

## **SUBCHAPTER B. COMMUNITY PHARMACY (CLASS A)**

### **22 TAC §291.33, §291.34**

The Texas State Board of Pharmacy proposes amendments to §291.33, concerning Operational Standards, and §291.34, concerning Records. The amendments, if adopted, allow for the secure storage, management, and purchase/delivery of prescription medications during and after pharmacy hours from an automated storage and distribution device, and clarify that an original prescription may only be dispensed if the prescription is authorized by the prescriber.

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 ensure the safe use of automated storage and distribution devices and prescriptions are dispensed as authorized. 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) 305-8082. Comments must be received by 5 p.m., May 1, 2009.

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 this rule: Texas Pharmacy Act, Chapters 551 - 566 and 568 - 569, Texas Occupations Code.

#### *§291.33. Operational Standards.*

(a) (No change.)

(b) Environment.

(1) (No change.)

(2) Security.

(A) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of prescription drugs, and records for such drugs.

(B) The prescription department shall be locked by key, combination or other mechanical or electronic means to prohibit unauthorized access when a pharmacist is not on-site except as provided in subparagraphs (C) and (D) of this paragraph and paragraph (3) of this subsection. The following is applicable:

(i) If the prescription department is closed at any time when the rest of the facility is open, the prescription department must be physically or electronically secured. The security may be accomplished by means such as floor to ceiling walls; walls, partitions, or barriers at least 9 feet 6 inches high; electronically monitored motion detectors; pull down sliders; or other systems or technologies that will secure the pharmacy from unauthorized entrance when the pharmacy is closed. Pharmacies licensed prior to June 1, 2009, shall be exempt from this provision unless the pharmacy changes location. Change of location shall include the relocation of the pharmacy within the licensed address. A pharmacy licensed prior to June 1, 2009 that files a change of ownership but does not change location shall be exempt from the provisions.

(ii) Effective, June 1, 2009, the pharmacy's key, combination, or other mechanical or electronic means of locking the pharmacy may not be duplicated without the authorization of the pharmacist-in-charge or owner.

(iii) Effective, June 1, 2009, at a minimum, the pharmacy must have a basic alarm system with off-site monitoring and perimeter and motion sensors. The pharmacy may have additional security by video surveillance camera systems.

(C) Prior to authorizing individuals to enter the prescription department, the pharmacist-in-charge or owner may designate persons who may enter the prescription department to perform functions, other than dispensing functions or prescription processing, documented by the pharmacist-in-charge including access to the prescription department by other pharmacists, pharmacy personnel and other individuals. The pharmacy must maintain written documentation of authorized individuals other than individuals employed by the pharmacy who accessed the prescription department when a pharmacist is not on-site.

(D) Only persons designated either by name or by title including such titles as "relief" or "floater" pharmacist, in writing by the pharmacist-in-charge may unlock the prescription department except in emergency situations. An additional key to or instructions on accessing the prescription department may be maintained in a secure location outside the prescription department for use during an emergency or as designated by the pharmacist-in-charge for entry by another pharmacist.

(E) Written policies and procedures for the pharmacy's security shall be developed and implemented by the pharmacist-in-charge and/or the owner of the pharmacy. Such policies and procedures may include quarterly audits of controlled substances commonly abused or diverted; perpetual inventories for the comparison of the receipt, dispensing, and distribution of controlled substances; monthly reports from the pharmacy's wholesaler(s) of controlled substances purchased by the pharmacy; opening and closing procedures; product storage and placement; and central management oversight.

(3) Temporary absence of pharmacist.

(A) (No change.)

(B) Pharmacist is off-site.

(i) The prescription department must be secured with procedures for entry during the time that a pharmacy is not under the continuous on-site supervision of a pharmacist and the pharmacy is not open for pharmacy services.

(ii) Pharmacy technicians and pharmacy technician trainees may not perform any duties of a pharmacy technician or pharmacy technician trainee during the time that the [a] pharmacist is off-site.

(iii) A pharmacy may use an automated storage and distribution device as specified in subsection (i) of this section for pick-up of a previously verified prescription by a patient or patient's agent, provided the following conditions are met:

(I) a notice is posted which includes the following information:

(-a-) the pharmacist is off-site and not present in the pharmacy;

(-b-) no new prescriptions may be prepared at the pharmacy but previously verified prescriptions may be delivered to the patient or the patient's agent; and

(-c-) the date/time when the pharmacist will return.

(II) the pharmacy must maintain documentation of the absences of the pharmacist(s); and

(III) the prescription department is locked and secured to prohibit unauthorized entry.

