RULE ANALYSIS

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

Short Title: Records.

Rule Number: §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 a pharmacist may electronically sign the data entry attestation statement and 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 2145.

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

§291.34. Records.

The Texas State Board of Pharmacy proposes amendments to §291.34 concerning Records. The amendments, if adopted, clarify that a pharmacist may electronically sign the data entry attestation statement and 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 provide clearer regulatory language and 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 limit 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.

§291.34. Records.

(a) Maintenance of records.

(1) Every inventory or other record required to be kept under the provisions of Subchapter B of this chapter (relating to Community Pharmacy (Class A)) shall be:

(A) kept by the pharmacy at the pharmacy's licensed location 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 to 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 of controlled substances listed in Schedule II shall be maintained separately from all other records of the pharmacy.

(3) Records of controlled substances, other than prescription drug orders, 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, red-lined, 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 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) Prescriptions.

(1) Professional responsibility.

(A) 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.

(B) 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 unless the pharmacist complies with the requirements of §562.056 and §562.112 of the Act, and §291.29 of this title (relating to Professional Responsibility of Pharmacists).

(C) Subparagraph (B) 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).

(D) The owner of a Class A pharmacy shall have responsibility for ensuring its agents and employees engage in appropriate decisions regarding dispensing of valid prescriptions as set forth in §562.112 of the Act.

(2) Written prescription drug orders.

(A) Practitioner's signature.

(i) Dangerous drug prescription orders. Written prescription drug orders shall be:

(I) manually signed by the practitioner; or

(II) electronically signed by the practitioner using a system that electronically replicates the practitioner's manual signature on the written prescription, provided:

(-a-) that security features of the system require the practitioner to authorize each use; and

(-b-) the prescription is printed on paper that is designed to prevent unauthorized copying of a completed prescription and to prevent the erasure or modification of information written on the prescription by the prescribing practitioner. (For example, the paper contains security provisions against copying that results in some indication on the copy that it is a copy and therefore render the prescription null and void.)

(ii) Controlled substance prescription orders. Prescription drug orders for Schedules II, III, IV, or V controlled substances shall be manually signed by the practitioner. Prescription drug orders for Schedule II controlled substances shall be issued on an official prescription form as required by the Texas Controlled Substances Act, §481.075.

(iii) Other provisions for a practitioner's signature.

(I) A practitioner may sign a prescription drug order in the same manner as he would sign a check or legal document, e.g., J.H. Smith or John H. Smith.

(II) Rubber stamped signatures may not be used.

(III) The prescription drug order may not be signed by a practitioner's agent but may be prepared by an agent for the signature of a practitioner. However, the prescribing practitioner is responsible in case the prescription drug order does not conform in all essential respects to the law and regulations.

(B) Prescription drug orders written by practitioners in another state.

(i) Dangerous drug prescription orders. A pharmacist may dispense prescription drug orders for dangerous drugs issued by practitioners in a state other than Texas in the same manner as prescription drug orders for dangerous drugs issued by practitioners in Texas are dispensed.

(ii) Controlled substance prescription drug orders.

(I) A pharmacist may dispense prescription drug orders for Schedule II controlled substances issued by a practitioner in another state provided:

(-a-) the prescription is dispensed as specified in §315.9 of this title (relating to Pharmacy Responsibility - Out-of-State Practitioner - Effective September 1, 2016);

(-b-) the prescription drug order is an original written prescription issued by 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 (DEA) registration number, and who may legally prescribe Schedule II controlled substances in such other state; and

(-c-) the prescription drug order is not dispensed after the end of the twenty-first day after the date on which the prescription is issued.

