RULE ANALYSIS

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

Short Title: Records.

Rule Number: §291.75

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, update references to DEA 222 form requirements to be consistent with federal regulations.

The Board reviewed and voted to propose the amendments during the February 2, 2021 meeting. The proposed amendments were published in the April 2, 2021, issue of the *Texas Register* at 46 TexReg 2155.

TITLE 22. EXAMINING BOARDS
PART 15. TEXAS STATE BOARD OF PHARMACY
CHAPTER 291. PHARMACIES
SUBCHAPTER D. INSTITUTIONAL PHARMACY (CLASS C)

§291.75. Records.

The Texas State Board of Pharmacy proposes amendments to §291.75, concerning Records. The amendments, if adopted, will update references to DEA 222 form requirements to be consistent with federal regulations.

Allison Vordenbaumen Benz, R.Ph., M.S., 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. Ms. Benz 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 ensure consistency between Board rules and federal regulations. 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, Ms. Benz 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 not limit or expand an existing regulation;

(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 Megan G. Holloway, Deputy General Counsel, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-500, Austin, Texas, 78701, FAX (512) 305-8061. Comments must be received by 5:00 p.m., May 4, 2021.

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.

§291.75. Records.

(a) Maintenance of records.

(1) Every inventory or other record required to be kept under the provisions of §291.71 of this title (relating to Purpose), §291.72 of this title (relating to Definitions), §291.73 of this title (relating to Personnel), §291.74 of this title (relating to Operational Standards), and this section contained in Institutional Pharmacy (Class C) shall be:

(A) kept by the institutional pharmacy and be available, for at least two years from the date of such inventory or 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 board. 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 subsection, 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 of controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy.

(3) Records of controlled substances listed in Schedules III - V shall be maintained separately or readily retrievable from all other records of the pharmacy. For purposes of this subsection, readily retrievable means that the controlled substances shall be asterisked, redlined, or in some other manner readily identifiable apart from all other items appearing on the record.

(4) 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 or direct imaging system, provided:

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

(B) the alternative data retention 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) Outpatient records.

(1) Outpatient records shall be maintained as provided in §291.34 (relating to Records), and §291.35 (relating to Official Prescription Requirements), in chapter 291, subchapter B of this title.

(2) Outpatient prescriptions, including, but not limited to, furlough and discharge prescriptions, that are written by a practitioner must be written on a form which meets the requirements of §291.34(b)(7)(A) of this title. Medication order forms or copies thereof do not meet the requirements for outpatient forms.

(3) Controlled substances listed in Schedule II must be written on an official prescription form in accordance with the Texas Controlled Substances Act, §481.075, and rules promulgated pursuant to the Texas Controlled Substances Act, unless exempted by chapter 315 of this title (relating to Controlled Substances). Outpatient prescriptions for Schedule II controlled substances that are exempted from the official prescription requirement must be manually signed by the practitioner.

(c) Patient records.

(1) Original medication orders.

(A) Each original medication order shall bear the following information:

(i) patient name and room number or identification number;

(ii) drug name, strength, and dosage form;

(iii) directions for use;

(iv) date; and

(v) signature or electronic signature of the practitioner or that of his or her authorized agent.

(B) Original medication orders shall be maintained with the medication administration records of the patients.

(2) Patient medication records (PMR). A patient medication record shall be maintained for each patient of the facility. The PMR shall contain at a minimum the following information:

(A) Patient information:

(i) patient name and room number or identification number;

(ii) gender, and date of birth or age;

(iii) weight and height;

(iv) known drug sensitivities and allergies to drugs and/or food;

(v) primary diagnoses and chronic conditions;

(vi) primary physician; and

(vii) other drugs the patient is receiving; and

(B) Medication order information:

(i) date of distribution;

(ii) drug name, strength, and dosage form; and

(iii) directions for use.