(iv) [(iii)] An agent of the pharmacist may deliver a previously verified prescription to a patient or patient's agent during short periods of time when a pharmacist is off-site, provided the following conditions are met:

(I) short periods of time may not exceed two consecutive hours in a 24 hour period;

(II) a notice is posted which includes the following information:

(-a-) the pharmacist is off-site and not present in the pharmacy;

(-b-) no new prescriptions may be prepared at the pharmacy but previously verified prescriptions may be delivered to the patient or the patient's agent; and

(-c-) the date/time when the pharmacist will return.

(III) the pharmacy must maintain documentation of the absences of the pharmacist(s); and

(IV) the prescription department is locked and secured to prohibit unauthorized entry.

(v) [~~(iv)~~] During the time a pharmacist is absent from the prescription department and is off-site, a record of prescriptions delivered must be maintained and contain the following information:

(I) date and time of the delivery;

(II) unique identification number of the prescription drug order;

(III) patient's name;

(IV) patient's phone number or the phone number of the person picking up the prescription;  
and

(V) signature of the person picking up the prescription.

(vi) [~~(v)~~] Any prescription delivered to a patient when a pharmacist is not on-site at the pharmacy must meet the requirements for a prescription delivered to a patient as described in subsection (c)(1)(F) of this section.

(c) - (h) (No change.)

(i) Automated devices and systems.

(1) - (4) (No change.)

(5) Automated storage and distribution device. A pharmacy may use an automated storage and distribution device to deliver a previously verified prescription to a patient or patient's agent provided:

(A) the device is used to deliver refills of prescription drug orders and shall not be used to deliver new prescriptions as defined by §291.31(26) of the title (Relating to Definitions);

(B) the automated storage and distribution device may not be used to deliver a controlled substance;

(C) drugs stored in the automated storage and distribution device are stored at proper temperatures;

(D) the patient or patient's agent is given the option to use the system;

(E) the patient or patient's agent has access to a pharmacist for questions regarding the prescription either at the pharmacy where the automated storage and distribution device is located or by a telephone available at the pharmacy that connects directly to another pharmacy;

(F) the pharmacist-in-charge is responsible for the supervision of the operation of the system;

(G) the automated storage and distribution device has been tested by the pharmacy and found to dispense prescriptions accurately. The pharmacy shall make the results of such testing available to the board upon request;

(H) the automated storage and distribution device may be loaded with previously verified prescriptions only by a pharmacist or by pharmacy technicians under the direction and direct supervision of a pharmacist;

(I) the pharmacy will make the automated storage and distribution device available for inspection by the board;

(J) the automated storage and distribution device is located within the pharmacy building whereby pharmacy staff has access to the device from within the prescription department and patients have access to the device from outside the prescription department. The device may not be located on an outside wall of the pharmacy and may not be accessible from a drive-thru;

(K) the automated storage and distribution device is secure from access and removal of prescription drug orders by unauthorized individuals;

(L) the automated storage and distribution device has adequate security system to prevent unauthorized access and to maintain patient confidentiality; and

(M) the automated storage and distribution device records a digital image of the individual accessing the device to pick-up a prescription and such record is maintained by the pharmacy for two years.

*§291.34.Records.*

(a) (No change.)

(b) Prescriptions.

(1) - (4) (No change.)

(5) Original prescription drug order records.

(A) Original prescriptions may be dispensed only in accordance with the prescriber's authorization as indicated on the original prescription drug order.

(B) [~~A~~] Original prescriptions shall be maintained by the pharmacy in numerical order and remain legible for a period of two years from the date of filling or the date of the last refill dispensed.

(C) [~~B~~] If an original prescription drug order is changed, such prescription order shall be invalid and of no further force and effect; if additional drugs are to be dispensed, a new prescription drug order with a new and separate number is required.

(D) [~~C~~] Original prescriptions shall be maintained in three separate files as follows:

- (i) prescriptions for controlled substances listed in Schedule II;
- (ii) prescriptions for controlled substances listed in Schedules III - V; and
- (iii) prescriptions for dangerous drugs and nonprescription drugs.

(E) [~~(D)~~] Original prescription records other than prescriptions for Schedule II controlled substances may be stored on microfilm, microfiche, or other system which is capable of producing a direct image of the original prescription record, e.g., digitalized imaging system. If original prescription records are stored in a direct imaging system, the following is applicable:

- (i) the record of refills recorded on the original prescription must also be stored in this system;
- (ii) the original prescription records must be maintained in numerical order and separated in three files as specified in subparagraph (D) [~~(C)~~] of this paragraph; and
- (iii) the pharmacy must provide immediate access to equipment necessary to render the records easily readable.

(6) - (7) (No change.)

(c) - (j) (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 March 16, 2009.

TRD-200901091

Gay Dodson, R.Ph.

Executive Director/Secretary

Texas State Board of Pharmacy

Earliest possible date of adoption: April 26, 2009

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