CHAPTER 789

S.B. No. 472

AN ACT

relating to the practice of pharmacy, including the Texas State Board of Pharmacy, dangerous drugs, and controlled substances; providing penalties.

Be it enacted by the Legislature of the State of Texas:

SECTION 1. Section 5, Texas Pharmacy Act (Article 4542a-1, Vernon's Texas Civil Statutes), is amended to read as follows:

Sec. 5. DEFINITIONS. In this Act, unless the context of its use clearly indicates otherwise:

(1) "A.C.P.E." means the American Council on Pharmaceutical Education.

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

(A) a practitioner, [~~or~~] an authorized agent under his supervision, *or other person authorized by law*; or

(B) the patient at the direction of a practitioner.

(3) "Administrative Procedure Act" means the Administrative Procedure and Texas Register Act, as amended (Article 6252–13a, Vernon's Texas Civil Statutes).

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

(5) "Class A pharmacy license" or "community pharmacy license" means a license issued to a pharmacy dispensing drugs or devices to the general public pursuant to a prescription drug order.

(6) "Class B pharmacy license" or "nuclear pharmacy license" means a license issued to a pharmacy dispensing or providing radioactive drugs or devices for administration to an ultimate user.

(7) "Class C pharmacy license" or "institutional pharmacy license" means a license issued to a pharmacy located in a hospital or other in-patient facility that is licensed under Chapter 241, Health and Safety Code, or Chapter 6, Texas Mental Health Code (Article 5547–1 et seq., Vernon's Texas Civil Statutes), or to a pharmacy located in a hospital maintained or operated by the state.

(8) "Class D pharmacy license" or "clinic pharmacy license" means a license issued to a pharmacy dispensing a limited type of drugs or devices pursuant to a prescription drug order.

(9) "Class E pharmacy license" or "nonresident pharmacy license" means a license issued under this Act to a pharmacy located in a state of the United States other than this state whose primary business is to dispense a prescription drug or device under a prescription drug order and to deliver the drug or device to a patient, including a patient in this state, by the United States mail, a common carrier, or a delivery service.

(10) *"Class F pharmacy license" means a license issued to a pharmacy located in a facility licensed under Chapter 142, Health and Safety Code, for the purpose of dispensing, distributing, or administering to their patients under physicians' orders the following dangerous drugs: sterile water for injection and irrigation, sterile saline for injection and irrigation, and heparin flush kits for intravenous flushes.*

(11) "College of pharmacy" means a school, university, or college of pharmacy that satisfies the accreditation standards of A.C.P.E. as adopted by the board; or that has degree requirements which meet the standards of accreditation set by the board.

(12) "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 or initiative based on the practitioner-patient-pharmacist relationship in the course of professional practice;

(B) in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns; or

(C) for the purpose of or as an incident to research, teaching, or chemical analysis and not for sale or dispensing.

(13) "Confidential record" means any health-related record maintained by a pharmacy or pharmacist such as a patient medication record, prescription drug order, or medication order.

(14) [~~(11)~~]"Controlled substance" means a drug, immediate precursor, or other substance listed in Schedules I-V or Penalty Groups 1–4 of Chapter 481, Health and Safety Code, or a drug, immediate precursor, or other substance included in Schedule I, II, III, IV, or V of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. Section 801 et seq.).

(15) [~~(12)~~]"Controlled Substances Act" means Chapter 481, Health and Safety Code, or the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. Section 801 et seq.).

(16) [~~(13)~~]"Dangerous drug" means any drug or device that is not included in Penalty Groups 1–4 of the Controlled Substances Act and that is unsafe for self-medication or any drug or device that bears or is required to bear the legend:

(A) "Caution: federal law prohibits dispensing without prescription"; or

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

(17) [~~(14)~~]"Dangerous Drug Act" means Chapter 483, Health and Safety Code.

(18) [~~(15)~~]"Deliver" or "delivery" means the actual, constructive, or attempted transfer of a prescription drug or device or controlled substance from one person to another, whether or not for a consideration.

(19) [~~(15)~~]"Designated agent" means:

(A) a licensed nurse, physician assistant, pharmacist, or other [~~an~~] individual [~~under the supervision of a practitioner,~~] designated by *a* [~~the~~] practitioner, and for whom the practitioner assumes legal responsibility, who communicates *prescription drug orders* [~~the practitioner's instructions~~] to a pharmacist;

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

(C) a registered nurse or physician assistant authorized by a practitioner to carry out a prescription drug order for dangerous drugs under Subdivision (5), Subsection (d), Section 3.06, Medical Practice Act (Article 4495b, Vernon's Texas Civil Statutes).

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

(21) [~~(17)~~]"Dispense" means preparing, packaging, compounding, or labeling for delivery a prescription drug or device in the course of professional practice to an ultimate user or his agent by or pursuant to the lawful order of a practitioner.

(22) [~~(18)~~]"Distribute" means the delivery of a prescription drug or device other than by administering or dispensing.

(23) [~~(19)~~]"Drug" means:

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

(B) a substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;

(C) a substance, other than food, intended to affect the structure or any function of the body of man or other animals;

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

(E) a dangerous drug; or

(F) a controlled substance.