(3) Controlled substances records. Controlled substances records shall be maintained as follows:

(A) All records for controlled substances shall be maintained in a readily retrievable manner; and

(B) Controlled substances records shall be maintained in a manner to establish receipt and distribution of all controlled substances.

(4) Schedule II controlled substances records. Records of controlled substances listed in Schedule II shall be maintained as follows:

(A) Records of controlled substances listed in Schedule II shall be maintained separately from records of controlled substances in Schedules III, IV, and V, and all other records;

(B) An institutional pharmacy shall maintain a perpetual inventory of any controlled substance listed in Schedule II; and

(C) Distribution records for controlled substances listed in Schedule II shall bear the following information:

(i) patient's name;

(ii) prescribing or attending practitioner;

(iii) name of drug, dosage form, and strength;

(iv) time and date of administration to patient and quantity administered;

(v) name, initials, or electronic signature of the individual administering the controlled substance;

(vi) returns to the pharmacy; and

(vii) waste (waste is required to be witnessed and cosigned, electronically or manually, by another individual).

(5) Floor stock records.

(A) Distribution records for Schedules II - V controlled substances floor stock shall include the following information:

(i) patient's name;

(ii) prescribing or attending practitioner;

(iii) name of controlled substance, dosage form, and strength;

(iv) time and date of administration to patient;

(v) quantity administered;

(vi) name, initials, or electronic signature of the individual administering drug;

(vii) returns to the pharmacy; and

(viii) waste (waste is required to be witnessed and cosigned, manually or electronically, by another individual).

(B) The record required by subparagraph (A) of this paragraph shall be maintained separately from patient records.

(C) A pharmacist shall review distribution records with medication orders on a periodic basis to verify proper usage of drugs, not to exceed 30 days between such reviews.

(6) General requirements for records maintained in a data processing system.

(A) Noncompliance with data processing requirements. If a hospital pharmacy's data processing system is not in compliance with the board's requirements, the pharmacy must maintain a manual recordkeeping system.

(B) Requirements for backup systems. The facility shall maintain a backup copy of information stored in the data processing system using disk, tape, or other electronic backup system and update this backup copy on a regular basis, at least monthly, to assure that data is not lost due to system failure.

(C) Change or discontinuance of a data processing system.

(i) Records of distribution and return for all controlled substances. A pharmacy that changes or discontinues use of a data processing system must:

(I) transfer the records to the new data processing system; or

(II) purge the records to a printout which contains the same information as required on the audit trail printout as specified in paragraph (7)(B) of this subsection. The information on this printout shall be sorted and printed by drug name and list all distributions/returns chronologically.

(ii) Other records. A pharmacy that changes or discontinues use of a data processing system must:

(I) transfer the records to the new data processing system; or

(II) purge the records to a printout which contains all of the information required on the original document.

(iii) Maintenance of purged records. Information purged from a data processing system must be maintained by the pharmacy for two years from the date of initial entry into the data processing system.

(D) Loss of data. The pharmacist-in-charge shall report to the board in writing any significant loss of information from the data processing system within 10 days of discovery of the loss.

(7) Data processing system maintenance of records for the distribution and return of all controlled substances to the pharmacy.

(A) Each time a controlled substance is distributed from or returned to the pharmacy, a record of such distribution or return shall be entered into the data processing system.

(B) The data processing system shall have the capacity to produce a hard copy printout of an audit trail of drug distribution and return for any strength and dosage form of a drug (by either brand or generic name or both) during a specified time period. This printout shall contain the following information:

(i) patient's name and room number or patient's facility identification number;

(ii) prescribing or attending practitioner's name;

(iii) name, strength, and dosage form of the drug product actually distributed;

(iv) total quantity distributed from and returned to the pharmacy;

(v) if not immediately retrievable via electronic image, the following shall also be included on the printout:

(I) prescribing or attending practitioner's address; and

(II) practitioner's DEA registration number, if the medication order is for a controlled substance.