(II) A pharmacist may dispense prescription drug orders for controlled substances in Schedules III, IV, or V issued by a physician, dentist, veterinarian, or podiatrist in another state provided:

(-a-) the prescription drug order is issued by a person practicing in another state and licensed by another state as a physician, dentist, veterinarian, or podiatrist, who has a current federal DEA registration number, and who may legally prescribe Schedules III, IV, or V controlled substances in such other state;

(-b-) the prescription drug order is not dispensed or refilled more than six months from the initial date of issuance and may not be refilled more than five times; and

(-c-) if there are no refill instructions on the original prescription drug order (which shall be interpreted as no refills authorized) or if all refills authorized on the original prescription drug order have been dispensed, a new prescription drug order is obtained from the prescribing practitioner prior to dispensing any additional quantities of controlled substances.

(C) Prescription drug orders written by practitioners in the United Mexican States or the Dominion of Canada.

(i) Controlled substance prescription drug orders. A pharmacist may not dispense a prescription drug order for a Schedule II, III, IV, or V controlled substance issued by a practitioner in the Dominion of Canada or the United Mexican States.

(ii) Dangerous drug prescription drug orders. A pharmacist may dispense a dangerous drug prescription issued by a person licensed in the Dominion of Canada or the United Mexican States as a physician, dentist, veterinarian, or podiatrist provided:

(I) the prescription drug order is an original written prescription; and

(II) if there are no refill instructions on the original written prescription drug order (which shall be interpreted as no refills authorized) or if all refills authorized on the original written prescription drug order have been dispensed, a new written prescription drug order shall be obtained from the prescribing practitioner prior to dispensing any additional quantities of dangerous drugs.

(D) Prescription drug orders issued by an advanced practice registered nurse, physician assistant, or pharmacist.

(i) A pharmacist may dispense a prescription drug order that is:

(I) issued by an advanced practice registered nurse or physician assistant provided the advanced practice registered nurse or physician assistant is practicing in accordance with Subtitle B, Chapter 157, Occupations Code; and

(II) for a dangerous drug and signed by a pharmacist under delegated authority of a physician as specified in Subtitle B, Chapter 157, Occupations Code.

(ii) Each practitioner shall designate in writing the name of each advanced practice registered nurse or physician assistant authorized to issue a prescription drug order pursuant to Subtitle B, Chapter 157, Occupations Code. A list of the advanced practice registered nurses or physician assistants designated by the practitioner must be maintained in the practitioner's usual place of business. On request by a pharmacist, a practitioner shall furnish the pharmacist with a copy of the written authorization for a specific advanced practice registered nurse or physician assistant.

(E) Prescription drug orders for Schedule II controlled substances. No Schedule II controlled substance may be dispensed without a written prescription drug order of a practitioner on an official prescription form as required by the Texas Controlled Substances Act, §481.075.

(3) Oral prescription drug orders.

(A) An oral prescription drug order for a controlled substance from a practitioner or a practitioner's designated agent may only be received by a pharmacist or a pharmacist-intern under the direct supervision of a pharmacist.

(B) A practitioner shall designate in writing the name of each agent authorized by the practitioner to communicate prescriptions orally for the practitioner. The practitioner shall maintain at the practitioner's usual place of business a list of the designated agents. The practitioner shall provide a pharmacist with a copy of the practitioner's written authorization for a specific agent on the pharmacist's request.

(C) A pharmacist may not dispense an oral prescription drug order for a dangerous drug or a controlled substance issued by a practitioner licensed in the Dominion of Canada or the United Mexican States unless the practitioner is also licensed in Texas.

(4) Electronic prescription drug orders.

(A) Dangerous drug prescription orders.

(i) An electronic prescription drug order for a dangerous drug may be transmitted by a practitioner or a practitioner's designated agent:

(I) directly to a pharmacy; or

(II) through the use of a data communication device provided:

(-a-) the confidential prescription information is not altered during transmission; and

(-b-) confidential patient information is not accessed or maintained by the operator of the data communication device other than for legal purposes under federal and state law.

