drug" means a nonnarcotic drug

or device that may be sold without a prescription and that is labeled and packaged in compliance with state or federal law.

(26) "Patient counseling" means communication by a pharmacist of information, as specified by board rule, to a patient or caregiver to improve therapy by ensuring proper use of a drug or device.

(27) "Pharmaceutical care" means providing drug therapy and other pharmaceutical services defined by board rule and intended to assist in curing or preventing a disease, eliminating or reducing a patient's symptom, or arresting or slowing a disease process.

(28) "Pharmacist" means a person licensed by the board to practice pharmacy.

(29) "Pharmacist-in-charge" means the pharmacist designated on a pharmacy license as the pharmacist who has the authority or responsibility for the pharmacy's compliance with statutes and rules relating to the practice of pharmacy.

(30) "Pharmacist-intern" means:

(A) an undergraduate student who is enrolled in the professional sequence of a college of pharmacy approved by the board and who is participating in a board-approved internship program; or

(B) a graduate of a college of pharmacy who is participating in a board-approved internship.

(31) "Pharmacy" means a facility at which a prescription drug or medication order is received, processed, or dispensed under this subtitle, Chapter 481 or 483, Health and Safety Code, or the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. Section 801 et seq.). The term does not include a narcotic drug treatment program that is regulated under Chapter 466, Health and Safety Code.

(32) "Pharmacy technician" means an individual employed by a pharmacy whose responsibility is to provide technical services that do not require professional judgment regarding preparing and distributing drugs and who works under the direct supervision of and is responsible to a pharmacist. The term does not include a pharmacy technician trainee.

(32-a) "Pharmacy technician trainee" means an individual who is registered with the board as a pharmacy technician trainee and is authorized to participate in a pharmacy technician training program.

(33) "Practice of pharmacy" means:

(A) providing an act or service necessary to provide pharmaceutical care;

(B) interpreting or evaluating a prescription drug order or medication order;

(C) participating in drug or device selection as authorized by law, and participating in drug administration, drug regimen review, or drug or drug-related research;

(D) providing patient counseling;

(E) being responsible for:

(i) dispensing a prescription drug order or distributing a medication order;

(ii) compounding or labeling a drug or device, other than labeling by a manufacturer, repackager, or distributor of a nonprescription drug or commercially packaged prescription drug or device;

(iii) properly and safely storing a drug or device; or

(iv) maintaining proper records for a drug or device;

(F) performing for a patient a specific act of drug therapy management delegated to a pharmacist by a written protocol from a physician licensed in this state in compliance with Subtitle B; or

(G) administering an immunization or vaccination under a physician's written protocol.

(34) "Practitioner" means:

(A) a person licensed or registered to prescribe, distribute, administer, or dispense a prescription drug or device in the course of professional practice in this state, including a physician, dentist, podiatrist, or veterinarian but excluding a person licensed under this subtitle;

(B) a person licensed by another state, Canada,

or the United Mexican States in a health field in which, under the law of this state, a license holder in this state may legally prescribe a dangerous drug;

(C) a person practicing in another state and licensed by another state as a physician, dentist, veterinarian, or podiatrist, who has a current federal Drug Enforcement Administration registration number and who may legally prescribe a Schedule II, III, IV, or V controlled substance, as specified under Chapter 481, Health and Safety Code, in that other state; or

(D) an advanced practice registered nurse or physician assistant to whom a physician has delegated the authority to prescribe or order a drug or device under Section 157.0511, 157.0512, or 157.054.

(35) "Preceptor" has the meaning assigned by Section 558.057.

(36) "Prescription drug" means:

(A) a substance for which federal or state law requires a prescription before the substance may be legally dispensed to the public;

(B) a drug or device that under federal law is required, before being dispensed or delivered, to be labeled with the statement:

(i) "Caution: federal law prohibits dispensing without prescription" or "Rx only" or another legend that complies with federal law; or

(ii) "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian"; or

(C) a drug or device that is required by federal or state statute or regulation to be dispensed on prescription or that is restricted to use by a practitioner only.

(37) "Prescription drug order" means:

(A) an order from a practitioner or a practitioner's designated agent to a pharmacist for a drug or device to be dispensed; or

(B) an order under Subchapter B, Chapter 157.

(38) "Prospective drug use review" means the review of a patient's drug therapy and prescription drug order or medication

order, as defined by board rule, before dispensing or distributing a drug to the patient.

(39) "Provide" means to supply one or more unit doses of a nonprescription drug or dangerous drug to a patient.

(40) "Radioactive drug" means a drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons, including a nonradioactive reagent kit or nuclide generator that is intended to be used in the preparation of the substance.

(41) "Substitution" means the dispensing of a drug or a brand of drug other than the drug or brand of drug ordered or prescribed.

(42) "Texas trade association" means a cooperative and voluntarily joined statewide association of business or professional competitors in this state designed to assist its members and its industry or profession in dealing with mutual business or professional problems and in promoting their common interest.

(42-a) "Therapeutic contact lens" means a contact lens that contains one or more drugs and that delivers the drugs into the wearer's eye.

(43) "Ultimate user" means a person who obtains or possesses a prescription drug or device for the person's own use or for the use of a member of the person's household or for administering to an animal owned by the person or by a member of the person's household.

