RULE ANALYSIS

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

Short Title: Written Agreements

Rule Numbers: §§291.131, 291.133

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 the requirements regarding written agreements for supplying compounded preparations for office use and make formatting changes.

TITLE 22 EXAMINING BOARDS
PART 15 TEXAS STATE BOARD OF PHARMACY
CHAPTER 291 PHARMACIES
SUBCHAPTER G SERVICES PROVIDED BY PHARMACIES

§291.131 Pharmacies Compounding Non-Sterile Preparations

(a) – (e) (No change.)

(f) Office Use Compounding and Distribution of Compounded Preparations to Class C Pharmacies or Veterinarians in Accordance With §563.054 of the Act.

(1) General.

(A) A pharmacy may dispense and deliver a reasonable quantity of a compounded preparation to a practitioner for office use by the practitioner in accordance with this subsection.

(B) A Class A [~~(Community)~~] pharmacy is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute non-sterile compounded preparations to a Class C [~~(Institutional)~~] pharmacy.

(C) A Class C [~~(Institutional)~~] pharmacy is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute non-sterile compounded preparations that the Class C pharmacy has compounded for other Class C pharmacies under common ownership.

(D) To dispense and deliver a compounded preparation under this subsection, a pharmacy must:

(i) verify the source of the raw materials to be used in a compounded drug;

(ii) comply with applicable United States Pharmacopoeia guidelines, including the testing requirements, and the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191);

(iii) enter into a written agreement with a practitioner for the practitioner's office use of a compounded preparation;

(iv) comply with all applicable competency and accrediting standards as determined by the board; and

(v) comply with the provisions of this subsection.

(2) Written Agreement. A pharmacy that provides non-sterile compounded preparations to practitioners for office use or to another pharmacy shall enter into a written agreement with the practitioner or pharmacy. The written agreement shall:

(A) address acceptable standards of practice for a compounding pharmacy and a practitioner and receiving pharmacy that enter into the agreement including a statement that the compounded preparations may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity except as authorized by §563.054 of the Act;

(B) **state that** [~~require~~] the practitioner or receiving pharmacy **should** [~~to~~] include on a **separate log or in a** patient's chart, medication order, or medication administration record, the lot number and beyond-use date of a compounded preparation administered to a patient; and

(C) describe the scope of services to be performed by the pharmacy and practitioner or receiving pharmacy, including a statement of the process for:

(i) a patient to report an adverse reaction or submit a complaint; and

(ii) the pharmacy to recall batches of compounded preparations.

(3) Recordkeeping.

(A) Maintenance of Records.

(i) Records of orders and distribution of non-sterile compounded preparations to a practitioner for office use or to a Class C ~~[(Institutional)]~~ pharmacy for administration to a patient shall:

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

(II) maintained separately from the records of products dispensed pursuant to a prescription or medication order; and

(III) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy or its representative. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format. Failure to provide the records set out in this subsection, either on site or within 72 hours for whatever reason, constitutes prima facie evidence of failure to keep and maintain records.

(ii) Records may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided 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) Orders. The pharmacy shall maintain a record of all non-sterile compounded preparations ordered by a practitioner for office use or by a Class C pharmacy for administration to a patient. The record shall include the following information:

(i) date of the order;

(ii) name, address, and phone number of the practitioner who ordered the preparation and if applicable, the name, address and phone number of the Class C pharmacy ordering the preparation; and

(iii) name, strength, and quantity of the preparation ordered.

(C) Distributions. The pharmacy shall maintain a record of all non-sterile compounded preparations distributed pursuant to an order to a practitioner for office use or by a Class C pharmacy for administration to a patient. The record shall include the following information:

(i) date the preparation was compounded;

(ii) date the preparation was distributed;

(iii) name, strength and quantity in each container of the preparation;

(iv) pharmacy's lot number;

(v) quantity of containers shipped; and

(vi) name, address, and phone number of the practitioner or Class C pharmacy to whom the preparation is distributed.

(D) Audit Trail.

(i) The pharmacy shall store the order and distribution records of preparations for all non-sterile compounded preparations ordered by and or distributed to a practitioner for office use or by a Class C pharmacy for administration to a patient in such a manner as to be able to provide a audit trail for all orders and distributions of any of the following during a specified time period.

(I) any strength and dosage form of a preparation (by either brand or generic name or both);

(II) any ingredient;

(III) any lot number;

(IV) any practitioner;

(V) any facility; and

(VI) any pharmacy, if applicable.

(ii) The audit trail shall contain the following information:

(I) date of order and date of the distribution;

(II) practitioner's name, address, and name of the Class C pharmacy, if applicable;

(III) name, strength and quantity of the preparation in each container of the preparation;

(IV) name and quantity of each active ingredient;
(V) quantity of containers distributed; and
(VI) pharmacy's lot number;
(4) Labeling. The pharmacy shall affix a label to the preparation containing the following information:
(A) name, address, and phone number of the compounding pharmacy;
(B) the statement: "For Institutional or Office Use Only--Not for Resale"; or if the preparation is distributed to a veterinarian the statement: "Compounded Preparation";
(C) name and strength of the preparation or list of the active ingredients and strengths;
(D) pharmacy's lot number;
(E) beyond-use date as determined by the pharmacist using appropriate documented criteria;
(F) quantity or amount in the container;
(G) appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and
(H) device-specific instructions, where appropriate.