(ii) A practitioner shall designate in writing the name of each agent authorized by the practitioner to electronically transmit prescriptions for the practitioner. The practitioner shall maintain at the practitioner's usual place of business a list of the designated agents. The practitioner shall provide a pharmacist with a copy of the practitioner's written authorization for a specific agent on the pharmacist's request.

(B) Controlled substance prescription orders. A pharmacist may only dispense an electronic prescription drug order for a Schedule II, III, IV, or V controlled substance in compliance with federal and state laws and the rules of the Drug Enforcement Administration outlined in Part 1300 of the Code of Federal Regulations.

(C) Prescriptions issued by a practitioner licensed in the Dominion of Canada or the United Mexican States. A pharmacist may not dispense an electronic prescription drug order for a dangerous drug or controlled substance issued by a practitioner licensed in the Dominion of Canada or the United Mexican States unless the practitioner is also licensed in Texas.

(5) Facsimile (faxed) prescription drug orders.

(A) A pharmacist may dispense a prescription drug order for a dangerous drug transmitted to the pharmacy by facsimile.

(B) A pharmacist may dispense a prescription drug order for a Schedule III-V controlled substance transmitted to the pharmacy by facsimile provided the prescription is manually signed by the practitioner and not electronically signed using a system that electronically replicates the practitioner's manual signature on the prescription drug order.

(C) A pharmacist may not dispense a facsimile prescription drug order for a dangerous drug or controlled substance issued by a practitioner licensed in the Dominion of Canada or the United Mexican States unless the practitioner is also licensed in Texas.

(6) Original prescription drug order records.

(A) Original prescriptions may be dispensed only in accordance with the prescriber's authorization as indicated on the original prescription drug order, including clarifications to the order given [to the pharmacist] by the practitioner or the practitioner's agent and recorded on the prescription.

(B) Notwithstanding subparagraph (A) of this paragraph, a pharmacist may dispense a quantity less than indicated on the original prescription drug order at the request of the patient or patient's agent.

(C) Original prescriptions shall be maintained by the pharmacy in numerical order and remain legible for a period of two years from the date of filling or the date of the last refill dispensed.

(D) If an original prescription drug order is changed, such prescription order shall be invalid and of no further force and effect; if additional drugs are to be dispensed, a new prescription drug order with a new and separate number is required. However, an original prescription drug order for a dangerous drug may be changed in accordance with paragraph (10) of this subsection relating to accelerated refills.

(E) Original prescriptions shall be maintained in three separate files as follows:

(i) prescriptions for controlled substances listed in Schedule II;

(ii) prescriptions for controlled substances listed in Schedules III-V; and

(iii) prescriptions for dangerous drugs and nonprescription drugs.

(F) Original prescription records other than prescriptions for Schedule II controlled substances may be stored in a system that is capable of producing a direct image of the original prescription record, e.g., a digitalized imaging system. If original prescription records are stored in a direct imaging system, the following is applicable:

(i) the record of refills recorded on the original prescription must also be stored in this system;

(ii) the original prescription records must be maintained in numerical order and separated in three files as specified in subparagraph (D) of this paragraph; and

(iii) the pharmacy must provide immediate access to equipment necessary to render the records easily readable.

(7) Prescription drug order information.

(A) All original prescriptions shall bear:

(i) the name of the patient, or if such drug is for an animal, the species of such animal and the name of the owner;

(ii) the address of the patient; provided, however, that a prescription for a dangerous drug is not required to bear the address of the patient if such address is readily retrievable on another appropriate, uniformly maintained pharmacy record, such as medication records;

(iii) the name, address and telephone number of the practitioner at the practitioner's usual place of business, legibly printed or stamped, and if for a controlled substance, the DEA registration number of the practitioner;

(iv) the name and strength of the drug prescribed;

(v) the quantity prescribed numerically, and if for a controlled substance:

(I) numerically, followed by the number written as a word, if the prescription is written;

(II) numerically, if the prescription is electronic; or

(III) if the prescription is communicated orally or telephonically, as transcribed by the receiving pharmacist;

