RULE ANALYSIS

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

Short Title: Prescription Records

Rule Numbers: §291.34

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 prescriptions must be transferred by the close of the following business day; update the rules regarding distribution to include dangerous drugs; and implement provisions of HB 751 regarding interchangeable biological products.

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

§291.34 Records

(a) (No change.)

(b) Prescriptions.

(1) – (6) (No change.)

(7) Prescription drug order information.

(A) (No change.)

(B) At the time of dispensing, a pharmacist is responsible for documenting the following information on either the original hard copy prescription or in the pharmacy's data processing system:

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

(ii) initials or identification code of the dispensing pharmacist;

(iii) initials or identification code of the pharmacy technician or pharmacy technician trainee performing data entry of the prescription, if applicable;

(iv) quantity dispensed, if different from the quantity prescribed;

(v) date of dispensing, if different from the date of issuance; and

(vi) brand name or manufacturer of the drug **or biological** product actually dispensed, if the drug was prescribed by generic name **or interchangeable biological name** or if a drug **or interchangeable biological** product other than the one prescribed was dispensed pursuant to the provisions of the Act, Chapters 562 and 563.

(8) – (10) (No change.)

(c) – (f) (No change.)

(g) Transfer of prescription drug order information. For the purpose of initial or refill dispensing, the transfer of original prescription drug order information is permissible between pharmacies, subject to the following requirements.

(1) The transfer of original prescription drug order information for controlled substances listed in Schedule III, IV, or V is permissible between pharmacies on a one-time basis only. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

(2) The transfer of original prescription drug order information for dangerous drugs is permissible between pharmacies without limitation up to the number of originally authorized refills.

(3) The transfer is communicated orally by telephone or via facsimile directly by a pharmacist to another pharmacist; by a pharmacist to a student-intern, extended-intern, or resident-intern; or by a student-intern, extended-intern, or resident-intern to another pharmacist.

(4) Both the original and the transferred prescription drug orders are maintained for a period of two years from the date of last refill.

(5) The individual transferring the prescription drug order information shall ensure the following occurs:

(A) write the word "void" on the face of the invalidated prescription or the prescription is voided in the data processing system;

(B) record the name, address, if for a controlled substance, the DEA registration number of the pharmacy to which it was transferred, and the name of the receiving individual on the reverse of the invalidated prescription or stored with the invalidated prescription drug order in the data processing system;

(C) record the date of the transfer and the name of the individual transferring the information; and

(D) if the prescription is transferred electronically, provide the following information:

(i) date of original dispensing and prescription number;

(ii) number of refills remaining and if a controlled substance, the date(s) and location(s) of previous refills;

(iii) name, address, and if a controlled substance, the DEA registration number of the transferring pharmacy;

(iv) name of the individual transferring the prescription; and

(v) if a controlled substance, name, address and DEA registration number, and prescription number from the pharmacy that originally dispensed the prescription, if different.

(6) The individual receiving the transferred prescription drug order information shall:

(A) write the word "transfer" on the face of the prescription or the prescription record indicates the prescription was a transfer; and

(B) reduce to writing all of the information required to be on a prescription as specified in subsection (b)(7) of this section (relating to Prescriptions) and including the following information;

(i) date of issuance and prescription number;

(ii) original number of refills authorized on the original prescription drug order;

(iii) date of original dispensing;

(iv) number of valid refills remaining and if a controlled substance, date(s) and location(s) of previous refills;

(v) name, address, and if for a controlled substance, the DEA registration number of the transferring pharmacy;

(vi) name of the individual transferring the prescription; and

(vii) name, address, and if for a controlled substance, the DEA registration number, of the pharmacy that originally dispensed the prescription, if different; or

(C) if the prescription is transferred electronically, create an electronic record for the prescription that includes the receiving pharmacist's name and all of the information transferred with the prescription including all of the information required to be on a prescription as specified in subsection (b)(7) of this section (relating to Prescriptions) and the following:

(i) date of original dispensing;

(ii) number of refills remaining and if a controlled substance, the prescription number(s), date(s) and location(s) of previous refills;

(iii) name, address, and if for a controlled substance, the DEA registration number;

(iv) name of the individual transferring the prescription; and

(v) name, address, and if for a controlled substance, the DEA registration number, of the pharmacy that originally filled the prescription.

(7) Both the individual transferring the prescription and the individual receiving the prescription must engage in confirmation of the prescription information by such means as:

(A) the transferring individual faxes the hard copy prescription to the receiving individual; or

(B) the receiving individual repeats the verbal information from the transferring individual and the transferring individual verbally confirms that the repeated information is correct.

(8) Pharmacies transferring prescriptions electronically shall comply with the following:

(A) Prescription drug orders may not be transferred by non-electronic means during periods of downtime except on consultation with and authorization by a prescribing practitioner; provided however, during downtime, a hard copy of a prescription drug order may be made available for informational purposes only, to the patient or a pharmacist, and the prescription may be read to a pharmacist by telephone.

(B) The original prescription drug order shall be invalidated in the data processing system for purposes of filling or refilling, but shall be maintained in the data processing system for refill history purposes.

(C) If the data processing system does not have the capacity to store all the information as specified in paragraphs (5) and (6) of this subsection, the pharmacist is required to record this information on the original or transferred prescription drug order.

(D) The data processing system shall have a mechanism to prohibit the transfer or refilling of controlled substance prescription drug orders that have been previously transferred.

(E) Pharmacies electronically accessing the same prescription drug order records may electronically transfer prescription information if the following requirements are met.

(i) The original prescription is voided and the pharmacies' data processing systems shall store all the information as specified in paragraphs (5) and (6) of this subsection.

