

Vernon's Texas Statutes and Codes Annotated [Currentness](#)

Occupations Code ([Refs & Annos](#))

Title 3. Health Professions

▢ [Subtitle J. Pharmacy and Pharmacists \(Refs & Annos\)](#)

→ [Chapter 551. General Provisions \(Refs & Annos\)](#)

→ [§ 551.001. Short Title](#)

This subtitle may be cited as the Texas Pharmacy Act.

→ [§ 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.

→ [§ 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. [\[FN1\]](#)

(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.

(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.

[FN1] V.T.C.A., Occupations Code § 157.051 et seq.

→ **§ 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; or

(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](#).

(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.

#### → [§ 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, 2017.

### **Chapter 552. Texas State Board of Pharmacy**

#### → [§ 552.001. Membership](#)

(a) The Texas State Board of Pharmacy consists of 11 members appointed by the governor with the advice and consent of the senate as follows:

(1) seven members who are pharmacists;

(2) one member who is a pharmacy technician; and

(3) three members who represent the public.

(b) Appointments to the board shall be made without regard to the race, color, disability, sex, religion, age, or national origin of the appointee.

→ **§ 552.002. Qualifications**

(a) The board must include representation for pharmacists who are primarily employed in Class A pharmacies and Class C pharmacies.

(b) A pharmacist board member must, at the time of appointment:

(1) be a resident of this state;

(2) have been licensed for the five years preceding appointment;

(3) be in good standing to practice pharmacy in this state; and

(4) be practicing pharmacy in this state.

(b-1) A pharmacy technician board member must, at the time of appointment:

(1) be a resident of this state;

(2) have been registered as a pharmacy technician for the five years preceding appointment;

(3) be in good standing to act as a pharmacy technician in this state; and

(4) be acting as a pharmacy technician in this state.

(c) Each person appointed to the board shall, not later than the 15th day after the date of appointment, qualify by taking the constitutional oath of office.

→ **§ 552.003. Public Membership Eligibility**

A person is not eligible for appointment as a public member of the board if the person or the person's spouse:

- (1) is registered, certified, or licensed by an occupational regulatory agency in the field of health care;
- (2) is employed by or participates in the management of a business entity or other organization regulated by or receiving funds from the board;
- (3) owns or controls, directly or indirectly, more than a 10 percent interest in a business entity or other organization regulated by or receiving funds from the board; or
- (4) uses or receives a substantial amount of tangible goods, services, or funds from the board, other than compensation or reimbursement authorized by law for board membership, attendance, or expenses.

→ **§ 552.004. Membership Restrictions**

(a) A person may not be a member of the board if the person is required to register as a lobbyist under Chapter 305, Government Code, because of the person's activities for compensation on behalf of a profession related to the operation of the board.

(b) A person may not be a member of the board if:

(1) the person is an officer, employee, or paid consultant of a Texas trade association in the field of health care; or

(2) the person's spouse is an officer, manager, or paid consultant of a Texas trade association in the field of health care.

→ **§ 552.005. Terms; Vacancy**

(a) Members of the board are appointed for staggered six-year terms, with either three or four members' terms, as applicable, expiring every other year at midnight on the last day of the state fiscal year in the last year of the member's term.

(b) If a vacancy occurs during a member's term, the governor shall appoint a replacement to fill the unexpired term.

(c) A board member may not serve more than two consecutive full terms. The completion of the unexpired portion of a full term is not service for a full term for purposes of this subsection.

(d) A person appointed by the governor to a full term before the expiration of the term of the member being

succeeded becomes a member of the board on the first day of the next state fiscal year following the appointment.

(e) A person appointed to an unexpired portion of a full term becomes a member of the board on the day after the date of appointment.

→ **§ 552.006. Board Member Training**

(a) A person who is appointed to and qualifies for office as a member of the board may not vote, deliberate, or be counted as a member in attendance at a meeting of the board until the person completes a training program that complies with this section.

(b) The training program must provide the person with information regarding:

(1) this subtitle and the programs, functions, rules, and budget of the board;

(2) the results of the most recent formal audit of the board;

(3) the requirements of laws relating to open meetings, public information, administrative procedure, and conflicts of interest; and

(4) any applicable ethics policies adopted by the board or the Texas Ethics Commission.

(c) A person appointed to the board is entitled to reimbursement, as provided by the General Appropriations Act, for the travel expenses incurred in attending the training program regardless of whether the attendance at the program occurs before or after the person qualifies for office.

→ **§ 552.007. Officers**

(a) The governor shall designate a member of the board as the president of the board to serve in that capacity at the pleasure of the governor. The board shall elect from its members for one-year terms a vice president, treasurer, and other officers the board considers appropriate and necessary to conduct board business.

(b) The board's president shall preside at each board meeting and is responsible for the performance of the board's duties and functions under this subtitle.

(c) An officer, other than the president, shall perform the duties normally associated with the officer's position and other duties assigned to the officer by the board.

(d) The term of an officer begins on the first day of the state fiscal year following the officer's election and ends on election of a successor.

(e) A member elected as an officer may not serve more than two consecutive full terms in each office to which the member is elected.

→ **§ 552.008. Grounds for Removal**

(a) It is a ground for removal from the board that a member:

(1) does not have at the time of appointment the qualifications required for appointment to the board;

(2) does not maintain during service on the board the qualifications required for appointment to the board;

(3) violates a prohibition established by [Section 552.004](#);

(4) cannot, because of illness or disability, discharge the member's duties for a substantial part of the member's term; or

(5) is absent from more than half of the regularly scheduled board meetings the member is eligible to attend during a calendar year, unless the absence is excused by majority vote of the board.

(b) If the executive director has knowledge that a potential ground for removal exists, the executive director shall notify the president of the board of the ground. The president shall then notify the governor that a potential ground for removal exists.

(c) The validity of an action of the board is not affected by the fact that the action is taken when a ground for removal of a board member exists.

→ **§ 552.009. Per Diem; Reimbursement**

(a) Each member of the board is entitled to a per diem set by legislative appropriation for each day the member engages in board business.

(b) A member is entitled to reimbursement for travel expenses as prescribed by the General Appropriations Act.

**→ § 552.010. Meetings**

- (a) The board shall meet at least once every four months to transact board business .
- (b) The board may meet at other times at the call of the board's president or two-thirds of the board's members.

**→ § 552.011. Executive Session**

- (a) The board may, in accordance with Chapter 551, Government Code, conduct a portion of a board meeting in executive session.
- (b) The board may conduct in executive session a deliberation relating to discipline of a license holder. At the conclusion of the deliberation, in open session the board shall vote and announce the board's decision relating to the license holder.
- (c) The board may conduct in executive session a disciplinary hearing relating to a pharmacist or pharmacy student who is impaired because of chemical abuse or mental or physical illness.

**→ § 552.012. Quorum; Validity of Board Action**

Except when a greater number is required by this subtitle or by board rule, an action of the board must be by a majority of a quorum.

**Chapter 553. Executive Director and Other Board Personnel****→ § 553.001. Executive Director**

The board shall employ an executive director.

**→ § 553.002. Qualifications of Executive Director**

The executive director must be a pharmacist.

**→ § 553.003. General Duties of Executive Director**

- (a) The executive director is an ex officio member of the board without vote.

(b) The executive director is a full-time employee of the board and shall:

(1) serve as secretary to the board; and

(2) perform the regular administrative functions of the board and any other duty as the board directs.

(c) The executive director may not perform a discretionary or decision-making function for which the board is solely responsible.

(d) The executive director shall keep the seal of the board. The executive director may affix the seal only in the manner prescribed by the board.

→ **§ 553.004. Personnel**

The board may employ persons in positions or capacities the board considers necessary to properly conduct the board's business and fulfill the board's responsibilities under this subtitle.

→ **§ 553.005. Employee Restrictions**

(a) A person may not be an employee of the board employed in a “bona fide executive, administrative, or professional capacity,” as that phrase is used for purposes of establishing an exemption to the overtime provisions of the federal Fair Labor Standards Act of 1938 ([29 U.S.C. Section 201 et seq.](#)), if:

(1) the person is an officer, employee, or paid consultant of a Texas trade association in the field of health care; or

(2) the person's spouse is an officer, manager, or paid consultant of a Texas trade association in the field of health care.

(b) A person may not act as general counsel to the board if the person is required to register as a lobbyist under Chapter 305, Government Code, because of the person's activities for compensation on behalf of a profession related to the operation of the board.

→ **§ 553.006. Possession by Employee of Regulated Substance**

A board employee may possess a dangerous drug or controlled substance when acting in the employee's official capacity.



**→ § 553.007. Division of Responsibilities**

The board shall develop and implement policies that clearly define the responsibilities of the board and the staff of the board.

**→ § 553.008. Qualifications and Standards of Conduct Information**

The board shall provide, as often as necessary, to its members and employees information regarding their:

- (1) qualifications for office or employment under this subtitle; and
- (2) responsibilities under applicable laws relating to standards of conduct for state officers or employees.

**→ § 553.009. Career Ladder Program; Performance Evaluations**

(a) The executive director or the executive director's designee shall develop an intra-agency career ladder program. The program must require intra-agency postings of all nonentry level positions concurrently with any public posting.

(b) The executive director or the executive director's designee shall develop a system of annual performance evaluations. All merit pay for board employees must be based on the system established under this subsection.

**→ § 553.010. Equal Employment Opportunity Policy; Report**

(a) The executive director or the executive director's designee shall prepare and maintain a written policy statement to ensure implementation of an equal employment opportunity program under which all personnel transactions are made without regard to race, color, disability, sex, religion, age, or national origin. The policy statement must include:

- (1) personnel policies, including policies related to recruitment, evaluation, selection, appointment, training, and promotion of personnel that are in compliance with Chapter 21, Labor Code;
- (2) a comprehensive analysis of the board workforce that meets federal and state guidelines;
- (3) procedures by which a determination can be made of significant underuse in the board workforce of all persons for whom federal or state guidelines encourage a more equitable balance; and
- (4) reasonable methods to appropriately address those areas of significant underuse.

(b) A policy statement prepared under Subsection (a) must:

- (1) cover an annual period;
- (2) be updated annually;
- (3) be reviewed by the Commission on Human Rights for compliance with Subsection (a)(1); and
- (4) be filed with the governor.

(c) The governor shall deliver a biennial report to the legislature based on the information received under Subsection (b). The report may be made separately or as a part of other biennial reports made to the legislature.

## **Chapter 554. Board Powers and Duties; Rulemaking Authority**

### **Subchapter A. Powers and Duties**

#### **→ § 554.001. General Powers and Duties of Board**

(a) The board shall:

- (1) administer and enforce this subtitle and rules adopted under this subtitle and enforce other laws relating to the practice of pharmacy and other powers and duties granted under other law;
- (2) cooperate with other state and federal agencies in the enforcement of any law relating to the practice of pharmacy or any drug or drug-related law;
- (3) maintain an office in which permanent records are kept; and
- (4) preserve a record of the board's proceedings.

(b) The board may:

- (1) join a professional organization or association organized to promote the improvement of the standards of the practice of pharmacy for protecting the health and welfare of the public; and
- (2) appoint committees from the board's membership, an advisory committee from the pharmacy profession,

and any other group to assist in administering this subtitle.

(c) The board may:

(1) issue a duplicate copy of a license to practice pharmacy or a license renewal certificate on a request from the holder and on payment of a fee determined by the board; and

(2) inspect a facility licensed under this subtitle for compliance with this subtitle.

(d) The board may be represented by counsel, including the attorney general, district attorney, or county attorney, if necessary in a legal action taken under this subtitle.

(e) The board shall develop formal policies outlining the structure, role, and responsibilities of each committee established under Subsection (b)(2) that contains board members. The board may adopt rules to implement this subsection.

→ **§ 554.002. Regulation of Practice of Pharmacy**

The board shall regulate the practice of pharmacy in this state by:

(1) issuing a license after examination or by reciprocity to an applicant qualified to practice pharmacy and issuing a license to a pharmacy under this subtitle;

(2) renewing a license to practice pharmacy and a license to operate a pharmacy;

(3) determining and issuing standards for recognizing and approving degree requirements of colleges of pharmacy whose graduates are eligible for a license in this state;

(4) specifying and enforcing requirements for practical training, including an internship;

(5) enforcing the provisions of this subtitle relating to:

(A) the conduct or competence of a pharmacist practicing in this state and the conduct of a pharmacy operating in this state; and

(B) the suspension, revocation, retirement, or restriction of a license to practice pharmacy or to operate a pharmacy or the imposition of an administrative penalty or reprimand on a license holder;

(6) regulating the training, qualifications, and employment of a pharmacist-intern, pharmacy technician, and pharmacy technician trainee; and

(7) determining and issuing standards for recognizing and approving a pharmacy residency program for purposes of Subchapter W, Chapter 61, Education Code. [FN1]

[FN1] V.T.C.A., Education Code § 61.921 et seq.

→ **§ 554.0021. Recognition and Approval of Pharmacist Certification Programs**

(a) The board shall determine and issue standards for recognizing and approving pharmacist certification programs.

(b) In adopting standards under Subsection (a), the board shall include a requirement that a pharmacist may not use the designation “board certified” unless the pharmacist has successfully completed a certification program that meets the board’s standards.

→ **§ 554.003. Procedures**

The board by rule shall specify:

(1) the licensing procedures to be followed, including specification of forms to be used, in applying for a pharmacy license; and

(2) fees for filing an application for a pharmacy license.

→ **§ 554.004. Administration of Medication**

(a) The board shall specify conditions under which a pharmacist may administer medication, including an immunization and vaccination. The conditions must ensure that:

(1) a licensed health care provider authorized to administer the medication is not reasonably available to administer the medication;

(2) failure to administer the medication, other than an immunization or vaccination, might result in a significant delay or interruption of a critical phase of drug therapy;

(3) the pharmacist possesses the necessary skill, education, and certification as specified by the board to administer the medication;

(4) within a reasonable time after administering medication, the pharmacist notifies the licensed health care provider responsible for the patient's care that the medication was administered;

(5) the pharmacist may not administer medication to a patient at the patient's residence, except at a licensed nursing home or hospital;

(6) the pharmacist administers an immunization or vaccination under a physician's written protocol and meets the standards established by the board; and

(7) the authority of a pharmacist to administer medication may not be delegated.

(b) This section does not prohibit a pharmacist from preparing or manipulating a biotechnological agent or device.

(c) This section does not prohibit a pharmacist from performing an act delegated by a physician in accordance with Chapter 157. The pharmacist performing a delegated medical act under that chapter is considered to be performing a medical act and not to be engaging in the practice of pharmacy.

→ **§ 554.005. Prescription Drugs and Devices**

(a) In regulating the practice of pharmacy and the use in this state of prescription drugs and devices in the diagnosis, mitigation, or treatment or prevention of injury, illness, or disease, the board shall:

(1) regulate the delivery or distribution of a prescription drug or device;

(2) specify minimum standards for the professional environment, technical equipment, and security in a prescription dispensing area;

(3) specify minimum standards for:

(A) drug storage;

(B) maintenance of prescription drug records; and

(C) procedures for the:

(i) delivering and dispensing in a suitable, appropriately labeled container;

- (ii) providing of prescription drugs or devices;
  - (iii) monitoring of drug therapy; and
  - (iv) counseling of patients on proper use of a prescription drug or device in the practice of pharmacy;
- (4) adopt rules regulating a prescription drug order or medication order transmitted by electronic means; and
- (5) register a balance used for compounding drugs in a pharmacy licensed in this state and periodically inspect the balance to verify accuracy.
- (b) In implementing Subsection (a)(1), the board may, after notice and hearing, seize any prescription drug or device that poses a hazard to the public health and welfare.
- (c) In implementing Subsection (a)(1), the board may not regulate:
- (1) any manufacturer's representative or employee acting in the normal course of business;
  - (2) a person engaged in the wholesale drug business and licensed by the commissioner of public health as provided by Chapter 431, Health and Safety Code; or
  - (3) an employee of a person described by Subdivision (2) if the employee is acting in the normal course of business.

→ **§ 554.006. Fees**

The board by rule shall establish reasonable and necessary fees so that the fees, in the aggregate, produce sufficient revenue to cover the cost of administering this subtitle.

→ **§ 554.007. Funds**

- (a) The board shall deposit revenue collected under this subtitle to the credit of the general revenue fund.
- (b) The board may receive and spend money, or use gifts, grants, and other funds and assets , in addition to money collected under Subsection (a), in accordance with state law.

→ § 554.008. Repealed by Acts 2003, 78th Leg., ch. 285, § 31(37), eff. September 1, 2003

→ § 554.009. Lease or Purchase of Vehicles

(a) The board may lease or purchase vehicles for use in official board business.

(b) A vehicle acquired under Subsection (a) is exempt from a requirement to bear state government identification.

(c) The board may register a vehicle with the Texas Department of Motor Vehicles in an alias name only for investigative personnel.

→ § 554.010. Peace Officers

(a) The board may commission as a peace officer to enforce this subtitle an employee who has been certified as qualified to be a peace officer by the Texas Commission on Law Enforcement .

(b) An employee commissioned as a peace officer under this subtitle has the powers, privileges, and immunities of a peace officer while carrying out duties as a peace officer under this subtitle.

→ § 554.011. Pilot and Demonstration Research Projects

(a) The board may approve pilot and demonstration research projects for innovative applications in the practice of pharmacy.

(b) The board shall specify the procedures to be followed in applying for approval of a project.

(c) The approval may include a provision granting an exception to any rule adopted under this subtitle. The board may extend the time an exception to a rule is granted as necessary for the board to adopt an amendment or modification of the rule. The board may condition approval of a project on compliance with this section and rules adopted under this section.

(d) A project may not include therapeutic substitution or substitution of a medical device used in patient care.

(e) This section does not expand the definition of pharmacy under this subtitle.

→ § 554.012. Notification Relating to Therapeutic Optometrists

The board shall inform each holder of a license to practice pharmacy and each holder of a license to operate a pharmacy of the authority of a therapeutic optometrist to prescribe a drug under [Section 351.357](#) by annually mailing to each license holder a notice that:

- (1) describes the authority of a therapeutic optometrist to prescribe a drug; and
- (2) lists each drug that a therapeutic optometrist may lawfully prescribe.

→ **§ 554.013. Repealed by Acts 2011, 82nd Leg., ch. 1083 (S.B. 1179), § 25(150), eff. June 17, 2011**

→ **§ 554.014. Information Provided to License Holders**

At least once each biennium, the board shall provide to license holders information on:

- (1) prescribing and dispensing pain medications, with particular emphasis on Schedule II and Schedule III controlled substances;
- (2) abusive and addictive behavior of certain persons who use prescription pain medications;
- (3) common diversion strategies employed by certain persons who use prescription pain medications, including fraudulent prescription patterns; and
- (4) the appropriate use of pain medications and the differences between addiction, pseudo-addiction, tolerance, and physical dependence.

→ **§ 554.015. Poison Control Center Information**

The board shall provide to license holders information regarding the services provided by poison control centers.

→ **§ 554.016. Canadian Pharmacy Inspection; Designation; Fees; Information**

- (a) The board shall designate at least one and not more than 10 Canadian pharmacies whose primary business is to dispense prescription drugs under prescription drug orders to Canadian residents, as having passed inspection by the board for shipping, mailing, or delivering to this state a prescription dispensed under a prescription drug order to a resident in this state.
- (b) The board by rule shall set fees in amounts reasonable and necessary to cover the costs incurred by the



board in inspecting Canadian pharmacies as provided by Subsection (a).

(c) The board shall establish and maintain an Internet website to provide information necessary to enable residents of this state to conveniently order prescription drugs from Canadian pharmacies designated by the board as having passed inspection to dispense prescription drugs to residents in this state in accordance with this subtitle and board rules. The board shall include on the website a statement that the board is not liable for any act or omission of a Canadian pharmacy designated as having passed inspection to dispense prescription drugs to residents in this state.

→ **§ 554.017. List of Pharmacists Authorized to Sign Prescription Drug Orders**

The board shall provide on its Internet website a list of pharmacists who are authorized to sign a prescription drug order under [Section 157.101\(b-1\)](#), including the name of the pharmacist's delegating physician under the protocol required under that subsection.

**Subchapter B. Rulemaking**

→ **§ 554.051. Rulemaking: General Powers and Duties**

(a) The board shall adopt rules consistent with this subtitle for the administration and enforcement of this subtitle.