(vi) directions for use;

(vii) the intended use for the drug unless the practitioner determines the furnishing of this information is not in the best interest of the patient;

(viii) the date of issuance;

(ix) if a faxed prescription:

(I) a statement that indicates that the prescription has been faxed (e.g., Faxed to); and

(II) if transmitted by a designated agent, the name of the designated agent;

(x) if electronically transmitted:

(I) the date the prescription drug order was electronically transmitted to the pharmacy, if different from the date of issuance of the prescription; and

(II) if transmitted by a designated agent, the name of the designated agent; and

(xi) if issued by an advanced practice nurse or physician assistant in accordance with Subtitle B, Chapter 157, Occupations Code:

(I) the name, address, telephone number, and if the prescription is for a controlled substance, the DEA number of the supervising practitioner; and

(II) the address and telephone number of the clinic where the prescription drug order was carried out or signed; and

(xii) if communicated orally or telephonically:

(I) the initials or identification code of the transcribing pharmacist; and

(II) the name of the prescriber or prescriber's agent communicating the prescription information.

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

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

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

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

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

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

(vi) the 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 and563.

(C) Prescription drug orders may be utilized as authorized in Title 40, Part 1, Chapter 19 of the Texas Administrative Code.

(i) A prescription drug order is not required to bear the information specified in subparagraph (A) of this paragraph if the drug is prescribed for administration to an ultimate user who is institutionalized in a licensed health care institution (e.g., nursing home, hospice, hospital). Such prescription drug orders must contain the following information:

(I) the full name of the patient;

(II) the date of issuance;

(III) the name, strength, and dosage form of the drug prescribed;

(IV) directions for use; and

(V) the signature(s) required by 40 TAC §19.1506.

(ii) Prescription drug orders for dangerous drugs shall not be dispensed following one year after the date of issuance unless the authorized prescriber renews the prescription drug order.

(iii) Controlled substances shall not be dispensed pursuant to a prescription drug order under this subparagraph.

(8) Refills.

(A) General information.

(i) Refills may be dispensed only in accordance with the prescriber's authorization as indicated on the original prescription drug order except as authorized in paragraph (10) of this subsection relating to accelerated refills.

(ii) If there are no refill instructions on the original prescription drug order (which shall be interpreted as no refills authorized) or if all refills authorized on the original prescription drug order have been dispensed, authorization from the prescribing practitioner shall be obtained prior to dispensing any refills and documented as specified in subsection (l) of this section.

(B) Refills of prescription drug orders for dangerous drugs or nonprescription drugs.

(i) Prescription drug orders for dangerous drugs or nonprescription drugs may not be refilled after one year from the date of issuance of the original prescription drug order.

(ii) If one year has expired from the date of issuance of an original prescription drug order for a dangerous drug or nonprescription drug, authorization shall be obtained from the prescribing practitioner prior to dispensing any additional quantities of the drug.

(C) Refills of prescription drug orders for Schedules III-V controlled substances.

(i) Prescription drug orders for Schedules III-V controlled substances may not be refilled more than five times or after six months from the date of issuance of the original prescription drug order, whichever occurs first.

(ii) If a prescription drug order for a Schedule III, IV, or V controlled substance has been refilled a total of five times or if six months have expired from the date of issuance of the original prescription drug order, whichever occurs first, a new and separate prescription drug order shall be obtained from the prescribing practitioner prior to dispensing any additional quantities of controlled substances.