(24) "Drug regimen review" includes the following activities:

(A) evaluation of prescription drug or medication orders and patient medication records for:

(i) known allergies;

(ii) rational therapy-contraindications;

(iii) reasonable dose and route of administration; and

(iv) reasonable directions for use;

(B) evaluation of prescription drug or medication orders and patient medication records for duplication of therapy;

(C) evaluation of prescription drug or medication orders and patient medication records for:

(i) drug-drug interactions;

(ii) drug-food interactions;

(iii) drug-disease interactions;

(iv) adverse drug reactions; and

(D) evaluation of prescription drug and medication orders and patient medication records for proper utilization, including overutilization or underutilization.

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

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

(27) [~~(22)~~] "Labeling" means the process of affixing a label including all information required by federal and state law or regulation to any drug or device container. The term does not include the labeling by a manufacturer, packer, or distributor of a nonprescription drug or commercially packaged prescription drug or device, or unit dose packaging.

(28) "Manufacturing" means the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis and includes any packaging or repackaging of the substances or labeling or relabeling of the container and the promotion and marketing of such drugs or devices. Manufacturing also includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners, or other persons but does not include compounding.

(29) [~~(23)~~] "Medication order" means an order from a practitioner or a practitioner's designated agent for administration of a drug or device.

(30) [~~(24)~~] "Nonprescription drug" means a nonnarcotic drug or device that may be sold without a prescription and that is labeled and packaged in compliance with applicable state or federal law.

(31) "Patient counseling" means the communication by the pharmacist of information, as specified in the rules of the board, to the patient or caregiver, in order to improve therapy by ensuring proper use of drugs and devices.

(32) [~~(25)~~]"Person" means an individual, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership, association, or any other legal entity.

(33) "Pharmaceutical care" is the provision of drug therapy and other pharmaceutical services defined in the rules of the board and intended to assist in the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process.

(34) [~~(26)~~]"Pharmacist" means a person licensed by the board to practice pharmacy.

(35) [~~(27)~~]"Pharmacist-in-charge" means the pharmacist designated on a pharmacy license as the pharmacist who has the authority or responsibility for a pharmacy's compliance with laws and rules pertaining to the practice of pharmacy.

(36) [~~(28)~~]"Pharmacist-intern" means an undergraduate student enrolled in the professional sequence of a college of pharmacy approved by the board and participating in a school-based, board-approved internship program or a graduate of a college of pharmacy who is participating in a board-approved internship.

(37) [~~(29)~~]"Pharmacy" means a facility *licensed by the board pursuant to Section 29 of this Act* [~~where the practice of pharmacy occurs~~].

(38) [~~(30)~~]"Practice of pharmacy" means:

(A) provision of those acts or services necessary to provide pharmaceutical care;

(B) interpretation and evaluation of prescription drug orders or medication orders;

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

(D) provision of patient counseling; and

(E) responsibility for:

(i) dispensing of prescription drug orders or distribution of medication orders;

(ii) compounding and labeling of drugs and devices, except labeling by a manufacturer, repackager, or distributor of nonprescription drugs and commercially packaged prescription drugs and devices;

(iii) proper and safe storage of drugs and devices; or

(iv) maintenance of proper records for drugs and devices [~~interpreting and evaluating prescription or medication orders, dispensing and labeling drugs or devices, selecting drugs and reviewing drug utilization, storing prescription drugs and devices and maintaining prescription drug records in a pharmacy, advising or consulting when necessary or required by law about therapeutic value, content, hazard, or use of drugs or devices, or offering or performing the services and transactions necessary to operate a pharmacy~~].

(39) [~~(31)~~]"Practitioner" means:

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

(B) a person licensed by another state in a health field in which, under Texas law, licensees in this state may legally prescribe dangerous drugs or a person practicing in another state and licensed by another state as a physician, dentist, veterinarian, or podiatrist, having a current Federal Drug Enforcement Administration registration number, and who may legally prescribe Schedule II, III, IV, or V controlled substances in such other state; or

(C) a person licensed in the Dominion of Canada or the United Mexican States in a health field in which, under the laws of this state, a licensee may legally prescribe dangerous drugs. "Practitioner" does not include a person licensed under this Act.

(40) [~~(32)~~]"Preceptor" means a pharmacist in good standing licensed in this state to practice pharmacy and certified by the board to supervise and be responsible for the activities and functions of a pharmacist-intern in the internship program.

(41) [~~(33)~~]"Prescription drug" means:

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

(B) a drug or device that under federal law is required, prior to being dispensed or delivered, to be labeled with either of the following statements:

(i) "Caution: federal law prohibits dispensing without prescription"; 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 any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by a practitioner only.

(42) [~~(34)~~]"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 pursuant to Subdivision (5), Subsection (d), Section 3.06, Medical Practice Act (Article 4495b, Vernon's Texas Civil Statutes).

(43) "Prospective drug use review" means a review of the patient's drug therapy and prescription drug order or medication order, as defined in the rules of the board, prior to dispensing or distributing the drug.

(44) [~~(35)~~]"Provide" means to supply one or more unit doses of a nonprescription drug or dangerous drug to a patient.

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

(46) [~~(37)~~]"Substitution" means the dispensing of a drug or a brand of drug other than that which is ordered or prescribed.

