RULE ANALYSIS

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

Short Title: Operational Standards.

Rule Number: §291.33

Statutory Authority: Texas Pharmacy Act, Chapter 551-569, 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, specify prepackaging and labeling requirements for a participating provider to dispense donated prescription drugs under Chapter 442, Health and Safety Code, in accordance with House Bill 4332.

The Board reviewed and voted to propose the amendments during the August 1, 2023, meeting. The proposed amendments were published in the September 22, 2023, issue of the *Texas Register* (48 TexReg 5392).

TITLE 22. EXAMINING BOARDS
PART 15. TEXAS STATE BOARD OF PHARMACY
CHAPTER 291. PHARMACIES
SUBCHAPTER B. COMMUNITY PHARMACY (CLASS A)

§291.33. Operational Standards.

The Texas State Board of Pharmacy proposes amendments to §291.33, concerning Operational Standards. The amendments, if adopted, specify prepackaging and labeling requirements for a participating provider to dispense donated prescription drugs under Chapter 442, Health and Safety Code, in accordance with House Bill 4332.

Daniel Carroll, Pharm.D., Executive Director/Secretary, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule. Dr. Carroll 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 amendments will be to provide consistency between state law and Board rules. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

For each year of the first five years the proposed amendments will be in effect, Dr. Carroll has determined the following:

(1) The proposed amendments do not create or eliminate a government program;

(2) Implementation of the proposed amendments does not require the creation of new employee positions or the elimination of existing employee positions;

(3) Implementation of the proposed amendments does not require an increase or decrease in the future legislative appropriations to the agency;

(4) The proposed amendments do not require an increase or decrease in fees paid to the agency;

(5) The proposed amendments do not create a new regulation;

(6) The proposed amendments do limit an existing regulation in order to be consistent with state law;

(7) The proposed amendments do not increase or decrease the number of individuals subject to the rule's applicability; and

(8) The proposed amendments do not positively or adversely affect this state's economy.

Written comments on the amendments may be submitted to Eamon D. Briggs, Deputy General Counsel, Texas State Board of Pharmacy, 1801 Congress Avenue, Suite 13.100, Austin, Texas 78701-1319, FAX (512) 305-8061. Comments must be received by 5:00 p.m., October 30, 2023.

The amendments are proposed under §§551.002 and 554.051 of the Texas Pharmacy Act (Chapters 551 - 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 - 569, Texas Occupations Code.

§291.33.Operational Standards.

(a) Licensing requirements.

(1) A Class A pharmacy shall register annually or biennially with the board on a pharmacy license application provided by the board, following the procedures as specified in §291.1 of this title (relating to Pharmacy License Application).

(2) A Class A pharmacy which changes ownership shall notify the board within ten days of the change of ownership and apply for a new and separate license as specified in §291.3 of this title (relating to Required Notifications).

(3) A Class A pharmacy which changes location and/or name shall notify the board as specified in §291.3 of this title.

(4) A Class A pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within ten days of the change, following the procedures as specified in §291.3 of this title.

(5) A Class A pharmacy shall notify the board in writing within ten days of closing, following the procedures as specified in §291.5 of this title (relating to Closing a Pharmacy).

(6) A separate license is required for each principal place of business and only one pharmacy license may be issued to a specific location.

(7) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for the issuance and renewal of a license and the issuance of an amended license.

(8) A Class A pharmacy, licensed under the provisions of the Act, §560.051(a)(1), which also operates another type of pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(2) concerning Nuclear Pharmacy (Class B), is not required to secure a license for such other type of pharmacy; provided, however, such licensee is required to comply with the provisions of Subchapter C of this chapter (relating to Nuclear Pharmacy (Class B)), to the extent such sections are applicable to the operation of the pharmacy.

(9) A Class A pharmacy engaged in the compounding of non-sterile preparations shall comply with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

(10) A Class A pharmacy shall not compound sterile preparations.

(11) A Class A pharmacy engaged in the provision of remote pharmacy services, including storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of this title (relating to Remote Pharmacy Services).

(12) Class A pharmacy engaged in centralized prescription dispensing and/or prescription drug or medication order processing shall comply with the provisions of §291.123 of this title (relating to Central Prescription Drug or Medication Order Processing) and/or §291.125 of this title (relating to Centralized Prescription Dispensing).

(b) Environment.

(1) General requirements.

(A) The pharmacy shall be arranged in an orderly fashion and kept clean. All required equipment shall be clean and in good operating condition.

(B) A Class A pharmacy shall have a sink with hot and cold running water within the pharmacy, exclusive of restroom facilities, available to all pharmacy personnel and maintained in a sanitary condition.

(C) A Class A pharmacy which serves the general public shall contain an area which is suitable for confidential patient counseling.

(i) Such counseling area shall be:

(I) easily accessible to both patient and pharmacists and not allow patient access to prescription drugs; and

(II) designed to maintain the confidentiality and privacy of the pharmacist/patient communication.

(ii) In determining whether the area is suitable for confidential patient counseling and designed to maintain the confidentiality and privacy of the pharmacist/patient communication, the board may consider factors such as the following:

(I) the proximity of the counseling area to the check-out or cash register area;

(II) the volume of pedestrian traffic in and around the counseling area;

(III) the presence of walls or other barriers between the counseling area and other areas of the pharmacy; and

(IV) any evidence of confidential information being overheard by persons other than the patient or patient's agent or the pharmacist or agents of the pharmacist.

(D) The pharmacy shall be properly lighted and ventilated.

(E) The temperature of the pharmacy shall be maintained within a range compatible with the proper storage of drugs. The temperature of the refrigerator shall be maintained within a range compatible with the proper storage of drugs requiring refrigeration.

(F) Animals, including birds and reptiles, shall not be kept within the pharmacy and in immediately adjacent areas under the control of the pharmacy. This provision does not apply to fish in aquariums, service animals accompanying disabled persons, or animals for sale to the general public in a separate area that is inspected by local health jurisdictions.

(G) If the pharmacy has flammable materials, the pharmacy shall have a designated area for the storage of flammable materials. Such area shall meet the requirements set by local and state fire laws.

(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) 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) 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.

(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) On-site supervision by pharmacist.

(i) If a pharmacy is staffed by only one pharmacist, the pharmacist may leave the prescription department for short periods of time without closing the prescription department and removing pharmacy technicians, pharmacy technician trainees, and other pharmacy personnel from the prescription department provided the following conditions are met:

(I) at least one pharmacy technician remains in the prescription department;

(II) the pharmacist remains on-site at the licensed location of the pharmacy and is immediately available;

(III) the pharmacist reasonably believes that the security of the prescription department will be maintained in his or her absence. If in the professional judgment of the pharmacist, the pharmacist determines that the prescription department should close during his or her absence, then the pharmacist shall close the prescription department and remove the pharmacy technicians, pharmacy technician trainees, and other pharmacy personnel from the prescription department during his or her absence; and

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

(-a-) the pharmacist is on a break and the time the pharmacist will return; and

(-b-) pharmacy technicians may begin the processing of prescription drug orders or refills brought in during the pharmacist's absence, but the prescription or refill may not be delivered to the patient or the patient's agent until the pharmacist verifies the accuracy of the prescription.

(ii) During the time a pharmacist is absent from the prescription department, only pharmacy technicians who have completed the pharmacy's training program may perform the following duties, provided a pharmacist verifies the accuracy of all acts, tasks, and functions performed by the pharmacy technicians prior to delivery of the prescription to the patient or the patient's agent:

(I) initiating and receiving refill authorization requests;

(II) entering prescription data into a data processing system;

(III) taking a stock bottle from the shelf for a prescription;

(IV) preparing and packaging prescription drug orders (e.g., counting tablets/capsules, measuring liquids, or placing them in the prescription container);

(V) affixing prescription labels and auxiliary labels to the prescription container;

(VI) prepackaging and labeling prepackaged drugs;

(VII) receiving oral prescription drug orders for dangerous drugs and reducing these orders to writing, either manually or electronically;

(VIII) transferring or receiving a transfer of original prescription information for dangerous drugs on behalf of a patient; and

(IX) contacting a prescriber for information regarding an existing prescription for a dangerous drug.

(iii) Upon return to the prescription department, the pharmacist shall:

(I) conduct a drug regimen review as specified in subsection (c)(2) of this section; and

(II) verify the accuracy of all acts, tasks, and functions performed by the pharmacy technicians prior to delivery of the prescription to the patient or the patient's agent.

(iv) An agent of the pharmacist may deliver a previously verified prescription to the patient or his or her agent provided a record of the delivery is maintained containing the following information:

(I) date 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.

(v) Any prescription delivered to a patient when a pharmacist is not in the prescription department must meet the requirements for a prescription delivered to a patient as described in subsection (c)(1)(F) of this section.

(vi) During the times a pharmacist is absent from the prescription department a pharmacist intern shall be considered a registered pharmacy technician and may perform only the duties of a registered pharmacy technician.

(vii) In pharmacies with two or more pharmacists on duty, the pharmacists shall stagger their breaks and meal periods so that the prescription department is not left without a pharmacist on duty.

(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 pharmacist is off-site.

(iii) A pharmacy may use an automated dispensing and delivery system as specified in §291.121(d) of this title for pick-up of a previously verified prescription by a patient or patient's agent.

(iv) 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) 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) 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) Prescription dispensing and delivery.

(1) Patient counseling and provision of drug information.

(A) To optimize drug therapy, a pharmacist shall communicate to the patient or the patient's agent information about the prescription drug or device which in the exercise of the pharmacist's professional judgment the pharmacist deems significant, such as the following:

(i) name and description of the drug or device;

(ii) dosage form, dosage, route of administration, and duration of drug therapy;

(iii) special directions and precautions for preparation, administration, and use by the patient;

(iv) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(v) techniques for self-monitoring of drug therapy;

(vi) proper storage;

(vii) refill information; and

(viii) action to be taken in the event of a missed dose.

(B) Such communication shall be:

(i) provided to new and existing patients of a pharmacy with each new prescription drug order. A new prescription drug order is one that has not been dispensed by the pharmacy to the patient in the same dosage and strength within the last year;

(ii) provided for any prescription drug order dispensed by the pharmacy on the request of the patient or patient's agent;

(iii) communicated orally unless the patient or patient's agent is not at the pharmacy or a specific communication barrier prohibits such oral communication;

(iv) documented by recording the initials or identification code of the pharmacist providing the counseling in the prescription dispensing record as follows:

(I) on the original hard-copy prescription, provided the counseling pharmacist clearly records his or her initials on the prescription for the purpose of identifying who provided the counseling;

(II) in the pharmacy's data processing system;

(III) in an electronic logbook; or

(IV) in a hard-copy log; and

(v) reinforced with written information relevant to the prescription and provided to the patient or patient's agent. The following is applicable concerning this written information:

(I) Written information must be in plain language designed for the patient and printed in an easily readable font size comparable to but no smaller than ten-point Times Roman. This information may be provided to the patient in an electronic format, such as by e-mail, if the patient or patient's agent requests the information in an electronic format and the pharmacy documents the request.

(II) When a compounded preparation is dispensed, information shall be provided for the major active ingredient(s), if available.

(III) For new drug entities, if no written information is initially available, the pharmacist is not required to provide information until such information is available, provided:

(-a-) the pharmacist informs the patient or the patient's agent that the product is a new drug entity and written information is not available;

(-b-) the pharmacist documents the fact that no written information was provided; and

(-c-) if the prescription is refilled after written information is available, such information is provided to the patient or patient's agent.

(IV) The written information accompanying the prescription or the prescription label shall contain the statement "Do not flush unused medications or pour down a sink or drain." A drug product on a list developed by the Federal Food and Drug Administration of medicines recommended for disposal by flushing is not required to bear this statement.