(D) Pharmacist unable to contact prescribing practitioner. If a pharmacist is unable to contact the prescribing practitioner after a reasonable effort, a pharmacist may exercise his or her professional judgment in refilling a prescription drug order for a drug, other than a Schedule II controlled substance, without the authorization of the prescribing practitioner, provided:

(i) failure to refill the prescription might result in an interruption of a therapeutic regimen or create patient suffering;

(ii) the quantity of prescription drug dispensed does not exceed a 72-hour supply;

(iii) the pharmacist informs the patient or the patient's agent at the time of dispensing that the refill is being provided without such authorization and that authorization of the practitioner is required for future refills;

(iv) the pharmacist informs the practitioner of the emergency refill at the earliest reasonable time;

(v) the pharmacist maintains a record of the emergency refill containing the information required to be maintained on a prescription as specified in this subsection;

(vi) the pharmacist affixes a label to the dispensing container as specified in §291.33(c)(7) **of this title** (relating to Operational Standards) [~~of this title~~]; and

(vii) if the prescription was initially filled at another pharmacy, the pharmacist may exercise his or her professional judgment in refilling the prescription provided:

(I) the patient has the prescription container, label, receipt or other documentation from the other pharmacy that contains the essential information;

(II) after a reasonable effort, the pharmacist is unable to contact the other pharmacy to transfer the remaining prescription refills or there are no refills remaining on the prescription;

(III) the pharmacist, in his or her professional judgment, determines that such a request for an emergency refill is appropriate and meets the requirements of clause (i) of this subparagraph; and

(IV) the pharmacist complies with the requirements of clauses (ii) - (vi) of this subparagraph.

(E) Natural or **man-made** [~~manmade~~] disasters. If a natural or **man-made** [~~manmade~~] disaster has occurred that prohibits the pharmacist from being able to contact the practitioner, a pharmacist may exercise his or her professional judgment in refilling a prescription drug order for a drug, other than a Schedule II controlled substance, without the authorization of the prescribing practitioner, provided:

(i) failure to refill the prescription might result in an interruption of a therapeutic regimen or create patient suffering;

(ii) the quantity of prescription drug dispensed does not exceed a 30-day supply;

(iii) the governor **of Texas** has declared a state of disaster;

(iv) the board, through the executive director, has notified pharmacies that pharmacists may dispense up to a 30-day supply of prescription drugs;

(v) the pharmacist informs the patient or the patient's agent at the time of dispensing that the refill is being provided without such authorization and that authorization of the practitioner is required for future refills;

(vi) the pharmacist informs the practitioner of the emergency refill at the earliest reasonable time;

(vii) the pharmacist maintains a record of the emergency refill containing the information required to be maintained on a prescription as specified in this subsection;

(viii) the pharmacist affixes a label to the dispensing container as specified in §291.33(c)(7) of this title; and

(ix) if the prescription was initially filled at another pharmacy, the pharmacist may exercise his or her professional judgment in refilling the prescription provided:

(I) the patient has the prescription container, label, receipt or other documentation from the other pharmacy that contains the essential information;

(II) after a reasonable effort, the pharmacist is unable to contact the other pharmacy to transfer the remaining prescription refills or there are no refills remaining on the prescription;

(III) the pharmacist, in his or her professional judgment, determines that such a request for an emergency refill is appropriate and meets the requirements of clause (i) of this subparagraph; and

(IV) the pharmacist complies with the requirements of clauses (ii) - (viii) of this subparagraph.

(F) 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:

(i) 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.

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

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

(iv) 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.

(9) Records Relating to Dispensing Errors. If a dispensing error occurs, the following is applicable.

(A) Original prescription drug orders:

(i) shall not be destroyed and must be maintained in accordance with subsection (a) of this section; and

(ii) shall not be altered. Altering includes placing a label or any other item over any of the information on the prescription drug order (e.g., a dispensing tag or label that is affixed to back of a prescription drug order must not be affixed on top of another dispensing tag or label in such a manner as to obliterate the information relating to the error).

(B) Prescription drug order records maintained in a data processing system:

(i) shall not be deleted and must be maintained in accordance with subsection (a) of this section;

(ii) may be changed only in compliance with subsection (e)(2)(B) of this section; and

(iii) if the error involved incorrect data entry into the pharmacy's data processing system, this record must be either voided or cancelled in the data processing system, so that the incorrectly entered prescription drug order may not be dispensed, or the data processing system must be capable of maintaining an audit trail showing any changes made to the data in the system.

