

RULE ANALYSIS

Introduction: THE AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS ADOPTED RULES

Short Title: Definitions

Rule Numbers: §291.31

Statutory Authority: Texas Pharmacy Act, Chapter 551-566 and 568-569, Occupations Code:

- (1) Section 551.002 specifies that the purpose of the Act is to protect the public through the effective control and regulation of the practice of pharmacy; and
- (2) Section 554.051 gives the Board the authority to adopt rules for the proper administration and enforcement of the Act.

Purpose: The amendments, if adopted, add definitions for automated checking device, beyond use date, dispensing error, and patient med-pak which were defined elsewhere in the rules but not in the definitions; clarify the definition of electronic prescription drug order to be consistent with DEA requirements; update definitions to be consistent with other rules.

Background: Board staff presents the proposed amendments to update and clarify the definitions for Class A pharmacies.

The Board reviewed and voted to propose the amendments during the November 6, 2012, meeting. The proposed amendments were published in the December 14, 2012, issue of the *Texas Register* at 37 TexReg 9733.

permitted for any student unless they would make a particular test invalid. Decisions regarding testing accommodations shall take into consideration the needs of the student and the accommodations the student routinely receives in classroom instruction.

(b) For a student receiving special education services, the admission, review, and dismissal (ARD) committee shall determine the allowable accommodations necessary for the student to take the assessments administered under the TEC, Chapter 39, Subchapter B, and shall document them in the student's individualized education program.

(c) Permissible testing accommodations shall be described in the appropriate test administration materials.

§101.3014. Scoring and Reporting.

(a) The superintendent of a school district or chief administrative officer of each charter school shall accurately report all test results as required by the Texas Education Code (TEC), §39.030, with appropriate interpretations, to the school district board of trustees according to the schedule in the applicable test administration materials.

(b) A school district, charter school, or private school that administers criterion-referenced tests under the TEC, Chapter 39, Subchapter B, shall notify each of its students and his or her parent or guardian of test results, observing confidentiality requirements in the TEC, §39.030.

(c) All test results shall be included in each student's academic record and shall be furnished for each student transferring to another school district, charter school, or private school.

(d) The scoring contractor will provide school districts with the results of the machine-scorable assessments administered as required by the TEC, §28.0211, within a ten-day period following the receipt of the test materials from the school district or charter school.

§101.3015. Test Development.

(a) Texas educators shall assist Texas Education Agency staff in developing test objectives, assessment guidelines, and test items. Advisory committees composed of Texas educators shall reflect the diversity of the state by region, ethnicity, gender, and type and size of school district.

(b) Each public school and charter school shall assist with field-testing and other activities necessary to implement the requirements of the Texas Education Code, Chapter 39, Subchapter B.

§101.3016. National Comparative Data.

(a) In accordance with the Texas Education Code (TEC), §39.028, the commissioner of education shall develop a schedule to obtain nationally comparative results for the grades and subject areas for which academic content area assessments are adopted under the TEC, §39.023.

(b) The Texas Education Agency will use sampling and other techniques to minimize the disruption to schools and loss of instructional time required of school districts to obtain nationally comparative data.

(c) The nationally comparative data will be collected by using nationally recognized instruments for obtaining valid and reliable normative data from a sample of Texas students.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on November 30, 2012.

TRD-201206161

Cristina De La Fuente-Valadez
Director, Rulemaking
Texas Education Agency

Earliest possible date of adoption: January 13, 2013
For further information, please call: (512) 475-1497

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TITLE 22. EXAMINING BOARDS

PART 15. TEXAS STATE BOARD OF PHARMACY

CHAPTER 291. PHARMACIES
SUBCHAPTER B. COMMUNITY PHARMACY
(CLASS A)

22 TAC §291.31

The Texas State Board of Pharmacy proposes amendments to §291.31, concerning Definitions. The amendments, if adopted, add definitions for automated checking device, beyond use date, dispensing error, and patient med-pak which were defined elsewhere in the rules but not in the definitions; clarify the definition of electronic prescription drug order to be consistent with DEA requirements; and update definitions to be consistent with other rules.

Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year period the rule is in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule.

Ms. Dodson has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the rule will be to update and clarify the definitions for Class A pharmacies. There is no fiscal impact for individuals, small or large businesses, or to other entities which are required to comply with this section.

Comments on the proposed amendments may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600, Austin, Texas 78701, FAX (512) 305-8008. Comments must be received by 5:00 p.m., January 31, 2013.

The amendments are proposed under §551.002 and §554.051 of the Texas Pharmacy Act (Chapters 551 - 566 and 568 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 566 and 568 - 569, Texas Occupations Code.

§291.31. Definitions.

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Accurately as prescribed--Dispensing, delivering, and/or distributing a prescription drug order:

(A) - (B) (No change.)

(C) with correct labeling (including directions for use) as ordered by the practitioner. Provided, however, that nothing herein shall prohibit pharmacist substitution if substitution is conducted in strict accordance with applicable laws and rules, including Chapter 562 [Chapters 562 and 563] of the Texas Pharmacy Act.

(2) (No change.)

(3) Advanced practice nurse--A registered nurse approved by the Texas Board of Nursing to practice as an advanced practice nurse on the basis of completion of an advanced education program. The term includes [a] nurse practitioner, [a] nurse midwife, [a] nurse anesthetist, and [a] clinical nurse specialist.

(4) Automated checking device--A device that confirms that the correct drug and strength has been labeled with the correct label for the correct patient prior to delivery of the drug to the patient.

(5) [(4)] Automated compounding or counting device--An automated device that compounds, measures, counts, and/or packages a specified quantity of dosage units of a designated drug product.

(6) [(5)] Automated pharmacy dispensing systems--A [a] mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, dispensing, and distribution of medications, and which collects, controls, and maintains all transaction information. "Automated pharmacy dispensing systems" does not mean "Automated compounding or counting devices" or "Automated medication supply devices."

(7) Beyond use date--The date beyond which a product should not be used.

(8) [(6)] Board--The Texas State Board of Pharmacy.

(9) [(7)] Carrying out or signing a prescription drug order--The completion of a prescription drug order presigned by the delegating physician, or the signing of a prescription by an advanced practice nurse or physician assistant after the person has been designated with the Texas Medical Board by the delegating physician as a person delegated to sign a prescription. As specified in §157.056, of the Occupations Code, the [The] following information must [shall] be provided on each prescription:

(A) patient's name and address;

(B) the drug to be dispensed including the name, strength, and quantity of the drug [to be dispensed];

(C) directions to the patient regarding the taking of the drug and the dosage [for use];

(D) the intended use of the drug, if appropriate;

(E) the name, address, and telephone number of the physician;

(F) the name, address, telephone number, identification number, and if the prescription is for a controlled substance, the DEA number of the advanced practice nurse or physician assistant completing the prescription drug order;

(G) the date; and

(H) the number of refills permitted.

(10) [(8)] Confidential record--Any health-related record that contains information that identifies an individual and that is maintained by a pharmacy or pharmacist, such as a patient medication record, prescription drug order, or medication order.

(11) [(9)] Controlled substance--A drug, immediate precursor, or other substance listed in Schedules I - V or Penalty Groups 1-4 of the Texas Controlled Substances Act, as amended, or a drug, immediate precursor, or other substance included in Schedules I, II, III, IV, or V of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public Law 91-513).

(12) [(10)] Dangerous drug--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) [(11)] Data communication device--An electronic device that receives electronic information from one source and transmits or routes it to another (e.g., bridge, router, switch or gateway).

(14) [(12)] Deliver or delivery--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.

