RULE ANALYSIS

Introduction: **THE AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS A PROPOSED RULE**

Short Title: Operational Standards.

Rule Number: §291.104

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, clarify that a Class E Pharmacy engaged in outsourcing of prescription drug order dispensing to a central fill pharmacy shall comply with §291.125, regarding centralized prescription dispensing.

TITLE 22 EXAMINING BOARDS
PART 15 TEXAS STATE BOARD OF PHARMACY
CHAPTER 291 PHARMACIES
SUBCHAPTER F NON-RESIDENT PHARMACY (CLASS E)

§ 291.104 Operational Standards.

(a) Licensing requirements.

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

(2) On initial application, the pharmacy shall follow the procedures specified in §291.1 of this title (relating to Pharmacy License Application) and then provide the following additional information specified in §560.052(c) and (f) of the Act (relating to Qualifications):

(A) evidence that the applicant holds a pharmacy license, registration, or permit issued by the state in which the pharmacy is located;

(B) the name of the owner and pharmacist-in-charge of the pharmacy for service of process;

(C) evidence of the applicant's ability to provide to the board a record of a prescription drug order dispensed by the applicant to a resident of this state not later than 72 hours after the time the board requests the record;

(D) an affidavit by the pharmacist-in-charge which states that the pharmacist has read and understands the laws and rules relating to a Class E pharmacy;

(E) proof of creditworthiness; and

(F) an inspection report issued not more than two years before the date the license application is received and conducted by the pharmacy licensing board in the state of the pharmacy's physical location.

(i) A Class E pharmacy may submit an inspection report issued by an entity other than the pharmacy licensing board of the state in which the pharmacy is physically located if the state's licensing board does not conduct inspections as follows:

(I) an individual approved by the board who is not employed by the pharmacy but acting as a consultant to inspect the pharmacy;

(II) an agent of the National Association of Boards of Pharmacy;

(III) an agent of another State Board of Pharmacy; or

(IV) an agent of an accrediting body, such as the Joint Commission on Accreditation of Healthcare Organizations.

(ii) The inspection must be substantively equivalent to an inspection conducted by the board.

(3) On renewal of a license, the pharmacy shall complete the renewal application provided by the board and, as specified in §561.0031 of the Act, provide an inspection report issued not

more than three years before the date the renewal application is received and conducted by the pharmacy licensing board in the state of the pharmacy's physical location.

(A) A Class E pharmacy may submit an inspection report issued by an entity other than the pharmacy licensing board of the state in which the pharmacy is physically located if the state's licensing board does not conduct inspections as follows:

(i) an individual approved by the board who is not employed by the pharmacy but acting as a consultant to inspect the pharmacy;

(ii) an agent of the National Association of Boards of Pharmacy;

(iii) an agent of another State Board of Pharmacy; or

(iv) an agent of an accrediting body, such as the Joint Commission on Accreditation of Healthcare Organizations.

(B) The inspection must be substantively equivalent to an inspection conducted by the board.

(4) A Class E 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).

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

(6) A Class E 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 in §291.3 of this title.

(7) A Class E pharmacy shall notify the board in writing within ten days of closing.

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

(9) 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.

(10) The board may grant an exemption from the licensing requirements of this Act on the application of a pharmacy located in a state of the United States other than this state that restricts its dispensing of prescription drugs or devices to residents of this state to isolated transactions.

(11) A Class E pharmacy engaged in the centralized dispensing of prescription drug or medication orders **or outsourcing of prescription drug order dispensing to a central fill pharmacy** shall comply with the provisions of §291.125 of this title (relating to Centralized Prescription Dispensing).

(12) A Class E pharmacy engaged in central processing of prescription drug or medication orders shall comply with the provisions of §291.123 of this title (relating to Central Prescription or Medication Order Processing).

(13) A Class E 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).

(14) Class E pharmacy personnel shall not compound sterile preparations unless the pharmacy has applied for and obtained a Class E-S pharmacy.

(15) A Class E pharmacy, which operates as a community type of pharmacy which would otherwise be required to be licensed under the Act §560.051(a)(1) (Community Pharmacy (Class A)), shall comply with the provisions of §291.31 of this title (relating to Definitions), §291.32 of this title (relating to Personnel), §291.33 of this title (relating to Operational Standards), §291.34 of this title (relating to Records), and §291.35 of this title (relating to Official Prescription Requirements), contained in Community Pharmacy (Class A); or which operates as a nuclear type of pharmacy which would otherwise be required to be licensed under the Act §560.051(a)(2) (Nuclear Pharmacy (Class B)), shall comply with the provisions of §291.51 of this title (relating to Purpose), §291.52 of this title (relating to Definitions), §291.53 of this title (relating to Personnel), §291.54 of this title (relating to Operational Standards), and §291.55 of this title (relating to Records), contained in Nuclear Pharmacy (Class B), to the extent such sections are applicable to the operation of the pharmacy.