(10) Accelerated refills. In accordance with §562.0545 of the Act, a pharmacist may dispense up to a 90-day supply of a dangerous drug pursuant to a valid prescription that specifies the dispensing of a lesser amount followed by periodic refills of that amount if:

(A) the total quantity of dosage units dispensed does not exceed the total quantity of dosage units authorized by the prescriber on the original prescription, including refills;

(B) the patient consents to the dispensing of up to a 90-day supply and the physician has been notified electronically or by telephone;

(C) the physician has not specified on the prescription that dispensing the prescription in an initial amount followed by periodic refills is medically necessary;

(D) the dangerous drug is not a psychotropic drug used to treat mental or psychiatric conditions; and

(E) the patient is at least 18 years of age.

(c) Patient medication records.

(1) A patient medication record system shall be maintained by the pharmacy for patients to whom prescription drug orders are dispensed.

(2) The patient medication record system shall provide for the immediate retrieval of information for the previous 12 months that is necessary for the dispensing pharmacist to conduct a prospective drug regimen review at the time a prescription drug order is presented for dispensing.

(3) The pharmacist-in-charge shall assure that a reasonable effort is made to obtain and record in the patient medication record at least the following information:

(A) full name of the patient for whom the drug is prescribed;

(B) address and telephone number of the patient;

(C) patient's age or date of birth;

(D) patient's gender;

(E) any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs currently being used by the patient which may relate to prospective drug regimen review;

(F) pharmacist's comments relevant to the individual's drug therapy, including any other information unique to the specific patient or drug; and

(G) a list of all prescription drug orders dispensed (new and refill) to the patient by the pharmacy during the last two years. Such lists shall contain the following information:

(i) date dispensed;

(ii) name, strength, and quantity of the drug dispensed;

(iii) prescribing practitioner's name;

(iv) unique identification number of the prescription; and

(v) name or initials of the dispensing pharmacists.

(4) A patient medication record shall be maintained in the pharmacy for two years. If patient medication records are maintained in a data processing system, all of the information specified in this subsection shall be maintained in a retrievable form for two years and information for the previous 12 months shall be maintained online. A patient medication record must contain documentation of any modification, change, or manipulation to a patient profile.

(5) Nothing in this subsection shall be construed as requiring a pharmacist to obtain, record, and maintain patient information other than prescription drug order information when a patient or patient's agent refuses to provide the necessary information for such patient medication records.

(d) Prescription drug order records maintained in a manual system.

(1) Original prescriptions shall be maintained in three files as specified in subsection (b)(6)(D) of this section.

(2) Refills.

(A) Each time a prescription drug order is refilled, a record of such refill shall be made:

(i) on the back of the prescription by recording the date of dispensing, the written initials or identification code of the dispensing pharmacist, the initials or identification code of the pharmacy technician or pharmacy technician trainee preparing the prescription label, if applicable, and the amount dispensed. (If the pharmacist merely initials and dates the back of the prescription drug order, he or she shall be deemed to have dispensed a refill for the full face amount of the prescription drug order); or

(ii) on another appropriate, uniformly maintained, readily retrievable record, such as medication records, that indicates by patient name the following information:

(I) unique identification number of the prescription;

(II) name and strength of the drug dispensed;

(III) date of each dispensing;

(IV) quantity dispensed at each dispensing;

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

(VI) initials or identification code of the pharmacy technician or pharmacy technician trainee preparing the prescription label, if applicable; and

(VII) total number of refills for the prescription.

(B) If refill records are maintained in accordance with subparagraph (A)(ii) of this paragraph, refill records for controlled substances in Schedules III-V shall be maintained separately from refill records of dangerous drugs and nonprescription drugs.

(3) Authorization of refills. Practitioner authorization for additional refills of a prescription drug order shall be noted on the original prescription, in addition to the documentation of dispensing the refill as specified in subsection (l) of this section.