(47) [~~(38)~~]"Supportive personnel" means those individuals utilized in pharmacies whose responsibility it shall be to provide [~~nonjudgmental~~] technical services *that do not require professional judgment* concerned with the preparation and distribution of drugs under the direct supervision of and responsible to a pharmacist.

(48) [~~(39)~~]"Ultimate user" means a person who has obtained and 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.

(49) [~~(40)~~]"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 name, strength, and expiration date of the drug.

[~~(41) "Authorized agent" means an individual under the supervision of a practitioner, designated by the practitioner, and for whom the practitioner assumes legal responsibility, who communicates the practitioner's instructions to the pharmacist.~~]

SECTION 2. Section 16, Texas Pharmacy Act (Article 4542a–1, Vernon's Texas Civil Statutes), is amended to read as follows:

Sec. 16. RULES. (a) The board shall adopt, *amend, and repeal* rules for the proper administration and enforcement of this Act, consistent with this Act. The rules shall be adopted, *amended, or repealed* in accordance with the Administrative Procedure Act.

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

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

SECTION 3. Subsections (a), (b), and (q), Section 17, Texas Pharmacy Act (Article 4542a–1, Vernon's Texas Civil Statutes), are amended to read as follows:

(a) The board is responsible for the regulation of the practice of pharmacy in this state, including the following:

(1) the licensing by examination or by reciprocity of applicants who are qualified to engage in the practice of pharmacy and the licensing of pharmacies under this Act;

(2) the renewal of licenses to engage in the practice of pharmacy and licenses to operate pharmacies;

(3) the determination and issuance of standards for recognition and approval of degree requirements of colleges of pharmacy whose graduates shall be eligible for licensing in this state and the specification and enforcement of requirements for practical training, including internship;

(4) the enforcement of those provisions of this Act relating to the conduct or competence of pharmacists practicing in this state and the conduct of pharmacies operating in this state and the suspension, revocation, fining, reprimanding, cancellation, or restriction of licenses to engage in the practice of pharmacy or to operate a pharmacy;

(5) *the specifications of conditions under which a pharmacist may administer medications which at a minimum shall include the following:*

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

(7) a drug or alcohol dependency;

(8) failed to keep and maintain records required by this Act or failed to keep and maintain complete and accurate records of purchases and disposals of drugs listed in the Controlled Substances Act or the Dangerous Drug Act;

(9) violated any provision of the Controlled Substances Act or Dangerous Drug Act or a rule relating to those acts or any provision of Sections 485.031–485.035, Health and Safety Code, or a rule adopted under Section 485.011, Health and Safety Code;

(10) aided or abetted an unlicensed individual to engage in the practice of pharmacy if the pharmacist knew or reasonably should have known that the individual was unlicensed at the time;

(11) refused an entry into any pharmacy for any inspection authorized by this Act if the pharmacist had received notification from which the pharmacist knew or reasonably should have known that the attempted inspection was authorized;

(12) violated the pharmacy or drug laws or rules of this state or any other state or of 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 pursuant to Subdivision (4) of this subsection;

(15) dispensed prescription drugs while acting outside the usual course and scope of professional practice; or

(16) had a license to practice pharmacy issued by another state canceled, revoked, surrendered, or suspended for conduct substantially equivalent to conduct described in Subdivisions (1) through (15) of this subsection. A certified copy of the record of the state taking action as set out above shall be conclusive evidence of the action taken by such state.

SECTION 7. Subsections (a) and (b), Section 26A, Texas Pharmacy Act (Article 4542a–1, Vernon's Texas Civil Statutes), are amended to read as follows:

(a) On the entry of an initial order against *an applicant for a license to practice pharmacy or* a person licensed by the board to practice pharmacy, the board may *refuse to issue a license to the applicant or* suspend the person's license. On the person's final conviction, the board may revoke the person's license.

(b) On the entry of an initial order against *an applicant for a license for a pharmacy or* a person who has been issued a license or renewal license for a pharmacy under this Act, or against a managing officer of the licensee *or applicant* if the licensee *or applicant* is an association, joint-stock company, partnership, or corporation, the board may *refuse to issue the license or* suspend the license. On final conviction, the board may revoke the license.

SECTION 8. Subsection (a), Section 26B, Texas Pharmacy Act (Article 4542a–1, Vernon's Texas Civil Statutes), is amended to read as follows:

(a) The board may in its discretion refuse to issue or renew a license or may fine or reprimand any licensee or revoke, restrict, cancel, or suspend any license granted by the board, if the board finds that an applicant or licensee has:

(1) dispensed a drug, quantity, or strength of drug other than that which is ordered for the patient by a practitioner or labeled a prescription with incorrect directions for use;

(2) violated any of the following provisions of this Act:

(A) Section 29(a), (b)(5), or (c)(5);

(B) Section 30(i) or (j);

(C) Section 32(a);

(3) failed to comply with the following requirements unless compliance would violate the pharmacy or drug laws or rules in the state in which the pharmacy is located:

(A) Section 481.074 or 481.075, Health and Safety Code;

(B) Texas substitution requirements regarding:

(i) the practitioner's directions relative to generic substitution;

(ii) the patient's right to refuse generic substitution; or

(iii) notification to the patient of the patient's right to refuse substitution; [~~or~~]

(C) board rules relating to the provision of drug information to the patient or patient's agent in written form or by telephone; or

(D) board rules adopted pursuant to Section 16(a) of this Act and determined by the board to be applicable pursuant to Section 16(b) of this Act; or

(4) engaged in conduct which caused serious bodily injury to a Texas resident.