(b) Prescription dispensing and delivery.

(1) General.

(A) All prescription drugs and/or devices shall be dispensed and delivered safely and accurately as prescribed.

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

(C) The pharmacy shall utilize a delivery system which is designed to assure that the drugs are delivered to the appropriate patient.

(D) All pharmacists shall exercise sound professional judgment with respect to the accuracy and authenticity of any prescription drug order they dispense. If the pharmacist questions the accuracy or authenticity of a prescription drug order, he/she shall verify the order with the practitioner prior to dispensing.

(E) Prior to dispensing a prescription, pharmacists shall determine, in the exercise of sound professional judgment, that the prescription is a valid prescription. A pharmacist may not dispense a prescription drug if the pharmacist knows or should have known that the prescription was issued on the basis of an Internet-based or telephonic consultation without a valid patient-practitioner relationship.

(F) Subparagraph (E) of this paragraph does not prohibit a pharmacist from dispensing a prescription when a valid patient-practitioner relationship is not present in an emergency situation (e.g. a practitioner taking calls for the patient's regular practitioner).

(2) Drug regimen review.

(A) 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) inappropriate drug utilization;

(ii) therapeutic duplication;

(iii) drug-disease contraindications;

(iv) drug-drug interactions;

(v) incorrect drug dosage or duration of drug treatment;

(vi) drug-allergy interactions; and

(vii) clinical abuse/misuse.

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

(3) 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) the 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 in person unless the patient or patient's agent is not at the pharmacy or a specific communication barrier prohibits such oral communication; and

(iv) reinforced with written information. 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 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 product 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 orally provide drug information to a patient or patient's agent and answer questions concerning prescription drugs. Non-pharmacist personnel may not ask questions of a patient or patient's agent which are intended to screen and/or limit interaction with the pharmacist.

(D) 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.

(E) 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 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)."

(F) 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).

(G) Upon delivery of a refill prescription, a pharmacist shall ensure that the patient or patient's agent is offered information about the refilled prescription and that a pharmacist is available to discuss the patient's prescription and provide information.

(H) 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.

(4) Labeling. At the time of delivery, the dispensing container shall bear a label that contains the following information:

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

(B) 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;

(C) 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

(D) any other information that is required by the pharmacy or drug laws or rules in the state in which the pharmacy is located.

(c) Substitution requirements.

(1) Unless compliance would violate the pharmacy or drug laws or rules in the state in which the pharmacy is located a pharmacist in a Class E pharmacy 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) and §309.7 of this title (relating to Dispensing Responsibilities).

(2) The pharmacy must include on the prescription order form completed by the patient or the patient's agent information that clearly and conspicuously:

(A) states that if a less expensive generically equivalent drug or interchangeable biological product is available for the brand prescribed, the patient or the patient's agent may choose between the generically equivalent drug or interchangeable biological product and the brand prescribed; and

(B) allows the patient or the patient's agent to indicate the choice of the generically equivalent drug or interchangeable biological product or the brand prescribed.

(d) 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 subsection does not apply to generic substitution. For generic substitution, see the requirements of subsection (c) of this section.

(1) 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:

(A) a description of the change;

(B) the reason for the change;

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

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

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

(A) the date of the notification;

(B) the method of notification;

(C) a description of the change; and

(D) the reason for the change.

(e) Transfer of Prescription Drug Order Information. Unless compliance would violate the pharmacy or drug laws or rules in the state in which the pharmacy is located, a pharmacist in a Class E pharmacy may not refuse to transfer prescriptions to another pharmacy that is making the transfer request on behalf of the patient. The transfer of original prescription information must be done within four business hours of the request.

(f) Prescriptions for Schedules II - V controlled substances. Unless compliance would violate the pharmacy or drug laws or rules in the state in which the pharmacy is located, a pharmacist in a Class E pharmacy who dispenses a prescription for a Schedules II - V controlled substance for a resident of Texas shall electronically send the prescription information to the Texas State Board of Pharmacy as specified in §315.6 of this title (relating to Pharmacy Responsibility - Electronic Reporting) not later than the next business day after the prescription is dispensed.