(15) [(13)] Designated agent--

(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;

(C) an advanced practice nurse or physician assistant authorized by a practitioner to carry out or sign a prescription drug order for dangerous drugs under Chapter 157 of the Medical Practice Act (Subtitle B, Occupations Code); or

(D) a person who is a licensed vocational nurse or has an education equivalent to or greater than that required for a licensed vocational nurse designated by the practitioner to communicate prescriptions for an advanced practice nurse or physician assistant authorized by the practitioner to sign prescription drug orders under Chapter 157 of the Medical Practice Act (Subtitle B, Occupations Code).

(16) [(14)] Dispense--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.

(17) Dispensing error--An action committed by a pharmacist or other pharmacy personnel that causes the patient or patient's agent to take possession of a dispensed prescription drug and an individual subsequently discovers that the patient has received an incorrect drug product, which includes incorrect strength, incorrect dosage form, and/or incorrect directions for use.

(18) [(15)] Dispensing pharmacist--The pharmacist responsible for the final check of the dispensed prescription before delivery to the patient.

(19) [(16)] Distribute--The delivery of a prescription drug or device other than by administering or dispensing.

(20) [(17)] Downtime--Period of time during which a data processing system is not operable.

(21) [(18)] Drug regimen review--An evaluation of prescription drug orders and patient medication records for:

- (A) known allergies;
- (B) rational therapy-contraindications;
- (C) reasonable dose and route of administration;
- (D) reasonable directions for use;
- (E) duplication of therapy;
- (F) drug-drug interactions;
- (G) drug-food interactions;
- (H) drug-disease interactions;
- (I) adverse drug reactions; and
- (J) proper utilization, including overutilization or underutilization.

(22) [(19)] Electronic prescription drug order--A prescription drug order that is generated on an electronic application and transmitted as an electronic data file [which is transmitted by an electronic device to the receiver (pharmacy)].

(23) [(20)] Electronic signature--A unique security code or other identifier which specifically identifies the person entering information into a data processing system. A facility which utilizes electronic signatures must:

(A) maintain a permanent list of the unique security codes assigned to persons authorized to use the data processing system; and

(B) have an ongoing security program which is capable of identifying misuse and/or unauthorized use of electronic signatures.

(24) [(21)] Full-time pharmacist--A pharmacist who works in a pharmacy from 30 to 40 hours per week or, if the pharmacy is open less than 60 hours per week, one-half of the time the pharmacy is open.

(25) [(22)] Hard copy--A physical document that is readable without the use of a special device [(i.e., cathode ray tube (CRT), microfiche reader, etc.)].

(26) [(23)] Hot water--The temperature of water from the pharmacy's sink maintained at a minimum of 105 degrees F (41 degrees C).

(27) [(24)] Medical Practice Act--The Texas Medical Practice Act, Subtitle B, Occupations Code, as amended.

(28) [(25)] Medication order--A written order from a practitioner or a verbal order from a practitioner or his authorized agent for administration of a drug or device.

(29) [(26)] New prescription drug order--A prescription drug order that:

- (A) has not been dispensed to the patient in the same strength and dosage form by this pharmacy within the last year;
- (B) is transferred from another pharmacy; and/or
- (C) is a discharge prescription drug order. (Note: furlough prescription drug orders are not considered new prescription drug orders.)

(30) [(27)] Original prescription--The:

- (A) original written prescription drug order; or

(B) original verbal or electronic prescription drug order reduced to writing either manually or electronically by the pharmacist.

(31) [(28)] Part-time pharmacist--A pharmacist who works less than full-time.

(32) Patient med-pak--A package prepared by a pharmacist for a specific patient comprised of a series of containers and containing two or more prescribed solid oral dosage forms. The patient med-pak is so designed or each container is so labeled as to indicate the day and time, or period of time, that the contents within each container are to be taken.

(33) [(29)] Patient counseling--Communication by the pharmacist of information to the patient or patient's agent in order to improve therapy by ensuring proper use of drugs and devices.

(34) [(30)] Pharmaceutical care--The provision of drug therapy and other pharmaceutical services 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.

(35) [(31)] Pharmacist-in-charge--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) [(32)] Pharmacy technician--An individual who is registered with the board as a pharmacy technician and whose responsibility in a pharmacy 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.