(b) If the board determines it necessary to protect the health and welfare of the citizens of this state, the board may make a rule concerning the operation of a licensed pharmacy located in this state applicable to a pharmacy licensed by the board that is located in another state.

(c) The board shall adopt rules regarding records to be maintained by a pharmacist performing a specific act under a written protocol.

(d) The board by rule shall specify minimum standards for professional responsibility in the conduct of a pharmacy.

→ **§ 554.052. Immunizations and Vaccinations; Physician Supervision**

(a) The board by rule shall require a pharmacist to notify a physician who prescribes an immunization or vaccination within 24 hours after the pharmacist administers the immunization or vaccination.

(b) The board shall establish minimum education and continuing education standards for a pharmacist who administers an immunization or vaccination. The standards must include Centers for Disease Control and Prevention training, basic life support training, and hands-on training in techniques for administering

immunizations and vaccinations.

(c) Supervision by a physician is adequate if the delegating physician:

(1) is responsible for formulating or approving an order or protocol, including the physician's order, standing medical order, or standing delegation order, and periodically reviews the order or protocol and the services provided to a patient under the order or protocol;

(2) except as provided by Subsection (c-1), has established a physician-patient relationship with each patient under 14 years of age and referred the patient to the pharmacist;

(3) is geographically located to be easily accessible to the pharmacy where an immunization or vaccination is administered;

(4) receives, as appropriate, a periodic status report on the patient, including any problem or complication encountered; and

(5) is available through direct telecommunication for consultation, assistance, and direction.

(c-1) A pharmacist may administer an influenza vaccination to a patient over seven years of age without an established physician-patient relationship.

(d) The Texas Medical Board by rule shall establish the minimum content of a written order or protocol. The order or protocol may not permit delegation of medical diagnosis.

→ **§ 554.053. Rulemaking: Pharmacy Technician and Pharmacy Technician Trainee**

(a) The board shall establish rules for the use and the duties of a pharmacy technician and pharmacy technician trainee in a pharmacy licensed by the board. A pharmacy technician and pharmacy technician trainee shall be responsible to and must be directly supervised by a pharmacist.

(b) The board may not adopt a rule establishing a ratio of pharmacists to pharmacy technicians and pharmacy technician trainees in a Class C pharmacy or limiting the number of pharmacy technicians or pharmacy technician trainees that may be used in a Class C pharmacy.

(c) The board shall determine and issue standards for recognition and approval of a training program for pharmacy technicians and maintain a list of board-approved training programs that meet those standards.

**→ § 554.054. Rules Restricting Advertising or Competitive Bidding**

(a) The board may not adopt rules restricting advertising or competitive bidding by a person regulated by the board except to prohibit false, misleading, or deceptive practices by that person.

(b) The board may not include in rules to prohibit false, misleading, or deceptive practices by a person regulated by the board a rule that:

(1) restricts the use of any advertising medium;

(2) restricts the person's personal appearance or use of the person's voice in an advertisement;

(3) relates to the size or duration of an advertisement used by the person; or

(4) restricts the use of a trade name in advertising by the person.

**→ § 554.055. Rulemaking; Electronic Media**

The board shall adopt rules regarding the sale and delivery of drugs by use of electronic media, including the Internet.

**→ § 554.056. Rulemaking; Addition of Flavoring to Commercial Product**

The board may adopt rules governing the procedures for a pharmacist, as part of compounding, to add flavoring to a commercial product at the request of a patient or a patient's agent.

**→ § 554.057. Rulemaking; Implementation of Drug Therapy under Protocol**

The board, with the advice of the Texas Medical Board, shall adopt rules that allow a pharmacist to implement or modify a patient's drug therapy pursuant to a physician's delegation under [Section 157.101\(b-1\)](#).

**Chapter 555. Public Interest Information and Complaint Procedures****→ § 555.001. Public Interest Information**

(a) The board shall prepare information of public interest describing the functions of the board and procedures by which complaints are filed with and resolved by the board.

(b) The board shall make the information available to the public and appropriate state agencies.

(c) The board shall provide on its website a list of all Internet pharmacies licensed by the board and shall provide information about each pharmacy, including the pharmacy's name, license number, and state of physical location. In this subsection, an Internet pharmacy is a pharmacy physically located in this state or another state that:

(1) dispenses a prescription drug or device under a prescription drug order in response to a request received by way of the Internet to dispense the drug or device; and

(2) delivers the drug or device to a patient in this state by United States mail, common carrier, or delivery service.

(d) Information regarding the home address or home telephone number of a person licensed or registered under this subtitle, including a pharmacy owner, is confidential and not subject to disclosure under Chapter 552, Government Code, but each person licensed or registered must provide the board with a business address or address of record that is subject to disclosure under Chapter 552, Government Code, and that may be posted on the board's Internet site or in the board's licensure verification database.

→ **§ 555.002. Complaints**

(a) The board by rule shall establish methods by which consumers and service recipients are notified of the name, mailing address, and telephone number of the board for the purpose of directing complaints to the board. The board may provide for that notice:

(1) on each registration form, application, or written contract for services of a person regulated by the board;

(2) on a sign prominently displayed in the place of business of each person regulated by the board; or

(3) in a bill for service provided by a person regulated by the board.

(b) The board shall list with its regular telephone number any toll-free telephone number established under other state law that may be called to present a complaint about a health professional.

(c) Any person who has knowledge relating to an action or omission of a pharmacist or pharmacy licensed by the board that constitutes a ground for disciplinary action under [Section 565.001](#) or [565.002](#), or a rule adopted under one of those sections, may provide relevant records, report relevant information, or provide assistance to the board.

(d) A complaint directed to the board under this section may be made through the Internet.

→ **§ 555.003. Complaint Form**

The board by rule shall adopt a form on which a person may file a complaint with the board.

→ **§ 555.004. Assistance with Complaint**

The board shall provide reasonable assistance to a person who wants to file a complaint with the board.

→ **§ 555.005. Records of Complaints**

For each complaint received by the board, the board shall maintain information about parties to the complaint, including the complainant's identity, the subject matter of the complaint, a summary of the results of the review or investigation of the complaint, and the disposition of the complaint.

→ **§ 555.006. Notification Concerning Complaint**

(a) The board shall notify the complainant not later than the 30th day after the date the board receives the complaint and shall provide an estimated time for resolution of the complaint.

(b) If a written complaint is filed with the board that the board has authority to resolve, the board, at least every four months and until final disposition of the complaint, shall notify the parties to the complaint of the status of the complaint unless the notice would jeopardize an undercover investigation.

→ **§ 555.007. General Rules Regarding Complaint Investigation and Disposition**

(a) The board shall adopt policies and procedures concerning the investigation of a complaint filed with the board. The policies and procedures must:

(1) determine the seriousness of the complaint;

(2) ensure that a complaint is not closed without appropriate consideration;

(3) ensure that a letter is sent to the person who filed the complaint explaining the action taken on the complaint;

(4) ensure that the person who filed the complaint has an opportunity to explain the allegations made in the complaint;

(5) prescribe guidelines concerning the types of complaints that require the use of a private investigator and the procedures for the board to obtain the services of a private investigator; and

(6) allow appropriate employees of the board to dismiss a complaint if an investigation shows that:

(A) no violation occurred; or

(B) the subject of the complaint is outside the board's jurisdiction.

(b) The board shall:

(1) dispose of a complaint in a timely manner; and

(2) establish a schedule for conducting each phase of the investigation or disposition that is under the control of the board.

(c) At each public meeting of the board, the executive director shall report to the board each complaint dismissed under Subsection (a)(6) since the board's last public meeting.

(d) The board may not consider or act on a complaint involving a violation alleged to have occurred more than seven years before the date the complaint is received by the board.

→ **§ 555.008. Notice to Board Concerning Complaints**

(a) The executive director shall notify the board of the number of complaints that are unresolved after two years after the date of the filing of the complaint. The executive director shall provide the board with an explanation of the reason that a complaint has not been resolved.

(b) The executive director shall provide the notice and explanation required under Subsection (a) periodically at regularly scheduled board meetings.

→ **§ 555.009. Public Participation**

(a) The board shall develop and implement policies that provide the public with a reasonable opportunity to appear before the board and to speak on an issue under the board's jurisdiction.

(b) The board shall prepare and maintain a written plan that describes how a person who does not speak English may be provided reasonable access to the board's programs.

→ **§ 555.010. Confidentiality**

The identity of a person who reports to or assists the board under [Section 555.002\(c\)](#) and a document that could disclose the identity of that person are confidential and are not considered public information for the purposes of Chapter 552, Government Code.

→ **§ 555.011. Immunity**

(a) A person who provides information or assistance under [Section 555.002\(c\)](#) is immune from civil liability arising from providing the information or assistance.

(b) Subsection (a) shall be liberally construed to accomplish the purposes of this chapter, and the immunity provided under that subsection is in addition to any other immunity provided by law.

(c) A person who provides information or assistance to the board under this chapter is presumed to have acted in good faith. A person who alleges a lack of good faith has the burden of proof on that issue.

→ **§ 555.012. Counterclaim or Suit**

(a) A person who provides information or assistance under [Section 555.002\(c\)](#) and who is named as a defendant in a civil action filed as a result of the information or assistance may file a counterclaim in a pending action or may prove a cause of action in a subsequent suit to recover defense costs, including court costs, attorney's fees, and damages incurred as a result of the civil action, if the plaintiff's original suit is determined to be frivolous, unreasonable, without foundation, or brought in bad faith.

(b) A board employee or member or an agent of the board who is named as a defendant in a civil action filed as a result of an action taken in the person's official capacity or in the course and scope of employment may file a counterclaim in a pending action or may prove a cause of action in a subsequent suit to recover defense costs, including court costs, attorney's fees, and damages incurred as a result of the civil action, if the plaintiff's original suit is determined to be frivolous, unreasonable, without foundation, or brought in bad faith.

## **Chapter 556. Administrative Inspections and Warrants**

### **Subchapter A. General Provisions**

→ **§ 556.001. Definition**

In this chapter, “facility” means a place:

- (1) for which an application has been made for a pharmacy license under this subtitle;
- (2) at which a pharmacy licensed under this subtitle is located;
- (3) at which a pharmacy is being operated in violation of this subtitle; or
- (4) where the practice of pharmacy occurs.

### **Subchapter B. Inspections**

#### **→ § 556.051. Authorization to Enter and Inspect**

The board or a representative of the board may enter and inspect a facility relative to the following:

- (1) drug storage and security;
- (2) equipment;
- (3) components used in compounding, finished and unfinished products, containers, and labeling of any item;
- (4) sanitary conditions; or
- (5) records, reports, or other documents required to be kept or made 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.](#)) or rules adopted under one of those laws.

#### **→ § 556.052. Requirements Before Entry and Inspection**

- (a) Before an entry and inspection of the facility, the person authorized to represent the board must:
  - (1) state the purpose for the inspection; and
  - (2) present to the owner, pharmacist, or agent in charge of the facility:
    - (A) appropriate credentials; and



(B) written notice of the authority for the inspection.

(b) If an inspection is required by or is supported by an administrative inspection warrant, the warrant is the notice for purposes of Subsection (a)(2)(B).

→ **§ 556.053. Extent of Inspection; Confidentiality**

(a) Except as otherwise provided in an inspection warrant, the person authorized to represent the board may:

(1) inspect and copy documents, including records or reports, required to be kept or made 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.) or rules adopted under one of those laws;

(2) inspect, within reasonable limits and in a reasonable manner, a facility's storage, equipment, security, prescription drugs or devices, components used in compounding, finished and unfinished products, or records; or

(3) perform an inventory of any stock of prescription drugs or devices, components used in compounding, or finished and unfinished products in a facility and obtain samples of those substances.

(b) Reports, records, formulas, and test results of samples of products compounded by pharmacies obtained by the board may be provided to the pharmacy that compounded the product but otherwise are confidential and do not constitute public information for purposes of Chapter 552, Government Code. The board may create, use, or disclose statistical information from the test results of samples of compounded products.

(c) The board may disclose information confidential under Subsection (b):

(1) in a disciplinary hearing before the board or in a subsequent trial or appeal of a board action or order;

(2) to a pharmacist licensing or disciplinary authority of another jurisdiction; or

(3) under a court order.

(d) The board shall require a pharmacy to recall a compounded product and may release the results of the tests of the samples of the compounded product if the board determines that:

(1) the test results indicate a patient safety problem that may involve potential harm to a patient; and

(2) the release of the test results is necessary to protect the public.

(e) The board shall release the test results described by Subsection (d) if a pharmacy is unable to or does not recall the compounded product within 48 hours after the board's request under that subsection.

→ **§ 556.054. Limitation on Inspection**

Unless the owner, pharmacist, or agent in charge of a facility consents in writing, an inspection of the facility authorized by this chapter may not extend to:

(1) financial data;

(2) sales data, other than shipment data; or

(3) pricing data.

→ **§ 556.055. Inspections with Warning Notice**

Before a complaint may be filed with the board as the result of a written warning notice that is issued during an inspection authorized by this chapter and that lists a specific violation of this subtitle or a rule adopted under this subtitle, the license holder must be given a reasonable time, as determined by the board, to comply with this subtitle or rules adopted under this subtitle.

→ **§ 556.0551. Inspection of Licensed Nonresident Pharmacy**

(a) The board may inspect a nonresident pharmacy licensed by the board that compounds sterile preparations as necessary to ensure compliance with the safety standards and other requirements of this subtitle and board rules.

(b) A nonresident pharmacy shall reimburse the board for all expenses, including travel, incurred by the board in inspecting the pharmacy as provided by Subsection (a).

→ **§ 556.0555. Inspections**

(a) At least annually, the board shall conduct random inspections of Canadian pharmacies designated under [Section 554.016](#) as necessary to ensure compliance with the safety standards and other requirements of this subtitle and board rules.

(b) Notwithstanding the requirements of this chapter, the board by rule may establish the standards and procedures for inspections under this section.

(c) The board may enter into a written agreement with another state for an agency or employee of the state to perform services for the board related to inspecting a Canadian pharmacy designated by the board under [Section 554.016](#) to dispense prescription drugs to residents in this state. This subsection does not apply to the initial inspection of the pharmacy.

#### → § 556.056. Code of Professional Responsibility

(a) The board shall adopt a code of professional responsibility to regulate the conduct of a representative of the board authorized to inspect and survey a pharmacy.

(b) The code must contain:

(1) a procedure to be followed by a person authorized to represent the board:

(A) on entering a pharmacy;

(B) during inspection of the pharmacy; and

(C) during an exit conference; and

(2) standards of conduct that the person must follow in dealing with the staff and management of the pharmacy and the public.

(c) The board shall establish a procedure for receiving and investigating a complaint of a code violation. The board shall investigate each complaint of a code violation. The board shall forward results of an investigation to the complainant.

(d) The board may adopt rules establishing sanctions for code violations.

#### Subchapter C. Warrants

##### → § 556.101. Warrant Not Required

A warrant is not required under this chapter to:

- (1) inspect books or records under an administrative subpoena issued under this subtitle; or
- (2) enter a facility or conduct an administrative inspection of a facility if:
  - (A) the owner, pharmacist, or agent in charge of the facility consents to the inspection;
  - (B) the situation presents imminent danger to the public health and safety;
  - (C) the situation involves inspection of a conveyance, if there is reasonable cause to believe that the mobility of the conveyance makes it impracticable to obtain a warrant; or
  - (D) any other exceptional situation or emergency exists involving an act of God or natural disaster in which time or opportunity to apply for a warrant is lacking.

→ **§ 556.102. Compliance with Chapter**

An administrative inspection warrant may be issued and executed only in accordance with this chapter.

→ **§ 556.103. Issuance of Warrant**

- (a) In this section, “probable cause” means a valid public interest exists in the effective enforcement of this subtitle or a rule adopted under this subtitle that is sufficient to justify an administrative inspection of the facility, area, building, or conveyance, or its contents in the circumstances specified in the application for the warrant.
- (b) A district judge may, on proper oath or affirmation that shows probable cause, issue a warrant to:
  - (1) conduct an administrative inspection authorized by this chapter or rules adopted under this subtitle; and
  - (2) seize property appropriate to the inspection.
- (c) A warrant may be issued only on an affidavit that:
  - (1) is given by a board representative who has knowledge of the facts alleged;
  - (2) is sworn to before the judge; and

(3) establishes the grounds for issuance of the warrant.

(d) The judge shall issue a warrant if the judge is satisfied that grounds for the application exist or that there is probable cause to believe they exist.

→ **§ 556.104. Contents of Warrant**

The warrant must:

(1) identify:

(A) the facility, area, building, or conveyance to be inspected;

(B) the purpose of the inspection;

(C) the type of property to be inspected, if appropriate; and

(D) each item or type of property to be seized, if any;

(2) state the grounds for issuance of the warrant and the name of each person whose affidavit has been taken in support of the warrant;

(3) be directed to a person authorized under this chapter to execute the warrant;

(4) command the person to whom the warrant is directed to inspect the facility, area, building, or conveyance identified for the purpose specified;

(5) direct the seizure of the property specified, if appropriate;

(6) direct that the warrant be served during normal business hours; and

(7) designate the judge to whom the warrant is to be returned.

→ **§ 556.105. Execution and Return of Warrant**

(a) A warrant issued under this chapter must be executed and returned not later than the 10th day after the date of the warrant's issuance unless the judge allows additional time in the warrant after a showing by the board of

a need for additional time.

(b) A person who seizes property under a warrant shall provide a copy of the warrant and a receipt for the property taken by:

(1) giving the copy and receipt to the person from whom or from whose facility the property was taken; or

(2) leaving the copy and receipt at the facility from which the property was taken.

(c) The return of the warrant shall be made promptly and be accompanied by a written inventory of any property taken. The inventory shall be:

(1) prepared in the presence of the person executing the warrant and of:

(A) the person from whose possession or facility the property was taken, if present; or

(B) at least one credible person other than the person preparing the inventory; and

(2) verified by the person executing the warrant.

(d) The judge, on request, shall deliver a copy of the inventory to:

(1) the person from whose possession or facility the property was taken; and

(2) the applicant for the warrant.

→ **§ 556.106. Filing with District Court**

(a) A judge who issues a warrant under this chapter shall attach to the warrant:

(1) a copy of the return; and

(2) the papers filed in connection with the warrant.

(b) The judge shall file the copy of the return and the papers with the clerk of the district court with jurisdiction of the area in which the inspection was conducted.

**→ § 556.107. Disposal of Seized Property**

Property seized under this chapter must be disposed of in a manner considered appropriate by the board if the board has jurisdiction over the property or the district court if the court has jurisdiction over the property.

**Chapter 557. Pharmacist-Interns****→ § 557.001. Pharmacist-Intern Registration**

A person must register with the board before beginning a board-approved internship in this state.

**→ § 557.002. Application for Registration**

An application for registration as a pharmacist-intern must be on a form prescribed by the board.

**→ § 557.003. Duration of Registration**

A person's registration as a pharmacist-intern remains in effect as long as the person meets the qualifications for an internship specified by board rule.

**→ § 557.004. Limitations on Registration**

(a) The board may:

(1) refuse to issue a registration to an applicant; or

(2) restrict, suspend, or revoke a pharmacist-intern registration for a violation of this subtitle.

(b) The board may take disciplinary action against an applicant for a pharmacist-intern registration or the holder of a current or expired pharmacist-intern registration in the same manner as against an applicant for a license or a license holder by imposing a sanction authorized under [Section 565.051](#) if the board finds that the applicant or registration holder has engaged in conduct described by [Section 565.001](#).

**Chapter 558. License to Practice Pharmacy (Refs & Annos)****Subchapter A. License****→ § 558.001. License Required**

(a) A person may not practice pharmacy unless the person holds a license to practice pharmacy under this subtitle.

(b) A person may not:

(1) impersonate a pharmacist; or

(2) use the title “Registered Pharmacist” or “R.Ph.,” or words of similar intent, unless the person is licensed to practice pharmacy in this state.

(c) A person may not dispense or distribute prescription drugs unless the person:

(1) is a pharmacist; or

(2) is otherwise authorized by this subtitle to dispense or distribute prescription drugs.

#### → § 558.002. Unauthorized Acquisition of License

A person may not:

(1) impersonate before the board an applicant applying for a license under this subtitle; or

(2) acquire, with the intent to fraudulently acquire the license, a license in a manner other than the manner provided by this subtitle.