SECTION 9. Section 27A, Texas Pharmacy Act (Article 4542a–1, Vernon's Texas Civil Statutes), is amended by amending Subsection (d) and adding Subsection (j) to read as follows:

(d) The records and proceedings of the board, its authorized agents, or any pharmaceutical organization committee as set out in Subsections (a) and (b) of this section shall be confidential and are not considered open records for the purposes of Chapter 424, Acts of the 63rd Legislature, Regular Session, 1973, as amended (Article 6252–17a, Vernon's Texas Civil Statutes); provided, however, the board may disclose this confidential information only:

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

(2) to the pharmacist licensing or disciplinary authorities of other jurisdictions; [~~or~~]

(3) pursuant to an order of a court of competent jurisdiction; *or*

(4) pursuant to Subsection (j) of this section.

(j) The board may disclose that the license of a pharmacist who is the subject of an order of the board deemed confidential by Subsection (d) of this section is suspended, revoked, canceled, restricted, or retired or that the pharmacist is in any manner otherwise limited in the practice of pharmacy; however, the board may not disclose the nature of the impairment or other information that resulted in such action.

SECTION 10. Subsection (b), Section 28, Texas Pharmacy Act (Article 4542a–1, Vernon's Texas Civil Statutes), is amended to read as follows:

(b) A person whose pharmacy license or license to practice pharmacy in this state has been canceled, revoked, or restricted under this Act, whether voluntarily or by action of the board, may, after 12 months from the effective date of the cancellation, revocation, or restriction, petition the board for reinstatement or removal of the restriction of the license. The petition shall be in writing and in the form prescribed by the board. On investigation and *review of the petition* [~~hearing~~], the board may in its discretion grant or deny the petition or it may modify its original finding to reflect any circumstances that have changed sufficiently to warrant the modification. *If such petition is denied by the board, a subsequent petition may not be considered by the board until 12 months from the date of denial of the previous petition. The board in its discretion may require such person to pass an examination or examinations for reentry into the practice of pharmacy.*

SECTION 11. Subsections (b) and (c), Section 29, Texas Pharmacy Act (Article 4542a–1, Vernon's Texas Civil Statutes), are amended to read as follows:

(b) Each pharmacy 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; [~~or~~]

(5) Class E; *or*

(6) Class F.

(c) Each pharmacy shall be under the supervision of a pharmacist as follows:

(1) a Class A pharmacy shall be under the continuous on-site supervision of a pharmacist during the time it is open for pharmacy services;

(2) a Class B pharmacy shall be under the continuous on-site supervision of a pharmacist during the time it is open for pharmacy services;

(3) a Class C pharmacy shall be under the continuous on-site supervision of a pharmacist in institutions with more than 100 beds during the time it is open for pharmacy services; in institutions with 100 beds or fewer, the services of a pharmacist shall be required on a part-time or consulting basis according to the needs of the institution;

(4) a Class D pharmacy shall be under the continuous supervision of a pharmacist whose services shall be required according to the needs of the pharmacy; [~~and~~]

(5) a Class E pharmacy shall 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 license; *and*

(6) a Class F pharmacy shall be under the continuous supervision of a pharmacist whose services shall be required according to the needs of the pharmacy.

SECTION 12. Subsection (a), Section 32, Texas Pharmacy Act (Article 4542a–1, Vernon's Texas Civil Statutes), is amended to read as follows:

(a) A pharmacy shall report in writing to the board not later than the 10th day after the date of the occurrence, unless immediate notification is required by this section, any of the following:

(1) permanent closing;

(2) change of ownership;

(3) change of location;

(4) change of pharmacist-in-charge;

(5) the theft or significant loss of any controlled substances, immediately on discovery of the theft or loss, by including with the notification to the board of the theft or loss a list of all controlled substances stolen or lost;

(6) the sale or transfer of controlled substances or dangerous drugs on the permanent closing or change of ownership of the pharmacy;

(7) any matters and occurrences that the board may require by rule;

(8) out-of-state purchases of controlled substances as determined by the board; [~~and~~]

(9) 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 the treatment of injury, illness, and disease, immediately on the occurrence of the disaster, accident, or emergency;

(10) [~~.—(9)~~] a final order against the holder of a Class E pharmacy license by the regulatory or licensing agency of the state in which the pharmacy is located; and

(11) [~~(10)~~] a final order against a pharmacist who is designated as the pharmacist-in-charge of a Class E pharmacy by the regulatory or licensing agency of the state in which the pharmacy is located.

SECTION 13. Section 40, Texas Pharmacy Act (Article 4542a–1, Vernon's Texas Civil Statutes), is amended by amending Subsections (d) through (k) to read as follows:

(d) *With the patient's consent and notification to the practitioner, a pharmacist may dispense a dosage form of a drug product different from that prescribed, such as tablet instead of capsule or liquid instead of tablet, provided the dosage form so dispensed:*

(1) contains the identical amount of the active ingredients as the dosage prescribed for the patient;

(2) is not an enteric-coated or time release product; and

(3) does not alter desired clinical outcomes.