(37) [(33)] Pharmacy technician trainee--An individual who is registered with the board as a pharmacy technician trainee and is authorized to participate in a pharmacy's technician training program.

(38) [(34)] Physician assistant--A physician assistant recognized by the Texas Medical Board as having the specialized education and training required under Subtitle B, Chapter 157, Occupations Code, and issued an identification number by the Texas Medical Board.

(39) [(35)] Practitioner--

(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 Act [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 nurse or physician assistant to whom a physician has delegated the authority to carry out or sign prescription drug orders under §§157.0511, 157.052, 157.053, 157.054, 157.0541, or 157.0542, Occupations Code, or, for the purpose of this subchapter, a pharmacist who practices in a hospital, hospital-based clinic, or an academic health care institution and a physician has del-

egated the authority to sign a prescription for a dangerous drug under §157.101, Occupations Code.

(40) [(36)] Prepackaging--The act of repackaging and relabeling quantities of drug products from a manufacturer's original commercial container into a prescription container for dispensing by a pharmacist to the ultimate consumer.

(41) [(37)] Prescription department--The area of a pharmacy that contains prescription drugs.

(42) [(38)] Prescription drug--

(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.

(43) [(39)] Prescription drug order--

(A) a written order from a practitioner or a verbal order from a practitioner or his authorized agent to a pharmacist for a drug or device to be dispensed; or

(B) a written order or a verbal order pursuant to Subtitle B, Chapter 157, Occupations Code.

(44) [(40)] Prospective drug use review--A review of the patient's drug therapy and prescription drug order or medication order prior to dispensing or distributing the drug.

(45) [(41)] State--One of the 50 United States of America, a U.S. territory, or the District of Columbia.

(46) [(42)] Texas Controlled Substances Act--The Texas Controlled Substances Act, Health and Safety Code, Chapter 481, as amended.

(47) [(43)] Written protocol--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 the Texas Medical Practice Act.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on November 30, 2012.

TRD-201206162

Gay Dodson, R.Ph.

Executive Director/Secretary

Texas State Board of Pharmacy

Earliest possible date of adoption: January 13, 2013

For further information, please call: (512) 305-8028



22 TAC §291.32

The Texas State Board of Pharmacy proposes amendments to §291.32, concerning Personnel. The amendments, if adopted, clarify that pharmacists, while on duty, are responsible for the legal operation of the pharmacy; and correct grammar.

Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year period the rule is in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule.

Ms. Dodson has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the rule will be to update and clarify the personnel requirements for Class A pharmacies. There is no fiscal impact for individuals, small or large businesses, or to other entities which are required to comply with this section.

Comments on the proposed amendments may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600, Austin, Texas 78701, FAX (512) 305-8008. Comments must be received by 5:00 p.m., January 31, 2013.

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The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 566 and 568 - 569, Texas Occupations Code.

§291.32. *Personnel.*

(a) Pharmacist-in-charge.

(1) (No change.)

(2) Responsibilities. The pharmacist-in-charge shall have responsibility for the practice of pharmacy at the pharmacy for which he or she is the pharmacist-in-charge. The pharmacist-in-charge may advise the owner on administrative or operational concerns. The pharmacist-in-charge shall have responsibility for, at a minimum, the following:

(A) educating [education] and training of pharmacy technicians and pharmacy technician trainees;

(B) (No change.)

(C) disposing of and distributing [disposal and distribution of] drugs from the Class A pharmacy;

(D) storing [storage of] all materials, including drugs, chemicals, and biologicals;

(E) - (F) (No change.)

(G) adhering [adherence] to policies and procedures regarding the maintenance of records in a data processing system such that the data processing system is in compliance with Class A (community) pharmacy requirements;

(H) legally operating [legal operation of] the pharmacy, including meeting all inspection and other requirements of all state and federal laws or sections governing the practice of pharmacy; and

(I) (No change.)