### **Subchapter B. Licensing by Examination**

#### → § 558.051. Qualifications for License by Examination

(a) To qualify for a license to practice pharmacy, an applicant for licensing by examination must submit to the board:

(1) a license fee set by the board; and

(2) a completed application on a form prescribed by the board with satisfactory sworn evidence that the applicant:



(A) is at least 18 years of age;

(B) is of good moral character;

(C) has completed a minimum of a 1,000-hour internship or other program that has been approved by the board or has demonstrated, to the board's satisfaction, experience in the practice of pharmacy that meets or exceeds the board's minimum internship requirements;

(D) has graduated and received a professional practice degree, as defined by board rule, from an accredited pharmacy degree program approved by the board;

(E) has passed the examination required by the board; and

(F) has not had a pharmacist license granted by another state restricted, suspended, revoked, or surrendered, for any reason.

(b) Each applicant must obtain practical experience in the practice of pharmacy concurrent with college attendance or after college graduation, or both, under conditions the board determines.

→ **§ 558.052. Content, Preparation, and Validation of Examination**

(a) The board shall determine the content and subject matter of a licensing examination.

(b) The examination shall be prepared to measure the competence of the applicant to practice pharmacy.

(c) The board may employ and cooperate with an organization or consultant in preparing an appropriate examination.

(d) A written examination prepared or offered by the board, including a standardized national examination, must be validated by an independent testing professional.

→ **§ 558.053. Grading of Examination**

(a) The board may employ and cooperate with an organization or consultant in grading the examination.

(b) The board shall determine whether an applicant has passed the examination. The board has sole discretion and responsibility for that determination.

**→ § 558.054. Frequency of Offering Examination**

The board shall give the examination at least two times during each state fiscal year.

**→ § 558.055. Failure to Pass; Reexamination**

(a) An applicant who on the applicant's first attempt fails the examination may take the examination two additional times.

(b) Before an applicant who has failed the examination three times is allowed to retake the examination, the applicant must provide documentation from a college of pharmacy that the applicant has successfully completed additional college course work in each examination subject area the applicant failed.

(c) If requested in writing by a person who fails the examination, the board shall furnish the person with an analysis of the person's performance on the examination.

**→ § 558.056. Notification**

The board shall notify each person taking an examination of the results of the examination not later than the 30th day after the date the board receives the results from a national testing service if the board uses a national testing service.

**→ § 558.057. Internship or Other Program to Qualify for Examination**

(a) In this section, "preceptor" means a pharmacist licensed in this state to practice pharmacy or another health care professional who meets the preceptor requirements specified by rule and who is recognized by the board to supervise and be responsible for the activities and functions of a pharmacist-intern in an internship program.

(b) The board shall:

(1) establish standards for an internship or other program necessary to qualify an applicant for the licensing examination; and

(2) determine the qualifications necessary for a preceptor used in the program.

**→ § 558.058. Accessibility of Examination**

The board by rule shall ensure that an examination under this subchapter is administered to applicants with

disabilities in compliance with the Americans with Disabilities Act of 1990 (42 U.S.C. Section 12101 et seq.).

→ **§ 558.059. Examination Fee Refund**

- (a) The board may retain all or part of an examination fee paid by an applicant who is unable to take the examination.
- (b) The board shall adopt policies allowing the board to refund the examination fee paid by an applicant who:
  - (1) provides advance notice of the applicant's inability to take the examination; or
  - (2) is unable to take the examination because of an emergency.
- (c) The board's policy must establish the required notification period and the emergencies that warrant a refund.
- (d) The board shall make efforts to ensure that the policy does not conflict with the policy of a national testing body involved in administering the examination.

**Subchapter C. Licensing by Reciprocity**

→ **§ 558.101. Qualifications for License by Reciprocity**

- (a) To qualify for a license to practice pharmacy, an applicant for licensing by reciprocity must:
  - (1) submit to the board:
    - (A) a reciprocity fee set by the board; and
    - (B) a completed application in the form prescribed by the board, given under oath;
  - (2) be of good moral character;
  - (3) have graduated and received a professional practice degree, as defined by board rule, from an accredited pharmacy degree program approved by the board;
  - (4) have presented to the board:

(A) proof of current or initial licensing by examination; and

(B) proof that the current license and any other license granted to the applicant by another state has not been restricted, suspended, revoked, or surrendered for any reason; and

(5) pass the Texas Pharmacy Jurisprudence examination.

(b) An applicant is not eligible for licensing by reciprocity unless the state in which the applicant is currently or was initially licensed as a pharmacist grants reciprocal licensing to pharmacists licensed by examination in this state, under like circumstances and conditions.

#### **Subchapter D. Provisional and Temporary Licensing**

##### **→ § 558.151. Qualifications for Provisional License**

(a) The board may grant a provisional license to practice pharmacy to an applicant licensed in another state who seeks a license in this state. An applicant for a provisional license under this section must:

(1) pay a fee set by the board;

(2) be licensed in good standing as a pharmacist in another state that has professional standards and licensing requirements that the board considers to be substantially equivalent to the requirements of this subtitle;

(3) have passed a national or other examination recognized by the board relating to pharmacy; and

(4) be sponsored by a person licensed under this subtitle with whom the provisional license holder may practice under this subchapter.

(b) The board may waive the requirement of Subsection (a)(4) for an applicant if the board determines that compliance with that subsection constitutes a hardship to the applicant.

##### **→ § 558.152. Duration of Provisional License**

A provisional license is valid until the date the board approves or denies the license application under this subtitle.

##### **→ § 558.153. Processing of License Application**

The board must complete the processing of a provisional license holder's application for a license not later than the 180th day after the date the provisional license is issued or at the time licenses are issued following the successful completion of the examination, whichever date is later.

→ **§ 558.154. Issuance of License to Provisional License Holder**

The board shall issue a license to practice pharmacy under this subtitle to the holder of a provisional license if:

- (1) the provisional license holder passes the jurisprudence examination required under this subtitle;
- (2) the board verifies that the provisional license holder has the academic and experience requirements for a license to practice pharmacy under this subtitle; and
- (3) the provisional license holder satisfies all other requirements for a license to practice pharmacy under this subtitle.

→ **§ 558.155. Temporary License**

The board by rule may provide for the issuance of a temporary license.

**Subchapter E. Certain Prohibited Practices**

→ **§ 558.201. Duplicating License or Certificate**

Except as expressly provided under this subtitle, a person may not in any manner duplicate a license to practice pharmacy or a license renewal certificate.

→ **§ 558.202. False Affidavit**

A person who falsely makes the affidavit prescribed by [Section 558.051](#) or [558.101](#) is guilty of fraudulent and dishonorable conduct and malpractice.

**Chapter 559. Renewal of License to Practice Pharmacy**

**Subchapter A. General Provisions**

→ **§ 559.001. Expiration of License**

- (a) Except as provided by Subsection (b), a license to practice pharmacy expires December 31 of each year or

of every other year, as determined by the board.

(b) The board may adopt a system under which licenses to practice pharmacy expire on various dates during the year.

(c) If the board changes the expiration date of a license, the board shall prorate the license renewal fee to cover the months for which the license is valid for the year in which the date is changed. The total license renewal fee is due on the new expiration date.

→ **§ 559.002. Renewal Period**

A license to practice pharmacy may be renewed for one or two years, as determined by the board.

→ **§ 559.003. Requirements for Renewal**

(a) To renew a license to practice pharmacy, the license holder must before the expiration date of the license:

(1) pay a renewal fee as determined by the board;

(2) comply with the continuing education requirements prescribed by the board; and

(3) file with the board a completed application for a license renewal certificate that:

(A) is given under oath; and

(B) is accompanied by a certified statement executed by the license holder that attests that the license holder has satisfied the continuing education requirements during the preceding license period.

(b) A person whose license has been expired for 90 days or less may renew the expired license by paying to the board a renewal fee that is equal to one and one-half times the normally required renewal fee for the license.

(c) A person whose license has been expired for more than 90 days but less than one year may renew the expired license by paying to the board a renewal fee that is equal to two times the normally required renewal fee for the license.

(d) A person whose license has been expired for one year or more may not renew the license. The person may obtain a new license by complying with the requirements and procedures for obtaining an original license,

including the examination requirement.

(e) A person may not renew a license to practice pharmacy if the person holds a license to practice pharmacy in another state that has been suspended, revoked, canceled, or subject to an action that prohibits the person from practicing pharmacy in that state.

→ **§ 559.004. Issuance of License Renewal Certificate**

(a) The board shall issue a license renewal certificate to an applicant after the board has received, in a time prescribed by [Section 559.003](#):

- (1) the completed application;
- (2) the renewal fee; and
- (3) proof of completion of the continuing education requirements prescribed by Subchapter B. [\[FN1\]](#)

(b) The renewal certificate must contain:

- (1) the pharmacist's license number;
- (2) the period for which the license is renewed; and
- (3) other information the board determines necessary.

[\[FN1\]](#) V.T.C.A., Occupations Code § 559.051 et seq.

→ **§ 559.005. Issuance of New License**

(a) The board may issue a new license to practice pharmacy to a person who is prohibited under [Section 559.003\(d\)](#) from renewing a license if the person has not had a license granted by any other state restricted, suspended, revoked, canceled, or surrendered for any reason and qualifies under this section.

(b) A person qualifies for a license under this section if the person:

- (1) was licensed as a pharmacist in this state, moved to another state, and is licensed and has been practicing pharmacy in the other state for the two years preceding the date the application for a new license is submitted;

(2) pays to the board an amount equal to the examination fee for the license; and

(3) passes the Texas Pharmacy Jurisprudence examination.

(c) A person qualifies for a license under this section if the person:

(1) was licensed as a pharmacist in this state;

(2) pays to the board an amount equal to the examination fee for the license; and

(3) passes the Texas Pharmacy Jurisprudence examination and any other examination required by the board and in addition to or instead of passing the examination as required by the board, participates in continuing pharmacy education and practices under conditions set by the board.

(d) A person qualifies for a license under this section if the person:

(1) submits to reexamination; and

(2) complies with the requirements and procedures for obtaining an original license.

#### → § 559.006. License Expiration Notice

At least 30 days before the expiration of a person's license, the board shall send written notice of the impending license expiration to the person at the license holder's last known address according to the board's records.

#### → § 559.007. Practicing Pharmacy Without Renewal Certificate

A person who practices pharmacy without a current license renewal certificate as required by this chapter is practicing pharmacy without a license and is subject to all penalties for practicing pharmacy without a license.

### Subchapter B. Mandatory Continuing Education

#### → § 559.051. Satisfaction of Continuing Education Requirement

(a) A holder of a license to practice pharmacy may meet the continuing education requirement by:



(1) completing continuing education programs approved by the board; or

(2) passing a standardized pharmacy examination approved by the board.

(b) A license holder who takes the examination under Subsection (a)(2) must pay the examination fee assessed by the board under [Section 554.006](#).

→ **§ 559.052. Rules Relating to Continuing Education**

(a) The board shall adopt rules relating to:

(1) the adoption or approval of mandatory continuing education programs;

(2) the approval of providers and the operation of continuing education programs; and

(3) the evaluation of the effectiveness of continuing education programs and a license holder's participation and performance in those programs.

(b) In establishing the requirement for continuing education, the board shall consider:

(1) factors that lead to the competent performance of professional duties; and

(2) the continuing education needs of license holders.

(c) In adopting rules relating to the approval of continuing education programs or providers, the board may consider:

(1) programs approved by the Texas Pharmacy Foundation; and

(2) providers approved by the American Council on Pharmaceutical Education.

(d) The board shall approve home study courses, correspondence courses, or other similar programs.

(e) The board by rule may grant an extension for the completion of a continuing education requirement for good cause.

(f) The board by rule may exempt a person from all or part of the continuing education requirements.

**→ § 559.0525. Continuing Education Relating to Opioid Drugs**

(a) The board shall develop a continuing education program regarding opioid drug abuse and the delivery, dispensing, and provision of tamper-resistant opioid drugs after considering input from interested persons.

(b) The board by rule may require a license holder to satisfy a number of the continuing education hours required by [Section 559.053](#) through attendance of a program developed under this section.

**→ § 559.053. Program Hours Required**

A license holder satisfies the continuing education requirement by presenting evidence satisfactory to the board of completion of at least 30 hours of continuing education during the preceding 24 months of the person's license period.

**→ § 559.054. Certificate of Completion**

Each continuing education program approved by the board shall issue a certificate of completion to a license holder who satisfactorily completes the program.

**→ § 559.055. Records**

Each license holder shall maintain records for three years showing the continuing education programs completed by the license holder.

**→ § 559.056. Demonstration of Compliance**

On an audit by the board, a license holder is in compliance with the continuing education requirements if the license holder submits to the board:

- (1) an affidavit stating that the license holder has complied with those requirements; and
- (2) records showing completion of the continuing education programs.

**Subchapter C. Inactive Status****→ § 559.101. Eligibility for Inactive Status**

The board by rule shall adopt a system for placing on inactive status a license held by a person who:

- (1) is licensed by the board to practice pharmacy;
- (2) is not eligible to renew the license because of failure to comply with the continuing education requirements under Subchapter B; [FN1] and
- (3) is not practicing pharmacy in this state.

[FN1] V.T.C.A., Occupations Code § 559.051 et seq.

→ **§ 559.102. Restriction on Length of Inactive Status**

The board may restrict the length of time a license may remain on inactive status.

→ **§ 559.103. Application for Inactive Status**

A license holder may place the holder's license on inactive status by:

- (1) applying for inactive status on a form prescribed by the board before the expiration date of the license; and
- (2) complying with all other requirements for renewal of a license other than the continuing education requirements under Subchapter B. [FN1]

[FN1] V.T.C.A., Occupations Code § 559.051 et seq.

→ **§ 559.104. Return to Active Status**

A holder of a license that is on inactive status may return the license to active status by:

- (1) applying for active status on a form prescribed by the board; and
- (2) providing evidence satisfactory to the board that the license holder has completed the number of hours of continuing education, up to 36 hours, that would otherwise have been required for renewal of the license.

→ **§ 559.105. Practicing Pharmacy During Inactive Status**

- (a) A holder of a license that is on inactive status may not practice pharmacy in this state.
- (b) A license holder who practices pharmacy while the holder's license is on inactive status is practicing

pharmacy without a license.

## **Chapter 560. Licensing of Pharmacies**

### **Subchapter A. License Required**

#### **→ § 560.001. License Required**

- (a) A person may not operate a pharmacy in this state unless the pharmacy is licensed by the board.
- (b) A pharmacy located in another state may not ship, mail, or deliver to this state a prescription drug or device dispensed under a prescription drug order, or dispensed or delivered as authorized by Subchapter D, Chapter 562, unless the pharmacy is licensed by the board or is exempt under [Section 560.004](#).
- (c) A pharmacy located in Canada may not ship, mail, or deliver to this state a prescription drug dispensed under a prescription drug order to a resident of this state unless the pharmacy is designated by the board under [Section 554.016](#).

#### **→ § 560.002. Use of “Pharmacy”; Providing Pharmacy Services Without License**

- (a) A person may not display in or on a place of business the word “pharmacy” or “apothecary” in any language, any word or combination of words of the same or similar meaning, or a graphic representation that would lead or tend to lead the public to believe that the business is a pharmacy unless the facility is a pharmacy licensed under this chapter.
- (b) A person may not advertise a place of business as a pharmacy or provide pharmacy services unless the facility is a pharmacy licensed under this chapter.

#### **→ § 560.003. Prohibited Advertising of Pharmacy**

- (a) A pharmacy that is not licensed under this chapter may not advertise the pharmacy's services in this state.
- (b) A person who is a resident of this state may not advertise the pharmacy services of a pharmacy that is not licensed by the board if the pharmacy or person makes the advertisement with the knowledge that the advertisement will or is likely to induce a resident of this state to use the pharmacy to dispense a prescription drug order.

#### **→ § 560.004. Exemption**

The board may grant an exemption from the licensing requirements of this chapter on the application of a pharmacy located in another state that restricts to isolated transactions the pharmacy's dispensing of a prescription drug or device to a resident of this state.

## **Subchapter B. Pharmacy Classification**

### **→ § 560.051. License Classifications**

(a) Each applicant for a pharmacy license shall apply for a license in one or more of the following classifications:

(1) Class A;

(2) Class B;

(3) Class C;

(4) Class D;

(5) Class E; or

(6) another classification established by the board under [Section 560.053](#).

(b) A Class A pharmacy license or community pharmacy license authorizes a pharmacy to dispense a drug or device to the public under a prescription drug order.

(c) A Class B pharmacy license or nuclear pharmacy license authorizes a pharmacy to dispense a radioactive drug or device for administration to an ultimate user.

(d) A Class C pharmacy license or institutional pharmacy license may be issued to a pharmacy located in:

(1) an inpatient facility, including a hospital, licensed under Chapter 241 or 577, Health and Safety Code;

(2) a hospital maintained or operated by the state;

(3) a hospice inpatient facility licensed under Chapter 142, Health and Safety Code; or

- (4) an ambulatory surgical center licensed under Chapter 243, Health and Safety Code.
- (e) A Class D pharmacy license or clinic pharmacy license authorizes a pharmacy to dispense a limited type of drug or device under a prescription drug order.
- (f) A Class E pharmacy license or nonresident pharmacy license may be issued to a pharmacy located in another state whose primary business is to:
  - (A) dispense a prescription drug or device under a prescription drug order; and
  - (B) deliver the drug or device to a patient, including a patient in this state, by United States mail, common carrier, or delivery service.
- (g) The board may determine the classification under which a pharmacy may be licensed.

→ § 560.052. Qualifications

- (a) The board by rule shall establish the standards that each pharmacy and the pharmacy's employees involved in the practice of pharmacy must meet to qualify for licensing as a pharmacy in each classification.
- (b) To qualify for a pharmacy license, an applicant must submit to the board:
  - (1) a license fee set by the board, except as provided by Subsection (d); and
  - (2) a completed application that:
    - (A) is on a form prescribed by the board;
    - (B) is given under oath;
    - (C) includes proof that a license held in this state or another state, if applicable, has not been restricted, suspended, revoked, or surrendered for any reason; and
    - (D) includes a statement of:
      - (i) the ownership;

(ii) the location of the pharmacy;

(iii) the license number of each pharmacist who is employed by the pharmacy, if the pharmacy is located in this state, or who is licensed to practice pharmacy in this state, if the pharmacy is located in another state ;

(iv) the license number of the pharmacist-in-charge; and

(v) any other information the board determines necessary.

(c) A pharmacy located in another state that applies for a license , in addition to satisfying the other requirements of this chapter, must provide to the board:

(1) evidence that the applicant holds a pharmacy license, registration, or permit in good standing issued by the state in which the pharmacy is located;

(2) the name of the owner and pharmacist-in-charge of the pharmacy for service of process;

(3) evidence of the applicant's ability to provide to the board a record of a prescription drug order dispensed or delivered as authorized by Subchapter D, Chapter 562, by the applicant to a resident of or practitioner in this state not later than 72 hours after the time the board requests the record;

(4) an affidavit by the pharmacist-in-charge that states that the pharmacist has read and understands the laws and rules relating to the applicable license ;

(5) proof of creditworthiness;

(6) an inspection report issued:

(A) not more than two years before the date the license application is received; and

(B) by the pharmacy licensing board in the state of the pharmacy's physical location, except as provided by Subsection (f); and

(7) any other information the board determines necessary.

(d) A pharmacy operated by the state or a local government that qualifies for a Class D pharmacy license is not required to pay a fee to obtain a license.

(e) With respect to a Class C pharmacy license, the board may issue a license to a pharmacy on certification by the appropriate agency that the facility in which the pharmacy is located has substantially completed the requirements for licensing.

(f) A Class E pharmacy may submit an inspection report issued by an entity other than the pharmacy licensing board of the state in which the pharmacy is physically located if:

(1) the state's licensing board does not conduct inspections;

(2) the inspection is substantively equivalent to an inspection conducted by the board, as determined by board rule; and

(3) the inspecting entity meets specifications adopted by the board for inspecting entities.

(g) A license may not be issued to a pharmacy that compounds sterile preparations unless the pharmacy has been inspected by the board to ensure the pharmacy meets the safety standards and other requirements of this subtitle and board rules.

(h) The board may accept, as satisfying the inspection requirement in Subsection (g) for a pharmacy located in another state, an inspection report issued by the pharmacy licensing board in the state in which the pharmacy is located if:

(1) the board determines that the other state has comparable standards and regulations applicable to pharmacies, including standards and regulations related to health and safety; and

(2) the pharmacy provides to the board any requested documentation related to the inspection.