(C) Only a pharmacist may verbally provide drug information to a patient or patient's agent and answer questions concerning prescription drugs. Non-pharmacist personnel and/or the pharmacy's computer system may not ask questions of a patient or patient's agent which are intended to screen and/or limit interaction with the pharmacist.

(D) Nothing in this subparagraph shall be construed as requiring a pharmacist to provide consultation when a patient or patient's agent refuses such consultation. The pharmacist shall document such refusal for consultation.

(E) In addition to the requirements of subparagraphs (A) - (D) of this paragraph, if a prescription drug order is delivered to the patient at the pharmacy, the following is applicable:

(i) So that a patient will have access to information concerning his or her prescription, a prescription may not be delivered to a patient unless a pharmacist is in the pharmacy, except as provided in subsection (b)(3) of this section.

(ii) Any prescription delivered to a patient when a pharmacist is not in the pharmacy must meet the requirements described in subparagraph (F) of this paragraph.

(F) In addition to the requirements of subparagraphs (A) - (D) of this paragraph, if a prescription drug order is delivered to the patient or his or her agent at the patient's residence or other designated location, the following is applicable:

(i) The information as specified in subparagraph (A) of this paragraph shall be delivered with the dispensed prescription in writing.

(ii) If prescriptions are routinely delivered outside the area covered by the pharmacy's local telephone service, the pharmacy shall provide a toll-free telephone line which is answered during normal business hours to enable communication between the patient and a pharmacist.

(iii) The pharmacist shall place on the prescription container or on a separate sheet delivered with the prescription container in both English and Spanish the local and, if applicable, toll-free telephone number of the pharmacy and the statement: "Written information about this prescription has been provided for you. Please read this information before you take the medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions at (insert the pharmacy's local and toll-free telephone numbers)."

(iv) The pharmacy shall maintain and use adequate storage or shipment containers and use shipping processes to ensure drug stability and potency. Such shipping processes shall include the use of appropriate packaging material and/or devices to ensure that the drug is maintained at an appropriate temperature range to maintain the integrity of the medication throughout the delivery process.

(v) The pharmacy shall use a delivery system which is designed to ensure that the drugs are delivered to the appropriate patient.

(G) The provisions of this paragraph do not apply to patients in facilities where drugs are administered to patients by a person required to do so by the laws of the state (i.e., nursing homes).

(2) Pharmaceutical care services.

(A) Drug regimen review.

(i) For the purpose of promoting therapeutic appropriateness, a pharmacist shall, prior to or at the time of dispensing a prescription drug order, review the patient's medication record. Such review shall at a minimum identify clinically significant:

(I) known allergies;

(II) rational therapy-contraindications;

(III) reasonable dose and route of administration;

(IV) reasonable directions for use;

(V) duplication of therapy;

(VI) drug-drug interactions;

(VII) drug-food interactions;

(VIII) drug-disease interactions;

(IX) adverse drug reactions; and

(X) proper utilization, including overutilization or underutilization.

(ii) Upon identifying any clinically significant conditions, situations, or items listed in clause (i) of this subparagraph, the pharmacist shall take appropriate steps to avoid or resolve the problem including consultation with the prescribing practitioner. The pharmacist shall document such occurrences as specified in subparagraph (C) of this paragraph.

(iii) The drug regimen review may be conducted by remotely accessing the pharmacy's electronic database from outside the pharmacy by:

(I) an individual Texas licensed pharmacist employee of the pharmacy provided the pharmacy establishes controls to protect the privacy of the patient and the security of confidential records; or

(II) a pharmacist employed by a Class E pharmacy provided the pharmacies have entered into a written contract or agreement which outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations.

(iv) Prior to dispensing, any questions regarding a prescription drug order must be resolved with the prescriber and written documentation of these discussions made and maintained as specified in subparagraph (C) of this paragraph.

(B) Other pharmaceutical care services which may be provided by pharmacists include, but are not limited to, the following:

(i) managing drug therapy as delegated by a practitioner as allowed under the provisions of the Medical Practice Act;

(ii) administering immunizations and vaccinations under written protocol of a physician;

(iii) managing patient compliance programs;

(iv) providing preventative health care services; and

(v) providing case management of patients who are being treated with high-risk or high-cost drugs, or who are considered "high risk" due to their age, medical condition, family history, or related concern.

(C) Documentation of consultation. When a pharmacist consults a prescriber as described in subparagraph (A) of this paragraph, the pharmacist shall document on the prescription or in the pharmacy's data processing system associated with the prescription such occurrences and shall include the following information:

(i) date the prescriber was consulted;

(ii) name of the person communicating the prescriber's instructions;

(iii) any applicable information pertaining to the consultation; and

(iv) initials or identification code of the pharmacist performing the consultation clearly recorded for the purpose of identifying the pharmacist who performed the consultation.

(3) Substitution of generically equivalent drugs or interchangeable biological products. A pharmacist may dispense a generically equivalent drug or interchangeable biological product and shall comply with the provisions of §309.3 of this title (relating to Substitution Requirements).

(4) Substitution of dosage form.

(A) As specified in §562.012 of the Act, a pharmacist may dispense a dosage form of a drug product different from that prescribed, such as a tablet instead of a capsule or liquid instead of tablets, provided:

(i) the patient consents to the dosage form substitution; and

(ii) the dosage form so dispensed:

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

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

(III) does not alter desired clinical outcomes.

(B) Substitution of dosage form may not include the substitution of a product that has been compounded by the pharmacist unless the pharmacist contacts the practitioner prior to dispensing and obtains permission to dispense the compounded product.

(5) Therapeutic Drug Interchange. A switch to a drug providing a similar therapeutic response to the one prescribed shall not be made without prior approval of the prescribing practitioner. This paragraph does not apply to generic substitution. For generic substitution, see the requirements of paragraph (3) of this subsection.

(A) The patient shall be notified of the therapeutic drug interchange prior to, or upon delivery of, the dispensed prescription to the patient. Such notification shall include:

(i) a description of the change;

(ii) the reason for the change;

(iii) whom to notify with questions concerning the change; and

(iv) instructions for return of the drug if not wanted by the patient.

(B) The pharmacy shall maintain documentation of patient notification of therapeutic drug interchange which shall include:

(i) the date of the notification;

(ii) the method of notification;

(iii) a description of the change; and

(iv) the reason for the change.

(C) The provisions of this paragraph do not apply to prescriptions for patients in facilities where drugs are administered to patients by a person required to do so by the laws of this state if the practitioner issuing the prescription has agreed to use of a formulary that includes a listing of therapeutic interchanges that the practitioner has agreed to allow. The pharmacy must maintain a copy of the formulary including a list of the practitioners that have agreed to the formulary and the signatures of these practitioners.

(6) Prescription containers.

(A) A drug dispensed pursuant to a prescription drug order shall be dispensed in a child-resistant container unless:

(i) the patient or the practitioner requests the prescription not be dispensed in a child-resistant container; or

(ii) the product is exempted from requirements of the Poison Prevention Packaging Act of 1970.

(B) A drug dispensed pursuant to a prescription drug order shall be dispensed in an appropriate container as specified on the manufacturer's container.

(C) Prescription containers or closures shall not be re-used. However, if a patient or patient's agent has difficulty reading or understanding a prescription label, a prescription container may be reused provided:

(i) the container is designed to provide audio-recorded information about the proper use of the prescription medication;

(ii) the container is reused for the same patient;

(iii) the container is cleaned; and

(iv) a new safety closure is used each time the prescription container is reused.

(7) Labeling.

(A) At the time of delivery of the drug, the dispensing container shall bear a label in plain language and printed in an easily readable font size, unless otherwise specified, with at least the following information:

(i) name, address and phone number of the pharmacy;

(ii) unique identification number of the prescription that is printed in an easily readable font size comparable to but no smaller than ten-point Times Roman;

(iii) date the prescription is dispensed;

(iv) initials or an identification code of the dispensing pharmacist;

(v) name of the prescribing practitioner;

(vi) if the prescription was signed by a pharmacist, the name of the pharmacist who signed the prescription for a dangerous drug under delegated authority of a physician as specified in Subtitle B, Chapter 157, Occupations Code;

(vii) name of the patient or if such drug was prescribed for an animal, the species of the animal and the name of the owner that is printed in an easily readable font size comparable to but no smaller than ten-point Times Roman. The name of the patient's partner or family member is not required to be on the label of a drug prescribed for a partner for a sexually transmitted disease or for a patient's family members if the patient has an illness determined by the Centers for Disease Control and Prevention, the World Health Organization, or the Governor's office to be pandemic;

(viii) instructions for use that are printed in an easily readable font size comparable to but no smaller than ten-point Times Roman;

(ix) quantity dispensed;

(x) appropriate ancillary instructions such as storage instructions or cautionary statements such as warnings of potential harmful effects of combining the drug product with any product containing alcohol;

(xi) if the prescription is for a Schedule II - IV controlled substance, the statement "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed";

(xii) if the pharmacist has selected a generically equivalent drug or interchangeable biological product pursuant to the provisions of the Act, Chapter 562, the statement "Substituted for Brand Prescribed" or "Substituted for 'Brand Name'" where "Brand Name" is the actual name of the brand name product prescribed;

(xiii) the name and strength of the actual drug or biological product dispensed that is printed in an easily readable size comparable to but no smaller than ten-point Times Roman, unless otherwise directed by the prescribing practitioner;

(I) The name shall be either:

(-a-) the brand name; or

(-b-) if no brand name, then the generic drug or interchangeable biological product name and name of the manufacturer or distributor of such generic drug or interchangeable biological product. (The name of the manufacturer or distributor may be reduced to an abbreviation or initials, provided the abbreviation or initials are sufficient to identify the manufacturer or distributor. For combination drug products or non-sterile compounded drug preparations having no brand name, the principal active ingredients shall be indicated on the label).

(II) Except as provided in clause (xii) of this subparagraph, the brand name of the prescribed drug or biological product shall not appear on the prescription container label unless it is the drug product actually dispensed.

(xiv) if the drug is dispensed in a container other than the manufacturer's original container, the date after which the prescription should not be used or beyond-use-date. Unless otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date the drug is dispensed or the manufacturer's expiration date, whichever is earlier. The beyond-use-date may be placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is not required on the label of a prescription dispensed to a person at the time of release from prison or jail if the prescription is for not more than a 10-day supply of medication; and

(xv) either on the prescription label or the written information accompanying the prescription, the statement "Do not flush unused medications or pour down a sink or drain." A drug product on a list developed by the Federal Food and Drug Administration of medicines recommended for disposal by flushing is not required to bear this statement.

(B) If the prescription label required in subparagraph (A) of this paragraph is printed in a type size smaller than ten-point Times Roman, the pharmacy shall provide the patient written information containing the information as specified in subparagraph (A) of this paragraph in an easily readable font size comparable to but no smaller than ten-point Times Roman.

(C) The label is not required to include the initials or identification code of the dispensing pharmacist as specified in subparagraph (A) of this paragraph if the identity of the dispensing pharmacist is recorded in the pharmacy's data processing system. The record of the identity of the dispensing pharmacist shall not be altered in the pharmacy's data processing system.