(ii) Pharmacies not owned by the same **entity** [~~person~~] may electronically access the same prescription drug order records, provided the owner, chief executive officer, or designee of each pharmacy signs an agreement allowing access to such prescription drug order records.

(iii) An electronic transfer between pharmacies may be initiated by a pharmacist intern, pharmacy technician, or pharmacy technician trainee acting under the direct supervision of a pharmacist.

(9) An individual may not refuse to transfer original prescription information to another individual who is acting on behalf of a patient and who is making a request for this information as specified in this subsection. The transfer of original prescription information must be **completed by the close of business the day following the request.** [~~done in a timely manner.~~]

(10) When transferring a compounded prescription, a pharmacy is required to provide all of the information regarding the compounded preparation including the formula unless the formula is patented or otherwise protected, in which case, the transferring pharmacy shall, at a minimum, provide the quantity or strength of all of the active ingredients of the compounded preparation.

(11) [~~(10)~~] The electronic transfer of multiple or bulk prescription records between two pharmacies is permitted provided:

(A) a record of the transfer as specified in paragraph (5) of this section is maintained by the transferring pharmacy;

(B) the information specified in paragraph (6) of this subsection is maintained by the receiving pharmacy; and

(C) in the event that the patient or patient's agent is unaware of the transfer of the prescription drug order record, the transferring pharmacy must notify the patient or patient's agent of the transfer and must provide the patient or patient's agent with the telephone number of the pharmacy receiving the multiple or bulk prescription drug order records.

(h) Distribution of **prescription drugs** [~~controlled substa~~nces] to another registrant. A pharmacy may distribute **prescription drugs** [~~controlled substances~~] to a practitioner, another pharmacy, or other registrant, without being registered to distribute, under the following conditions.

(1) **If the distribution is for a controlled substance, the** [~~The~~] registrant to whom the controlled substance is to be distributed is registered under the Controlled Substances Act to **possess** [~~dispense~~] that controlled substance.

(2) The total number of dosage units of **prescription drugs** [~~controlled substances~~] distributed by a pharmacy may not exceed 5.0% of all **prescription drugs** [~~controlled substances~~] dispensed and distributed by the pharmacy during the 12-month period in which the pharmacy is registered; if at any time it does exceed 5.0%, the pharmacy is required to obtain an additional registration to distribute **prescription drugs** [~~controlled substances~~].

(3) If the distribution is for a **dangerous drug, a record shall be maintained that indicates the:**

(A) date of distribution;

(B) name, strength, and quantity of dangerous drug distributed;

(C) name and address of the distributing pharmacy; and

(D) name and address of the pharmacy, practitioner, or other registrant to whom the dangerous drugs are distributed.

(4) If the distribution is for a Schedule III, IV, or V controlled substance, a record shall be maintained that indicates **the**:

(A) [~~the actual~~] date of distribution;

(B) [~~the~~] name, strength, and quantity of controlled substances distributed;

(C) [~~the~~] name, address, and DEA registration number of the distributing pharmacy; and

(D) [~~the~~] name, address, and DEA registration number of the pharmacy, practitioner, or other registrant to whom the controlled substances are distributed.

(5) [~~(4)~~] If the distribution is for a Schedule II controlled substance, the following is applicable.

(A) The pharmacy, practitioner, or other registrant who is receiving the controlled substances shall issue Copy 1 and Copy 2 of a DEA order form (DEA 222) to the distributing pharmacy.

(B) The distributing pharmacy shall:

(i) complete the area on the DEA order form (DEA 222) titled "To Be Filled in by Supplier";

(ii) maintain Copy 1 of the DEA order form (DEA 222) at the pharmacy for two years; and

(iii) forward Copy 2 of the DEA order form (DEA 222) to the Divisional Office of the Drug Enforcement Administration.

(i) Other records. Other records to be maintained by a pharmacy:

(1) a [~~permanent~~] log of the initials or identification codes that will identify each pharmacist, pharmacy technician, and pharmacy technician trainee**, who is involved in the dispensing process, in the pharmacy's data processing system,** [~~by name performing data entry of prescription information~~] (the initials or identification code shall be unique to ensure that each individual can be identified, i.e., identical initials or identification codes shall not be used)**. Such log shall be maintained at the pharmacy for at least seven years from the date of the transaction**;

(2) Copy 3 of DEA order form (DEA 222) that has been properly dated, initialed, and filed, and all copies of each unaccepted or defective order form and any attached statements or other documents and/or for each order filled using the DEA Controlled Substance Ordering System (CSOS) the original signed order and all linked records for that order;

(3) a [~~hard~~] copy of the power of attorney to sign DEA 222 order forms (if applicable);

(4) suppliers' invoices of dangerous drugs and controlled substances; a pharmacist shall verify that the controlled drugs listed on the invoices were actually received by clearly recording his/her initials and the actual date of receipt of the controlled substances;

(5) suppliers' credit memos for controlled substances and dangerous drugs;

(6) a [~~hard~~] copy of inventories required by §291.17 of this title (relating to Inventory Requirements);

(7) [~~hard copy~~] reports of surrender or destruction of controlled substances and/or dangerous drugs to an appropriate state or federal agency;

(8) [~~a hard copy of~~] the Schedule V nonprescription register book;

(9) records of distribution of controlled substances and/or dangerous drugs to other pharmacies, practitioners, or registrants; and

(10) a [~~hard~~] copy of any notification required by the Texas Pharmacy Act or the sections in this chapter, including, but not limited to, the following:

(A) reports of theft or significant loss of controlled substances to DEA, Department of Public Safety, and the board;

(B) notifications of a change in pharmacist-in-charge of a pharmacy; and

(C) reports of a fire or other disaster that may affect the strength, purity, or labeling of drugs, medications, devices, or other materials used in the diagnosis or treatment of injury, illness, and disease

(j) – (l) (No change.)