(g) (No change.)

§291.133 Pharmacies Compounding Sterile Preparations

(a) – (e) (No change.)

(f) Office Use Compounding and Distribution of Sterile Compounded Preparations
(1) General.
(A) A pharmacy may compound, dispense, deliver, and distribute a compounded sterile preparation as specified in Subchapter D, Texas Pharmacy Act Chapter 562.
(B) A Class A-S pharmacy is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute sterile compounded preparations to a Class C or Class C-S pharmacy.
(C) A Class C-S pharmacy is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute sterile compounded preparations that the Class C-S pharmacy has compounded for other Class C or Class C-S pharmacies under common ownership.
(D) To compound and deliver a compounded preparation under this subsection, a pharmacy must:
(i) verify the source of the raw materials to be used in a compounded drug;
(ii) comply with applicable United States Pharmacopoeia guidelines, including the testing requirements, and the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191);
(iii) enter into a written agreement with a practitioner for the practitioner's office use of a compounded preparation;
(iv) comply with all applicable competency and accrediting standards as determined by the board; and
(v) comply with the provisions of this subsection.
(E) This subsection does not apply to Class B pharmacies compounding sterile radiopharmaceuticals that are furnished for departmental or physicians' use if such authorized users maintain a Texas radioactive materials license.
(2) Written Agreement. A pharmacy that provides sterile compounded preparations to practitioners for office use or to another pharmacy shall enter into a written agreement with the practitioner or pharmacy. The written agreement shall:

(A) address acceptable standards of practice for a compounding pharmacy and a practitioner and receiving pharmacy that enter into the agreement including a statement that the compounded drugs may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity except to a veterinarian as authorized by §563.054 of the Act;

(B)) **state that** [~~require~~] the practitioner or receiving pharmacy **should** [~~to~~] include on a **separate log, or in a** patient's chart, medication order, or medication administration record, the lot number and beyond-use date of a compounded preparation administered to a patient; and

(C) describe the scope of services to be performed by the pharmacy and practitioner or receiving pharmacy, including a statement of the process for:

(i) a patient to report an adverse reaction or submit a complaint; and

(ii) the pharmacy to recall batches of compounded preparations.

(3) Recordkeeping.

(A) Maintenance of Records.

(i) Records of orders and distribution of sterile compounded preparations to a practitioner for office use or to an institutional pharmacy for administration to a patient shall:

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

(II) maintained separately from the records of preparations dispensed pursuant to a prescription or medication order; and

(III) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy or its representative. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format. Failure to provide the records set out in this subsection, either on site or within 72 hours for whatever reason, constitutes prima facie evidence of failure to keep and maintain records.

(ii) Records may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided 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) Orders. The pharmacy shall maintain a record of all sterile compounded preparations ordered by a practitioner for office use or by an institutional pharmacy for administration to a patient. The record shall include the following information:

(i) date of the order;

(ii) name, address, and phone number of the practitioner who ordered the preparation and if applicable, the name, address and phone number of the institutional pharmacy ordering the preparation; and

(iii) name, strength, and quantity of the preparation ordered.

(C) Distributions. The pharmacy shall maintain a record of all sterile compounded preparations distributed pursuant to an order to a practitioner for office use or by an institutional pharmacy for administration to a patient. The record shall include the following information:

(i) date the preparation was compounded;

(ii) date the preparation was distributed;

(iii) name, strength and quantity in each container of the preparation;

(iv) pharmacy's lot number;

(v) quantity of containers shipped; and

(vi) name, address, and phone number of the practitioner or institutional pharmacy to whom the preparation is distributed.

(D) Audit Trail.

(i) The pharmacy shall store the order and distribution records of preparations for all sterile compounded preparations ordered by and or distributed to a practitioner for office use or by a

pharmacy licensed to compound sterile preparations for administration to a patient in such a manner as to be able to provide an audit trail for all orders and distributions of any of the following during a specified time period:

(I) any strength and dosage form of a preparation (by either brand or generic name or both);

(II) any ingredient;

(III) any lot number;

(IV) any practitioner;

(V) any facility; and

(VI) any pharmacy, if applicable.

(ii) The audit trail shall contain the following information:

(I) date of order and date of the distribution;

(II) practitioner's name, address, and name of the institutional pharmacy, if applicable;

(III) name, strength and quantity of the preparation in each container of the preparation;

(IV) name and quantity of each active ingredient;

(V) quantity of containers distributed; and

(VI) pharmacy's lot number.

(4) Labeling. The pharmacy shall affix a label to the preparation containing the following information:

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

(B) the statement: "For Institutional or Office Use Only--Not for Resale"; or if the preparation is distributed to a veterinarian the statement: "Compounded Preparation";

(C) name and strength of the preparation or list of the active ingredients and strengths;

(D) pharmacy's lot number;

(E) beyond-use date as determined by the pharmacist using appropriate documented criteria;

(F) quantity or amount in the container;

(G) appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and

(H) device-specific instructions, where appropriate.

(g) (No change.)