(D) The dispensing container is not required to bear the label as specified in subparagraph (A) of this paragraph if:

(i) the drug is prescribed for administration to an ultimate user who is institutionalized in a licensed health care institution (e.g., nursing home, hospice, hospital);

(ii) no more than a 90-day supply is dispensed at one time;

(iii) the drug is not in the possession of the ultimate user prior to administration;

(iv) the pharmacist-in-charge has determined that the institution:

(I) maintains medication administration records which include adequate directions for use for the drug(s) prescribed;

(II) maintains records of ordering, receipt, and administration of the drug(s); and

(III) provides for appropriate safeguards for the control and storage of the drug(s); and

(v) the dispensing container bears a label that adequately:

(I) identifies the:

(-a-) pharmacy by name and address;

(-b-) unique identification number of the prescription;

(-c-) name and strength of the drug dispensed;

(-d-) name of the patient; and

(-e-) name of the prescribing practitioner or, if applicable, the name of the pharmacist who signed the prescription drug order;

(II) if the drug is dispensed in a container other than the manufacturer's original container, specifies the date after which the prescription should not be used or beyond-use-date. Unless otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date the drug is dispensed or the manufacturer's expiration date, whichever is earlier. The beyond-use-date may be placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is not required on the label of a prescription dispensed to a person at the time of release from prison or jail if the prescription is for not more than a 10-day supply of medication; and

(III) sets forth the directions for use and cautionary statements, if any, contained on the prescription drug order or required by law.

(8) Returning Undelivered Medication to Stock.

(A) A pharmacist may not accept an unused prescription or drug, in whole or in part, for the purpose of resale or re-dispensing to any person after the prescription or drug has been originally dispensed or sold, except as provided in §291.8 of this title (relating to Return of Prescription Drugs) or Subchapter M, Chapter 431, Health and Safety Code, or Chapter 442,

Health and Safety Code. Prescriptions that have not been picked up by or delivered to the patient or patient's agent may be returned to the pharmacy's stock for dispensing.

(B) A pharmacist shall evaluate the quality and safety of the prescriptions to be returned to stock.

(C) Prescriptions returned to stock for dispensing shall not be mixed within the manufacturer's container.

(D) Prescriptions returned to stock for dispensing should be used as soon as possible and stored in the dispensing container. The expiration date of the medication shall be the lesser of one year from the dispensing date on the prescription label or the manufacturer's expiration date if dispensed in the manufacturer's original container.

(E) At the time of dispensing, the prescription medication shall be placed in a new prescription container and not dispensed in the previously labeled container unless the label can be completely removed. However, if the medication is in the manufacturer's original container, the pharmacy label must be removed so that no confidential patient information is released.

(9) Redistribution of Donated Prepackaged Prescription Drugs.

(A) A participating provider may dispense to a recipient donated prescription drugs that are prepackaged and labeled in accordance with §442.0515, Health and Safety Code, and this paragraph.

(B) Drugs may be prepackaged in quantities suitable for distribution to a recipient only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist.

(C) The label of a prepackaged prescription drug a participating provider dispenses to a recipient shall indicate:

(i) brand name and strength of the drug; or if no brand name, then the generic name, strength, and name of the manufacturer or distributor;

(ii) facility's lot number;

(iii) facility's beyond use date; and

(iv) quantity of the drug, if the quantity is greater than one.

(D) Records of prepackaging shall be maintained to show:

(i) name of the drug, strength, and dosage form;

(ii) facility's lot number;

(iii) manufacturer or distributor;

(iv) manufacturer's lot number;

(v) manufacturer's expiration date;

(vi) quantity per prepackaged unit;

(vii) number of prepackaged units;

(viii) date packaged;

(ix) name, initials, or electronic signature of the prepacker; and

(x) signature, or electronic signature of the responsible pharmacist.

(E) Stock packages, repackaged units, and control records shall be quarantined together until checked/released by the pharmacist.

(d) Equipment and supplies. Class A pharmacies dispensing prescription drug orders shall have the following equipment and supplies:

(1) data processing system including a printer or comparable equipment;

(2) refrigerator;

(3) adequate supply of child-resistant, light-resistant, tight, and if applicable, glass containers;

(4) adequate supply of prescription, poison, and other applicable labels;

(5) appropriate equipment necessary for the proper preparation of prescription drug orders; and

(6) metric-apothecary weight and measure conversion charts.

(e) Library. A reference library shall be maintained which includes the following in hard-copy or electronic format:

(1) current copies of the following:

(A) Texas Pharmacy Act and rules;

(B) Texas Dangerous Drug Act and rules;

(C) Texas Controlled Substances Act and rules; and

(D) Federal Controlled Substances Act and rules (or official publication describing the requirements of the Federal Controlled Substances Act and rules);

(2) at least one current or updated reference from each of the following categories:

(A) a patient prescription drug information reference text or leaflets which are designed for the patient and must be available to the patient;

(B) at least one current or updated general drug information reference which is required to contain drug interaction information including information needed to determine severity or significance of the interaction and appropriate recommendations or actions to be taken; and

(C) if the pharmacy dispenses veterinary prescriptions, a general reference text on veterinary drugs; and

(3) basic antidote information and the telephone number of the nearest Regional Poison Control Center.

(f) Drugs.

(1) Procurement and storage.

(A) The pharmacist-in-charge shall have the responsibility for the procurement and storage of drugs, but may receive input from other appropriate staff relative to such responsibility.

(B) Prescription drugs and devices and nonprescription Schedule V controlled substances shall be stored within the prescription department or a locked storage area.

(C) All drugs shall be stored at the proper temperature, as defined in the USP/NF and §291.15 of this title (relating to Storage of Drugs).

(2) Out-of-date drugs or devices.

(A) Any drug or device bearing an expiration date shall not be dispensed beyond the expiration date of the drug or device.

(B) Outdated drugs or devices shall be removed from dispensing stock and shall be quarantined together until such drugs or devices are disposed of properly.

(3) Nonprescription Schedule V controlled substances.

(A) Schedule V controlled substances containing codeine, dihydrocodeine, or any of the salts of codeine or dihydrocodeine may not be distributed without a prescription drug order from a practitioner.

(B) A pharmacist may distribute nonprescription Schedule V controlled substances which contain no more than 15 milligrams of opium per 29.5729 ml or per 28.35 Gm provided:

(i) such distribution is made only by a pharmacist; a nonpharmacist employee may not distribute a nonprescription Schedule V controlled substance even if under the supervision of a pharmacist; however, after the pharmacist has fulfilled professional and legal responsibilities, the actual cash, credit transaction, or delivery may be completed by a nonpharmacist:

(ii) not more than 240 ml (eight fluid ounces), or not more than 48 solid dosage units of any substance containing opium, may be distributed to the same purchaser in any given 48-hour period without a prescription drug order;

(iii) the purchaser is at least 18 years of age; and

(iv) the pharmacist requires every purchaser not known to the pharmacist to furnish suitable identification (including proof of age where appropriate).

(C) A record of such distribution shall be maintained by the pharmacy in a bound record book. The record shall contain the following information:

(i) true name of the purchaser;

(ii) current address of the purchaser;

(iii) name and quantity of controlled substance purchased;

(iv) date of each purchase; and

(v) signature or written initials of the distributing pharmacist.

(4) Class A Pharmacies may not sell, purchase, trade or possess prescription drug samples, unless the pharmacy meets the requirements as specified in §291.16 of this title (relating to Samples).

(g) Prepackaging of drugs.

(1) Drugs may be prepackaged in quantities suitable for internal distribution only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist.

(2) The label of a prepackaged unit shall indicate:

(A) brand name and strength of the drug; or if no brand name, then the generic name, strength, and name of the manufacturer or distributor;

(B) facility's lot number;

(C) facility's beyond use date; and

(D) quantity of the drug, if the quantity is greater than one.

(3) Records of prepackaging shall be maintained to show:

(A) name of the drug, strength, and dosage form;

(B) facility's lot number;

(C) manufacturer or distributor;

(D) manufacturer's lot number;

(E) manufacturer's expiration date;

(F) quantity per prepackaged unit;

(G) number of prepackaged units;

(H) date packaged;

(I) name, initials, or electronic signature of the prepacker; and

(J) signature, or electronic signature of the responsible pharmacist.

(4) Stock packages, repackaged units, and control records shall be quarantined together until checked/released by the pharmacist.

(h) Customized patient medication packages.

(1) Purpose. In lieu of dispensing two or more prescribed drug products in separate containers, a pharmacist may, with the consent of the patient, the patient's caregiver, or the prescriber, provide a customized patient medication package (patient med-pak).

(2) Label.

(A) The patient med-pak shall bear a label stating:

(i) the name of the patient;

(ii) the unique identification number for the patient med-pak itself and a separate unique identification number for each of the prescription drug orders for each of the drug products contained therein;

(iii) the name, strength, physical description or identification, and total quantity of each drug product contained therein;

(iv) the directions for use and cautionary statements, if any, contained in the prescription drug order for each drug product contained therein;

(v) if applicable, a warning of the potential harmful effect of combining any form of alcoholic beverage with any drug product contained therein;

(vi) any storage instructions or cautionary statements required by the official compendia;

(vii) the name of the prescriber of each drug product;

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

(ix) the initials or an identification code of the dispensing pharmacist;

(x) the date after which the prescription should not be used or beyond-use-date. Unless otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date the med-pak is dispensed or the earliest manufacturer's expiration date for a product contained in the med-pak if it is less than one-year from the date dispensed. The beyond-use-date may be placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is not required on the label of a prescription dispensed to a person at the time of release from prison or jail if the prescription is for not more than a 10-day supply of medication;

(xi) either on the prescription label or the written information accompanying the prescription, the statement "Do not flush unused medications or pour down a sink or drain." A drug product on a list developed by the Federal Food and Drug Administration of medicines recommended for disposal by flushing is not required to bear this statement; and

(xii) any other information, statements, or warnings required for any of the drug products contained therein.

(B) If the patient med-pak allows for the removal or separation of the intact containers therefrom, each individual container shall bear a label identifying each of the drug product contained therein.

(C) The dispensing container is not required to bear the label as specified in subparagraph (A) of this paragraph if:

(i) the drug is prescribed for administration to an ultimate user who is institutionalized in a licensed health care institution (e.g., nursing home, hospice, hospital);

(ii) no more than a 90-day supply is dispensed at one time;

(iii) the drug is not in the possession of the ultimate user prior to administration;

(iv) the pharmacist-in-charge has determined that the institution:

(I) maintains medication administration records which include adequate directions for use for the drug(s) prescribed;

(II) maintains records of ordering, receipt, and administration of the drug(s); and

(III) provides for appropriate safeguards for the control and storage of the drug(s); and

(v) the dispensing container bears a label that adequately:

(I) identifies the:

(-a-) pharmacy by name and address;

(-b-) name and strength of each drug product dispensed;

(-c-) name of the patient; and

(-d-) name of the prescribing practitioner of each drug product, or the pharmacist who signed the prescription drug order;

(II) the date after which the prescription should not be used or beyond-use-date. Unless otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date the med-pak is dispensed or the earliest manufacturer's expiration date for a product contained in the med-pak if it is less than one-year from the date dispensed. The beyond-use-date may be placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is not required on the label of a prescription dispensed to a person at the time of release from prison or jail if the prescription is for not more than a 10-day supply of medication; and

(III) for each drug product sets forth the directions for use and cautionary statements, if any, contained on the prescription drug order or required by law.

(3) Labeling. The patient med-pak shall be accompanied by a patient package insert, in the event that any drug contained therein is required to be dispensed with such insert as accompanying labeling. Alternatively, such required information may be incorporated into a single, overall educational insert provided by the pharmacist for the total patient med-pak.

(4) Packaging. In the absence of more stringent packaging requirements for any of the drug products contained therein, each container of the patient med-pak shall comply with official packaging standards. Each container shall be either not reclosable or so designed as to show evidence of having been opened.

(5) Guidelines. It is the responsibility of the dispensing pharmacist when preparing a patient med-pak, to take into account any applicable compendial requirements or guidelines and the physical and chemical compatibility of the dosage forms placed within each container, as well as any therapeutic incompatibilities that may attend the simultaneous administration of the drugs.