→ **§ 560.0525. Additional Qualification Requirements for Canadian Pharmacies**

(a) To pass an inspection by the board, a Canadian pharmacy must meet Texas licensing standards.

(b) In addition to satisfying the other requirements of this chapter, to qualify for designation by the board under [Section 554.016](#), a Canadian pharmacy applicant must submit to the board:

(1) evidence satisfactory to the board that the applicant holds a pharmacy license, registration, or permit in good standing issued by Canada or the Canadian province in which the pharmacy is located and is not subject to any pending disciplinary action or legal action by any regulatory authority;



- (2) the name and address of the pharmacy's owner and pharmacist-in-charge for service of process;
  - (3) evidence of the applicant's ability to provide to the board, not later than 72 hours after the time the board requests the record, a record of a prescription drug order authorizing the pharmacy to dispense a prescription drug to a resident of this state;
  - (4) an affidavit by the pharmacist-in-charge that states the pharmacist has read and understands this subtitle and the rules adopted under this subtitle that relate to a Canadian pharmacy designated by the board as having passed inspection to dispense prescription drugs to residents in this state;
  - (5) evidence satisfactory to the board that the applicant meets the standards established by board rule to ensure customer safety for each order filled and in the dispensing, storing, packaging, shipping, and delivering of prescription drugs; and
  - (6) evidence satisfactory to the board that the applicant's employees hold the appropriate Canadian licenses required to dispense prescription drugs in Canada.
- (c) Before a Canadian pharmacy is designated as having passed inspection to dispense prescription drugs to residents in this state, a representative of the board shall visit the pharmacy's facilities and review the pharmacy's compliance with the requirements and safety standards established under this subtitle.

→ **§ 560.053. Establishment of Additional Pharmacy Classifications**

The board by rule may establish classifications of pharmacy licenses in addition to the classifications under [Section 560.051](#) if the board determines that:

- (1) the practice setting will provide pharmaceutical care services to the public;
- (2) the existing classifications of pharmacy licenses are not appropriate for that practice setting; and
- (3) establishment of a new classification of pharmacy license is necessary to protect the public health, safety, and welfare.

**Subchapter C. Restrictions on License**

→ **§ 560.101. License Not Transferable**

A pharmacy license issued under this chapter is not transferable or assignable.

**→ § 560.102. Separate License for Each Location**

- (a) A separate pharmacy license is required for each principal place of business of a pharmacy.
- (b) Only one pharmacy license may be issued for a specific location.

**Subchapter D. Certain Prohibited Practices****→ § 560.103. False Affidavit**

A person who falsely makes the affidavit prescribed by [Section 560.052](#) is guilty of fraudulent and dishonorable conduct and malpractice.

**Chapter 561. Renewal of Pharmacy License****→ § 561.001. Expiration of License**

- (a) A pharmacy license expires May 31 of each year.
- (b) The board may adopt a system under which pharmacy licenses expire on various dates during the year or every other year, as appropriate.
- (c) If the board changes the expiration date of a license, the board shall prorate the license renewal fee to cover the number of months for which the license is valid for the year in which the date is changed. The total license renewal fee is due on the new expiration date.

**→ § 561.002. Pharmacy License Renewal**

A pharmacy license must be renewed annually or biennially as determined by the board.

**→ § 561.003. Requirements for Renewal**

- (a) The board by rule shall establish:
  - (1) procedures to be followed for renewal of a pharmacy license;
  - (2) the fees to be paid for renewal of a pharmacy license; and

(3) the standards in each classification that each pharmacy and the pharmacy's employees involved in the practice of pharmacy must meet to qualify for relicensing as a pharmacy.

(b) A pharmacy license may be renewed by:

(1) payment of a renewal fee set by the board; and

(2) filing with the board a completed application for a license renewal certificate given under oath before the expiration date of the license or license renewal certificate.

(c) A pharmacy whose license has been expired for 90 days or less may renew the expired license by paying to the board a renewal fee that is equal to one and one-half times the normally required renewal fee for the license.

(d) A pharmacy whose license has been expired for more than 90 days but less than one year may renew the expired license by paying to the board a renewal fee that is equal to two times the normally required renewal fee for the license.

(e) If a pharmacy's license has been expired for one year or more, the pharmacy may not renew the license. The pharmacy may obtain a new license by complying with the requirements and procedures for obtaining an original license.

(f) A pharmacy may not renew a license under this section if the pharmacy's license to operate in another state has been suspended, revoked, canceled, or subject to an action that prohibits the pharmacy from operating in that state.

→ **§ 561.0031. Additional Renewal Requirement for Class E Pharmacy**

(a) In addition to the renewal requirements under [Section 561.003](#), the board shall require that a Class E pharmacy have on file with the board an inspection report issued:

(1) not more than three years before the date the renewal application is received; and

(2) by the pharmacy licensing board in the state of the pharmacy's physical location, except as provided by Subsection (b).

(b) A Class E pharmacy may have on file with the board an inspection report issued by an entity other than the pharmacy licensing board of the state in which the pharmacy is physically located if the requirements of [Section 560.052\(f\)](#) are met.

**→ § 561.0032. Additional Renewal Requirement for Compounding Pharmacy**

(a) In addition to the renewal requirements under [Section 561.003](#), a pharmacy that compounds sterile preparations may not renew a pharmacy license unless the pharmacy:

- (1) has been inspected as provided by board rule; and
  - (2) if the pharmacy is located in another state, has reimbursed the board for all expenses, including travel, incurred by the board in inspecting the pharmacy during the term of the expiring license.
- (b) The board may accept, as satisfying the inspection requirement in Subsection (a) for a pharmacy located in another state, an inspection report issued by the pharmacy licensing board in the state in which the pharmacy is located if:
- (1) the board determines that the other state has comparable standards and regulations applicable to pharmacies, including standards and regulations related to health and safety; and
  - (2) the pharmacy provides to the board any requested documentation related to the inspection.

**→ § 561.004. Issuance of License Renewal Certificate**

On timely receipt of a completed application and renewal fee, the board shall issue a license renewal certificate that contains:

- (1) the pharmacy license number;
- (2) the period for which the license is renewed; and
- (3) other information the board determines necessary.

**→ § 561.005. Suspension of Pharmacy License for Nonrenewal**

(a) The board shall suspend the license and remove from the register of licensed pharmacies the name of a pharmacy that does not file a completed application and pay the renewal fee on or before the date the license expires.

(b) After review by the board, the board may determine that Subsection (a) does not apply if the license is the subject of a pending investigation or disciplinary action.

## **Chapter 562. Practice by License Holder (Refs & Annos)**

### **Subchapter A. Prescription and Substitution Requirements**

#### **→ § 562.001. Definitions**

In this subchapter:

(1) “Generically equivalent” means a drug that is pharmaceutically equivalent and therapeutically equivalent to the drug prescribed.

(2) “Pharmaceutically equivalent” means drug products that have identical amounts of the same active chemical ingredients in the same dosage form and that meet the identical compendial or other applicable standards of strength, quality, and purity according to the United States Pharmacopoeia or another nationally recognized compendium.

(3) “Therapeutically equivalent” means pharmaceutically equivalent drug products that, if administered in the same amounts, will provide the same therapeutic effect, identical in duration and intensity.

#### **→ § 562.002. Legislative Intent**

It is the intent of the legislature to save consumers money by allowing the substitution of lower-priced generically equivalent drug products for certain brand name drug products and for pharmacies and pharmacists to pass on the net benefit of the lower costs of the generically equivalent drug product to the purchaser.

#### **→ § 562.003. Disclosure of Price; Patient's Option**

If the price of a drug to a patient is lower than the amount of the patient's copayment under the patient's prescription drug insurance plan, the pharmacist shall offer the patient the option of paying for the drug at the lower price instead of paying the amount of the copayment.

#### **→ § 562.004. Prescription Transmitted Orally by Practitioner**

A pharmacist to whom a prescription is transmitted orally shall:

(1) note on the file copy of the prescription the dispensing instructions of the practitioner or the practitioner's agent; and

(2) retain the prescription for the period specified by law.

**→ § 562.005. Record of Dispensed Drug**

A pharmacist shall record on the prescription form the name, strength, and manufacturer or distributor of a drug dispensed as authorized by this subchapter.

**→ § 562.006. Label**

(a) Unless otherwise directed by the practitioner, the label on the dispensing container must indicate the actual drug dispensed, indicated by either:

(1) the brand name; or

(2) if there is not a brand name, the generic name, the strength of the drug, and the name of the manufacturer or distributor of the drug.

(a-1) In addition to the information required by Subsection (a), the label on the dispensing container of a drug dispensed by a Class A or Class E pharmacy must indicate:

(1) the name, address, and telephone number of the pharmacy;

(2) the date the prescription is dispensed;

(3) the name of the prescribing practitioner;

(4) the name of the patient or, if the drug was prescribed for an animal, the species of the animal and the name of the owner;

(5) instructions for use;

(6) the quantity dispensed;

(7) if the drug is dispensed in a container other than the manufacturer's original container, the date after which the prescription should not be used, determined according to criteria established by board rule based on standards in the United States Pharmacopeia-National Formulary; and

(8) any other information required by board rule.

(a-2) The information required by Subsection (a-1)(7) may be recorded on any label affixed to the dispensing

container.

(a-3) Subsection (a-1) does not apply to a prescription dispensed to a person at the time of release from prison or jail if the prescription is for not more than a 10-day supply of medication.

(b) If a drug has been selected other than the one prescribed, the pharmacist shall place on the container the words “Substituted for brand prescribed” or “Substituted for ‘brand name’” where “brand name” is the name of the brand name drug prescribed.

(c) The board shall adopt rules requiring the label on a dispensing container to be in plain language and printed in an easily readable font size for the consumer.

#### → § 562.0061. Other Prescription Information

The board shall adopt rules specifying the information a pharmacist must provide to a consumer when dispensing a prescription to the consumer for self-administration. The information must be:

- (1) written in plain language;
- (2) relevant to the prescription; and
- (3) printed in an easily readable font size.

#### → § 562.0062. Required Statement Regarding Medication Disposal

The board by rule shall require pharmacists, when dispensing certain drugs, to include on the dispensing container label or in the information required by [Section 562.0061](#) the statement “Do not flush unused medications or pour down a sink or drain.”

#### → § 562.007. Refills

Except as provided by [Section 562.0545](#), a properly authorized prescription refill shall follow the original dispensing instruction unless otherwise indicated by the practitioner or the practitioner's agent.

#### → § 562.008. Generic Equivalent Authorized

(a) If a practitioner certifies on the prescription form that a specific prescribed brand is medically necessary, the pharmacist shall dispense the drug as written by the practitioner. The certification must be made as

required by the dispensing directive adopted under [Section 562.015](#). This subchapter does not permit a pharmacist to substitute a generically equivalent drug unless the substitution is made as provided by this subchapter.

(b) Except as otherwise provided by this subchapter, a pharmacist who receives a prescription for a drug for which there is one or more generic equivalents may dispense any of the generic equivalents.

→ **§ 562.009. Requirements Concerning Selection of Generically Equivalent Drug**

(a) Before delivery of a prescription for a generically equivalent drug, a pharmacist must personally, or through the pharmacist's agent or employee:

(1) inform the patient or the patient's agent that a less expensive generically equivalent drug is available for the brand prescribed; and

(2) ask the patient or the patient's agent to choose between the generically equivalent drug and the brand prescribed.

(a-1) In addition to the requirements of Subsection (a), a pharmacist must display, in a prominent place that is in clear public view where prescription drugs are dispensed, a sign in block letters not less than one inch in height that reads, in both English and Spanish:

“TEXAS LAW REQUIRES A PHARMACIST TO INFORM YOU IF A LESS EXPENSIVE GENERICALLY EQUIVALENT DRUG IS AVAILABLE FOR CERTAIN BRAND NAME DRUGS AND TO ASK YOU TO CHOOSE BETWEEN THE GENERIC AND THE BRAND NAME DRUG. YOU HAVE A RIGHT TO ACCEPT OR REFUSE THE GENERICALLY EQUIVALENT DRUG.”

(b) A pharmacy is not required to comply with the provisions of Subsection (a):

(1) in the case of the refill of a prescription for which the pharmacy previously complied with Subsection (a) with respect to the same patient or patient's agent; or

(2) if the patient's physician or physician's agent advises the pharmacy that:

(A) the physician has informed the patient or the patient's agent that a less expensive generically equivalent drug is available for the brand prescribed; and

(B) the patient or the patient's agent has chosen either the brand prescribed or the less expensive generically equivalent drug.



(c) A pharmacy that supplies a prescription by mail is considered to have complied with the provisions of Subsection (a) if the pharmacy includes on the prescription order form completed by the patient or the patient's agent language that clearly and conspicuously:

(1) states that if a less expensive generically equivalent drug is available for the brand prescribed, the patient or the patient's agent may choose between the generically equivalent drug and the brand prescribed; and

(2) allows the patient or the patient's agent to indicate the choice of the generically equivalent drug or the brand prescribed.

(d) If the patient or the patient's agent fails to indicate otherwise to a pharmacy on the prescription order form under Subsection (c), the pharmacy may dispense a generically equivalent drug.

(e) If the prescription is for an immunosuppressant drug, as defined by [Section 562.0141\(a\)\(1\)](#), the pharmacist must comply with the provisions of [Section 562.0141](#). This subsection expires if [Section 562.0141](#) expires under the requirements of [Section 562.0142](#).

#### → [§ 562.010. Responsibility Concerning Generically Equivalent Drug; Liability](#)

(a) A pharmacist who selects a generically equivalent drug to be dispensed under this subchapter assumes the same responsibility for selecting the generically equivalent drug as the pharmacist does in filling a prescription for a drug prescribed by generic name.

(b) The prescribing practitioner is not liable for a pharmacist's act or omission in selecting, preparing, or dispensing a drug under this subchapter.

#### → [§ 562.011. Restriction on Selection of and Charging for Generically Equivalent Drug](#)

(a) A pharmacist may not select a generically equivalent drug unless the generically equivalent drug selected costs the patient less than the prescribed drug.

(b) A pharmacist may not charge for dispensing a generically equivalent drug a professional fee higher than the fee the pharmacist customarily charges for dispensing the brand name drug prescribed.

#### → [§ 562.012. Substitution of Dosage Form Permitted](#)

With the patient's consent, a pharmacist may dispense a dosage form of a drug different from that prescribed, such as a tablet instead of a capsule or a liquid instead of a tablet, if the dosage form dispensed:

- (1) contains the identical amount of the active ingredients as the dosage prescribed for the patient;
- (2) is not an enteric-coated or timed release product; and
- (3) does not alter desired clinical outcomes.

→ **§ 562.013. Applicability of Subchapter**

Unless a drug is determined to be generically equivalent to the brand prescribed, drug selection as authorized by this subchapter does not apply to:

- (1) an enteric-coated tablet;
- (2) a controlled release product;
- (3) an injectable suspension, other than an antibiotic;
- (4) a suppository containing active ingredients for which systemic absorption is necessary for therapeutic activity; or
- (5) a different delivery system for aerosol or nebulizer drugs.

→ **§ 562.014. Narrow Therapeutic Index Drugs**

(a) Except as provided by this section, drug selection as authorized by this subchapter does not apply to the refill of a prescription for a narrow therapeutic index drug. The board, in consultation with the Texas Medical Board, shall by rule establish a list of narrow therapeutic index drugs to which this subsection applies. A prescription for a narrow therapeutic index drug may be refilled only by using the same drug product by the same manufacturer that the pharmacist last dispensed under the prescription, unless otherwise agreed to by the prescribing practitioner. If a pharmacist does not have the same drug product by the same manufacturer in stock to refill the prescription, the pharmacist may dispense a drug product that is generically equivalent if the pharmacist, before dispensing the generically equivalent drug product, notifies:

- (1) the patient, at the time the prescription is dispensed, that a substitution of the prescribed drug product has been made; and
- (2) the prescribing practitioner of the drug product substitution by telephone, facsimile, or mail, at the earliest reasonable time, but not later than 72 hours after dispensing the prescription.

(b) The board and the Texas Medical Board shall establish a joint committee to recommend to the board a list of narrow therapeutic index drugs and the rules, if any, by which this section applies to those drugs. The committee must consist of an equal number of members from each board. The committee members shall select a member of the committee to serve as presiding officer for a one year term. The presiding officer may not represent the same board as the presiding officer's predecessor.

(c) Expired.

(d) Expired.

→ **§ 562.0141. Transplant Immunosuppressant Drug Product Selection Prohibited**

<Text of section effective subject to conditions established by § 562.0142>

(a) In this section:

(1) “Immunosuppressant drug” means any drug prescribed for immunosuppressant therapy following a transplant.

(2) “Interchange” means the substitution of one version of the same immunosuppressant drug, including a generic version for the prescribed brand, a brand version for the prescribed generic version, a generic version by one manufacturer for a generic version by a different manufacturer, a different formulation of the prescribed immunosuppressant drug, or a different immunosuppressant drug for the immunosuppressant drug originally prescribed.

(b) A pharmacist may not interchange an immunosuppressant drug or formulation of an immunosuppressant drug, brand or generic, for the treatment of a patient following a transplant without prior consent to the interchange from the prescribing practitioner.

(c) To comply with Subsection (b), a pharmacist shall notify a prescribing practitioner orally or electronically to secure permission to interchange an immunosuppressant drug or formulation of an immunosuppressant drug, brand or generic. The practitioner's authorization or denial of authorization must be documented by the pharmacist and by the practitioner.

(d) If a pharmacist does not have the same drug product by the same manufacturer in stock to refill the prescription, or if the practitioner is unavailable to give authorization, the pharmacist may dispense a drug product that is generically equivalent if the pharmacist, before dispensing the generally equivalent drug product:

- (1) notifies and receives consent from the patient, at the time the prescription is dispensed, to substitute the prescribed drug product; and
  - (2) notifies the prescribing practitioner of the drug product substitution orally or electronically at the earliest reasonable time, but not later than 24 hours after dispensing the prescription.
- (e) This section is only effective subject to the conditions established by [Section 562.0142](#).

→ **§ 562.0142. Adoption of Rules**

- (a) If, not later than October 1, 2007, a drug manufacturer requests that the joint committee under [Section 562.014](#) conduct a hearing and make a recommendation to include a drug listed in [Section 562.014\(c\)](#) on the list of narrow therapeutic index drugs, the joint committee shall make a recommendation to the board to enable the board to adopt a rule and issue findings not later than July 1, 2008.
- (b) If, not later than October 1, 2007, no drug manufacturer requests that the joint committee conduct a hearing and make recommendations to the board to include a drug listed in [Section 562.014\(c\)](#) on the list of narrow therapeutic index drugs, [Section 562.0141](#) expires October 1, 2007.
- (c) If all drug manufacturers that request, before October 1, 2007, the joint committee to conduct a hearing and make a recommendation to the board to include a drug listed in [Section 562.014\(c\)](#) on the list of narrow therapeutic index drugs subsequently withdraw those requests before the date the joint committee makes a recommendation to include the drug on that list, [Section 562.0141](#) expires effective on the date of the manufacturers' withdrawal of those requests.
- (d) If the joint committee receives a request under Subsection (a), the recommendation of the joint committee under that subsection may include the drugs listed in [Section 562.014\(c\)](#) or the joint committee may recommend that no drug should be added to the list of narrow therapeutic index drugs following the review by the joint committee.
- (e) If the joint committee receives a request under Subsection (a) and, not later than July 1, 2008, the board adopts a rule to include any drug listed in [Section 562.014\(c\)](#) on the list of narrow therapeutic index drugs or determines by rule that no drug should be added to the list of narrow therapeutic index drugs, [Section 562.0141](#) expires on July 1, 2008.
- (f) If the joint committee receives a request under Subsection (a) and the board does not before July 1, 2008, adopt a rule to include any drug listed in [Section 562.014\(c\)](#) on the list of narrow therapeutic index drugs or determine by rule that no drug should be added to the list of narrow therapeutic index drugs, [Section 562.0141](#) takes effect July 1, 2008.

(g) If the joint committee receives a request under Subsection (a) and litigation or a request for an attorney general's opinion regarding this section, [Section 562.014](#), or [Section 562.0141](#) is filed by a drug manufacturer between the effective date of this section and July 1, 2008, the time limits established by Subsections (e) and (f) are tolled until the litigation is resolved or the attorney general renders an opinion.