(e) Unless otherwise directed by the practitioner, the label on the dispensing container shall indicate the actual drug product dispensed, either (1) the brand name, or if none (2) the generic name, the strength, and the name of the manufacturer or distributor. In instances where a drug product 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 actual name of the brand name drug product*

prescribed.[~~" The brand name of the prescribed drug shall not appear on the prescription container label unless it is the drug product actually dispensed.~~]

(f) [~~(e)~~] A pharmacist may not select a generically equivalent drug unless the generically equivalent drug selected costs the patient less than the prescribed drug product. A pharmacist may not charge a higher professional fee for dispensing a generically equivalent drug product than the fee he or she customarily charges for dispensing the brand name product prescribed.

(g)(1) [~~(f)~~] A pharmacist who selects a generically equivalent drug product as authorized by this section shall:

(A) [~~(1)~~] personally, or through his or her agent or employee and prior to delivery of a generically equivalent drug product, inform the patient or the patient's agent that a less expensive generically equivalent drug product has been substituted for the brand prescribed and the patient or patient's agent's right to refuse such substitution; or

(B) [~~(2)~~] cause to be displayed, 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 ALLOWS A LESS EXPENSIVE GENERICALLY EQUIVALENT DRUG TO BE SUBSTITUTED FOR CERTAIN BRAND NAME DRUGS UNLESS YOUR PHYSICIAN DIRECTS OTHERWISE. YOU HAVE A RIGHT TO REFUSE SUCH SUBSTITUTION. CONSULT YOUR PHYSICIAN OR PHARMACIST CONCERNING THE AVAILABILITY OF A SAFE, LESS EXPENSIVE DRUG FOR YOUR USE."

Only one sign displayed in a pharmacy, as required above, shall be deemed compliance with this subsection.

(2) [~~(3)~~] A pharmacist complies with the requirements of this section if an employee or agent of the pharmacist notifies a purchaser as required by *Paragraph (A) of* Subdivision (1) of this subsection. The patient or patient's agent shall have the right to refuse such product selection.

(h) [~~(g)~~]No written prescription issued by a practitioner, as such term is defined in Section *5(39)(A)* [~~5(30)(A)~~] of this Act, may be dispensed unless it is ordered on a form containing two signature lines of equal prominence, side by side, at the bottom of the form. Under either signature line shall be printed clearly the words "product selection permitted," and under the other signature line shall be printed clearly the words "dispense as written." The practitioner shall communicate dispensing instructions to the pharmacist by signing on the appropriate line. If the practitioner's signature does not clearly indicate that the prescription must be dispensed as written, generically equivalent drug selection is permitted. No prescription form furnished a practitioner shall contain a preprinted order for a drug product by brand name, generic name, or manufacturer.

(i) [~~(h)~~]If a prescription is transmitted to a pharmacist orally, the pharmacist shall note any dispensing instructions by the practitioner or the practitioner's agent on the file copy of the prescription and retain the prescription for the period of time specified by law. Properly authorized prescription refills shall follow the original dispensing instructions unless otherwise indicated by the practitioner or practitioner's agent.

(j) [~~(i)~~]A pharmacist shall record on the prescription form the name, strength, and manufacturer or distributor of any drug product dispensed as herein authorized.

(k) [~~(j)~~]A pharmacist who selects a generically equivalent drug to be dispensed pursuant to this section assumes the same responsibility for selecting the generically equivalent drug that he does in filling a prescription for a drug product prescribed by generic name. There shall be no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a drug product pursuant to this section.

(l) [~~(k)~~]Drug product selection as authorized in this section shall not apply to enteric-coated tablets; controlled release products; injectable suspensions, other than antibiotics; suppositories containing active ingredients for which systemic absorption is necessary for therapeutic activity; and different delivery systems for aerosol or nebulizer drugs. This subsection shall

not apply to any drug product which is determined to be generically equivalent to the brand prescribed.

SECTION 14. The Texas Pharmacy Act (Article 4542a–1, Vernon's Texas Civil Statutes) is amended by adding Sections 40B and 40C to read as follows:

Sec. 40B. EMERGENCY REFILLS. A pharmacist may exercise his professional judgment in refilling a prescription for a prescription drug, other than a controlled substance listed in Schedule II, without the authorization of the prescribing practitioner, provided:

(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 which 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 such authorization and that authorization of the practitioner is required for future refills; and

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

Sec. 40C. RELEASE OF CONFIDENTIAL RECORDS. Confidential records are privileged and may be released only to:

(1) the patient or the patient's agent;

(2) practitioners and other pharmacists when, in the pharmacist's professional judgment, such release is necessary to protect the patient's health and well-being;

(3) other persons, the board, or other state or federal agencies authorized by law to receive such confidential records;

(4) a law enforcement agency engaged in investigation of suspected violations of the Controlled Substances Act or the Dangerous Drug Act;

(5) a person employed by any state agency which licenses a practitioner as defined in this Act if such person is engaged in the performance of the person's official duties; or

(6) an insurance carrier or other third party payor authorized by a patient to receive such information.