(6) Recordkeeping. In addition to any individual prescription filing requirements, a record of each patient med-pak shall be made and filed. Each record shall contain, as a minimum:

(A) the name and address of the patient;

(B) the unique identification number for the patient med-pak itself and a separate unique identification number for each of the prescription drug orders for each of the drug products contained therein;

(C) the name of the manufacturer or distributor and lot number for each drug product contained therein;

(D) information identifying or describing the design, characteristics, or specifications of the patient med-pak sufficient to allow subsequent preparation of an identical patient med-pak for the patient;

(E) the date of preparation of the patient med-pak and the beyond-use date that was assigned;

(F) any special labeling instructions; and

(G) the initials or an identification code of the dispensing pharmacist.

(7) The patient med-pak label is not required to include the initials or identification code of the dispensing pharmacist as specified in paragraph (2)(A) of this subsection if the identity of the dispensing pharmacist is recorded in the pharmacy's data processing system. The record of the identity of the dispensing pharmacist shall not be altered in the pharmacy's data processing system.

(i) Automated devices and systems in a pharmacy.

(1) Automated counting devices. If a pharmacy uses automated counting devices:

(A) the pharmacy shall have a method to calibrate and verify the accuracy of the automated counting device and document the calibration and verification on a routine basis;

(B) the devices may be loaded with bulk drugs only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist;

(C) the label of an automated counting device container containing a bulk drug shall indicate the brand name and strength of the drug; or if no brand name, then the generic name, strength, and name of the manufacturer or distributor;

(D) records of loading bulk drugs into an automated counting device shall be maintained to show:

(i) name of the drug, strength, and dosage form;

(ii) manufacturer or distributor;

(iii) manufacturer's lot number;

(iv) expiration date;

(v) date of loading;

(vi) name, initials, or electronic signature of the person loading the automated counting device; and

(vii) name, initials, or electronic signature of the responsible pharmacist; and

(E) the automated counting device shall not be used until a pharmacist verifies that the system is properly loaded and affixes his or her name, initials, or electronic signature to the record as specified in subparagraph (D) of this paragraph.

(2) Automated pharmacy dispensing systems.

(A) Authority to use automated pharmacy dispensing systems. A pharmacy may use an automated pharmacy dispensing system to fill prescription drug orders provided that:

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

(ii) the automated pharmacy dispensing system has been tested by the pharmacy and found to dispense accurately. The pharmacy shall make the results of such testing available to the board upon request; and

(iii) the pharmacy will make the automated pharmacy dispensing system available for inspection by the board for the purpose of validating the accuracy of the system.

(B) Automated pharmacy dispensing systems may be stocked or loaded by a pharmacist or by a pharmacy technician or pharmacy technician trainee under the supervision of a pharmacist.

(C) Quality assurance program. A pharmacy which uses an automated pharmacy dispensing system to fill prescription drug orders shall operate according to a quality assurance program of the automated pharmacy dispensing system which:

(i) requires continuous monitoring of the automated pharmacy dispensing system; and

(ii) establishes mechanisms and procedures to test the accuracy of the automated pharmacy dispensing system at least every twelve months and whenever any upgrade or change is made to the system and documents each such activity.

(D) Policies and procedures of operation.

(i) When an automated pharmacy dispensing system is used to fill prescription drug orders, it shall be operated according to written policies and procedures of operation. The policies and procedures of operation shall:

(I) provide for a pharmacist's review, approval, and accountability for the transmission of each original or new prescription drug order to the automated pharmacy dispensing system before the transmission is made;

(II) provide for access to the automated pharmacy dispensing system for stocking and retrieval of medications which is limited to licensed healthcare professionals or pharmacy technicians acting under the supervision of a pharmacist;

(III) require that a pharmacist checks, verifies, and documents that the correct medication and strength of bulk drugs, prepackaged containers, or manufacturer's unit of use packages were properly stocked, filled, and loaded in the automated pharmacy dispensing system prior to initiating the fill process; alternatively, an electronic verification system may be used for verification of manufacturer's unit of use packages or prepacked medication previously verified by a pharmacist;

(IV) provide for an accountability record to be maintained that documents all transactions relative to stocking and removing medications from the automated pharmacy dispensing system;

(V) require a prospective drug regimen review is conducted as specified in subsection (c)(2) of this section; and

(VI) establish and make provisions for documentation of a preventative maintenance program for the automated pharmacy dispensing system.

(ii) A pharmacy that uses an automated pharmacy dispensing system to fill prescription drug orders shall, at least annually, review its written policies and procedures, revise them if necessary, and document the review.

(E) Recovery Plan. A pharmacy that uses an automated pharmacy dispensing system to fill prescription drug orders shall maintain a written plan for recovery from a disaster or any other situation which interrupts the ability of the automated pharmacy dispensing system to provide services necessary for the operation of the pharmacy. The written plan for recovery shall include:

(i) planning and preparation for maintaining pharmacy services when an automated pharmacy dispensing system is experiencing downtime;

(ii) procedures for response when an automated pharmacy dispensing system is experiencing downtime; and

(iii) procedures for the maintenance and testing of the written plan for recovery.

(F) Final check of prescriptions dispensed using an automated pharmacy dispensing system. For the purpose of §291.32(c)(2)(D) of this title (relating to Personnel), a pharmacist must perform the final check of all prescriptions prior to delivery to the patient to ensure that the prescription is dispensed accurately as prescribed.

(i) This final check shall be considered accomplished if:

(I) a check of the final product is conducted by a pharmacist after the automated pharmacy dispensing system has completed the prescription and prior to delivery to the patient; or

(II) the following checks are conducted:

(-a-) if the automated pharmacy dispensing system contains bulk stock drugs, a pharmacist verifies that those drugs have been accurately stocked as specified in subparagraph (D)(i)(III) of this paragraph;

(-b-) if the automated pharmacy dispensing system contains manufacturer's unit of use packages or prepackaged medication previously verified by a pharmacist, an electronic verification system has confirmed that the medications have been accurately stocked as specified in subparagraph (D)(i)(III) of this paragraph;

(-c-) a pharmacist checks the accuracy of the data entry of each original or new prescription drug order entered into the automated pharmacy dispensing system; and

(-d-) an electronic verification process is used to verify the proper prescription label has been affixed to the correct medication container, prepackaged medication or manufacturer unit of use package for the correct patient.

(ii) If the final check is accomplished as specified in clause (i)(II) of this subparagraph, the following additional requirements must be met:

(I) the dispensing process must be fully automated from the time the pharmacist releases the prescription to the automated pharmacy dispensing system until a completed, labeled prescription ready for delivery to the patient is produced;

(II) the pharmacy has conducted initial testing and has a continuous quality assurance program which documents that the automated pharmacy dispensing system dispenses accurately as specified in subparagraph (C) of this paragraph;

(III) the automated pharmacy dispensing system documents and maintains:

(-a-) the name(s), initials, or identification code(s) of each pharmacist responsible for the checks outlined in clause (i)(II) of this subparagraph; and

(-b-) the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist, pharmacy technician, or pharmacy technician trainee who performs any other portion of the dispensing process; and

(IV) the pharmacy establishes mechanisms and procedures to test the accuracy of the automated pharmacy dispensing system at least every month rather than every twelve months as specified in subparagraph (C) of this paragraph.

(3) Automated checking device.

(A) For the purpose of §291.32(c)(2)(D) of this title, the final check of a dispensed prescription shall be considered accomplished using an automated checking device provided a check of the final product is conducted by a pharmacist prior to delivery to the patient or the following checks are performed:

(i) the drug used to fill the order is checked through the use of an automated checking device which verifies that the drug is labeled and packaged accurately; and

(ii) a pharmacist checks the accuracy of each original or new prescription drug order and is responsible for the final check of the order through the automated checking device.

(B) If the final check is accomplished as specified in subparagraph (A) of this paragraph, the following additional requirements must be met:

(i) the pharmacy has conducted initial testing of the automated checking device and has a continuous quality assurance program which documents that the automated checking device accurately confirms that the correct drug and strength has been labeled with the correct label for the correct patient;

(ii) the pharmacy documents and maintains:

(I) the name(s), initials, or identification code(s) of each pharmacist responsible for the checks outlined in subparagraph (A)(i) of this paragraph; and

(II) the name(s) initials, or identification code(s) and specific activity(ies) of each pharmacist, pharmacy technician, or pharmacy technician trainee who performs any other portion of the dispensing process;

(iii) the pharmacy establishes mechanisms and procedures to test the accuracy of the automated checking device at least monthly; and

(iv) the pharmacy establishes procedures to ensure that errors identified by the automated checking device may not be overridden by a pharmacy technician and must be reviewed and corrected by a pharmacist.

TITLE 22. EXAMINING BOARDS
PART 15. TEXAS STATE BOARD OF PHARMACY
CHAPTER 291. PHARMACIES
SUBCHAPTER B. COMMUNITY PHARMACY (CLASS A)

§291.33. Operational Standards.

The Texas State Board of Pharmacy proposes amendments to §291.33, concerning Operational Standards. The amendments, if adopted, specify prepackaging and labeling requirements for a participating provider to dispense donated prescription drugs under Chapter 442, Health and Safety Code, in accordance with House Bill 4332.

Daniel Carroll, Pharm.D., Executive Director/Secretary, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule. Dr. Carroll 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 amendments will be to provide consistency between state law and Board rules. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

For each year of the first five years the proposed amendments will be in effect, Dr. Carroll has determined the following:

(1) The proposed amendments do not create or eliminate a government program;

(2) Implementation of the proposed amendments does not require the creation of new employee positions or the elimination of existing employee positions;

(3) Implementation of the proposed amendments does not require an increase or decrease in the future legislative appropriations to the agency;

(4) The proposed amendments do not require an increase or decrease in fees paid to the agency;

(5) The proposed amendments do not create a new regulation;

(6) The proposed amendments do limit an existing regulation in order to be consistent with state law;

(7) The proposed amendments do not increase or decrease the number of individuals subject to the rule's applicability; and

(8) The proposed amendments do not positively or adversely affect this state's economy.

Written comments on the amendments may be submitted to Eamon D. Briggs, Deputy General Counsel, Texas State Board of Pharmacy, 1801 Congress Avenue, Suite 13.100, Austin, Texas 78701-1319, FAX (512) 305-8061. Comments must be received by 5:00 p.m., October 30, 2023.

The amendments are proposed under §§551.002 and 554.051 of the Texas Pharmacy Act (Chapters 551 - 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 - 569, Texas Occupations Code.

§291.33.Operational Standards.

(a) Licensing requirements.

(1) A Class A pharmacy shall register annually or biennially with the board on a pharmacy license application provided by the board, following the procedures as specified in §291.1 of this title (relating to Pharmacy License Application).

(2) A Class A pharmacy which changes ownership shall notify the board within ten days of the change of ownership and apply for a new and separate license as specified in §291.3 of this title (relating to Required Notifications).

(3) A Class A pharmacy which changes location and/or name shall notify the board as specified in §291.3 of this title.

(4) A Class A pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within ten days of the change, following the procedures as specified in §291.3 of this title.

(5) A Class A pharmacy shall notify the board in writing within ten days of closing, following the procedures as specified in §291.5 of this title (relating to Closing a Pharmacy).

(6) A separate license is required for each principal place of business and only one pharmacy license may be issued to a specific location.

(7) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for the issuance and renewal of a license and the issuance of an amended license.

(8) A Class A pharmacy, licensed under the provisions of the Act, §560.051(a)(1), which also operates another type of pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(2) concerning Nuclear Pharmacy (Class B), is not required to secure a license for such other type of pharmacy; provided, however, such licensee is required to comply with the provisions of Subchapter C of this chapter (relating to Nuclear Pharmacy (Class B)), to the extent such sections are applicable to the operation of the pharmacy.

