

## RULE ANALYSIS

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

**Short Title:** Personnel

**Rule Numbers:** §291.32

**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 verifying controlled substances listed on invoices are received by initial and date of receipt to the pharmacist's duties; and correct grammar.

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

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.

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.

### §291.32. 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.)

(b) Owner. The owner of a Class A pharmacy shall have responsibility for all administrative and operational functions of the pharmacy. The pharmacist-in-charge may advise the owner on administrative and operational concerns. The owner shall have responsibility for, at a minimum, the following, and if the owner is not a Texas licensed pharmacist, the owner shall consult with the pharmacist-in-charge or another Texas licensed pharmacist:

(1) (No change.)

(2) establishment of policies [policies] and procedures for the security of the prescription department including the maintenance of effective controls against the theft or diversion of prescription drugs;

(3) - (5) (No change.)

(c) Pharmacists.

(1) General.

(A) - (D) (No change.)

(E) All pharmacists, while on duty, shall be responsible for the legal operation of the pharmacy and for complying with all state and federal laws or rules governing the practice of pharmacy.

(F) (No change.)

(2) Duties. Duties which may only be performed by a pharmacist are as follows:

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

(C) selecting [selection of] drug products;

(D) - (J) (No change.)

(3) (No change.)

(d) Pharmacy Technicians and Pharmacy Technician Trainees.

(1) (No change.)

(2) Duties.

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

(C) Pharmacy technicians and pharmacy technician trainees may perform only nonjudgmental technical duties associated with the preparation and distribution of prescription drugs, as follows:

(i) - (ix) (No change.)

(x) compounding bulk preparations [bulk compounding].

(3) (No change.)

(e) (No change.)

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.

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Gay Dodson, R.Ph.

Executive Director/Secretary

Texas State Board of Pharmacy

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## CHAPTER 295. PHARMACISTS

### 22 TAC §295.8

The Texas State Board of Pharmacy proposes amendments to §295.8, concerning Continuing Education Requirements. The amendments, if adopted, update the definitions to include CPE Monitor and to be consistent with ACPE definitions; remove references to requirements regarding pharmacists licensed for 50 years that are not needed; allow pharmacist to receive credit for CME courses; and require pharmacists to obtain at least one hour of CE in Texas pharmacy law.

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 definitions and CE requirements for pharmacists. 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.

§295.8. *Continuing Education Requirements.*

(a) Authority and purpose.

(1) Authority. In accordance with §559.053 [§559.003] of the Texas Pharmacy Act, (Chapters 551 - 566, and 568 - 569, Occupations Code), all pharmacists must complete and report 30 contact hours (3.0 CEUs) of approved continuing education obtained during the previous license period in order to renew their license to practice pharmacy.

(2) (No change.)

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) - (3) (No change.)

(4) Approved provider--An individual, institution, organization, association, corporation, or agency that is approved by the board [and recognized by ACPE in accordance with its policy and procedures, as having met criteria indicative of the ability to provide quality continuing education programs].

(5) (No change.)

(6) Certificate of completion--A certificate or other official document presented to a participant upon the successful completion of an approved [a] continuing education program. [Certificates presented