SECTION 15. Subdivision (41), Section 481.002, Health and Safety Code, is amended to read as follows:

(41) "Prescription" means an order by a practitioner to a pharmacist for a controlled substance for a particular patient that specifies:

(A) the date of issue;

(B) the name and address of the patient or, if the controlled substance is prescribed for an animal, the species of the animal and the name and address of its owner;

(C) the name and quantity of the controlled substance prescribed with the quantity shown numerically followed by the number written as a word if the order is written or, if the order is communicated orally or telephonically, with the quantity given by the practitioner and transcribed by the pharmacist numerically; [~~and~~]

(D) directions for the use of the drug;

(E) the intended use of the drug unless the practitioner determines the furnishing of this information is not in the best interest of the patient; and

(F) the name, address, Federal Drug Enforcement Administration registration number, and telephone number of the practitioner at the practitioner's usual place of business, legibly printed or stamped.

SECTION 16. Section 481.074, Health and Safety Code, is amended by amending Subsections (d) through (i) and adding Subsection (*l*) to read as follows:

(d) *Except as specified in Subsections (e) and (f) of this section, a* [A] person may not fill a prescription for a controlled substance listed in Schedule II after the end of the seventh day after the date on which the prescription is issued. A person may not refill a prescription for a substance listed in Schedule II.

(e). *The partial filling of a prescription for a controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and the pharmacist makes a notation of the quantity supplied on the face of the written prescription or written record of the emergency oral prescription. The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.*

(f) A prescription for a Schedule II controlled substance written for a patient in a long-term care facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question about whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. Both the pharmacist and the practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient." A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been filled in violation of this Act. For each partial filling, the dispensing pharmacist shall record on the back of Copy 1 and Copy 2 of the prescription the date of the partial filling, the quantity dispensed, the remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. Prior to any subsequent partial filling the pharmacist is to determine that the additional partial filling is necessary. The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions for patients in a long-term care facility or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 30 days from the issue date unless sooner terminated by discontinuance of the medication.

(g) A person may not dispense a controlled substance in Schedule III or IV that is a prescription drug under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 301 et seq.) without a written, oral, or telephonically communicated prescription of a practitioner defined by Section 481.002(39)(A), except that the practitioner may dispense the substance directly to an ultimate user. A prescription for a controlled substance listed in Schedule III or IV may not be filled or refilled later than six months after the date on which the prescription is issued and may not be refilled more than five times, unless the prescription is renewed by the practitioner.

(h) [~~(f)~~] A pharmacist may dispense a controlled substance listed in Schedule III, IV, or V under an original written prescription issued by a practitioner defined by Section 481.002(38)(C) and only if the pharmacist determines that the prescription was issued for a valid medical purpose and in the course of professional practice. A prescription issued under this subsection may not be filled or refilled later than six months after the date the prescription is issued, and a prescription authorized to be refilled on the original prescription may not be refilled more than five times.

(i) [~~(g)~~]A person may not dispense a controlled substance listed in Section 481.036(1) or (2) without the prescription of a practitioner defined by Section 481.002(39)(A), except that a practitioner may dispense the substance directly to an ultimate user. A prescription issued under this subsection may not be filled or refilled later than six months after the date the prescription is issued and may not be refilled more than five times, unless the prescription is renewed by the practitioner.

(j) [~~(h)~~]A practitioner or institutional practitioner may not allow a patient, on the patient's release from the hospital, to possess a controlled substance prescribed by the practitioner unless:

(1) the substance was dispensed under a medication order while the patient was admitted to the hospital;

(2) the substance is in a properly labeled container; and

(3) the patient possesses not more than a seven-day supply of the substance.

(k) [~~(i)~~] A prescription for a controlled substance must show:

(1) the quantity of the substance prescribed:

(A) *numerically, followed by the number* written as a word, if the prescription is written; or

(B) if the prescription is communicated orally or telephonically, as transcribed by the receiving pharmacist;

(2) the date of issue;

(3) the name and address of the patient or, if the controlled substance is prescribed for an animal, the species of the animal and the name and address of its owner;

(4) the name and strength of the controlled substance prescribed;

(5) the directions for use of the controlled substance; [~~and~~]

(6) *the intended use of the drug unless the practitioner determines the furnishing of this information is not in the best interest of the patient; and*

(7) the name, address, [~~and~~] Federal Drug Enforcement Administration registration number, *and telephone number* of the practitioner *at the practitioner's usual place of business, legibly printed or stamped.*

(l) A pharmacist may exercise his professional judgment in refilling a prescription for a controlled substance in Schedule III, IV, or V without the authorization of the prescribing practitioner provided:

(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 which 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 such authorization and that authorization of the practitioner is required for future refills; and

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

SECTION 17. Subsections (d), (e), and (f), Section 481.075, Health and Safety Code, are amended to read as follows:

(d) Except for oral prescriptions prescribed under Section 481.074(b), the prescribing practitioner shall:

(1) legibly fill in, or direct a designated agent to legibly fill in, on all three copies of the form in the space provided:

(A) the date the prescription is written;

(B) the drug prescribed, the quantity (shown numerically followed by the number written as a word), [~~and~~] instructions for use, *and the intended use of the drug or the diagnosis for which the controlled substance is prescribed;* and

(C) the name, address, and age of the patient or, in the case of an animal, its owner, for whom the controlled substance is prescribed;

(2) sign Copies 1 and 2 of the form and give them to the person authorized to receive the prescription; and

(3) retain Copy 3 of the form with the practitioner's records for at least two years after the date the prescription is written.