(9) A Class A pharmacy engaged in the compounding of non-sterile preparations shall comply with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

(10) A Class A pharmacy shall not compound sterile preparations.

(11) A Class A pharmacy engaged in the provision of remote pharmacy services, including storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of this title (relating to Remote Pharmacy Services).

(12) Class A pharmacy engaged in centralized prescription dispensing and/or prescription drug or medication order processing shall comply with the provisions of §291.123 of this title (relating to Central Prescription Drug or Medication Order Processing) and/or §291.125 of this title (relating to Centralized Prescription Dispensing).

(b) Environment.

(1) General requirements.

(A) The pharmacy shall be arranged in an orderly fashion and kept clean. All required equipment shall be clean and in good operating condition.

(B) A Class A pharmacy shall have a sink with hot and cold running water within the pharmacy, exclusive of restroom facilities, available to all pharmacy personnel and maintained in a sanitary condition.

(C) A Class A pharmacy which serves the general public shall contain an area which is suitable for confidential patient counseling.

(i) Such counseling area shall be:

(I) easily accessible to both patient and pharmacists and not allow patient access to prescription drugs; and

(II) designed to maintain the confidentiality and privacy of the pharmacist/patient communication.

(ii) In determining whether the area is suitable for confidential patient counseling and designed to maintain the confidentiality and privacy of the pharmacist/patient communication, the board may consider factors such as the following:

(I) the proximity of the counseling area to the check-out or cash register area;

(II) the volume of pedestrian traffic in and around the counseling area;

(III) the presence of walls or other barriers between the counseling area and other areas of the pharmacy; and

(IV) any evidence of confidential information being overheard by persons other than the patient or patient's agent or the pharmacist or agents of the pharmacist.

(D) The pharmacy shall be properly lighted and ventilated.

(E) The temperature of the pharmacy shall be maintained within a range compatible with the proper storage of drugs. The temperature of the refrigerator shall be maintained within a range compatible with the proper storage of drugs requiring refrigeration.

(F) Animals, including birds and reptiles, shall not be kept within the pharmacy and in immediately adjacent areas under the control of the pharmacy. This provision does not apply to fish in aquariums, service animals accompanying disabled persons, or animals for sale to the general public in a separate area that is inspected by local health jurisdictions.

(G) If the pharmacy has flammable materials, the pharmacy shall have a designated area for the storage of flammable materials. Such area shall meet the requirements set by local and state fire laws.

(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) 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) 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.

(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) On-site supervision by pharmacist.

(i) If a pharmacy is staffed by only one pharmacist, the pharmacist may leave the prescription department for short periods of time without closing the prescription department and removing pharmacy technicians, pharmacy technician trainees, and other pharmacy personnel from the prescription department provided the following conditions are met:

(I) at least one pharmacy technician remains in the prescription department;

(II) the pharmacist remains on-site at the licensed location of the pharmacy and is immediately available;

(III) the pharmacist reasonably believes that the security of the prescription department will be maintained in his or her absence. If in the professional judgment of the pharmacist, the pharmacist determines that the prescription department should close during his or her absence, then the pharmacist shall close the prescription department and remove the pharmacy technicians, pharmacy technician trainees, and other pharmacy personnel from the prescription department during his or her absence; and

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

(-a-) the pharmacist is on a break and the time the pharmacist will return; and

(-b-) pharmacy technicians may begin the processing of prescription drug orders or refills brought in during the pharmacist's absence, but the prescription or refill may not be delivered to the patient or the patient's agent until the pharmacist verifies the accuracy of the prescription.

(ii) During the time a pharmacist is absent from the prescription department, only pharmacy technicians who have completed the pharmacy's training program may perform the following duties, provided a pharmacist verifies the accuracy of all acts, tasks, and functions performed by the pharmacy technicians prior to delivery of the prescription to the patient or the patient's agent:

(I) initiating and receiving refill authorization requests;

(II) entering prescription data into a data processing system;

(III) taking a stock bottle from the shelf for a prescription;

(IV) preparing and packaging prescription drug orders (e.g., counting tablets/capsules, measuring liquids, or placing them in the prescription container);

(V) affixing prescription labels and auxiliary labels to the prescription container;

(VI) prepackaging and labeling prepackaged drugs;

(VII) receiving oral prescription drug orders for dangerous drugs and reducing these orders to writing, either manually or electronically;

(VIII) transferring or receiving a transfer of original prescription information for dangerous drugs on behalf of a patient; and

(IX) contacting a prescriber for information regarding an existing prescription for a dangerous drug.

(iii) Upon return to the prescription department, the pharmacist shall:

(I) conduct a drug regimen review as specified in subsection (c)(2) of this section; and

(II) verify the accuracy of all acts, tasks, and functions performed by the pharmacy technicians prior to delivery of the prescription to the patient or the patient's agent.

(iv) An agent of the pharmacist may deliver a previously verified prescription to the patient or his or her agent provided a record of the delivery is maintained containing the following information:

(I) date 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.

(v) Any prescription delivered to a patient when a pharmacist is not in the prescription department must meet the requirements for a prescription delivered to a patient as described in subsection (c)(1)(F) of this section.

(vi) During the times a pharmacist is absent from the prescription department a pharmacist intern shall be considered a registered pharmacy technician and may perform only the duties of a registered pharmacy technician.

(vii) In pharmacies with two or more pharmacists on duty, the pharmacists shall stagger their breaks and meal periods so that the prescription department is not left without a pharmacist on duty.

(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 pharmacist is off-site.

(iii) A pharmacy may use an automated dispensing and delivery system as specified in §291.121(d) of this title for pick-up of a previously verified prescription by a patient or patient's agent.

(iv) 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) 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) 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) Prescription dispensing and delivery.

(1) Patient counseling and provision of drug information.

(A) To optimize drug therapy, a pharmacist shall communicate to the patient or the patient's agent information about the prescription drug or device which in the exercise of the pharmacist's professional judgment the pharmacist deems significant, such as the following:

(i) name and description of the drug or device;

(ii) dosage form, dosage, route of administration, and duration of drug therapy;

(iii) special directions and precautions for preparation, administration, and use by the patient;

(iv) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(v) techniques for self-monitoring of drug therapy;

(vi) proper storage;

(vii) refill information; and

(viii) action to be taken in the event of a missed dose.

(B) Such communication shall be:

(i) provided to new and existing patients of a pharmacy with each new prescription drug order. A new prescription drug order is one that has not been dispensed by the pharmacy to the patient in the same dosage and strength within the last year;

(ii) provided for any prescription drug order dispensed by the pharmacy on the request of the patient or patient's agent;

(iii) communicated orally unless the patient or patient's agent is not at the pharmacy or a specific communication barrier prohibits such oral communication;

(iv) documented by recording the initials or identification code of the pharmacist providing the counseling in the prescription dispensing record as follows:

(I) on the original hard-copy prescription, provided the counseling pharmacist clearly records his or her initials on the prescription for the purpose of identifying who provided the counseling;

(II) in the pharmacy's data processing system;

(III) in an electronic logbook; or

(IV) in a hard-copy log; and

(v) reinforced with written information relevant to the prescription and provided to the patient or patient's agent. The following is applicable concerning this written information:

(I) Written information must be in plain language designed for the patient and printed in an easily readable font size comparable to but no smaller than ten-point Times Roman. This information may be provided to the patient in an electronic format, such as by e-mail, if the patient or patient's agent requests the information in an electronic format and the pharmacy documents the request.

(II) When a compounded preparation is dispensed, information shall be provided for the major active ingredient(s), if available.

(III) For new drug entities, if no written information is initially available, the pharmacist is not required to provide information until such information is available, provided:

(-a-) the pharmacist informs the patient or the patient's agent that the product is a new drug entity and written information is not available;

(-b-) the pharmacist documents the fact that no written information was provided; and

(-c-) if the prescription is refilled after written information is available, such information is provided to the patient or patient's agent.

(IV) The written information accompanying the prescription or the prescription label shall contain the statement "Do not flush unused medications or pour down a sink or drain." A drug product on a list developed by the Federal Food and Drug Administration of medicines recommended for disposal by flushing is not required to bear this statement.

(C) Only a pharmacist may verbally provide drug information to a patient or patient's agent and answer questions concerning prescription drugs. Non-pharmacist personnel and/or the pharmacy's computer system may not ask questions of a patient or patient's agent which are intended to screen and/or limit interaction with the pharmacist.

(D) Nothing in this subparagraph shall be construed as requiring a pharmacist to provide consultation when a patient or patient's agent refuses such consultation. The pharmacist shall document such refusal for consultation.

(E) In addition to the requirements of subparagraphs (A) - (D) of this paragraph, if a prescription drug order is delivered to the patient at the pharmacy, the following is applicable:

(i) So that a patient will have access to information concerning his or her prescription, a prescription may not be delivered to a patient unless a pharmacist is in the pharmacy, except as provided in subsection (b)(3) of this section.

(ii) Any prescription delivered to a patient when a pharmacist is not in the pharmacy must meet the requirements described in subparagraph (F) of this paragraph.

(F) In addition to the requirements of subparagraphs (A) - (D) of this paragraph, if a prescription drug order is delivered to the patient or his or her agent at the patient's residence or other designated location, the following is applicable:

(i) The information as specified in subparagraph (A) of this paragraph shall be delivered with the dispensed prescription in writing.

(ii) If prescriptions are routinely delivered outside the area covered by the pharmacy's local telephone service, the pharmacy shall provide a toll-free telephone line which is answered during normal business hours to enable communication between the patient and a pharmacist.

(iii) The pharmacist shall place on the prescription container or on a separate sheet delivered with the prescription container in both English and Spanish the local and, if applicable, toll-free telephone number of the pharmacy and the statement: "Written information about this prescription has been provided for you. Please read this information before you take the medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions at (insert the pharmacy's local and toll-free telephone numbers)."

(iv) The pharmacy shall maintain and use adequate storage or shipment containers and use shipping processes to ensure drug stability and potency. Such shipping processes shall include the use of appropriate packaging material and/or devices to ensure that the drug is maintained at an appropriate temperature range to maintain the integrity of the medication throughout the delivery process.

(v) The pharmacy shall use a delivery system which is designed to ensure that the drugs are delivered to the appropriate patient.

(G) The provisions of this paragraph do not apply to patients in facilities where drugs are administered to patients by a person required to do so by the laws of the state (i.e., nursing homes).

(2) Pharmaceutical care services.

(A) Drug regimen review.

(i) For the purpose of promoting therapeutic appropriateness, a pharmacist shall, prior to or at the time of dispensing a prescription drug order, review the patient's medication record. Such review shall at a minimum identify clinically significant:

(I) known allergies;

(II) rational therapy-contraindications;

(III) reasonable dose and route of administration;

(IV) reasonable directions for use;

(V) duplication of therapy;

(VI) drug-drug interactions;

(VII) drug-food interactions;

(VIII) drug-disease interactions;

(IX) adverse drug reactions; and

(X) proper utilization, including overutilization or underutilization.

(ii) Upon identifying any clinically significant conditions, situations, or items listed in clause (i) of this subparagraph, the pharmacist shall take appropriate steps to avoid or resolve the problem including consultation with the prescribing practitioner. The pharmacist shall document such occurrences as specified in subparagraph (C) of this paragraph.

(iii) The drug regimen review may be conducted by remotely accessing the pharmacy's electronic database from outside the pharmacy by:

(I) an individual Texas licensed pharmacist employee of the pharmacy provided the pharmacy establishes controls to protect the privacy of the patient and the security of confidential records; or

(II) a pharmacist employed by a Class E pharmacy provided the pharmacies have entered into a written contract or agreement which outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations.

