RULE REVIEW ANALYSIS

Introduction: **THIS RULE REVIEW IS SUBMITTED TO THE BOARD FOR CONSIDERATION AS A PROPOSED REVIEW**

Short Title: Pharmacies

Rule Number: Chapter 291, Subchapter F

Statutory Authority: Government Code, §2001.039, added by Acts 1999, 76th Legislature, Chapter 1499, Article 1, Section 1.11.

Background: Review of these sections follow the Board's rule review plan.

TITLE 22 EXAMINING BOARDS

PART 15 TEXAS STATE BOARD OF PHARMACY

CHAPTER 291 PHARMACIES

SUBCHAPTER F NON-RESIDENT PHARMACY (CLASS E)

§291.101 Purpose

(a) The purpose of these rules is to provide standards for the operation of non-resident pharmacies (Class E) which dispense a prescription drug or device under a prescription drug order and deliver the drug or device to a patient in this state, by the United States mail, a common carrier, or a delivery service.

(b) These rules are in accordance with §554.051(a) and (b) of the Act which permit the board to make rules concerning the operation of licensed pharmacies in this state applicable to pharmacies licensed by the board that are located in another state. The board has determined that these rules are necessary to protect the health and welfare of the citizens of this state.

(c) Unless compliance would violate the pharmacy or drug laws or rules in the state in which the pharmacy is located, Class E Pharmacies are required to comply with the provisions of §§291.101-291.105 of this chapter (relating to Purpose, Definitions, Personnel, Operational Standards, and Records).

§291.102 Definitions

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

(1) Act--The Texas Pharmacy Act, Chapters 551-566, Occupations Code, as amended.

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

(A) to the correct patient (or agent of the patient) for whom the drug or device was prescribed;

(B) with the correct drug in the correct strength, quantity, and dosage form ordered by the practitioner; and

(C) with correct labeling (including directions for use) as ordered by the practitioner. Provided, however, that nothing herein shall prohibit pharmacist substitution if substitution is conducted in strict accordance with applicable laws and rules, including Subchapter A of Chapter 562 of the Texas Pharmacy Act relating to Prescription and Substitution Requirements.

(3) Board--The Texas State Board of Pharmacy.

(4) Class E pharmacy license or non-resident pharmacy license--a license issued to a pharmacy located in another state whose primary business is to:

(A) dispense a prescription drug or device under a prescription drug order; and

(B) to deliver the drug or device to a patient, including a patient in this state, by the United States mail, common carrier, or delivery service.

(5) Confidential Record--Any health related record, including a patient medication record, prescription drug order, or medication order that:

(A) contains information that identifies an individual; and

(B) is maintained by a pharmacy or pharmacist.

(6) Deliver or delivery--The actual, constructive, or attempted transfer of a prescription drug or device or controlled substance from one person to another, whether or not for a consideration.

(7) Dispense--Preparing, packaging, compounding, or labeling, in the course of professional practice, a prescription drug or device for delivery to an ultimate user or the user's agent under a practitioner's lawful order.

(8) Distribute--To deliver a prescription drug or device other than by administering or dispensing.

(9) Generically equivalent--A drug that is "pharmaceutically equivalent" and "therapeutically equivalent" to the drug prescribed.

(10) New prescription drug order--A prescription drug order that:

(A) has not been dispensed to the patient in the same strength and dosage form by this pharmacy within the last year;

(B) is transferred from another pharmacy; and/or

(C) is a discharge prescription drug order. (Note: furlough prescription drug orders are not considered new prescription drug orders.)

(11) Pharmaceutically equivalent--Drug products which have identical amounts of the same active chemical ingredients in the same dosage form and which meet the identical compendial or other applicable standards of strength, quality, and purity according to the United States Pharmacopoeia or other nationally recognized compendium.

(12) Pharmacist--For the purpose of this subchapter, a person licensed to practice pharmacy in the state where the Class E pharmacy is located.

(13) Pharmacist-in-charge--The pharmacist designated on a pharmacy license as the pharmacist who has the authority or responsibility for a pharmacy's compliance with statutes and rules pertaining to the practice of pharmacy.

(14) Practitioner--

(A) a person licensed or registered to prescribe, distribute, administer, or dispense a prescription drug or device in the course of professional practice in this state, including a physician, dentist, podiatrist, or veterinarian but excluding a person licensed under the Act;

(B) a person licensed by another state, Canada, or the United Mexican States in a health field in which, under the law of this state, a license holder in this state may legally prescribe a dangerous drug; or

(C) a person practicing in another state and licensed by another state as a physician, dentist, veterinarian, or podiatrist, who has a current federal Drug Enforcement Administration registration number and who may legally prescribe a Schedule II, III, IV, or V controlled substance, as specified under Chapter 481, Health and Safety Code, in that other state.

(15) Prescription drug order--an order from a practitioner or a practitioner's designated agent to a pharmacist for a drug or device to be dispensed.

(16) Therapeutically equivalent--Pharmaceutically equivalent drug products which, when administered in the same amounts, will provide the same therapeutic effect, identical in duration and intensity.