(h) For purposes of this section, notice of the following must be published in the Texas Register not later than the third business day after the date of occurrence:

(1) a request by a drug manufacturer for inclusion of a drug on the list of narrow therapeutic index drugs;

(2) withdrawal of a request described by Subdivision (1);

(3) litigation described by Subsection (g);

(4) resolution of litigation described by Subsection (g); and

(5) a request for an attorney general's opinion described by Subsection (g).

→ **§ 562.015. Dispensing Directive; Compliance with Federal Law**

(a) The board shall adopt rules to provide a dispensing directive to instruct pharmacists on the manner in which to dispense a drug according to the contents of a prescription. The rules adopted under this section must:

(1) require the use of the phrase “brand necessary” or “brand medically necessary” on a prescription form to prohibit the substitution of a generically equivalent drug for a brand name drug;

(2) be in a format that protects confidentiality as required by the Health Insurance Portability and Accountability Act of 1996 ([29 U.S.C. Section 1181 et seq.](#)) and its subsequent amendments;

(3) comply with federal and state law, including rules, with regard to formatting and security requirements;

(4) be developed to coordinate with [42 C.F.R. Section 447.331\(c\)](#); and

(5) include an exemption for electronic prescriptions as provided by Subsection (b).

(b) The board shall provide an exemption from the directive adopted under this section for prescriptions transmitted electronically. The board may regulate the use of electronic prescriptions in the manner provided

by federal law, including rules.

### **Subchapter B. Other Practice by Pharmacist**

#### **→ § 562.051. Display of Pharmacist License**

A pharmacist shall publicly display the pharmacist's license to practice pharmacy and license renewal certificate in the pharmacist's primary place of practice.

#### **→ § 562.052. Release of Confidential Records**

A confidential record is privileged and a pharmacist may release a confidential record only to:

- (1) the patient or the patient's agent;
- (2) a practitioner or another pharmacist if, in the pharmacist's professional judgment, the release is necessary to protect the patient's health and well-being;
- (3) the board or to a person or another state or federal agency authorized by law to receive the confidential record;
- (4) a law enforcement agency engaged in investigation of a suspected violation of 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.](#));
- (5) a person employed by a state agency that licenses a practitioner, if the person is performing the person's official duties; or
- (6) an insurance carrier or other third party payor authorized by the patient to receive the information.

#### **→ § 562.053. Reports to Board**

A pharmacist shall report in writing to the board not later than the 10th day after the date of a change of address or place of employment.

#### **→ § 562.054. Emergency Refills**

- (a) A pharmacist may exercise the pharmacist's professional judgment in refilling a prescription for a

prescription drug, other than a controlled substance listed in Schedule II as established by the commissioner of state health services under Chapter 481, Health and Safety Code, without the authorization of the prescribing practitioner if:

(1) failure to refill the prescription might result in an interruption of a therapeutic regimen or create patient suffering;

(2) either:

(A) a natural or manmade disaster has occurred that prohibits the pharmacist from being able to contact the practitioner; or

(B) the pharmacist is unable to contact the practitioner after reasonable effort;

(3) the quantity of prescription drug dispensed does not exceed a 72-hour supply;

(4) the pharmacist informs the patient or the patient's agent at the time of dispensing that the refill is being provided without the practitioner's authorization and that authorization of the practitioner is required for a future refill; and

(5) the pharmacist informs the practitioner of the emergency refill at the earliest reasonable time.

(b) Notwithstanding Subsection (a), in the event of a natural or manmade disaster, a pharmacist may dispense not more than a 30-day supply of a prescription drug, other than a controlled substance listed in Schedule II as established by the commissioner of state health services under Chapter 481, Health and Safety Code, without the authorization of the prescribing practitioner if:

(1) failure to refill the prescription might result in an interruption of a therapeutic regimen or create patient suffering;

(2) the natural or manmade disaster prohibits the pharmacist from being able to contact the practitioner;

(3) the governor has declared a state of disaster under Chapter 418, Government Code; and

(4) the board, through the executive director, has notified pharmacies in this state that pharmacists may dispense up to a 30-day supply of a prescription drug.

(c) The prescribing practitioner is not liable for an act or omission by a pharmacist in dispensing a prescription

drug under Subsection (b).

→ **§ 562.0545. 90-Day Supply and Accelerated Refills**

A pharmacist may dispense up to a 90-day supply of a dangerous drug pursuant to a valid prescription that specifies the dispensing of a lesser amount followed by periodic refills of that amount if:

- (1) the total quantity of dosage units dispensed does not exceed the total quantity of dosage units authorized by the prescriber on the original prescription, including refills;
- (2) the patient consents to the dispensing of up to a 90-day supply and the physician has been notified electronically or by telephone;
- (3) the physician has not specified on the prescription that dispensing the prescription in an initial amount followed by periodic refills is medically necessary;
- (4) the dangerous drug is not a psychotropic drug; and
- (5) the patient is at least 18 years of age.

→ **§ 562.055. Report to Texas Department of Health**

A pharmacist shall report to the Texas Department of Health any unusual or increased prescription rates, unusual types of prescriptions, or unusual trends in pharmacy visits that may be caused by bioterrorism, epidemic or pandemic disease, or novel and highly fatal infectious agents or biological toxins that might pose a substantial risk of a significant number of human fatalities or incidents of permanent or long-term disability. Prescription-related events that require a report include:

- (1) an unusual increase in the number of:
  - (A) prescriptions to treat respiratory or gastrointestinal complaints or fever;
  - (B) prescriptions for antibiotics; and
  - (C) requests for information on over-the-counter pharmaceuticals to treat respiratory or gastrointestinal complaints or fever; and
- (2) any prescription that treats a disease that is relatively uncommon and has bioterrorism potential.



**→ § 562.056. Practitioner-Patient Relationship Required**

(a) Before dispensing a prescription, a pharmacist shall determine, in the exercise of sound professional judgment, that the prescription is a valid prescription. A pharmacist may not dispense a prescription drug if the pharmacist knows or should know that the prescription was issued on the basis of an Internet-based or telephonic consultation without a valid practitioner-patient relationship.

(a-1) To be a valid prescription, a prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of the practitioner's professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is on the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

(b) This section does not prohibit a pharmacist from dispensing a prescription when a valid practitioner-patient relationship is not present in an emergency.

**→ § 562.057. Expired****Subchapter C. Practice by Pharmacy****→ § 562.101. Supervision of Pharmacy**

(a) A pharmacy is required to be under the supervision of a pharmacist as provided by this section.

(b) A Class A or Class B pharmacy is required to be under the continuous on-site supervision of a pharmacist during the time the pharmacy is open for pharmacy services.

(c) A Class C pharmacy that is in an institution with more than 100 beds is required to be under the continuous on-site supervision of a pharmacist during the time the pharmacy is open for pharmacy services.

(d) A Class C pharmacy that is in an institution with 100 beds or fewer is required to have the services of a pharmacist on a part-time or consulting basis according to the needs of the institution.

(e) A Class D pharmacy is required to be under the continuous supervision of a pharmacist whose services are required according to the needs of the pharmacy.

(f) A Class E pharmacy is required to be under the continuous on-site supervision of a pharmacist and shall designate one pharmacist licensed to practice pharmacy by the regulatory or licensing agency of the state in which the Class E pharmacy is located to serve as the pharmacist-in-charge of the Class E pharmacy.

(f-1) A Canadian pharmacy designated by the board as having passed inspection to dispense prescription drugs

to residents in this state is required to be under the continuous on-site supervision of a pharmacist and shall designate one pharmacist licensed to practice pharmacy by the regulatory or licensing agency of Canada or of the Canadian province in which the Canadian pharmacy is located to serve as the pharmacist-in-charge of the Canadian pharmacy.

(g) For a pharmacy license classification established under [Section 560.053](#), the board shall adopt rules that provide for the supervision of the pharmacy by a pharmacist. Supervision under the board rules must require at least continuous supervision by a pharmacist according to the needs of the pharmacy.

→ **§ 562.1011. Operation of Class C Pharmacy in Certain Rural Hospitals**

(a) In this section:

(1) “Nurse” has the meaning assigned by [Section 301.002](#). The term includes a nurse who is also registered as a pharmacy technician.

(2) “Rural hospital” means a licensed hospital with 75 beds or fewer that:

(A) is located in a county with a population of 50,000 or less; or

(B) has been designated by the Centers for Medicare and Medicaid Services as a critical access hospital, rural referral center, or sole community hospital.

(b) If a practitioner orders a prescription drug or device for a patient in a rural hospital when the hospital pharmacist is not on duty or when the institutional pharmacy is closed, a nurse or practitioner may withdraw the drug or device from the pharmacy in sufficient quantity to fill the order.

(c) The hospital pharmacist shall verify the withdrawal of a drug or device under Subsection (b) and perform a drug regimen review not later than the seventh day after the date of the withdrawal.

(d) In a rural hospital that uses a floor stock method of drug distribution, a nurse or practitioner may withdraw a prescription drug or device from the institutional pharmacy in the original manufacturer's container or a prepackaged container.

(e) The hospital pharmacist shall verify the withdrawal of a drug or device under Subsection (d) and perform a drug regimen review not later than the seventh day after the date of the withdrawal.

(f) A rural hospital may allow a pharmacy technician to perform the duties specified in Subsection (g) if:

- (1) the pharmacy technician is registered and meets the training requirements specified by the board;
  - (2) a pharmacist is accessible at all times to respond to any questions and needs of the pharmacy technician or other hospital employees, by telephone, answering or paging service, e-mail, or any other system that makes a pharmacist accessible; and
  - (3) a nurse or practitioner or a pharmacist by remote access verifies the accuracy of the actions of the pharmacy technician.
- (g) If the requirements of Subsection (f) are met, the pharmacy technician may, during the hours that the institutional pharmacy in the hospital is open, perform the following duties in the pharmacy without the direct supervision of a pharmacist:
- (1) enter medication order and drug distribution information into a data processing system;
  - (2) prepare, package, or label a prescription drug according to a medication order if a licensed nurse or practitioner verifies the accuracy of the order before administration of the drug to the patient;
  - (3) fill a medication cart used in the rural hospital;
  - (4) distribute routine orders for stock supplies to patient care areas;
  - (5) access and restock automated medication supply cabinets; and
  - (6) perform any other duty specified by the board by rule.
- (h) The pharmacist-in-charge of an institutional pharmacy in a rural hospital shall develop and implement policies and procedures for the operation of the pharmacy when a pharmacist is not on-site.
- (i) On or after September 1, 2011, the board may establish, by rule, a requirement for prospective and retrospective drug use review by a pharmacist for each new drug order. A drug use review is not required when a delay in administration of the drug would harm the patient in an urgent or emergency situation, including sudden changes in a patient's clinical status.
- (j) Rural hospitals may establish standing orders and protocols, to be developed jointly by the pharmacist and medical staff, that may include additional exceptions to instances in which prospective drug use review is required.

(k) This section does not restrict or prohibit the board from adopting a rule related to authorizing the withdrawal of a drug or device by a nurse or practitioner from, or the supervision of a pharmacy technician in, an institutional pharmacy not located in a rural hospital. As part of the rulemaking process, the board shall consider the effect that a proposed rule, if adopted, would have on access to pharmacy services in hospitals that are not rural hospitals.

(l) The board shall adopt rules to implement this section, including rules specifying:

(1) the records that must be maintained under this section;

(2) the requirements for policies and procedures for operation of a pharmacy when a pharmacist is not on-site; and

(3) the training requirements for pharmacy technicians.

→ **§ 562.102. Confidential Record**

A pharmacy shall comply with [Section 562.052](#) concerning the release of a confidential record.

→ **§ 562.103. Display of Licenses by Pharmacy**

(a) A pharmacy shall display in the pharmacy in full public view the license under which the pharmacy operates.

(b) A Class A or Class C pharmacy that serves the public shall:

(1) display the word “pharmacy” or a similar word or symbol as determined by the board in a prominent place on the front of the pharmacy; and

(2) display in public view the license of the pharmacist-in-charge of the pharmacy.

(c) A pharmacy shall maintain and make available to the public on request proof that each pharmacist, pharmacist-intern, pharmacy technician, and pharmacist technician trainee working in the pharmacy holds the appropriate license or registration.

→ **§ 562.104. Toll-Free Telephone Number Required**

A pharmacy whose primary business is to dispense a prescription drug or device under a prescription drug

order to a patient located outside the area covered by the pharmacy's telephone area code shall provide a toll-free telephone line that is answered during normal business hours to enable communication between a patient or the patient's physician and a pharmacist at the pharmacy who has access to the patient's records.

→ **§ 562.1045. Linking Internet Sites**

(a) This section applies only to a pharmacy that:

(1) maintains a generally accessible Internet site; and

(2) sells or distributes drugs through the Internet.

(b) A pharmacy subject to this section shall link its site to the Internet site maintained by the board. The link must be:

(1) on the pharmacy's initial home page; and

(2) if the pharmacy sells drugs through its site, on the page where the sale occurs.

(c) A pharmacy subject to this section shall post:

(1) on its initial home page general information on how to file a complaint about the pharmacy with the board; and

(2) specific information on how to file a complaint with the board not more than two links away from its initial home page.

(d) Information under Subsection (c) must include the board's telephone number, mailing address, and Internet website address.

→ **§ 562.105. Maintenance of Records**

A pharmacy shall maintain a permanent record of:

(1) any civil litigation initiated against the pharmacy by a resident of this state; or

(2) a complaint that arises out of a prescription for a resident of this state that was lost during delivery.

**→ § 562.106. Notification**

(a) A pharmacy shall report in writing to the board not later than the 10th day after the date of:

(1) a permanent closing of the pharmacy;

(2) a change of ownership of the pharmacy;

(3) a change of location of the pharmacy;

(4) a change of the person designated as the pharmacist-in-charge of the pharmacy;

(5) a sale or transfer of any controlled substance or dangerous drug as a result of the permanent closing or change of ownership of the pharmacy;

(6) any matter or occurrence that the board requires by rule to be reported;

(7) as determined by the board, an out-of-state purchase of any controlled substance;

(8) a final order against the pharmacy license holder by the regulatory or licensing agency of the state in which the pharmacy is located if the pharmacy is located in another state ; or

(9) a final order against a pharmacist who is designated as the pharmacist-in-charge of the pharmacy by the regulatory or licensing agency of the state in which the pharmacy is located if the pharmacy is located in another state .

(b) A pharmacy shall report in writing to the board a theft or significant loss of any controlled substance immediately on discovery of the theft or loss. The pharmacy shall include with the report a list of all controlled substances stolen or lost.

(c) A pharmacy shall report in writing to the board a disaster, accident, or emergency that may affect the strength, purity, or labeling of a drug, medication, device, or other material used in the diagnosis or treatment of injury, illness, or disease, immediately on the occurrence of the disaster, accident, or emergency.

(d) The reporting pharmacy shall maintain a copy of any notification required by this section or [Section 562.053](#) for two years and make the copy available for inspection.

**→ § 562.107. Written Consumer Information Required**

(a) Each pharmacy shall make available to a consumer written information designed for the consumer that provides at a minimum:

- (1) the therapeutic use of a drug; and
- (2) the names of generically equivalent drugs.

(b) The information must be in a conspicuous location that is easily accessible to pharmacy customers. The information shall be periodically updated, as necessary, to reflect a change in the information.

(c) On request by a consumer, the pharmacy shall make available to the consumer the cost index ratio of the prescribed drug and any generic equivalents of the prescribed drug.

→ **§ 562.108. Emergency Medication Kits**

(a) A Class A or Class C pharmacy, or a Class E pharmacy located not more than 20 miles from any institution in this state that is licensed under Chapter 242 or 252, Health and Safety Code, may maintain controlled substances and dangerous drugs in an emergency medication kit used at an institution licensed under those chapters. A United States Department of Veterans Affairs pharmacy or another federally operated pharmacy may maintain controlled substances and dangerous drugs in an emergency medication kit used at an institution licensed under Chapter 242, Health and Safety Code, that is a veterans home, as defined by [Section 164.002, Natural Resources Code](#). The controlled substances and dangerous drugs may be used only for the emergency medication needs of a resident at the institution. A Class E pharmacy may not maintain drugs in an emergency medication kit for an institution that is located more than 20 miles from a pharmacy.

(b) The board shall adopt rules relating to emergency medication kits, including:

- (1) the amount and type of dangerous drugs and controlled substances that may be maintained in an emergency medication kit;
- (2) procedures regarding the use of drugs from an emergency medication kit;
- (3) recordkeeping requirements; and
- (4) security requirements.

→ **§ 562.1085. Unused Drugs Returned by Certain Pharmacists**

(a) A pharmacist who practices in or serves as a consultant for a health care facility or a licensed health care professional responsible for administration of drugs in a penal institution, as defined by [Section 1.07, Penal Code](#), in this state may return to a pharmacy certain unused drugs, other than a controlled substance as defined by Chapter 481, Health and Safety Code, purchased from the pharmacy as provided by board rule. The unused drugs must:

(1) be approved by the federal Food and Drug Administration and be:

(A) sealed in unopened tamper-evident packaging and either individually packaged or packaged in unit-dose packaging;

(B) oral or parenteral medication in sealed single-dose containers approved by the federal Food and Drug Administration;

(C) topical or inhalant drugs in sealed units-of-use containers approved by the federal Food and Drug Administration; or

(D) parenteral medications in sealed multiple-dose containers approved by the federal Food and Drug Administration from which doses have not been withdrawn; and

(2) not be the subject of a mandatory recall by a state or federal agency or a voluntary recall by a drug seller or manufacturer.

(b) A pharmacist for the pharmacy shall examine a drug returned under this section to ensure the integrity of the drug product. A health care facility or penal institution may not return a drug that:

(1) has been compounded;

(2) appears on inspection to be adulterated;

(3) requires refrigeration; or

(4) has less than 120 days until the expiration date or end of the shelf life.

(c) The pharmacy may restock and redistribute unused drugs returned under this section.

(d) The pharmacy shall reimburse or credit the state Medicaid program for an unused drug returned under this section.



(e) The board shall adopt the rules, policies, and procedures necessary to administer this section, including rules that require a health care facility to inform the Health and Human Services Commission of medicines returned to a pharmacy under this section.

(f) The tamper-evident packaging required under Subsection (a)(1) for the return of unused drugs is not required to be the manufacturer's original packaging unless that packaging is required by federal law.

→ **§ 562.1086. Limitation on Liability**

(a) A pharmacy that returns unused drugs and a manufacturer that accepts the unused drugs under [Section 562.1085](#) and the employees of the pharmacy or manufacturer are not liable for harm caused by the accepting, dispensing, or administering of drugs returned in strict compliance with [Section 562.1085](#) unless the harm is caused by:

(1) wilful or wanton acts of negligence;

(2) conscious indifference or reckless disregard for the safety of others; or

(3) intentional conduct.

(b) This section does not limit, or in any way affect or diminish, the liability of a drug seller or manufacturer under Chapter 82, Civil Practice and Remedies Code.

(c) This section does not apply if harm results from the failure to fully and completely comply with the requirements of [Section 562.1085](#).

(d) This section does not apply to a pharmacy or manufacturer that fails to comply with the insurance provisions of Chapter 84, Civil Practice and Remedies Code.

→ **§ 562.109. Automated Pharmacy Systems**

(a) In this section, “automated pharmacy system” means a mechanical system that:

(1) dispenses prescription drugs; and

(2) maintains related transaction information.

(b) A Class A or Class C pharmacy may provide pharmacy services through an automated pharmacy system in

a facility that is not at the same location as the Class A or Class C pharmacy. The pharmacist in charge of the Class A or Class C pharmacy is responsible for filling and loading the storage containers for medication stored in bulk at the facility.

(c) An automated pharmacy system is required to be under the continuous supervision of a pharmacist as determined by board rule. To qualify as continuous supervision for an automated pharmacy system, the pharmacist is not required to be physically present at the site of the automated pharmacy system and may supervise the system electronically.

(d) An automated pharmacy system may be located only at a health care facility regulated by the state.

(e) The board shall adopt rules regarding the use of an automated pharmacy system under this section, including:

(1) the types of health care facilities at which an automated pharmacy system may be located, which shall include a facility regulated under Chapter 142, 242, or 252, Health and Safety Code;

(2) recordkeeping requirements; and

(3) security requirements.

#### → § 562.110. Telepharmacy Systems

(a) In this section, “telepharmacy system” means a system that monitors the dispensing of prescription drugs and provides for related drug use review and patient counseling services by an electronic method, including the use of the following types of technology:

(1) audio and video;

(2) still image capture; and

(3) store and forward.