(iv) Prior to dispensing, any questions regarding a prescription drug order must be resolved with the prescriber and written documentation of these discussions made and maintained as specified in subparagraph (C) of this paragraph.

(B) Other pharmaceutical care services which may be provided by pharmacists include, but are not limited to, the following:

(i) managing drug therapy as delegated by a practitioner as allowed under the provisions of the Medical Practice Act;

(ii) administering immunizations and vaccinations under written protocol of a physician;

(iii) managing patient compliance programs;

(iv) providing preventative health care services; and

(v) providing case management of patients who are being treated with high-risk or high-cost drugs, or who are considered "high risk" due to their age, medical condition, family history, or related concern.

(C) Documentation of consultation. When a pharmacist consults a prescriber as described in subparagraph (A) of this paragraph, the pharmacist shall document on the prescription or in the pharmacy's data processing system associated with the prescription such occurrences and shall include the following information:

(i) date the prescriber was consulted;

(ii) name of the person communicating the prescriber's instructions;

(iii) any applicable information pertaining to the consultation; and

(iv) initials or identification code of the pharmacist performing the consultation clearly recorded for the purpose of identifying the pharmacist who performed the consultation.

(3) Substitution of generically equivalent drugs or interchangeable biological products. A pharmacist may dispense a generically equivalent drug or interchangeable biological product and shall comply with the provisions of §309.3 of this title (relating to Substitution Requirements).

(4) Substitution of dosage form.

(A) As specified in §562.012 of the Act, a pharmacist may dispense a dosage form of a drug product different from that prescribed, such as a tablet instead of a capsule or liquid instead of tablets, provided:

(i) the patient consents to the dosage form substitution; and

(ii) the dosage form so dispensed:

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

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

(III) does not alter desired clinical outcomes.

(B) Substitution of dosage form may not include the substitution of a product that has been compounded by the pharmacist unless the pharmacist contacts the practitioner prior to dispensing and obtains permission to dispense the compounded product.

(5) Therapeutic Drug Interchange. A switch to a drug providing a similar therapeutic response to the one prescribed shall not be made without prior approval of the prescribing practitioner. This paragraph does not apply to generic substitution. For generic substitution, see the requirements of paragraph (3) of this subsection.

(A) The patient shall be notified of the therapeutic drug interchange prior to, or upon delivery of, the dispensed prescription to the patient. Such notification shall include:

(i) a description of the change;

(ii) the reason for the change;

(iii) whom to notify with questions concerning the change; and

(iv) instructions for return of the drug if not wanted by the patient.

(B) The pharmacy shall maintain documentation of patient notification of therapeutic drug interchange which shall include:

(i) the date of the notification;

(ii) the method of notification;

(iii) a description of the change; and

(iv) the reason for the change.

(C) The provisions of this paragraph do not apply to prescriptions for patients in facilities where drugs are administered to patients by a person required to do so by the laws of this state if the practitioner issuing the prescription has agreed to use of a formulary that includes a listing of therapeutic interchanges that the practitioner has agreed to allow. The pharmacy must maintain a copy of the formulary including a list of the practitioners that have agreed to the formulary and the signatures of these practitioners.

(6) Prescription containers.

(A) A drug dispensed pursuant to a prescription drug order shall be dispensed in a child-resistant container unless:

(i) the patient or the practitioner requests the prescription not be dispensed in a child-resistant container; or

(ii) the product is exempted from requirements of the Poison Prevention Packaging Act of 1970.

(B) A drug dispensed pursuant to a prescription drug order shall be dispensed in an appropriate container as specified on the manufacturer's container.

(C) Prescription containers or closures shall not be re-used. However, if a patient or patient's agent has difficulty reading or understanding a prescription label, a prescription container may be reused provided:

(i) the container is designed to provide audio-recorded information about the proper use of the prescription medication;

(ii) the container is reused for the same patient;

(iii) the container is cleaned; and

(iv) a new safety closure is used each time the prescription container is reused.

(7) Labeling.

(A) At the time of delivery of the drug, the dispensing container shall bear a label in plain language and printed in an easily readable font size, unless otherwise specified, with at least the following information:

(i) name, address and phone number of the pharmacy;

(ii) unique identification number of the prescription that is printed in an easily readable font size comparable to but no smaller than ten-point Times Roman;

(iii) date the prescription is dispensed;

(iv) initials or an identification code of the dispensing pharmacist;

(v) name of the prescribing practitioner;

(vi) if the prescription was signed by a pharmacist, the name of the pharmacist who signed the prescription for a dangerous drug under delegated authority of a physician as specified in Subtitle B, Chapter 157, Occupations Code;

(vii) name of the patient or if such drug was prescribed for an animal, the species of the animal and the name of the owner that is printed in an easily readable font size comparable to but no smaller than ten-point Times Roman. The name of the patient's partner or family member is not required to be on the label of a drug prescribed for a partner for a sexually transmitted disease or for a patient's family members if the patient has an illness determined by the Centers for Disease Control and Prevention, the World Health Organization, or the Governor's office to be pandemic;

(viii) instructions for use that are printed in an easily readable font size comparable to but no smaller than ten-point Times Roman;

(ix) quantity dispensed;

(x) appropriate ancillary instructions such as storage instructions or cautionary statements such as warnings of potential harmful effects of combining the drug product with any product containing alcohol;

(xi) if the prescription is for a Schedule II - IV controlled substance, the statement "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed";

(xii) if the pharmacist has selected a generically equivalent drug or interchangeable biological product pursuant to the provisions of the Act, Chapter 562, the statement "Substituted for Brand Prescribed" or "Substituted for 'Brand Name'" where "Brand Name" is the actual name of the brand name product prescribed;

(xiii) the name and strength of the actual drug or biological product dispensed that is printed in an easily readable size comparable to but no smaller than ten-point Times Roman, unless otherwise directed by the prescribing practitioner;

(I) The name shall be either:

(-a-) the brand name; or

(-b-) if no brand name, then the generic drug or interchangeable biological product name and name of the manufacturer or distributor of such generic drug or interchangeable biological product. (The name of the manufacturer or distributor may be reduced to an abbreviation or initials, provided the abbreviation or initials are sufficient to identify the manufacturer or distributor. For combination drug products or non-sterile compounded drug preparations having no brand name, the principal active ingredients shall be indicated on the label).

(II) Except as provided in clause (xii) of this subparagraph, the brand name of the prescribed drug or biological product shall not appear on the prescription container label unless it is the drug product actually dispensed.

(xiv) if the drug is dispensed in a container other than the manufacturer's original container, the date after which the prescription should not be used or beyond-use-date. Unless otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date the drug is dispensed or the manufacturer's expiration date, whichever is earlier. The beyond-use-date may be placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is not required on the label of a prescription dispensed to a person at the time of release from prison or jail if the prescription is for not more than a 10-day supply of medication; and

(xv) either on the prescription label or the written information accompanying the prescription, the statement "Do not flush unused medications or pour down a sink or drain." A drug product on a list developed by the Federal Food and Drug Administration of medicines recommended for disposal by flushing is not required to bear this statement.

(B) If the prescription label required in subparagraph (A) of this paragraph is printed in a type size smaller than ten-point Times Roman, the pharmacy shall provide the patient written information containing the information as specified in subparagraph (A) of this paragraph in an easily readable font size comparable to but no smaller than ten-point Times Roman.

(C) The label is not required to include the initials or identification code of the dispensing pharmacist as specified in subparagraph (A) of this paragraph if the identity of the dispensing pharmacist is recorded in the pharmacy's data processing system. The record of the identity of the dispensing pharmacist shall not be altered in the pharmacy's data processing system.

(D) The dispensing container is not required to bear the label as specified in subparagraph (A) of this paragraph if:

(i) the drug is prescribed for administration to an ultimate user who is institutionalized in a licensed health care institution (e.g., nursing home, hospice, hospital);

(ii) no more than a 90-day supply is dispensed at one time;

(iii) the drug is not in the possession of the ultimate user prior to administration;

(iv) the pharmacist-in-charge has determined that the institution:

(I) maintains medication administration records which include adequate directions for use for the drug(s) prescribed;

(II) maintains records of ordering, receipt, and administration of the drug(s); and

(III) provides for appropriate safeguards for the control and storage of the drug(s); and

(v) the dispensing container bears a label that adequately:

(I) identifies the:

(-a-) pharmacy by name and address;

(-b-) unique identification number of the prescription;

(-c-) name and strength of the drug dispensed;

(-d-) name of the patient; and

(-e-) name of the prescribing practitioner or, if applicable, the name of the pharmacist who signed the prescription drug order;

(II) if the drug is dispensed in a container other than the manufacturer's original container, specifies the date after which the prescription should not be used or beyond-use-date. Unless otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date the drug is dispensed or the manufacturer's expiration date, whichever is earlier. The beyond-use-date may be placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is not required on the label of a prescription dispensed to a person at the time of release from prison or jail if the prescription is for not more than a 10-day supply of medication; and

(III) sets forth the directions for use and cautionary statements, if any, contained on the prescription drug order or required by law.

(8) Returning Undelivered Medication to Stock.

(A) A pharmacist may not accept an unused prescription or drug, in whole or in part, for the purpose of resale or re-dispensing to any person after the prescription or drug has been originally dispensed or sold, except as provided in §291.8 of this title (relating to Return of Prescription Drugs) or Subchapter M, Chapter 431, Health and Safety Code, or Chapter 442,

Health and Safety Code. Prescriptions that have not been picked up by or delivered to the patient or patient's agent may be returned to the pharmacy's stock for dispensing.

(B) A pharmacist shall evaluate the quality and safety of the prescriptions to be returned to stock.

(C) Prescriptions returned to stock for dispensing shall not be mixed within the manufacturer's container.

(D) Prescriptions returned to stock for dispensing should be used as soon as possible and stored in the dispensing container. The expiration date of the medication shall be the lesser of one year from the dispensing date on the prescription label or the manufacturer's expiration date if dispensed in the manufacturer's original container.

(E) At the time of dispensing, the prescription medication shall be placed in a new prescription container and not dispensed in the previously labeled container unless the label can be completely removed. However, if the medication is in the manufacturer's original container, the pharmacy label must be removed so that no confidential patient information is released.

(9) Redistribution of Donated Prepackaged Prescription Drugs.

(A) A participating provider may dispense to a recipient donated prescription drugs that are prepackaged and labeled in accordance with §442.0515, Health and Safety Code, and this paragraph.

(B) Drugs may be prepackaged in quantities suitable for distribution to a recipient only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist.

(C) The label of a prepackaged prescription drug a participating provider dispenses to a recipient shall indicate:

(i) brand name and strength of the drug; or if no brand name, then the generic name, strength, and name of the manufacturer or distributor;

(ii) participating provider's[~~facility's~~] lot number;

(iii) participating provider's[~~facility's~~] beyond use date; and

(iv) quantity of the drug, if the quantity is greater than one.

(D) Records of prepackaged prescription drugs dispensed to a recipient[~~prepackaging~~] shall be maintained to show:

(i) name of the drug, strength, and dosage form;

(ii) participating provider's[~~facility's~~] lot number;

(iii) manufacturer or distributor;

(iv) manufacturer's lot number;

(v) manufacturer's expiration date;

(vi) quantity per prepackaged unit;

(vii) number of prepackaged units;

(viii) date packaged;

(ix) name, initials, or electronic signature of the prepacker; and

(x) written[~~signature,~~] or electronic signature of the responsible pharmacist.

(E) Stock packages, repackaged units, and control records shall be quarantined together until checked/released by the pharmacist.