§291.103 Personnel

As specified in §562.101(f) of the Act (relating to Supervision of Pharmacy), a Class E pharmacy shall be under the continuous on-site supervision of a pharmacist and shall designate one pharmacist licensed to practice pharmacy by the regulatory or licensing agency of the state in which the Class E pharmacy is located to serve as the pharmacist-in-charge of the Class E pharmacy license.

§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 §561.031 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 within ten days of the change and file for an amended license 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 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) Prior to August 31, 2014, a Class E pharmacy engaged in the compounding of sterile preparations shall comply with the provisions of §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).

(15) Effective August 31, 2014, a Class E pharmacy shall not compound sterile preparations unless the pharmacy has applied for and obtained a Class E-S 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:

(i) shall be provided with each new prescription drug order;

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

(iii) shall be 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) shall be reinforced with written information. The following is applicable concerning this written information:

(I) Written information designed for the consumer, such as the USP DI patient information leaflets, shall be provided.

(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) Effective January 1, 2011, 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) effective June 1, 2010, 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 manufacture, 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) effective January 1, 2011, 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) Generic Substitution.

(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 product and shall comply with the provisions of §309.3 of this title (relating to Generic Substitution) 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 is available for the brand prescribed, the patient or the patient's agent may choose between the generically equivalent drug and the brand prescribed; and

(B) allows the patient or the patient's agent to indicate the choice of the generically equivalent drug 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.

(f) Prescriptions for Schedule 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 Schedule II - V controlled substance issued by a prescriber registered with the Texas Department of Public Safety shall:

(1) mail a copy of the prescription to the Texas Department of Public Safety, Texas Prescription Program, P.O. Box 4087, Austin, Texas 78773 within 7 days of dispensing; or

(2) electronically send the prescription information to the Texas Department of Public Safety per their requirements for electronic submissions within 7 days of dispensing

§291.105 Records

(a) Maintenance of records.

(1) Every record required to be kept under this section shall be:

(A) kept by the pharmacy and be available, for at least two years from the date of such record, for inspecting and copying by the board or its representative, and other authorized local, state, or federal law enforcement agencies; and

(B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in a mutually agreeable electronic format if specifically requested by the board or its representative. Failure to provide the records set out in this section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(2) Records, except when specifically required to be maintained in original or hard-copy form, may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided;

(A) the records maintained in the alternative system contain all of the information required on the manual record; and

(B) the data processing system is capable of producing a hard copy of the record upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.

(b) Auto-Refill Programs. A pharmacy may use a program that automatically refills prescriptions that have existing refills available in order to improve patient compliance with and adherence to prescribed medication therapy. The following is applicable in order to enroll patients into an auto-refill program.

(1) Notice of the availability of an auto-refill program shall be given to the patient or patient's agent, and the patient or patient's agent must affirmatively indicate that they wish to enroll in such a program and the pharmacy shall document such indication.

(2) The patients or patient's agent shall have the option to withdraw from such a program at any time.

(3) Auto-refill programs may be used for refills of dangerous drugs, and schedule IV and V controlled substances. Schedule II and III controlled substances may not be dispensed by an auto-refill program.

(4) As is required for all prescriptions, a drug regimen review shall be completed on all prescriptions filled as a result of the auto-refill program. Special attention shall be noted for drug regimen review warnings of duplication of therapy and all such conflicts shall be resolved with the prescribing practitioner prior to refilling the prescription.

(c) Civil litigation and complaint records. A Class E pharmacy shall keep a permanent record of:

(1) any civil litigation commenced against the pharmacy by a Texas resident; and

(2) complaints that arise out of a prescription for a Texas resident lost during delivery.

§291.106 Pharmacies Compounding Sterile Preparations (Class E-S)

Licensing requirements. A non-resident pharmacy engaged in the compounding of sterile preparations shall be licensed as a Class E-S pharmacy.

(1) A Class E-S 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) A Class E-S license may not be issued unless the pharmacy has been inspected by the board or its designee to ensure the pharmacy meets the requirements as specified in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations). A Class E-S pharmacy shall reimburse the board for all expenses, including travel, related to the inspection of the Class E-S pharmacy.

(3) On initial application, the pharmacy shall follow the procedures specified in §291.1 of this title 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; and

(E) proof of creditworthiness.

(4) A Class E-S pharmacy may not renew a pharmacy license unless the pharmacy has been inspected by the board or its designee within the last two years.

(5) A Class E-S 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).

(6) A Class E-S pharmacy which changes location and/or name shall notify the board within ten days of the change and file for an amended license as specified in §291.3 of this title.

(7) A Class E-S 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.

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

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

(10) 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.

(11) 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.

(12) A Class E-S pharmacy engaged in the centralized dispensing of prescription drug or medication orders shall comply with the provisions of §291.125 of this title (relating to Centralized Prescription Dispensing).

(13) A Class E-S 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).

(14) A Class E-S 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).

(15) A Class E-S pharmacy engaged in the compounding of sterile preparations shall comply with the provisions of §291.133 of this title.