(b) A Class A or Class C pharmacy located in this state may provide pharmacy services, including the dispensing of drugs, through a telepharmacy system in a facility that is not at the same location as the Class A or Class C pharmacy.

(c) A telepharmacy system is required to be under the continuous supervision of a pharmacist as determined

by board rule. To qualify as continuous supervision for a telepharmacy system, the pharmacist is not required to be physically present at the site of the telepharmacy system. The pharmacist shall supervise the system electronically by audio and video communication.

(d) A telepharmacy system may be located only at a health care facility in this state that is regulated by this state or the United States.

(e) The board shall adopt rules regarding the use of a telepharmacy system under this section, including:

(1) the types of health care facilities at which a telepharmacy system may be located, which must include the following facilities:

(A) a clinic designated as a rural health clinic regulated under [42 U.S.C. Section 1395x\(aa\)](#), as amended; and

(B) a health center as defined by [42 U.S.C. Section 254b](#), as amended;

(2) the areas that qualify under Subsection (f);

(3) recordkeeping requirements; and

(4) security requirements.

(f) A telepharmacy system may not be located in a community in which a Class A or Class C pharmacy is located as determined by board rule. If a Class A or Class C pharmacy is established in a community in which a telepharmacy system has been located under this section, the telepharmacy system may continue to operate in that community.

#### → § 562.111. Prescription Drug Order for Consumer

(a) A pharmacy in this state may order for a consumer a prescription drug from a Canadian pharmacy designated by the board under [Section 554.016](#) to dispense prescription drugs to residents in this state.

(b) A pharmacy may order a prescription drug under this section only with the knowledge and clear consent of the consumer.

#### → § 562.112. Practitioner-Patient Relationship Required

(a) A pharmacy shall ensure that its agents and employees, before dispensing a prescription, determine in the exercise of sound professional judgment that the prescription is a valid prescription. A pharmacy may not dispense a prescription drug if an agent or employee of the pharmacy knows or should know that the prescription was issued on the basis of an Internet-based or telephonic consultation without a valid practitioner-patient relationship.

(b) Subsection (a) does not prohibit a pharmacy from dispensing a prescription when a valid practitioner-patient relationship is not present in an emergency.

#### **Subchapter D. Compounded and Prepackaged Drugs (Refs & Annos)**

##### **→ § 562.151. Definitions**

In this subchapter:

(1) “Office use” means the provision and administration of a compounded drug to a patient by a practitioner in the practitioner's office or by the practitioner in a health care facility or treatment setting, including a hospital, ambulatory surgical center, or pharmacy in accordance with Chapter 563.

(2) “Prepackaging” means the act of repackaging and relabeling quantities of drug products from a manufacturer's original container into unit dose packaging or a multiple dose container for distribution within a facility licensed as a Class C pharmacy or to other pharmacies under common ownership for distribution within those facilities. The term as defined does not prohibit the prepackaging of drug products for use within other pharmacy classes.

(3) “Reasonable quantity” with reference to drug compounding means an amount of a drug that:

(A) does not exceed the amount a practitioner anticipates may be used in the practitioner's office before the expiration date of the drug;

(B) is reasonable considering the intended use of the compounded drug and the nature of the practitioner's practice; and

(C) for any practitioner and all practitioners as a whole, is not greater than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality, and purity of the compounded drug that are consistent with United States Pharmacopoeia guidelines and accreditation practices.

##### **→ § 562.152. Compounding for Office Use**

A pharmacy may dispense and deliver a reasonable quantity of a compounded drug to a practitioner for office use by the practitioner in accordance with this chapter.

→ **§ 562.153. Requirements for Office Use Compounding**

To dispense and deliver a compounded drug under [Section 562.152](#), a pharmacy must:

- (1) verify the source of the raw materials to be used in a compounded drug;
- (2) comply with applicable United States Pharmacopoeia guidelines, including the testing requirements, and the Health Insurance Portability and Accountability Act of 1996 ([Pub. L. No. 104-191](#));
- (3) comply with all applicable competency and accrediting standards as determined by the board; and
- (4) comply with board rules, including rules regarding the reporting of adverse events by practitioners and recall procedures for compounded products.

→ **§ 562.154. Distribution of Compounded and Prepackaged Products to Certain Pharmacies**

(a) A Class A pharmacy licensed under Chapter 560 is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute compounded pharmaceutical products to a Class C pharmacy licensed under Chapter 560.

(b) A Class C pharmacy licensed under Chapter 560 is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute compounded and prepackaged pharmaceutical products that the Class C pharmacy has compounded or prepackaged to other Class C pharmacies licensed under Chapter 560 and under common ownership.

→ **§ 562.155. Compounding Service and Compounded Drug Products**

A compounding pharmacist or pharmacy may advertise or promote:

- (1) nonsterile prescription compounding services provided by the pharmacist or pharmacy; and
- (2) specific compounded drug products that the pharmacy or pharmacist dispenses or delivers.

→ **§ 562.156. Compounded Sterile Preparation; Notice to Board**

(a) A pharmacy may not compound and dispense a sterile preparation unless the pharmacy holds a license as required by board rule.

(b) A pharmacy that compounds a sterile preparation shall notify the board:

(1) immediately of any adverse effects reported to the pharmacy or that are known by the pharmacy to be potentially attributable to a sterile preparation compounded by the pharmacy; and

(2) not later than 24 hours after the pharmacy issues a recall for a sterile preparation compounded by the pharmacy.

### **Subchapter E. Practice by Canadian Pharmacy**

#### **→ § 562.201. Additional Practice Requirements**

In addition to complying with the other requirements of this chapter, a Canadian pharmacy designated by the board under [Section 554.016](#) shall:

(1) dispense a prescription drug to a resident of this state only under the lawful order of a practitioner licensed in the United States;

(2) dispense to a resident of this state only a prescription drug that is approved by Canada's Therapeutic Products Directorate for sale to residents of Canada;

(3) dispense to a resident of this state a prescription drug in the original, unopened manufacturer's packaging whenever possible; and

(4) dispense to a resident of this state only drugs prescribed for long-term use.

#### **→ § 562.202. Limitations on Practice**

A Canadian pharmacy designated by the board under [Section 554.016](#) to dispense prescription drugs to residents in this state may not:

(1) dispense to a resident of this state a prescription drug for which there is not an equivalent drug approved by the United States Food and Drug Administration for sale in the United States;

(2) dispense to a resident of this state a prescription drug that cannot be safely shipped by mail, common carrier, or delivery service;

(3) dispense in one order to a resident of this state a quantity of a prescription drug that exceeds:

(A) a three-month supply; or

(B) the amount ordered by the practitioner;

(4) fill a prescription drug order for a consumer who is a resident of this state that the consumer indicates is the consumer's first prescription for that drug; or

(5) dispense to a resident of this state any of the following:

(A) a substance designated as a controlled substance under Chapter 481, Health and Safety Code (Texas Controlled Substances Act);

(B) a biological product, as described by Section 351, Public Health Service Act ([42 U.S.C. Section 262](#));

(C) an infused drug, including a peritoneal dialysis solution;

(D) an intravenously injected drug; or

(E) a drug that is inhaled during surgery.

→ **§ 562.203. Complaint Report**

A Canadian pharmacy designated by the board under [Section 554.016](#) to dispense prescription drugs to residents in this state shall provide to the board periodic reports in accordance with board rules on each complaint received by the pharmacy from a consumer in this state who purchases a prescription drug from the pharmacy.

→ **§ 562.204. Price List**

A Canadian pharmacy designated by the board under [Section 554.016](#) shall:

(1) compile and maintain a current price list for prescription drugs provided to residents in this state; and

(2) guarantee those prices for not less than 30 days from the date the list is effective.

**Chapter 563. Prescription Requirements; Delegation of Administration and Provision of Dangerous Drugs****Subchapter A. Prescription Requirements for Practitioners [Repealed]**

→ §§ 563.001, 563.002. Repealed by Acts 2001, 77th Leg., ch. 1254, § 13(a)(3), eff. June 1, 2002.

→ §§ 563.001, 563.002. Repealed by Acts 2001, 77th Leg., ch. 1254, § 13(a)(3), eff. June 1, 2002.

**Subchapter B. Delegation of Administration and Provision of Dangerous Drugs****→ § 563.051. General Delegation of Administration and Provision of Dangerous Drugs**

(a) A physician may delegate to any qualified and properly trained person acting under the physician's supervision the act of administering or providing dangerous drugs in the physician's office, as ordered by the physician, that are used or required to meet the immediate needs of the physician's patients. The administration or provision of the dangerous drugs must be performed in compliance with laws relating to the practice of medicine and state and federal laws relating to those dangerous drugs.

(b) A physician may also delegate to any qualified and properly trained person acting under the physician's supervision the act of administering or providing dangerous drugs through a facility licensed by the board, as ordered by the physician, that are used or required to meet the needs of the physician's patients. The administration of those dangerous drugs must be in compliance with laws relating to the practice of medicine, professional nursing, and pharmacy and state and federal drug laws. The provision of those dangerous drugs must be in compliance with:

(1) laws relating to the practice of medicine, professional nursing, and pharmacy;

(2) state and federal drug laws; and

(3) rules adopted by the board.

(c) The administration or provision of the drugs may be delegated through a physician's order, a standing medical order, a standing delegation order, or another order defined by the Texas State Board of Medical Examiners.

(d) This section does not authorize a physician or a person acting under the supervision of a physician to keep a pharmacy, advertised or otherwise, for the retail sale of dangerous drugs, other than as authorized under [Section 158.003](#), without complying with the applicable laws relating to the dangerous drugs.

(e) A practitioner may designate a licensed vocational nurse or a person having education equivalent to or greater than that required for a licensed vocational nurse to communicate the prescriptions of an advanced



practice nurse or physician assistant authorized by the practitioner to sign prescription drug orders under Subchapter B, Chapter 157. [FN1]

[FN1] V.T.C.A., Occupations Code § 157.051 et seq.

→ **§ 563.052. Suitable Container Required**

A drug or medicine provided under this subchapter must be supplied in a suitable container labeled in compliance with applicable drug laws. A qualified and trained person, acting under the supervision of a physician, may specify at the time of the provision of the drug the inclusion on the container of the date of the provision and the patient's name and address.

→ **§ 563.053. Dispensing of Dangerous Drugs in Certain Rural Areas**

(a) In this section, “reimbursement for cost” means an additional charge, separate from that imposed for the physician's professional services, that includes the cost of the drug product and all other actual costs to the physician incidental to providing the dispensing service. The term does not include a separate fee imposed for the act of dispensing the drug itself.

(b) This section applies to an area located in a county with a population of 5,000 or less, or in a municipality or an unincorporated town with a population of less than 2,500, that is within a 15-mile radius of the physician's office and in which a pharmacy is not located. This section does not apply to a municipality or an unincorporated town that is adjacent to a municipality with a population of 2,500 or more.

(c) A physician who practices medicine in an area described by Subsection (b) may:

(1) maintain a supply of dangerous drugs in the physician's office to be dispensed in the course of treating the physician's patients; and

(2) be reimbursed for the cost of supplying those drugs without obtaining a license under Chapter 558.

(d) A physician who dispenses dangerous drugs under Subsection (c) shall:

(1) comply with each labeling provision under this subtitle applicable to that class of drugs; and

(2) oversee compliance with packaging and recordkeeping provisions applicable to that class of drugs.

(e) A physician who desires to dispense dangerous drugs under this section shall notify both the board and the Texas State Board of Medical Examiners that the physician practices in an area described by Subsection (b).

The physician may continue to dispense dangerous drugs in the area until the board determines, after notice and hearing, that the physician no longer practices in an area described by Subsection (b).

→ **§ 563.054. Administration of Dangerous Drugs**

(a) A veterinarian may:

(1) administer or provide dangerous drugs to a patient in the veterinarian's office, or on the patient's premises, if the drugs are used or required to meet the needs of the veterinarian's patients;

(2) delegate the administration or provision of dangerous drugs to a person who:

(A) is qualified and properly trained; and

(B) acts under the veterinarian's supervision; and

(3) itemize and receive compensation for the administration or provision of the dangerous drugs under Subdivision (1).

(b) This section does not permit a veterinarian to maintain a pharmacy for the retailing of drugs without complying with applicable laws.

(c) The administration or provision of dangerous drugs must comply with:

(1) laws relating to the practice of veterinary medicine; and

(2) state and federal laws relating to dangerous drugs.

**Chapter 564. Program to Aid Impaired Pharmacists and Pharmacy Students; Pharmacy Peer Review (Refs & Annos)**

**Subchapter A. Reporting and Confidentiality**

→ **§ 564.001. Reports**

(a) An individual or entity, including a pharmaceutical peer review committee, who has knowledge relating to an action or omission of a pharmacist in this state or a pharmacy student who is enrolled in the professional sequence of an accredited pharmacy degree program approved by the board that might provide grounds for disciplinary action under [Section 565.001\(a\)\(4\) or \(7\)](#) may report relevant facts to the board.

(b) A committee of a professional society composed primarily of pharmacists, the staff of the committee, or a district or local intervenor participating in a program established to aid pharmacists or pharmacy students impaired by chemical abuse or mental or physical illness may report in writing to the board the name of an impaired pharmacist or pharmacy student and the relevant information relating to the impairment.

(c) The board may report to a committee of the professional society or the society's designated staff information that the board receives relating to a pharmacist or pharmacy student who may be impaired by chemical abuse or mental or physical illness.

→ **§ 564.002. Confidentiality**

(a) All records and proceedings of the board, an authorized agent of the board, or a pharmaceutical organization committee relating to the administration of this chapter are confidential and are not considered public information for purposes of Chapter 552, Government Code. Records considered confidential under this section include:

(1) information relating to a report made under [Section 564.001](#), including the identity of the individual or entity making the report;

(2) the identity of an impaired pharmacist or pharmacy student participating in a program administered under this chapter, except as provided by [Section 564.003](#);

(3) a report, interview, statement, memorandum, evaluation, communication, or other information possessed by the board, an authorized agent of the board, or a pharmaceutical organization committee, related to a potentially impaired pharmacist or pharmacy student;

(4) a policy or procedure of an entity that contracts with the board relating to personnel selection; and

(5) a record relating to the operation of the board, an authorized agent of the board, or a pharmaceutical organization committee, as the record relates to a potentially impaired pharmacist or pharmacy student.

(b) A record or proceeding described by this section is not subject to disclosure, subpoena, or discovery, except to a member of the board or an authorized agent of the board involved in the discipline of an applicant or license holder.

→ **§ 564.003. Disclosure of Certain Information**

(a) The board may disclose information confidential under [Section 564.002](#) only:

(1) during a proceeding conducted by the State Office of Administrative Hearings, the board, or a panel of the board, or in a subsequent trial or appeal of a board action or order;

(2) to a pharmacist licensing or disciplinary authority of another jurisdiction;

(3) under a court order;

(4) to a person providing a service to the board, including an expert witness, investigator, or employee of an entity that contracts with the board, related to a disciplinary proceeding against an applicant or license holder, if the information is necessary for preparation for, or a presentation in, the proceeding; or

(5) as provided by Subsection (b).

(a-1) Information that is disclosed under Subsection (a) remains confidential and is not subject to discovery or subpoena in a civil suit and may not be introduced as evidence in any action other than an appeal of a board action.

(a-2) Information that is confidential under [Section 564.002](#) and that is admitted under seal in a proceeding conducted by the State Office of Administrative Hearings is confidential information for the purpose of a subsequent trial or appeal.

(b) The board may disclose that the license of a pharmacist who is the subject of an order of the board that is confidential under [Section 564.002](#) is suspended, revoked, canceled, restricted, or retired or that the pharmacist is in any other manner limited in the practice of pharmacy. The board may not disclose the nature of the impairment or other information that resulted in the board's action.

#### → [§ 564.004. Immunity](#)

(a) Any person, including a board employee or member, peer review committee member, pharmaceutical organization committee member, or pharmaceutical organization district or local intervenor, who provides information, reports, or records under [Section 564.001](#) to aid an impaired pharmacist or pharmacy student is immune from civil liability if the person provides the information in good faith.

(b) Subsection (a) shall be liberally construed to accomplish the purposes of this subchapter, and the immunity provided under that subsection is in addition to any other immunity provided by law.

(c) A person who provides information or assistance to the board under this subchapter is presumed to have acted in good faith. A person who alleges a lack of good faith has the burden of proof on that issue.

**→ § 564.005. Record of Report**

On a determination by the board that a report submitted by a peer review committee or pharmaceutical organization committee under [Section 564.001\(a\)](#) or [\(b\)](#) is without merit, the board shall expunge the report from the pharmacist's or pharmacy student's individual record in the board's office.

**→ § 564.006. Examination of Report**

A pharmacist, a pharmacy student, or an authorized representative of the pharmacist or student is entitled on request to examine the peer review or the pharmaceutical organization committee report submitted to the board and to place into the record a statement of reasonable length of the pharmacist's or pharmacy student's view concerning information in the report.

**Subchapter B. Program Administration****→ § 564.051. Program Authorization; Funding**

(a) The board may add a surcharge of not more than \$10 for each 12 months in a license period to a license or license renewal fee authorized under this subtitle to fund a program to aid impaired pharmacists and pharmacy students.

(b) The board may accept, transfer, and spend funds from the federal or state government, from another public source, or from a private source to be used in the program authorized by this section.

(c) Funds and surcharges collected under this section shall be deposited in the general revenue fund and may only be used by the board to administer the program authorized by this section, including providing for initial evaluation and referral of an impaired pharmacist or pharmacy student by a qualified health professional and paying the administrative costs incurred by the board in connection with that funding. The money may not be used for costs incurred for treatment or rehabilitation after initial evaluation and referral.

**→ § 564.052. Rules or Criteria**

In administering and enforcing this subchapter, the board shall adopt rules or minimum criteria that are at least as strict as the rules or minimum criteria for the administration or enforcement of a peer assistance program adopted by the Texas Commission on Alcohol and Drug Abuse under Chapter 467, Health and Safety Code.

**Subchapter C. Pharmacy Peer Review****→ § 564.101. Definitions**

In this subchapter:

(1) “Pharmacy peer review committee” means:

(A) a pharmacy peer review, judicial, or grievance committee of a pharmacy society or association that is authorized to evaluate the quality of pharmacy services or the competence of pharmacists and suggest improvements in pharmacy systems to enhance patient care; or

(B) a pharmacy peer review committee established by a person who owns a pharmacy or employs pharmacists that is authorized to evaluate the quality of pharmacy services or the competence of pharmacists and suggest improvements in pharmacy systems to enhance patient care.

(2) “Pharmacy society or association” means a membership organization of pharmacists that is incorporated under the Texas Non-Profit Corporation Act ([Article 1396-1.01 et seq., Vernon's Texas Civil Statutes](#)) [FN1] or that is exempt from the payment of federal income taxes under [Section 501\(c\) of the Internal Revenue Code of 1986](#).

[FN1] Now expired. For similar subject matter, see, now, V.T.C.A., [Business Organizations Code § 22.001 et seq.](#)

→ **§ 564.102. Pharmacy Peer Review Committee**

(a) A pharmacy peer review committee may be established to evaluate the quality of pharmacy services or the competence of pharmacists and suggest improvements in pharmacy systems to enhance patient care.

(b) The committee may review documentation of quality-related activities in a pharmacy, assess system failures and personnel deficiencies, determine facts, and make recommendations or issue decisions in a written report that can be used for continuous quality improvement purposes.

(c) A pharmacy peer review committee includes the members, employees, and agents of the committee, including assistants, investigators, attorneys, and any other agent that serves the committee in any capacity.

→ **§ 564.103. Confidentiality**

(a) Except as otherwise provided by this subchapter, all proceedings and records of a pharmacy peer review committee are confidential and all communications made to a pharmacy peer review committee are privileged.

(b) If a court makes a preliminary finding that a proceeding, record, or communication described by Subsection (a) is relevant to an anticompetitive action or an action brought under federal civil rights provisions under [42 U.S.C. Section 1983](#), then the proceeding, record, or communication is not confidential to the extent it is considered to be relevant.

(c) The final report of, and any written or oral communication made to, a pharmacy peer review committee and the records and proceedings of the committee may be disclosed to another pharmacy peer review committee, appropriate state or federal agencies, national accreditation bodies, or the state board of registration or licensure of this or any other state.