(d) Equipment and supplies. Class A pharmacies dispensing prescription drug orders shall have the following equipment and supplies:

(1) data processing system including a printer or comparable equipment;

(2) refrigerator;

(3) adequate supply of child-resistant, light-resistant, tight, and if applicable, glass containers;

(4) adequate supply of prescription, poison, and other applicable labels;

(5) appropriate equipment necessary for the proper preparation of prescription drug orders; and

(6) metric-apothecary weight and measure conversion charts.

(e) Library. A reference library shall be maintained which includes the following in hard-copy or electronic format:

(1) current copies of the following:

(A) Texas Pharmacy Act and rules;

(B) Texas Dangerous Drug Act and rules;

(C) Texas Controlled Substances Act and rules; and

(D) Federal Controlled Substances Act and rules (or official publication describing the requirements of the Federal Controlled Substances Act and rules);

(2) at least one current or updated reference from each of the following categories:

(A) a patient prescription drug information reference text or leaflets which are designed for the patient and must be available to the patient;

(B) at least one current or updated general drug information reference which is required to contain drug interaction information including information needed to determine severity or significance of the interaction and appropriate recommendations or actions to be taken; and

(C) if the pharmacy dispenses veterinary prescriptions, a general reference text on veterinary drugs; and

(3) basic antidote information and the telephone number of the nearest Regional Poison Control Center.

(f) Drugs.

(1) Procurement and storage.

(A) The pharmacist-in-charge shall have the responsibility for the procurement and storage of drugs, but may receive input from other appropriate staff relative to such responsibility.

(B) Prescription drugs and devices and nonprescription Schedule V controlled substances shall be stored within the prescription department or a locked storage area.

(C) All drugs shall be stored at the proper temperature, as defined in the USP/NF and §291.15 of this title (relating to Storage of Drugs).

(2) Out-of-date drugs or devices.

(A) Any drug or device bearing an expiration date shall not be dispensed beyond the expiration date of the drug or device.

(B) Outdated drugs or devices shall be removed from dispensing stock and shall be quarantined together until such drugs or devices are disposed of properly.

(3) Nonprescription Schedule V controlled substances.

(A) Schedule V controlled substances containing codeine, dihydrocodeine, or any of the salts of codeine or dihydrocodeine may not be distributed without a prescription drug order from a practitioner.

(B) A pharmacist may distribute nonprescription Schedule V controlled substances which contain no more than 15 milligrams of opium per 29.5729 ml or per 28.35 Gm provided:

(i) such distribution is made only by a pharmacist; a nonpharmacist employee may not distribute a nonprescription Schedule V controlled substance even if under the supervision of a pharmacist; however, after the pharmacist has fulfilled professional and legal responsibilities, the actual cash, credit transaction, or delivery may be completed by a nonpharmacist:

(ii) not more than 240 ml (eight fluid ounces), or not more than 48 solid dosage units of any substance containing opium, may be distributed to the same purchaser in any given 48-hour period without a prescription drug order;

(iii) the purchaser is at least 18 years of age; and

(iv) the pharmacist requires every purchaser not known to the pharmacist to furnish suitable identification (including proof of age where appropriate).

(C) A record of such distribution shall be maintained by the pharmacy in a bound record book. The record shall contain the following information:

(i) true name of the purchaser;

(ii) current address of the purchaser;

(iii) name and quantity of controlled substance purchased;

(iv) date of each purchase; and

(v) signature or written initials of the distributing pharmacist.

(4) Class A Pharmacies may not sell, purchase, trade or possess prescription drug samples, unless the pharmacy meets the requirements as specified in §291.16 of this title (relating to Samples).

(g) Prepackaging of drugs.

(1) Drugs may be prepackaged in quantities suitable for internal distribution only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist.

(2) The label of a prepackaged unit shall indicate:

(A) brand name and strength of the drug; or if no brand name, then the generic name, strength, and name of the manufacturer or distributor;

(B) facility's lot number;

(C) facility's beyond use date; and

(D) quantity of the drug, if the quantity is greater than one.

(3) Records of prepackaging shall be maintained to show:

(A) name of the drug, strength, and dosage form;

(B) facility's lot number;

(C) manufacturer or distributor;

(D) manufacturer's lot number;

(E) manufacturer's expiration date;

(F) quantity per prepackaged unit;

(G) number of prepackaged units;

(H) date packaged;

(I) name, initials, or electronic signature of the prepacker; and

(J) signature, or electronic signature of the responsible pharmacist.

(4) Stock packages, repackaged units, and control records shall be quarantined together until checked/released by the pharmacist.

(h) Customized patient medication packages.

(1) Purpose. In lieu of dispensing two or more prescribed drug products in separate containers, a pharmacist may, with the consent of the patient, the patient's caregiver, or the prescriber, provide a customized patient medication package (patient med-pak).

(2) Label.

(A) The patient med-pak shall bear a label stating:

(i) the name of the patient;

(ii) the unique identification number for the patient med-pak itself and a separate unique identification number for each of the prescription drug orders for each of the drug products contained therein;

(iii) the name, strength, physical description or identification, and total quantity of each drug product contained therein;

(iv) the directions for use and cautionary statements, if any, contained in the prescription drug order for each drug product contained therein;

(v) if applicable, a warning of the potential harmful effect of combining any form of alcoholic beverage with any drug product contained therein;

(vi) any storage instructions or cautionary statements required by the official compendia;

(vii) the name of the prescriber of each drug product;

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

(ix) the initials or an identification code of the dispensing pharmacist;

(x) the date after which the prescription should not be used or beyond-use-date. Unless otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date the med-pak is dispensed or the earliest manufacturer's expiration date for a product contained in the med-pak if it is less than one-year from the date dispensed. The beyond-use-date may be placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is not required on the label of a prescription dispensed to a person at the time of release from prison or jail if the prescription is for not more than a 10-day supply of medication;

(xi) either on the prescription label or the written information accompanying the prescription, the statement "Do not flush unused medications or pour down a sink or drain." A drug product on a list developed by the Federal Food and Drug Administration of medicines recommended for disposal by flushing is not required to bear this statement; and

(xii) any other information, statements, or warnings required for any of the drug products contained therein.

(B) If the patient med-pak allows for the removal or separation of the intact containers therefrom, each individual container shall bear a label identifying each of the drug product contained therein.

(C) The dispensing container is not required to bear the label as specified in subparagraph (A) of this paragraph if:

(i) the drug is prescribed for administration to an ultimate user who is institutionalized in a licensed health care institution (e.g., nursing home, hospice, hospital);

(ii) no more than a 90-day supply is dispensed at one time;

(iii) the drug is not in the possession of the ultimate user prior to administration;

(iv) the pharmacist-in-charge has determined that the institution:

(I) maintains medication administration records which include adequate directions for use for the drug(s) prescribed;

(II) maintains records of ordering, receipt, and administration of the drug(s); and

(III) provides for appropriate safeguards for the control and storage of the drug(s); and

(v) the dispensing container bears a label that adequately:

(I) identifies the:

(-a-) pharmacy by name and address;

(-b-) name and strength of each drug product dispensed;

(-c-) name of the patient; and

(-d-) name of the prescribing practitioner of each drug product, or the pharmacist who signed the prescription drug order;

(II) the date after which the prescription should not be used or beyond-use-date. Unless otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date the med-pak is dispensed or the earliest manufacturer's expiration date for a product contained in the med-pak if it is less than one-year from the date dispensed. The beyond-use-date may be placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is not required on the label of a prescription dispensed to a person at the time of release from prison or jail if the prescription is for not more than a 10-day supply of medication; and

(III) for each drug product sets forth the directions for use and cautionary statements, if any, contained on the prescription drug order or required by law.

(3) Labeling. The patient med-pak shall be accompanied by a patient package insert, in the event that any drug contained therein is required to be dispensed with such insert as accompanying labeling. Alternatively, such required information may be incorporated into a single, overall educational insert provided by the pharmacist for the total patient med-pak.

(4) Packaging. In the absence of more stringent packaging requirements for any of the drug products contained therein, each container of the patient med-pak shall comply with official packaging standards. Each container shall be either not reclosable or so designed as to show evidence of having been opened.

(5) Guidelines. It is the responsibility of the dispensing pharmacist when preparing a patient med-pak, to take into account any applicable compendial requirements or guidelines and the physical and chemical compatibility of the dosage forms placed within each container, as well as any therapeutic incompatibilities that may attend the simultaneous administration of the drugs.

(6) Recordkeeping. In addition to any individual prescription filing requirements, a record of each patient med-pak shall be made and filed. Each record shall contain, as a minimum:

(A) the name and address of the patient;

(B) the unique identification number for the patient med-pak itself and a separate unique identification number for each of the prescription drug orders for each of the drug products contained therein;

(C) the name of the manufacturer or distributor and lot number for each drug product contained therein;

(D) information identifying or describing the design, characteristics, or specifications of the patient med-pak sufficient to allow subsequent preparation of an identical patient med-pak for the patient;

(E) the date of preparation of the patient med-pak and the beyond-use date that was assigned;

(F) any special labeling instructions; and

(G) the initials or an identification code of the dispensing pharmacist.

(7) The patient med-pak label is not required to include the initials or identification code of the dispensing pharmacist as specified in paragraph (2)(A) of this subsection if the identity of the dispensing pharmacist is recorded in the pharmacy's data processing system. The record of the identity of the dispensing pharmacist shall not be altered in the pharmacy's data processing system.

(i) Automated devices and systems in a pharmacy.

(1) Automated counting devices. If a pharmacy uses automated counting devices:

(A) the pharmacy shall have a method to calibrate and verify the accuracy of the automated counting device and document the calibration and verification on a routine basis;

(B) the devices may be loaded with bulk drugs only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist;

(C) the label of an automated counting device container containing a bulk drug shall indicate the brand name and strength of the drug; or if no brand name, then the generic name, strength, and name of the manufacturer or distributor;

(D) records of loading bulk drugs into an automated counting device shall be maintained to show:

(i) name of the drug, strength, and dosage form;

(ii) manufacturer or distributor;

(iii) manufacturer's lot number;

(iv) expiration date;

(v) date of loading;

(vi) name, initials, or electronic signature of the person loading the automated counting device; and

(vii) name, initials, or electronic signature of the responsible pharmacist; and

(E) the automated counting device shall not be used until a pharmacist verifies that the system is properly loaded and affixes his or her name, initials, or electronic signature to the record as specified in subparagraph (D) of this paragraph.

(2) Automated pharmacy dispensing systems.

(A) Authority to use automated pharmacy dispensing systems. A pharmacy may use an automated pharmacy dispensing system to fill prescription drug orders provided that:

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

(ii) the automated pharmacy dispensing system has been tested by the pharmacy and found to dispense accurately. The pharmacy shall make the results of such testing available to the board upon request; and

(iii) the pharmacy will make the automated pharmacy dispensing system available for inspection by the board for the purpose of validating the accuracy of the system.

(B) Automated pharmacy dispensing systems may be stocked or loaded by a pharmacist or by a pharmacy technician or pharmacy technician trainee under the supervision of a pharmacist.

(C) Quality assurance program. A pharmacy which uses an automated pharmacy dispensing system to fill prescription drug orders shall operate according to a quality assurance program of the automated pharmacy dispensing system which:

(i) requires continuous monitoring of the automated pharmacy dispensing system; and

(ii) establishes mechanisms and procedures to test the accuracy of the automated pharmacy dispensing system at least every twelve months and whenever any upgrade or change is made to the system and documents each such activity.

(D) Policies and procedures of operation.