(e) In the case of an oral prescription prescribed under Section 481.074(b), the prescribing practitioner shall give the dispensing pharmacy the information needed to complete the form.

(f) Each dispensing pharmacist shall:

(1) fill in on Copies 1 and 2 of the form in the space provided the information not required to be filled in by the prescribing practitioner or the Department of Public Safety;

(2) *indicate the total quantity dispensed on the face of the triplicate prescription form;*

(3) retain Copy 2 with the records of the pharmacy for at least two years; and

(4) [~~(3)~~]sign Copy 1 and send it to the Department of Public Safety not later than the 30th day after the date the prescription is filled *or not later than the 30th day after the completion of a prescription dispensed under Section 481.074(f).*

SECTION 18. Subchapter A, Chapter 483, Health and Safety Code, is amended by adding Section 483.0001 and amending Section 483.001 to read as follows:

Sec. 483.0001. SHORT TITLE. This Act may be cited as the Texas Dangerous Drug Act.

Sec. 483.001. DEFINITIONS. In this chapter:

(1) [~~(2)~~]"Board" means the Texas State Board of Pharmacy.

(2) [~~(3)~~]"Dangerous drug" means a device or a drug that is unsafe for self-medication and that is not included in Schedules I through V or Penalty Groups 1 through 4 of Chapter 481 (Texas Controlled Substances Act). The term includes a device or a drug that bears or is required to bear the legend:

(A) Caution: federal law prohibits dispensing without prescription; or

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

(3) [~~(4)~~] "Deliver" means to sell, dispense, give away, or supply in any other manner.

(4) "Designated agent" means:

(A) a licensed nurse, physician assistant, pharmacist, or other individual designated by a practitioner to communicate prescription drug orders to a pharmacist;

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

(C) a registered nurse or physician assistant authorized by a practitioner to carry out a prescription drug order for dangerous drugs under Section 3.06(d)(5), Medical Practice Act (Article 4495b, Vernon's Texas Civil Statutes).

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

(6) "Manufacturer" means a person, other than a pharmacist, who manufactures dangerous drugs. The term includes a person who prepares dangerous drugs in dosage form by mixing, compounding, encapsulating, entableting, or any other process.

(7) "Patient" means:

(A) an individual for whom a dangerous drug is prescribed or to whom a dangerous drug is administered; or

(B) an owner or the agent of an owner of an animal for which a dangerous drug is prescribed or to which a dangerous drug is administered.

(8) "Person" includes an individual, corporation, partnership, and association.

(9) "Pharmacist" means a person licensed by the Texas State Board of Pharmacy to practice pharmacy.

(10) "Pharmacy" means a facility *licensed by the board pursuant to Section 29, Texas Pharmacy Act (Article 4542a-1, Vernon's Texas Civil Statutes)* [~~in which the practice of pharmacy occurs~~].

(11) "Practice of pharmacy" means:

(A) provision of those acts or services necessary to provide pharmaceutical care;

(B) interpretation and evaluation of prescription drug orders or medication orders;

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

(D) provision of patient counseling; and

(E) responsibility for:

(i) dispensing of prescription drug orders or distribution of medication orders in the patient's best interest;

(ii) compounding and labeling of drugs and devices, except labeling by a manufacturer, repackager, or distributor of nonprescription drugs and commercially packaged prescription drugs and devices;

(iii) proper and safe storage of drugs and devices; and

(iv) maintenance of proper records for drugs and devices [~~the interpretation and evaluation of prescription or medication orders, the dispensing and labeling of drugs or devices, the selection of drugs and the review of drug use, the storage of prescription drugs and devices and the maintenance of prescription drug records in a pharmacy, the giving of advice or consultation if necessary or required by law about the therapeutic value, content, hazard, or use of drugs or devices, or the offer to perform or the performance of the services and transactions necessary to operate a pharmacy~~]. In this subdivision, "device" has the meaning assigned by the Texas Pharmacy Act (Article 4542a-1, Vernon's Texas Civil Statutes).

(12) "Practitioner" means a person licensed:

(A) by the Texas State Board of Medical Examiners, State Board of Dental Examiners, Texas State Board of Podiatry Examiners, Texas Optometry Board, or State Board of Veterinary Medical Examiners to prescribe and administer dangerous drugs;

(B) by another state in a health field in which, under the laws of this state, a licensee may legally prescribe dangerous drugs; or

(C) in Canada or Mexico in a health field in which, under the laws of this state, a licensee may legally prescribe dangerous drugs.

(13) "Prescription" means an order from a practitioner, or an agent of the practitioner designated in writing as authorized to communicate prescriptions, or an order made in accordance with Section 3.06(d)(5), Medical Practice Act (Article 4495b, Vernon's Texas Civil Statutes), to a pharmacist for a dangerous drug to be dispensed that states:

(A) the date of the order's issue;

(B) the name and address of the patient;

(C) if the drug is prescribed for an animal, the species of the animal;

(D) the name and quantity of the drug prescribed; [~~and~~]

(E) the directions for the use of the drug;

(F) the intended use of the drug unless the practitioner determines the furnishing of this information is not in the best interest of the patient; and

(G) the name, address, and telephone number of the practitioner at the practitioner's usual place of business, legibly printed or stamped.