(d) Disclosure to the affected pharmacist of confidential pharmacy peer review committee information pertinent to the matter under review does not constitute waiver of the confidentiality provisions provided by this section.

(e) If a pharmacy peer review committee takes action that could result in censure, license suspension, restriction, limitation, or revocation by the board or denial of membership or privileges in a health care entity, the affected pharmacist must be provided a written copy of the recommendation of the pharmacy peer review committee and a copy of the pharmacy peer review committee's final decision, including a statement of the basis for the decision.

(f) Unless disclosure is required or authorized by law, records or determinations of, or communications to, a pharmacy peer review committee are not subject to subpoena or discovery and are not admissible as evidence in any civil, judicial, or administrative proceeding without waiver of the privilege of confidentiality executed in writing by the committee. The evidentiary privilege created by this section may be invoked by any person or organization in any civil, judicial, or administrative proceeding unless the person or organization has secured a waiver of the privilege executed in writing by the presiding officer, assistant presiding officer, or secretary of the affected pharmacy peer review committee.

(g) Reports, information, or records received and maintained by the board under this subchapter are considered investigative files and are confidential and may only be released as specified in [Section 565.055](#).

#### → § 564.104. Use of Information in Civil and Criminal Actions

(a) If a pharmacy peer review committee, a person participating in peer review, or any organization named as a defendant in any civil action filed as a result of participation in peer review may use otherwise confidential information in the committee's, person's, or organization's own defense or in a claim or suit under [Section 564.106\(b\)](#), a plaintiff in the proceeding may disclose records or determinations of, or communications to, a peer review committee in rebuttal to information supplied by the defendant.

(b) Any person seeking access to privileged information must plead and prove waiver of the privilege.

(c) A member, employee, or agent of a pharmacy peer review committee who provides access to otherwise privileged communications or records in cooperation with a law enforcement authority in a criminal investigation is not considered to have waived any privilege established under this subchapter.

**→ § 564.105. Compliance with Subpoena**

All persons, including governing bodies and medical staffs of health care entities, shall comply fully with a subpoena issued by the board for documents or information as otherwise authorized by law. The disclosure of documents or information under the subpoena does not constitute a waiver of the privilege associated with a pharmacy peer review committee proceeding. Failure to comply with the subpoena is grounds for disciplinary action against the facility or individual by the appropriate licensing board.

**→ § 564.106. Immunity**

(a) A cause of action does not accrue against the members, agents, or employees of a pharmacy peer review committee from any act, statement, determination, or recommendation made or act reported, without malice, in the course of peer review according to this subchapter.

(b) A pharmacy peer review committee, a person participating in peer review, or a health care entity named as a defendant in any civil action filed as a result of participation in peer review may use otherwise confidential information obtained for legitimate internal business and professional purposes, including use in the committee's, person's, or entity's own defense. The use of the information does not waive the confidential and privileged nature of pharmacy peer review committee proceedings.

**Chapter 565. Disciplinary Actions and Procedures; Reinstatement of License****Subchapter A. Grounds for Discipline of Applicant or License Holder****→ § 565.001. Applicant for or Holder of License to Practice Pharmacy**

(a) The board may discipline an applicant for or the holder of a current or expired license to practice pharmacy if the board finds that the applicant or license holder has:

(1) violated this subtitle or a board rule adopted under this subtitle;

(2) engaged in unprofessional conduct as defined by board rule;

(3) engaged in gross immorality as defined by board rule;

(4) developed an incapacity that prevents or could prevent the applicant or license holder from practicing pharmacy with reasonable skill, competence, and safety to the public;

(5) engaged in fraud, deceit, or misrepresentation, as defined by board rule, in practicing pharmacy or in seeking a license to practice pharmacy;



(6) been convicted of or placed on deferred adjudication community supervision or deferred disposition or the applicable federal equivalent for:

(A) a misdemeanor:

(i) involving moral turpitude; or

(ii) under 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.](#)); or

(B) a felony;

(7) used alcohol or drugs in an intemperate manner that, in the board's opinion, could endanger a patient's life;

(8) failed to maintain records required by this subtitle or failed to maintain complete and accurate records of purchases or disposals of drugs listed in 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.](#));

(9) violated any provision of:

(A) 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.](#)), or rules relating to one of those laws; or

(B) [Section 485.031, 485.032, 485.033, or 485.034, Health and Safety Code](#);

(10) aided or abetted an unlicensed person in the practice of pharmacy if the pharmacist knew or reasonably should have known that the person was unlicensed at the time;

(11) refused entry into a pharmacy for an inspection authorized by this subtitle if the pharmacist received notification from which the pharmacist knew or reasonably should have known that the attempted inspection was authorized;

(12) violated any pharmacy or drug statute or rule of this state, another state, or the United States;

(13) been negligent in the practice of pharmacy;

(14) failed to submit to an examination after hearing and being ordered to do so by the board under [Section 565.052](#);

- (15) dispensed a prescription drug while acting outside the usual course and scope of professional practice;
  - (16) been disciplined by a pharmacy board or by another health regulatory board of this state or another state for conduct substantially equivalent to conduct described under this subsection;
  - (17) violated a disciplinary order, including a confidential order or contract under the program to aid impaired pharmacists and pharmacy students under Chapter 564;
  - (18) failed to adequately supervise a task delegated to a pharmacy technician or pharmacy technician trainee;
  - (19) inappropriately delegated a task delegated to a pharmacy technician or pharmacy technician trainee;
  - (20) been responsible for a drug audit shortage; or
  - (21) been convicted or adjudicated of a criminal offense that requires registration as a sex offender under Chapter 62, Code of Criminal Procedure.
- (b) A certified copy of the record of the state taking action described by Subsection (a)(16) is conclusive evidence of the action taken by that state.

→ **§ 565.002. Applicant for or Holder of Pharmacy License**

- (a) The board may discipline an applicant for or the holder of a pharmacy license, including a Class E pharmacy license subject to [Section 565.003\(b\)](#), if the board finds that the applicant or license holder has:
- (1) been convicted of or placed on deferred adjudication community supervision or deferred disposition or the applicable federal equivalent for:
    - (A) a misdemeanor:
      - (i) involving moral turpitude; or
      - (ii) under 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.](#)); or
    - (B) a felony;

- (2) advertised a prescription drug or device in a deceitful, misleading, or fraudulent manner;
- (3) violated any provision of this subtitle or any rule adopted under this subtitle or that an owner or employee of a pharmacy has violated any provision of this subtitle or any rule adopted under this subtitle;
- (4) sold without legal authorization a prescription drug or device to a person other than:
  - (A) a pharmacy licensed by the board;
  - (B) a practitioner;
  - (C) a person who procures a prescription drug or device for lawful research, teaching, or testing, and not for resale;
  - (D) a manufacturer or wholesaler licensed by the commissioner of public health as required by Chapter 431, Health and Safety Code; or
  - (E) a carrier or warehouseman;
- (5) allowed an employee who is not a pharmacist to practice pharmacy;
- (6) sold an adulterated or misbranded prescription or nonprescription drug;
- (7) failed to engage in or ceased to engage in the business described in the application for a license;
- (8) failed to maintain records as required by this subtitle, Chapter 481 or 483, Health and Safety Code, the Comprehensive Drug Abuse Prevention and Control Act of 1970 ([21 U.S.C. Section 801 et seq.](#)), or any rule adopted under this subtitle or Chapter 483, Health and Safety Code;
- (9) failed to establish and maintain effective controls against diversion of prescription drugs into other than a legitimate medical, scientific, or industrial channel as provided by this subtitle, another state statute or rule, or a federal statute or rule;
- (10) engaged in fraud, deceit, or misrepresentation as defined by board rule in operating a pharmacy or in applying for a license to operate a pharmacy;
- (11) violated a disciplinary order;

(12) been responsible for a drug audit shortage; or

(13) been disciplined by the regulatory board of another state for conduct substantially equivalent to conduct described under this subsection.

(b) This subsection applies only to an applicant or license holder that is a legal business entity. The board may discipline an applicant for or the holder of a pharmacy license, including a Class E pharmacy license, if the board finds that a managing officer of the applicant or license holder has been convicted of or placed on deferred adjudication community supervision or deferred disposition or the applicable federal equivalent for:

(1) a misdemeanor:

(A) involving moral turpitude; or

(B) under 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.](#)); or

(2) a felony.

(c) A certified copy of the record of the state taking action described by Subsection (a)(13) is conclusive evidence of the action taken by that state.

**→ § 565.003. Additional Grounds for Discipline Regarding Applicant for or Holder of Nonresident Pharmacy License**

Unless compliance would violate the pharmacy or drug statutes or rules in the state in which the pharmacy is located the board may discipline an applicant for or the holder of a nonresident pharmacy license if the board finds that the applicant or license holder has failed to comply with:

(1) [Section 481.074](#) or [481.075, Health and Safety Code](#);

(2) Texas substitution requirements regarding:

(A) the practitioner's directions concerning generic substitution;

(B) the patient's right to refuse generic substitution; or

(C) notification to the patient of the patient's right to refuse substitution;

(3) any board rule relating to providing drug information to the patient or the patient's agent in written form or by telephone; or

(4) any board rule adopted under [Section 554.051\(a\)](#) and determined by the board to be applicable under [Section 554.051\(b\)](#).

## **Subchapter B. Disciplinary Actions and Procedures**

### **→ § 565.051. Discipline Authorized**

On a determination that a ground for discipline exists under Subchapter A, or that a violation of this subtitle or a rule adopted under this subtitle has been committed by a license holder or applicant for a license or renewal of a license, the board may:

(1) suspend the person's license;

(2) revoke the person's license;

(3) restrict the person's license to prohibit the person from performing certain acts or from practicing pharmacy or operating a pharmacy in a particular manner for a term and under conditions determined by the board;

(4) impose an administrative penalty under Chapter 566;

(5) refuse to issue or renew the person's license;

(6) place the offender's license on probation and supervision by the board for a period determined by the board and impose a requirement that the license holder:

(A) report regularly to the board on matters that are the basis of the probation;

(B) limit practice to the areas prescribed by the board;

(C) continue or review professional education until the license holder attains a degree of skill satisfactory to the board in each area that is the basis of the probation; or

(D) pay the board a probation fee to defray the costs of monitoring the license holder during the period of probation;

- (7) reprimand the person;
- (8) retire the person's license as provided by board rule; or
- (9) impose more than one of the sanctions listed in this subsection.

→ **§ 565.052. Submission to Mental or Physical Examination**

(a) In enforcing [Section 565.001\(a\)\(4\) or \(7\)](#), the board or an authorized agent of the board on probable cause, as determined by the board or agent, shall request a pharmacist, pharmacist applicant, pharmacist-intern, or pharmacist-intern applicant to submit to a mental or physical examination by a physician or other health care professional designated by the board.

(b) If the pharmacist, pharmacist applicant, pharmacist-intern, or pharmacist-intern applicant refuses to submit to the examination, the board or the executive director of the board shall issue an order requiring the pharmacist, pharmacist applicant, pharmacist-intern, or pharmacist-intern applicant to show cause why the pharmacist, pharmacist applicant, pharmacist-intern, or pharmacist-intern applicant will not submit to the examination and shall schedule a hearing before a panel of three members of the board appointed by the president of the board on the order not later than the 30th day after the date notice is served on the pharmacist, pharmacist applicant, pharmacist-intern, or pharmacist-intern applicant. The pharmacist, pharmacist applicant, pharmacist-intern, or pharmacist-intern applicant shall be notified by either personal service or certified mail with return receipt requested.

(c) At the hearing, the pharmacist, pharmacist applicant, pharmacist-intern, or pharmacist-intern applicant and an attorney are entitled to present testimony or other evidence to show why the pharmacist, pharmacist applicant, pharmacist-intern, or pharmacist-intern applicant should not be required to submit to the examination. The pharmacist, pharmacist applicant, pharmacist-intern, or pharmacist-intern applicant has the burden of proof to show why the pharmacist, pharmacist applicant, pharmacist-intern, or pharmacist-intern applicant should not be required to submit to the examination.

(d) After the hearing, the panel shall by order require the pharmacist, pharmacist applicant, pharmacist-intern, or pharmacist-intern applicant to submit to the examination not later than the 60th day after the date of the order or withdraw the request for examination, as applicable.

→ **§ 565.053. Discipline of Nonresident Pharmacy; Notice to Resident State**

The board shall give notice of a disciplinary action by the board against a license holder located in another state to the regulatory or licensing agency of the state in which the pharmacy is located.

**→ § 565.054. Service of Process on Nonresident Pharmacy**

(a) Service of process on a nonresident pharmacy under [Section 565.058](#) or [566.051](#) or for disciplinary action taken by the board under [Section 565.061](#) shall be on the owner and pharmacist-in-charge of the pharmacy, as designated on the pharmacy's license application.

(b) The complaining party shall mail by certified mail, return receipt requested and postage prepaid, a copy of the process served to the license holder at the address of the license holder designated on the license application.

**→ § 565.055. Investigation; Confidentiality of Information**

(a) The board or the board's authorized representative may investigate and gather evidence concerning any alleged violation of this subtitle or a board rule.

(b) Information or material compiled by the board in connection with an investigation, including an investigative file of the board, is confidential and not subject to:

(1) disclosure under Chapter 552, Government Code; or

(2) any means of legal compulsion for release, including disclosure, discovery, or subpoena, to anyone other than the board or a board employee or board agent involved in discipline of a license holder.

(c) Notwithstanding Subsection (b), information or material compiled by the board in connection with an investigation may be disclosed:

(1) during any proceeding conducted by the State Office of Administrative Hearings, to the board, or a panel of the board, or in a subsequent trial or appeal of a board action or order;

(2) to a person providing a service to the board, including an expert witness, investigator, or employee of an entity that contracts with the board, related to a disciplinary proceeding against an applicant or license holder, or a subsequent trial or appeal, if the information is necessary for preparation for, or a presentation in, the proceeding;

(3) to an entity in another jurisdiction that:

(A) licenses or disciplines pharmacists or pharmacies; or

(B) registers or disciplines pharmacy technicians or pharmacy technician trainees;

- (4) to a pharmaceutical or pharmacy peer review committee as described under Chapter 564;
- (5) to a law enforcement agency;
- (6) to a person engaged in bona fide research, if all information identifying a specific individual has been deleted; or
- (7) to an entity that administers a board-approved pharmacy technician certification examination.

→ **§ 565.056. Informal Proceedings**

- (a) The board by rule shall adopt a procedure governing:
  - (1) informal disposition of a contested case under Chapter 2001, Government Code; and
  - (2) an informal proceeding held in compliance with Chapter 2001, Government Code.
- (b) A rule adopted under this section must:
  - (1) provide the complainant, if applicable and permitted by law, and the license holder an opportunity to be heard;
  - (2) require the presence of an attorney to advise the board or a board employee; and
  - (3) if an informal meeting will be held, require notice of the time and place of the informal meeting to be given to the license holder not later than the 45th day before the date the informal meeting is held.
- (c) The attorney must be a member of the board's legal staff, if the board has a legal staff. If the board does not have a legal staff, the attorney must be an employee of the office of the attorney general.
- (d) The notice required by Subsection (b)(3) must be accompanied by a written statement of the nature of the allegations against the license holder and the information the board intends to use at the informal meeting. If the board does not provide the statement or information when the notice is provided, the license holder may use that failure as grounds for rescheduling the informal meeting. The license holder must provide to the board the license holder's rebuttal not later than the 15th day before the date of the meeting in order for that information to be considered at the meeting.
- (e) On request by a license holder under review, the board shall make a recording of the informal meeting.



The recording is a part of the investigative file and may not be released to a third party unless authorized under this subtitle. The board may charge the license holder a fee to cover the cost of recording the meeting. The board shall provide a copy of the recording to the license holder on the license holder's request.

→ **§ 565.057. Monitoring of License Holder**

(a) The board shall develop a policy and procedure for monitoring a license holder's compliance with this subtitle.

(b) A policy or procedure adopted under this section must include a procedure to:

(1) monitor for compliance a license holder who is ordered by the board to perform a certain act; and

(2) identify and monitor a license holder who represents a risk to the public.

→ **§ 565.058. Subpoena Authority**

(a) The board or an officer of the board may:

(1) issue subpoenas ad testificandum or subpoenas duces tecum to compel the attendance of witnesses or the production of items, including books, records, or documents;

(2) administer oaths; and

(3) take testimony concerning matters in the board's or officer's jurisdiction.

(b) A person designated in the subpoena may serve the subpoena.

→ **§ 565.059. Temporary Suspension or Restriction of License**

(a) The president of the board shall appoint a three-member disciplinary panel consisting of board members to determine whether a license under this subtitle should be temporarily suspended or restricted. If a majority of the disciplinary panel determines from evidence or information presented to the panel that the holder of a license by continuation in the practice of pharmacy or in the operation of a pharmacy would constitute a continuing threat to the public welfare, the panel shall temporarily suspend or restrict the license as provided by Subsection (b).

(b) The disciplinary panel may temporarily suspend or restrict the license:

(1) after a hearing conducted by the panel after the 10th day after the date notice of the hearing is provided to the license holder; or

(2) without notice or hearing if, at the time the suspension or restriction is ordered, a hearing before the panel is scheduled to be held not later than the 14th day after the date of the temporary suspension or restriction to determine whether the suspension or restriction should be continued.

(c) Not later than the 90th day after the date of the temporary suspension or restriction, the board shall initiate a disciplinary action against the license holder, and a contested case hearing shall be held by the State Office of Administrative Hearings. If the State Office of Administrative Hearings does not hold the hearing in the time required by this subsection, the suspended or restricted license is automatically reinstated.

(d) Notwithstanding Chapter 551, Government Code, the disciplinary panel may hold a meeting by telephone conference call if immediate action is required and convening of the panel at one location is inconvenient for any member of the disciplinary panel.

→ **§ 565.060. Remedial Plan**

(a) The board may issue and establish the terms of a remedial plan to resolve the investigation of a complaint relating to this subtitle.

(b) A remedial plan may not be imposed to resolve a complaint:

(1) concerning:

(A) a death;

(B) a hospitalization;

(C) the commission of a felony; or

(D) any other matter designated by board rule; or

(2) in which the appropriate resolution may involve a restriction on the manner in which a license holder practices pharmacy.

(c) The board may not issue a remedial plan to resolve a complaint against a license holder if the license holder has entered into a remedial plan with the board in the preceding 24 months for the resolution of a

different complaint relating to this subtitle.

(d) If a license holder complies with and successfully completes the terms of a remedial plan, the board shall remove all records of the remedial plan from the board's records on the fifth anniversary of the date the board issued the terms of the remedial plan.

(e) The board may assess a fee against a license holder participating in a remedial plan in an amount necessary to recover the costs of administering the plan.

(f) The board shall adopt rules necessary to implement this section.

#### → § 565.061. Administrative Procedure

(a) Except as provided by Chapter 564, a disciplinary action taken by the board under [Section 565.060](#) or on the basis of a ground for discipline under Subchapter A [\[FN1\]](#) is governed by Chapter 2001, Government Code, and the rules of practice and procedure before the board.

(b) A final decision of the board under this chapter is subject to judicial review under Chapter 2001, Government Code.

[\[FN1\]](#) V.T.C.A., Occupations Code § 565.001 et seq.

#### → § 565.062. Burden of Proof

(a) In a proceeding under this subtitle, including a trial or hearing, the state is not required to negate an exemption or exception set forth by this subtitle in a pleading, including in a complaint, information, or indictment.

(b) The burden of going forward with the evidence with respect to an exemption or exception is on the person claiming the benefit of the exemption or exception.

(c) In the absence of proof that a person is the authorized holder of an appropriate license issued under this subtitle, the person is presumed not to be the holder of the license. The presumption is subject to rebuttal by a person charged with an offense under this subtitle.

#### → § 565.063. Liability

This subtitle does not impose liability on an authorized board employee or person acting under the supervision of a board employee, or on a state, county, or municipal officer, engaged in the lawful enforcement of this

subtitle.

→ **§ 565.064. Construction**

This subtitle does not bar a criminal prosecution for a violation of this subtitle if the violation is a criminal offense under another law of this state or a law of the United States.

**Subchapter C. Petition for Reinstatement or Removal of Restriction (Refs & Annos)**

→ **§ 565.101. Petition for Reinstatement or Removal of Restriction**

(a) A person whose pharmacy license, license to practice pharmacy, pharmacy technician registration, or pharmacy technician trainee registration in this state has been revoked or restricted under this subtitle, whether voluntarily or by board action, may, after the first anniversary of the effective date of the revocation or restriction, petition the board for reinstatement or removal of the restriction of the license or registration.