(44) "Unit dose packaging" means the ordered amount of drug in a dosage form ready for administration to a particular patient, by the prescribed route at the prescribed time, and properly labeled with the name, strength, and expiration date of the drug.

(45) "Written protocol" means a physician's order, standing medical order, standing delegation order, or other order or protocol as defined by rule of the Texas Medical Board under Subtitle B.

Acts 1999, 76th Leg., ch. 388, Sec. 1, eff. Sept. 1, 1999. Amended by Acts 2001, 77th Leg., ch. 112, Sec. 5, eff. May 11, 2001; Acts

2001, 77th Leg., ch. 1188, Sec. 10, eff. Sept. 1, 2001; Acts 2001, 77th Leg., ch. 1254, Sec. 1, eff. Sept. 1, 2001; Acts 2003, 78th Leg., ch. 88, Sec. 8, eff. May 20, 2003.

Amended by:

Acts 2005, 79th Leg., Ch. 28 (S.B. 492), Sec. 1, eff. September 1, 2005.

Acts 2005, 79th Leg., Ch. 1345 (S.B. 410), Sec. 2, eff. September 1, 2005.

Acts 2009, 81st Leg., R.S., Ch. 396 (H.B. 1740), Sec. 1, eff. June 19, 2009.

Acts 2013, 83rd Leg., R.S., Ch. 418 (S.B. 406), Sec. 19, eff. November 1, 2013.

Acts 2013, 83rd Leg., R.S., Ch. 583 (S.B. 869), Sec. 3, eff. June 14, 2013.

Acts 2017, 85th Leg., R.S., Ch. 929 (S.B. 1633), Sec. 1, eff. September 1, 2017.

Sec. 551.004. APPLICABILITY OF SUBTITLE. (a) This subtitle does not apply to:

(1) a practitioner licensed by the appropriate state board who supplies a patient of the practitioner with a drug in a manner authorized by state or federal law and who does not operate a pharmacy for the retailing of prescription drugs;

(2) a member of the faculty of a college of pharmacy recognized by the board who is a pharmacist and who performs the pharmacist's services only for the benefit of the college;

(3) a person who procures prescription drugs for lawful research, teaching, or testing and not for resale;

(4) a home and community support services agency that possesses a dangerous drug as authorized by Section 142.0061, 142.0062, or 142.0063, Health and Safety Code; or

(5) a dispensing organization, as defined by Section 487.001, Health and Safety Code, that cultivates, processes, and dispenses low-THC cannabis, as authorized by Chapter 487, Health and Safety Code, to a patient listed in the compassionate-use registry established under that chapter.

(b) This subtitle does not prevent a practitioner from

administering a drug to a patient of the practitioner.

(c) This subtitle does not prevent the sale by a person, other than a pharmacist, firm, joint stock company, partnership, or corporation, of:

(1) a nonprescription drug that is harmless if used according to instructions on a printed label on the drug's container and that does not contain a narcotic;

(2) an insecticide, a fungicide, or a chemical used in the arts if the insecticide, fungicide, or chemical is properly labeled; or

(3) an insecticide or fungicide that is mixed or compounded only for an agricultural purpose.

(d) A wholesaler or manufacturer may distribute a prescription drug as provided by state or federal law.

(e) This subtitle does not prevent a physician or therapeutic optometrist from dispensing and charging for therapeutic contact lenses. This subsection does not authorize a therapeutic optometrist to prescribe, administer, or dispense a drug that is otherwise outside the therapeutic optometrist's scope of practice.

Acts 1999, 76th Leg., ch. 388, Sec. 1, eff. Sept. 1, 1999.

Amended by:

Acts 2009, 81st Leg., R.S., Ch. 396 (H.B. 1740), Sec. 2, eff. June 19, 2009.

Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. 339), Sec. 5, eff. June 1, 2015.

Sec. 551.005. APPLICATION OF SUNSET ACT. The Texas State Board of Pharmacy is subject to Chapter 325, Government Code (Texas Sunset Act). Unless continued in existence as provided by that chapter, the board is abolished and this subtitle expires September 1, 2029.

Acts 1999, 76th Leg., ch. 388, Sec. 1, eff. Sept. 1, 1999.

Amended by:

Acts 2005, 79th Leg., Ch. 1345 (S.B. 410), Sec. 1, eff. September 1, 2005.

Acts 2017, 85th Leg., R.S., Ch. 485 (H.B. 2561), Sec. 8, eff.

September 1, 2017.

Sec. 551.006. EXCLUSIVE AUTHORITY. Notwithstanding any other law, a pharmacist has the exclusive authority to determine whether or not to dispense a drug.

Added by Acts 2017, 85th Leg., R.S., Ch. 485 (H.B. 2561), Sec. 9, eff. September 1, 2017.

Sec. 551.008. PROHIBITION ON RULE VIOLATING SINCERELY HELD RELIGIOUS BELIEF. (a) All rules, regulations, or policies adopted by the board may not violate Chapter 110, Civil Practice and Remedies Code.

(b) A person may assert a violation of Subsection (a) as an affirmative defense in an administrative hearing or as a claim or defense in a judicial proceeding under Chapter 37, Civil Practice and Remedies Code.

Added by Acts 2017, 85th Leg., R.S., Ch. 485 (H.B. 2561), Sec. 9, eff. September 1, 2017.