(14) "Warehouseman" means a person who stores dangerous drugs for others and who has no control over the disposition of the drugs except for the purpose of storage.

(15) "Wholesaler" means a person engaged in the business of distributing dangerous drugs to a person listed in Sections 483.041(c)(1)–(6).

SECTION 19. Section 483.022, Health and Safety Code, is amended to read as follows:

Sec. 483.022. PRACTITIONER'S DESIGNATED AGENT; PRACTITIONER'S RESPONSIBILITIES. (a) A practitioner shall provide in writing the name of each[~~:~~

[~~(1)~~]designated agent *as defined by Section 483.001(4)(A) and (C), and the name of each healthcare facility which employs persons defined by Section 483.001(4)(B)* [~~authorized by the practitioner to communicate prescriptions for the practitioner; and~~

[~~(2) registered nurse or physician assistant authorized to carry out a prescription drug order under Section 3.06(d)(5), Medical Practice Act (Article 4495b, Vernon's Texas Civil Statutes)~~].

(b) The practitioner shall maintain at the practitioner's usual place of business a list of the designated agents *or healthcare facilities as defined by Section 483.001(4)* [~~and a list of the designated registered nurses or physician assistants authorized to carry out a prescription drug order~~].

[~~(b) The practitioner shall maintain at the practitioner's usual place of business a list of each designated agent, registered nurse, or physician assistant who is authorized to carry out a prescription drug order.~~]

(c) The practitioner shall provide a pharmacist with a copy of the practitioner's written authorization for a designated agent *as defined by Section 483.001(4)*[~~, registered nurse, or physician assistant~~] on the pharmacist's request.

(d) This section does not relieve a practitioner or the practitioner's *designated* agent from the requirements of Section 40, Texas Pharmacy Act (Article 4542a-1, Vernon's Texas Civil Statutes).

(e) A practitioner remains personally responsible for the actions of a designated agent who communicates a prescription to a pharmacist.

SECTION 20. Subsection (d), Section 483.041, Health and Safety Code, is amended to read as follows:

(d) An offense under this section is a *felony of the third degree* [~~Class B misdemeanor unless it is shown on the trial of the defendant that the defendant has previously been convicted of an offense under this section, in which event the offense is a Class A misdemeanor~~].

SECTION 21. Section 483.042, Health and Safety Code, is amended by amending Subsections (c) and (d) to read as follows:

(c) *The labeling provisions of Subsection (a) do not apply when the dangerous drug is prescribed for administration to an ultimate user who is institutionalized. The board shall adopt rules for the labeling of such drugs.*

(d) Proof of an offer to sell a dangerous drug must be corroborated by a person other than the offeree or by evidence other than a statement by the offeree.

(e) [~~(d)~~] An offense under this section is a felony of the third degree.

SECTION 22. Section 483.047, Health and Safety Code, is amended to read as follows:

Sec. 483.047. REFILLING PRESCRIPTION WITHOUT AUTHORIZATION. (a) *Except as authorized by Subsection (b), a* [~~A~~] pharmacist commits an offense if the pharmacist refills a prescription unless:

~~(1) the prescription contains an authorization by the practitioner for the refilling of the prescription, and the pharmacist refills the prescription in the manner provided by the authorization; or~~

~~(2) at the time of refilling the prescription, the pharmacist is authorized to do so by the practitioner who issued the prescription.~~

(b) *A pharmacist may exercise his professional judgment in refilling a prescription for a dangerous drug without the authorization of the prescribing practitioner provided:*

(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 which 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 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 such authorization and that authorization of the practitioner is required for future refills; and

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

(c) An offense under this section is a Class B misdemeanor unless it is shown on the trial of the defendant that the defendant has previously been convicted under this chapter, in which event the offense is a Class A misdemeanor.

SECTION 23. Section 142.0061, Health and Safety Code, is amended to read as follows:

Sec. 142.0061. POSSESSION OF DANGEROUS DRUGS. A home health agency *that is licensed as a Class F Pharmacy under the Texas Pharmacy Act (Article 4542a-1, Vernon's Texas Civil Statutes)* or its employees who are registered nurses or licensed vocational nurses may purchase, store, or transport for the purpose of administering to their home health patients under physician's orders the following dangerous drugs: sterile water for injection and irrigation, sterile saline for injection and irrigation, and heparin flush kits for intravenous flushes.

SECTION 24. This Act takes effect September 1, 1993.

SECTION 25. (a) A change in law made by this Act which applies to a criminal offense applies only to an offense committed on or after the effective date of this Act. For purposes of this section, an offense is committed before the effective date of this Act if any element of the offense occurs before that date.

(b) A criminal offense committed before the effective date of this Act is covered by the law in effect when the offense was committed, and the former law is continued in effect for this purpose.

SECTION 26. The importance of this legislation and the crowded condition of the calendars in both houses create an emergency and an imperative public necessity that the constitutional rule requiring bills to be read on three several days in each house be suspended, and this rule is hereby suspended.

Passed the Senate on April 21, 1993, by a viva-voce vote; the Senate concurred in House amendments on May 25, 1993, by a viva-voce vote; passed the House, with amendments, on May 22, 1993, by a non-record vote.

Approved June 18, 1993.

Effective Sept. 1, 1993.