(b) The petition must be in writing and in the form prescribed by the board.

(c) A person petitioning for reinstatement or removal of a restriction has the burden of proof.

→ **§ 565.102. Action by Board**

(a) On investigation and review of a petition under this subchapter, the board may grant or deny the petition or may modify the board's original finding to reflect a circumstance that has changed sufficiently to warrant the modification.

(b) If the board denies the petition, the board may not consider a subsequent petition from the petitioner until the first anniversary of the date of denial of the previous petition.

→ **§ 565.103. Condition for Reinstatement or Removal of Restriction**

The board may require a person to pass one or more examinations to reenter the practice of pharmacy.

**Chapter 566. Penalties and Enforcement Provisions**

**Subchapter A. Administrative Penalty**

→ **§ 566.001. Imposition of Penalty**

The board may impose an administrative penalty on a person licensed or regulated under this subtitle who violates this subtitle or a rule or order adopted under this subtitle.

→ **§ 566.002. Amount of Penalty**

(a) The amount of the administrative penalty may not exceed \$5,000 for each violation, including a violation involving the diversion of a controlled substance.

(b) Each day a violation continues or occurs is a separate violation for purposes of imposing the penalty.

(c) The amount, to the extent possible, shall be based on:

(1) the seriousness of the violation, including the nature, circumstances, extent, and gravity of any prohibited act, and the hazard or potential hazard created to the health, safety, or economic welfare of the public;

(2) the economic harm to property or the environment caused by the violation;

(3) the history of previous violations;

(4) the amount necessary to deter a future violation;

(5) efforts to correct the violation; and

(6) any other matter that justice may require.

(d) The board by rule shall adopt an administrative penalty schedule for violations of this subtitle or board rules to ensure that the amounts of penalties imposed are appropriate to the violation.

→ **§ 566.003. Notice of Violation**

(a) If the board by order determines that a violation occurred and imposes an administrative penalty, the board shall give notice of the board's order to the person found to have committed the violation.

(b) The notice must include a statement of the person's right to judicial review of the order.

→ **§ 566.004. Options Following Decision: Pay or Appeal**

(a) Not later than the 30th day after the date the board's order becomes final, the person shall:

(1) pay the administrative penalty;

(2) pay the penalty and file a petition for judicial review contesting the fact of the violation, the amount of the penalty, or both; or

(3) without paying the penalty, file a petition for judicial review contesting the fact of the violation, the amount of the penalty, or both.

(b) Within the 30-day period, a person who acts under Subsection (a)(3) may:

(1) stay enforcement of the penalty by:

(A) paying the penalty to the court for placement in an escrow account; or

(B) giving to the court a supersedeas bond that is approved by the court and that:

(i) is for the amount of the penalty; and

(ii) is effective until judicial review of the board's order is final; or

(2) request the court to stay enforcement of the penalty by:

(A) filing with the court a sworn affidavit of the person stating that the person is financially unable to pay the penalty and is financially unable to give the supersedeas bond; and

(B) giving a copy of the affidavit to the executive director by certified mail.

(c) If the executive director receives a copy of an affidavit under Subsection (b)(2), the executive director may file with the court a contest to the affidavit not later than the fifth day after the date the copy is received.

(d) The court shall hold a hearing on the facts alleged in the affidavit as soon as practicable and shall stay the enforcement of the penalty on finding that the alleged facts are true. The person who files an affidavit has the burden of proving that the person is financially unable to pay the penalty and to give a supersedeas bond.

**→ § 566.005. Collection of Penalty**

If the person does not pay the administrative penalty and the enforcement of the penalty is not stayed, the executive director may refer the matter to the attorney general for collection of the penalty.

**→ § 566.006. Determination by Court**

(a) If the court sustains the determination that a violation occurred on appeal, the court may uphold or reduce the amount of the administrative penalty and order the person to pay the full or reduced penalty.

(b) If the court does not sustain the determination that a violation occurred, the court shall order that a penalty is not owed.

**→ § 566.007. Remittance of Penalty and Interest**

(a) If after judicial review, the administrative penalty is reduced or is not upheld by the court, the court shall, after the judgment becomes final:

(1) order that the appropriate amount, plus accrued interest, be remitted to the person if the person paid the penalty; or

(2) order the release of the bond in full if the penalty is not upheld or order the release of the bond after the person pays the penalty imposed if the person gave a supersedeas bond.

(b) The interest paid under Subsection (a)(1) is the rate charged on loans to depository institutions by the New York Federal Reserve Bank. The interest shall be paid for the period beginning on the date the penalty is paid and ending on the date the penalty is remitted.

**→ § 566.008. Effect of Subchapter**

This subchapter does not limit the board's ability to impose an administrative penalty under a consent order entered in accordance with board rules and requirements adopted under [Section 565.056](#).

**→ § 566.009. Administrative Procedure**

(a) The board by rule shall prescribe procedures, consistent with provisions of Chapter 2001, Government Code, relating to contested cases, by which the board may impose an administrative penalty.

(b) Chapter 2001, Government Code, applies to a proceeding under this subchapter.

## **Subchapter B. Injunctive Relief**

### **→ § 566.051. Injunctive Relief**

(a) The attorney general at the request of the board may petition a district court for an injunction to prohibit a person who is violating this subtitle from continuing the violation.

(b) Venue in a suit for injunctive relief is in Travis County.

(c) After application and a finding that a person is violating this subtitle, the district court shall grant the injunctive relief the facts warrant.

### **→ § 566.052. Cease and Desist Order**

(a) If it appears to the board that a person is engaging in an act or practice that constitutes the practice of pharmacy without a license or registration under this subtitle, the board, after notice and opportunity for a hearing, may issue a cease and desist order prohibiting the person from engaging in the activity.

(b) A violation of an order issued under this section constitutes grounds for imposing an administrative penalty under Subchapter A.

## **Subchapter C. Civil Penalty**

### **→ § 566.101. Civil Penalty**

(a) A person who violates the license requirements of this subtitle is liable to the state for a civil penalty not to exceed \$1,000 for each day the violation continues.

(b) A person found by the board to have unlawfully engaged in the practice of pharmacy or unlawfully operated a pharmacy is subject to a civil penalty under this section.

### **→ § 566.102. Collection by Attorney General**

At the request of the board, the attorney general shall institute an action to collect a civil penalty from a person who has violated this subtitle or any rule adopted under this subtitle.

### **→ § 566.103. Collection by District, County, or City Attorney**

(a) If the attorney general fails to take action before the 31st day after the date of referral from the board under [Section 566.102](#), the board shall refer the case to the local district attorney, county attorney, or city attorney.



(b) The district attorney, county attorney, or city attorney shall file suit in a district court to collect and retain the penalty.

→ **§ 566.104. Venue**

Venue for a suit under this subchapter is in Travis County.

**Subchapter D. Criminal Offenses**

→ **§ 566.151. Offenses; Criminal Penalty**

(a) A person commits an offense if the person violates this subtitle or any rule adopted under this subtitle relating to unlawfully engaging in the practice of pharmacy or unlawfully operating a pharmacy.

(b) A person commits an offense if the person knowingly violates the licensing requirements of this subtitle or [Section 558.001](#), [558.002](#), or [560.002](#).

(c) A person commits an offense if the person violates [Section 560.001](#) or [560.003](#).

(d) Each day of violation under Subsection (b) or (c) is a separate offense.

(e) An offense under this section is a Class A misdemeanor.

**Chapter 567. Labeling Requirements for Certain Prescription Drugs or Drug Products [Repealed]**

→ **§§ 567.001 to 567.003. Repealed by Acts 2013, 83rd Leg., ch. 583 (S.B. 869) § 33(1), eff. June 14, 2013**

→ **§§ 567.001 to 567.003. Repealed by Acts 2013, 83rd Leg., ch. 583 (S.B. 869) § 33(1), eff. June 14, 2013**

→ **§§ 567.001 to 567.003. Repealed by Acts 2013, 83rd Leg., ch. 583 (S.B. 869) § 33(1), eff. June 14, 2013**

**Chapter 568. Pharmacy Technicians and Pharmacy Technician Trainees**

→ **§ 568.001. Rules; Qualifications**

(a) In establishing rules under [Section 554.053\(c\)](#), the board shall require that:

(1) a pharmacy technician:

(A) have a high school diploma or a high school equivalency certificate or be working to achieve an equivalent diploma or certificate; and

(B) have passed a board-approved pharmacy technician certification examination; and

(2) a pharmacy technician trainee have a high school diploma or a high school equivalency certificate or be working to achieve an equivalent diploma or certificate.

(b) The board shall adopt rules that permit a pharmacy technician and pharmacy technician trainee to perform only nonjudgmental technical duties under the direct supervision of a pharmacist.

→ **§ 568.002. Registration Required**

(a) A person must register with the board before beginning work in a pharmacy in this state as a pharmacy technician or a pharmacy technician trainee.

(b) The board may allow a pharmacy technician to petition the board for a special exemption from the pharmacy technician certification requirement if the pharmacy technician is in a county with a population of less than 50,000.

(c) An applicant for registration as a pharmacy technician or a pharmacy technician trainee must:

(1) be of good moral character; and

(2) submit an application on a form prescribed by the board.

(d) A person's registration as a pharmacy technician or pharmacy technician trainee remains in effect as long as the person meets the qualifications established by board rule.

→ **§ 568.003. Grounds for Disciplinary Action**

(a) The board may take disciplinary action under [Section 568.0035](#) against an applicant for or the holder of a current or expired pharmacy technician or pharmacy technician trainee registration if the board determines that the applicant or registrant has:

(1) violated this subtitle or a rule adopted under this subtitle;

(2) engaged in gross immorality, as that term is defined by the rules of the board;

(3) engaged in any fraud, deceit, or misrepresentation, as those terms are defined by the rules of the board, in seeking a registration to act as a pharmacy technician or pharmacy technician trainee;

(4) been convicted of or placed on deferred adjudication community supervision or deferred disposition or the applicable federal equivalent for:

(A) a misdemeanor:

(i) involving moral turpitude; or

(ii) under 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.](#)); or

(B) a felony;

(5) developed an incapacity that prevents the applicant or registrant from practicing as a pharmacy technician or pharmacy technician trainee with reasonable skill, competence, and safety to the public;

(6) violated:

(A) Chapter 481 or 483, Health and Safety Code, or rules relating to those chapters;

(B) [Sections 485.031-485.035, Health and Safety Code](#); or

(C) a rule adopted under [Section 485.011, Health and Safety Code](#);

(7) violated the pharmacy or drug laws or rules of this state, another state, or the United States;

(8) performed duties in a pharmacy that only a pharmacist may perform, as defined by the rules of the board;

(9) used alcohol or drugs in an intemperate manner that, in the board's opinion, could endanger a patient's life;

(10) engaged in negligent, unreasonable, or inappropriate conduct when working in a pharmacy;

(11) violated a disciplinary order;

(12) been convicted or adjudicated of a criminal offense that requires registration as a sex offender under

Chapter 62, Code of Criminal Procedure; or

(13) been disciplined by a pharmacy or other health regulatory board of this state or another state for conduct substantially equivalent to conduct described by this subsection.

(b) A certified copy of the record of a state taking action described by Subsection (a)(13) is conclusive evidence of the action taken by the state.

→ **§ 568.0035. Discipline Authorized; Effect on Trainee**

(a) On a determination that a ground for discipline exists under [Section 568.003](#), the board may:

(1) suspend the person's registration;

(2) revoke the person's registration;

(3) restrict the person's registration to prohibit the person from performing certain acts or from practicing as a pharmacy technician or pharmacy technician trainee in a particular manner for a term and under conditions determined by the board;

(4) impose an administrative penalty under Chapter 566;

(5) refuse to issue or renew the person's registration;

(6) place the offender's registration on probation and supervision by the board for a period determined by the board and impose a requirement that the registrant:

(A) report regularly to the board on matters that are the basis of the probation;

(B) limit practice to the areas prescribed by the board;

(C) continue or review professional education until the registrant attains a degree of skill satisfactory to the board in each area that is the basis of the probation; or

(D) pay the board a probation fee to defray the costs of monitoring the registrant during the period of probation;

- (7) reprimand the person;
- (8) retire the person's registration as provided by board rule; or
- (9) impose more than one of the sanctions listed in this section.

(b) A disciplinary action affecting the registration of a pharmacy technician trainee remains in effect if the trainee obtains registration as a pharmacy technician.

→ **§ 568.0036. Submission to Mental or Physical Examination**

(a) This section applies to a pharmacy technician, pharmacy technician applicant, pharmacy technician trainee, or pharmacy technician trainee applicant.

(b) In enforcing [Section 568.003\(a\)\(5\) or \(7\)](#), the board or an authorized agent of the board on probable cause, as determined by the board or agent, may request a person subject to this section to submit to a mental or physical examination by a physician or other health care professional designated by the board.

(c) If the person refuses to submit to the examination, the board or the executive director of the board shall:

- (1) issue an order requiring the person to show cause why the person will not submit to the examination; and
- (2) schedule a hearing before a panel of three members of the board appointed by the president of the board on the order not later than the 30th day after the date notice of the order is served on the person under Subsection (d).

(d) The person shall be notified by either personal service or certified mail, return receipt requested.

(e) At the hearing, the person and the person's counsel may present testimony or other evidence to show why the person should not be required to submit to the examination. The person has the burden of proof to show why the person should not be required to submit to the examination.

(f) After the hearing, as applicable, the panel shall, by order:

- (1) require the person to submit to the examination not later than the 60th day after the date of the order; or
- (2) withdraw the request for examination.

**→ § 568.0037. Temporary Suspension or Restriction of Registration**

(a) The president of the board shall appoint a disciplinary panel consisting of three board members to determine whether a registration under this chapter should be temporarily suspended or restricted. If a majority of the panel determines from evidence or information presented to the panel that the registrant by continuation in practice as a pharmacy technician or pharmacy technician trainee would constitute a continuing threat to the public welfare, the panel shall temporarily suspend or restrict the registration as provided by Subsection (b).

(b) A disciplinary panel may temporarily suspend or restrict the registration:

(1) after a hearing conducted by the panel after the 10th day after the date notice of the hearing is provided to the registrant; or

(2) without notice or hearing if, at the time the suspension or restriction is ordered, a hearing before the panel is scheduled to be held not later than the 14th day after the date of the temporary suspension or restriction to determine whether the suspension or restriction should be continued.

(c) Not later than the 90th day after the date of the temporary suspension or restriction, the board shall initiate a disciplinary action under this chapter, and a contested case hearing shall be held by the State Office of Administrative Hearings. If the State Office of Administrative Hearings does not hold the hearing in the time required by this subsection, the suspended or restricted registration is automatically reinstated.

(d) Notwithstanding Chapter 551, Government Code, the disciplinary panel may hold a meeting by telephone conference call if immediate action is required and convening the panel at one location is inconvenient for any member of the disciplinary panel.

**→ § 568.004. Renewal of Registration**

The board may adopt a system in which the registrations of pharmacy technicians and pharmacy technician trainees expire on various dates during the year.

**→ § 568.005. Fees**

The board may adopt fees as necessary for the registration of pharmacy technicians and pharmacy technician trainees.

**→ § 568.006. Ratio of Pharmacists to Pharmacy Technicians and Pharmacy Technician Trainees**

The ratio of pharmacists to pharmacy technicians and pharmacy technician trainees in a Class A pharmacy

must be at least one pharmacist for every five pharmacy technicians or pharmacy technician trainees if the Class A pharmacy dispenses not more than 20 different prescription drugs and does not produce intravenous or intramuscular drugs on-site.

→ **§ 568.007. Repealed by Acts 2013, 83rd Leg., ch. 583 (S.B. 869), § 33(2), eff. June 14, 2013**

→ **§ 568.008. Pharmacy Technicians in Hospitals With Clinical Pharmacy Program**

(a) In this section, “clinical pharmacy program” means a program that provides pharmaceutical care services as specified by board rule.

(b) A Class C pharmacy that has an ongoing clinical pharmacy program may allow a pharmacy technician to verify the accuracy of work performed by another pharmacy technician relating to the filling of floor stock and unit dose distribution systems for a patient admitted to the hospital if the patient's orders have previously been reviewed and approved by a pharmacist.

(c) The pharmacist-in-charge of the clinical pharmacy program shall adopt policies and procedures for the verification process authorized by this section.

(d) A hospital must notify the board before implementing the verification process authorized by this section.

(e) The board shall adopt rules to implement this section, including rules specifying:

(1) the duties that may be verified by another pharmacy technician;

(2) the records that must be maintained for the verification process; and

(3) the training requirements for pharmacy technicians who verify the accuracy of the work of other pharmacy technicians.

→ **§ 568.009. Change of Address or Employment**

Not later than the 10th day after the date of a change of address or employment, a pharmacy technician or a pharmacy technician trainee shall notify the board in writing of the change.

**Chapter 569. Reporting Requirements for Professional Liability Insurers**

→ **§ 569.001. Duty to Report**

(a) Every insurer or other entity providing pharmacist's professional liability insurance, pharmacy technician professional and supplemental liability insurance, or druggist's professional liability insurance covering a pharmacist, pharmacy technician, pharmacy technician trainee, or pharmacy license holder in this state shall submit to the board the information described in [Section 569.002](#) at the time prescribed.

(b) The information shall be provided with respect to a notice of claim letter or complaint filed against an insured in a court, if the notice or complaint seeks damages relating to the insured's conduct in providing or failing to provide appropriate service within the scope of pharmaceutical care or services, and with respect to settlement of a claim or lawsuit made on behalf of the insured.

(c) If a pharmacist, pharmacy technician, pharmacy technician trainee, or pharmacy licensed in this state does not carry or is not covered by pharmacist's professional liability insurance, pharmacy technician professional and supplemental liability insurance, or druggist's professional liability insurance and is insured by a nonadmitted carrier or other entity providing pharmacy professional liability insurance that does not report under this subtitle, the duty to report information under [Section 569.002](#) is the responsibility of the pharmacist, pharmacy technician, pharmacy technician trainee, or pharmacy license holder.

#### → § 569.002. Information to Be Reported

(a) The following information must be furnished to the board not later than the 30th day after receipt by the insurer of the notice of claim letter or complaint from the insured:

(1) the name of the insured and the insured's state pharmacy technician registration number, pharmacy technician trainee registration number, or pharmacist or pharmacy license number;

(2) the policy number; and

(3) a copy of the notice of claim letter or complaint.

(b) The board shall, in consultation with the Texas Department of Insurance, adopt rules for reporting additional information as the board may require. Other claim reports required under state and federal law shall be considered in determining the information to be reported, the form of the report, and frequency of reporting under the rules. Additional information that the board may require may include:

(1) the date of any judgment, dismissal, or settlement; and

(2) whether an appeal has been taken and by which party.

#### → § 569.003. Immunity from Liability



An insurer reporting under this subchapter, its agents or employees, or the board or its employees or representatives are not liable for damages in a suit brought by any person or entity for reporting as required by this subchapter or for any other action taken under this subchapter.

→ **§ 569.004. Restriction on Use of Information Reported**

(a) Information submitted to the board under this subchapter and the fact that the information has been submitted to the board may not be:

(1) offered in evidence or used in any manner in the trial of a suit described in this subchapter; or

(2) used in any manner to determine the eligibility or credentialing of a pharmacy to participate in a health insurance plan defined by the Insurance Code.

(b) Information submitted under this subchapter is confidential and is not subject to disclosure under Chapter 552, Government Code.

(c) The board shall adopt rules to ensure the confidentiality of information submitted under this subchapter.

→ **§ 569.005. Investigation of Report**

(a) Except as otherwise provided in this section, a report received by the board under this subchapter is not a complaint for which a board investigation is required.

(b) The board shall review the information relating to a pharmacist, pharmacy technician, pharmacy technician trainee, or pharmacy license holder against whom at least three professional liability claims have been reported within a five-year period in the same manner as if a complaint against the pharmacist, pharmacy technician, pharmacy technician trainee, or pharmacy license holder had been made under Chapter 555.

→ **§ 569.006. Sanctions Imposed on Insurer**

The Texas Department of Insurance may impose on any insurer subject to this subtitle sanctions authorized by Chapter 82, Insurance Code, if the insurer fails to report information as required by this subchapter.

END OF DOCUMENT