(i) When an automated pharmacy dispensing system is used to fill prescription drug orders, it shall be operated according to written policies and procedures of operation. The policies and procedures of operation shall:

(I) provide for a pharmacist's review, approval, and accountability for the transmission of each original or new prescription drug order to the automated pharmacy dispensing system before the transmission is made;

(II) provide for access to the automated pharmacy dispensing system for stocking and retrieval of medications which is limited to licensed healthcare professionals or pharmacy technicians acting under the supervision of a pharmacist;

(III) require that a pharmacist checks, verifies, and documents that the correct medication and strength of bulk drugs, prepackaged containers, or manufacturer's unit of use packages were properly stocked, filled, and loaded in the automated pharmacy dispensing system prior to initiating the fill process; alternatively, an electronic verification system may be used for verification of manufacturer's unit of use packages or prepacked medication previously verified by a pharmacist;

(IV) provide for an accountability record to be maintained that documents all transactions relative to stocking and removing medications from the automated pharmacy dispensing system;

(V) require a prospective drug regimen review is conducted as specified in subsection (c)(2) of this section; and

(VI) establish and make provisions for documentation of a preventative maintenance program for the automated pharmacy dispensing system.

(ii) A pharmacy that uses an automated pharmacy dispensing system to fill prescription drug orders shall, at least annually, review its written policies and procedures, revise them if necessary, and document the review.

(E) Recovery Plan. A pharmacy that uses an automated pharmacy dispensing system to fill prescription drug orders shall maintain a written plan for recovery from a disaster or any other situation which interrupts the ability of the automated pharmacy dispensing system to provide services necessary for the operation of the pharmacy. The written plan for recovery shall include:

(i) planning and preparation for maintaining pharmacy services when an automated pharmacy dispensing system is experiencing downtime;

(ii) procedures for response when an automated pharmacy dispensing system is experiencing downtime; and

(iii) procedures for the maintenance and testing of the written plan for recovery.

(F) Final check of prescriptions dispensed using an automated pharmacy dispensing system. For the purpose of §291.32(c)(2)(D) of this title (relating to Personnel), a pharmacist must perform the final check of all prescriptions prior to delivery to the patient to ensure that the prescription is dispensed accurately as prescribed.

(i) This final check shall be considered accomplished if:

(I) a check of the final product is conducted by a pharmacist after the automated pharmacy dispensing system has completed the prescription and prior to delivery to the patient; or

(II) the following checks are conducted:

(-a-) if the automated pharmacy dispensing system contains bulk stock drugs, a pharmacist verifies that those drugs have been accurately stocked as specified in subparagraph (D)(i)(III) of this paragraph;

(-b-) if the automated pharmacy dispensing system contains manufacturer's unit of use packages or prepackaged medication previously verified by a pharmacist, an electronic verification system has confirmed that the medications have been accurately stocked as specified in subparagraph (D)(i)(III) of this paragraph;

(-c-) a pharmacist checks the accuracy of the data entry of each original or new prescription drug order entered into the automated pharmacy dispensing system; and

(-d-) an electronic verification process is used to verify the proper prescription label has been affixed to the correct medication container, prepackaged medication or manufacturer unit of use package for the correct patient.

(ii) If the final check is accomplished as specified in clause (i)(II) of this subparagraph, the following additional requirements must be met:

(I) the dispensing process must be fully automated from the time the pharmacist releases the prescription to the automated pharmacy dispensing system until a completed, labeled prescription ready for delivery to the patient is produced;

(II) the pharmacy has conducted initial testing and has a continuous quality assurance program which documents that the automated pharmacy dispensing system dispenses accurately as specified in subparagraph (C) of this paragraph;

(III) the automated pharmacy dispensing system documents and maintains:

(-a-) the name(s), initials, or identification code(s) of each pharmacist responsible for the checks outlined in clause (i)(II) of this subparagraph; and

(-b-) the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist, pharmacy technician, or pharmacy technician trainee who performs any other portion of the dispensing process; and

(IV) the pharmacy establishes mechanisms and procedures to test the accuracy of the automated pharmacy dispensing system at least every month rather than every twelve months as specified in subparagraph (C) of this paragraph.

(3) Automated checking device.

(A) For the purpose of §291.32(c)(2)(D) of this title, the final check of a dispensed prescription shall be considered accomplished using an automated checking device provided a check of the final product is conducted by a pharmacist prior to delivery to the patient or the following checks are performed:

(i) the drug used to fill the order is checked through the use of an automated checking device which verifies that the drug is labeled and packaged accurately; and

(ii) a pharmacist checks the accuracy of each original or new prescription drug order and is responsible for the final check of the order through the automated checking device.

(B) If the final check is accomplished as specified in subparagraph (A) of this paragraph, the following additional requirements must be met:

(i) the pharmacy has conducted initial testing of the automated checking device and has a continuous quality assurance program which documents that the automated checking device accurately confirms that the correct drug and strength has been labeled with the correct label for the correct patient;

(ii) the pharmacy documents and maintains:

(I) the name(s), initials, or identification code(s) of each pharmacist responsible for the checks outlined in subparagraph (A)(i) of this paragraph; and

(II) the name(s) initials, or identification code(s) and specific activity(ies) of each pharmacist, pharmacy technician, or pharmacy technician trainee who performs any other portion of the dispensing process;

(iii) the pharmacy establishes mechanisms and procedures to test the accuracy of the automated checking device at least monthly; and

(iv) the pharmacy establishes procedures to ensure that errors identified by the automated checking device may not be overridden by a pharmacy technician and must be reviewed and corrected by a pharmacist.

AN ACT

relating to the redistribution of donated prepackaged prescription drugs.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Section 442.001, Health and Safety Code, is amended by adding Subdivision (6-a) to read as follows:

(6-a) "Prepackage" means the act of repackaging and relabeling varying quantities of prescription drugs from a manufacturer's original commercial container into a prescription container, unit-dose packaging, or a multi-compartment container for a pharmacist to dispense to a consumer.

SECTION 2. Subchapter B, Chapter 442, Health and Safety Code, is amended by adding Section 442.0515 to read as follows:

Sec. 442.0515. REDISTRIBUTION OF DONATED PREPACKAGED PRESCRIPTION DRUGS. (a) A participating provider may dispense to a recipient donated prescription drugs that are prepackaged and labeled in accordance with this section and rules adopted by the Texas State Board of Pharmacy.

(b) A prepackaged prescription drug a participating provider dispenses to a recipient must contain a label that includes:

(1) the drug's brand name or, for a generic version of the drug, the drug's generic name and the manufacturer or distributor of the drug;

(2) the amount of the drug in a given dose;

(3) the drug's lot number;

(4) the earliest expiration date of the drug for that drug lot number; and

(5) the quantity of any drug the provider dispenses in more than one dose.

(c) A participating provider shall maintain a record of each prepackaged prescription drug dispensed to a recipient. The record must include:

(1) the drug's name, the amount of the drug in a given dose, and the dosage size or frequency;

(2) the provider's lot number for that drug;

(3) the drug's manufacturer or distributor;

(4) the manufacturer's lot number for that drug;

(5) the expiration dates of the drug from that drug's lot number;

(6) the quantity of the drug in each prepackaged unit;

(7) the number of prepackaged units that include the drug;

(8) the date the drug was prepackaged;

(9) the name, initials, or written or electronic signature of the individual who prepackaged the drug; and

(10) the written or electronic signature of the pharmacist responsible for the drug's prepackaging.

SECTION 3. As soon as practicable after the effective date of this Act, the Texas State Board of Pharmacy shall adopt any rules necessary to implement the changes in law made by this Act.

SECTION 4. This Act takes effect September 1, 2023.

President of the Senate

Speaker of the House

I certify that H.B. No. 4332 was passed by the House on April 28, 2023, by the following vote: Yeas 140, Nays 4, 2 present, not voting.

Chief Clerk of the House

I certify that H.B. No. 4332 was passed by the Senate on May 17, 2023, by the following vote: Yeas 31, Nays 0.

Secretary of the Senate

APPROVED: _____

Date

_____

Governor

October 27, 2023

Eamon D. Briggs
Deputy General Counsel
Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, Texas 78701-1319

RE: Comments on Proposed Amendments to §291.33, Concerning Operational Standards

Dear Mr. Briggs:

We are writing to comment on the Board of Pharmacy's proposed amendments to §291.33, concerning operational standards, as published on September 22, 2023 in the *Texas Register*. Thank you for the opportunity to submit these comments. Please let us know if we can further clarify anything or provide any additional information.

About SIRUM

SIRUM is a 501(c)3 nonprofit, founded at Stanford University that helps implement state-based programs to donate unused medications to patients in need. Donated medication is often the safety-net's last line of defense for vulnerable patients. SIRUM is the nation's largest distributor of surplus medicine, currently assisting operate donation programs in eight states, helping tens of thousands of patients access millions of dollars of donated medication that they would not otherwise have been able to afford or access. SIRUM has provided testimony on over 25 state laws and regulations.

Comments and Considerations

We believe that the Drug Donation Program has an enormous potential to reduce health care costs and reduce needless waste for Texas and Texas residents and we are overall supportive of the proposed amendments. Based on our experience operating drug donation programs, we have outlined some concerns and considerations below.

Sincerely,

George Wang, PhD
Co-Founder & Director

SIRUM | Saving Medicine. Saving Lives.

Comment on Proposed Amendments

Remain consistent with statutory provisions to prevent any unnecessary confusion in compliance with program rules

Section 442.0151 of the Health & Safety Code specifies the labeling and recordkeeping requirements for donated prepackaged prescription drugs dispensed to a recipient.

Subsection (b) of §442.0515 requires prepackaged drug labels to contain the drug's lot number and pursuant to §442.0515 (c), the record of dispensed prepackaged drugs must include the **participating provider's** lot number for that drug. As proposed, the rules require the **facility's** lot number to be on the label and in the record.

Subsection (c) of §442.0515 requires the record to include written or electronic signature of the responsible pharmacist. As currently written, the proposed amendments do not specify the option for the record to include a written or electronic signature. Additionally, the statute mandates the provider to maintain a record for those prepackaged prescriptions *dispensed* to recipients. The draft rules, as proposed, are ambiguous and we suggest mimicking the language from statute.

To remain consistent with statutory provisions and prevent any confusion in compliance with the program, we recommend the following amendments to the rules:

> (9) Redistribution of Donated Prepackaged Prescription Drugs.
> (A) A participating provider may dispense to a recipient donated prescription drugs that are prepackaged and labeled in accordance with §442.0515, Health and Safety Code, and this paragraph.
> (B) Drugs may be prepackaged in quantities suitable for distribution to a recipient only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist.
> (C) The label of a prepackaged prescription drug a participating provider dispenses to a recipient shall indicate:

(i) brand name and strength of the drug; or if no brand name, then the generic name, strength, and name of the manufacturer or distributor;
(ii) participating provider's ~~facility's~~ lot number;
(iii) participating provider's ~~facility's~~ beyond use date; and
(iv) quantity of the drug, if the quantity is greater than one.

(D) Records of prepackaged prescription drugs dispensed to a recipient ~~prepackaging~~ shall be maintained to show:
(i) name of the drug, strength, and dosage form;
(ii) participating provider's ~~facility's~~ lot number;
(iii) manufacturer or distributor;
(iv) manufacturer's lot number;
(v) manufacturer's expiration date;
(vi) quantity per prepackaged unit;
(vii) number of prepackaged units;
(viii) date packaged;
(ix) name, initials, or written or electronic signature of the prepacker; and
(x) written ~~signature~~, or electronic signature of the responsible pharmacist.

SIRUM

Fax

Date	October 27, 2023
Attn	Eamon D. Briggs, Deputy General Counsel
Company	Texas State Board of Pharmacy
Fax #	(512) 305-8061
Total # Pages **(including cover sheet)**	5

From:	George Wang, PhD
Company:	SIRUM
Phone #	650-488-7434
Email	George@sirum.org

Comments

Attached, please find comments on proposed amendments to §291.33, Concerning Operational Standards.