(C) An audit trail printout for each strength and dosage form of the drugs distributed during the preceding month shall be produced at least monthly and shall be maintained in a separate file at the facility unless the pharmacy complies with subparagraph (D) of this paragraph. The information on this printout shall be sorted by drug name and list all distributions/returns for that drug chronologically.

(D) The pharmacy may elect not to produce the monthly audit trail printout if the data processing system has a workable (electronic) data retention system which can produce an audit trail of

drug distribution and returns for the preceding two years. The audit trail required in this paragraph shall be supplied by the pharmacy within 72 hours, if requested by an authorized agent of the board, or other authorized local, state, or federal law enforcement or regulatory agencies.

(8) Failure to maintain records. Failure to provide 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.

(9) Data processing system downtime. In the event that a hospital pharmacy that uses a data processing system experiences system downtime, the pharmacy must have an auxiliary procedure which will ensure that all data is retained for on-line data entry as soon as the system is available for use again.

(10) Ongoing clinical pharmacy program records. If a pharmacy has an ongoing clinical pharmacy program and allows pharmacy technicians to verify the accuracy of work performed by other pharmacy technicians, the pharmacy must have a record of the pharmacy technicians and the duties performed.

(d) Distribution of controlled substances to another registrant. A pharmacy may distribute controlled substances to a practitioner, another pharmacy or other registrant, without being registered to distribute, under the following conditions:

(1) The registrant to whom the controlled substance is to be distributed is registered under the Controlled Substances Act to dispense that controlled substance; and

(2) The total number of dosage units of controlled substances distributed by a pharmacy may not exceed 5.0% of all controlled substances dispensed or 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 controlled substances.

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

(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.

(4) A pharmacy shall comply with 21 CFR 1305 regarding the DEA order form (DEA 222) requirements when distributing a Schedule II controlled substance.

~~[(4) If the distribution is for a Schedule I or 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; and~~]

[~~(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.~~]

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

(1) a log of the initials or identification codes which identifies pharmacy personnel by name. The initials or identification code shall be unique to ensure that each person can be identified, i.e., identical initials or identification codes cannot 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 forms (DEA 222) which have been properly dated, initialed, and filed, and all copies of each unaccepted or defective order form and any attached statements or other documents;~~]

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

(2) [~~(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;

(3) [~~(5)~~] suppliers' credit memos for controlled substances and dangerous drugs;

(4) [~~(6)~~] a hard copy of inventories required by §291.17 of this title (relating to Inventory Requirements) except that a perpetual inventory of controlled substances listed in Schedule II may be kept in a data processing system if the data processing system is capable of producing a hard copy of the perpetual inventory on-site;

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

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

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

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

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

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

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

(f) Permission to maintain central records. Any pharmacy that uses a centralized recordkeeping system for invoices and financial data shall comply with the following procedures.

(1) Controlled substance records. Invoices and financial data for controlled substances may be maintained at a central location provided the following conditions are met:

(A) Prior to the initiation of central recordkeeping, the pharmacy submits written notification by registered or certified mail to the divisional director of DEA as required by Title 21, Code of Federal Regulations, §1304.04(a), and submits a copy of this written notification to the board. Unless the registrant is informed by the divisional director of DEA that permission to keep central records is denied, the pharmacy may maintain central records commencing 14 days after receipt of notification by the divisional director;

(B) The pharmacy maintains a copy of the notification required in subparagraph (A) of this paragraph; and

(C) The records to be maintained at the central record location shall not include executed DEA order forms, prescription drug orders, or controlled substance inventories, which shall be maintained at the pharmacy.

(2) Dangerous drug records. Invoices and financial data for dangerous drugs may be maintained at a central location.

(3) Access to records. If the records are kept in any form requiring special equipment to render the records easily readable, the pharmacy shall provide access to such equipment with the records.

(4) Delivery of records. The pharmacy agrees to deliver all or any part of such records to the pharmacy location within two business days of written request of a board agent or any other authorized official.