(4) Each time a modification, change, or manipulation is made to a record of dispensing, documentation of such change shall be recorded on the back of the prescription or on another appropriate, uniformly maintained, readily retrievable record, such as medication records. The documentation of any modification, change, or manipulation to a record of dispensing shall include the identification of the individual responsible for the alteration.

(e) Prescription drug order records maintained in a data processing system.

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

(A) Compliance with data processing system requirements. If a Class A pharmacy's data processing system is not in compliance with this subsection, the pharmacy must maintain a manual record keeping system as specified in subsection (d) of this section.

(B) Original prescriptions. Original prescriptions shall be maintained in three files as specified in subsection (b)(6)(D) of this section.

(C) Requirements for backup systems.

(i) The pharmacy 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.

(ii) Data processing systems shall have a workable (electronic) data retention system that can produce an audit trail of drug usage for the preceding two years as specified in paragraph (2)(H) of this subsection.

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

(i) Records of dispensing. A pharmacy that changes or discontinues use of a data processing system must:

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

(II) purge the records of dispensing to a printout that contains the same information required on the daily printout as specified in paragraph (2)(C) of this subsection. The information on this hard copy printout shall be sorted and printed by prescription number and list each dispensing for this prescription 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 that 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.

(E) 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.

(2) Records of dispensing.

(A) Each time a prescription drug order is filled or refilled, a record of such dispensing shall be entered into the data processing system.

(B) Each time a modification, change or manipulation is made to a record of dispensing, documentation of such change shall be recorded in the data processing system. The documentation of any modification, change, or manipulation to a record of dispensing shall include the identification of the individual responsible for the alteration. Should the data processing system not be able to record a modification, change, or manipulation to a record of dispensing, the information should be clearly documented on the hard copy prescription.

(C) The data processing system shall have the capacity to produce a daily hard copy printout of all original prescriptions dispensed and refilled. This hard copy printout shall contain the following information:

(i) unique identification number of the prescription;

(ii) date of dispensing;

(iii) patient name;

(iv) prescribing practitioner's name and the supervising physician's name if the prescription was issued by an advanced practice registered nurse, physician assistant or pharmacist;

(v) name and strength of the drug product actually dispensed; if generic name, the brand name or manufacturer of drug dispensed;

(vi) quantity dispensed;

(vii) initials or an identification code of the dispensing pharmacist;

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

(ix) if not immediately retrievable via computer display, the following shall also be included on the hard copy printout:

(I) patient's address;

(II) prescribing practitioner's address;

(III) practitioner's DEA registration number, if the prescription drug order is for a controlled substance;

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

(V) date of issuance of the prescription drug order, if different from the date of dispensing; and

(VI) total number of refills dispensed to date for that prescription drug order; and

(x) any changes made to a record of dispensing.

(D) The daily hard copy printout shall be produced within 72 hours of the date on which the prescription drug orders were dispensed and shall be maintained in a separate file at the pharmacy. Records of controlled substances shall be readily retrievable from records of non-controlled substances.

(E) Each individual pharmacist who dispenses or refills a prescription drug order shall verify that the data indicated on the daily hard copy printout is correct, by dating and signing such document in the same manner as signing a check or legal document (e.g., J.H. Smith, or John H. Smith) within seven days from the date of dispensing.

(F) In lieu of the printout described in subparagraph (C) of this paragraph, the pharmacy shall maintain a log book in which each individual pharmacist using the data processing system shall sign **or electronically sign** a statement each day, attesting to the fact that the information entered into the data processing system that day has been reviewed by him or her and is

correct as entered. Such log book shall be maintained at the pharmacy employing such a system for a period of two years after the date of dispensing; provided, however, that the data processing system can produce the hard copy printout on demand by an authorized agent of the Texas State Board of Pharmacy. If no printer is available on site, the hard copy printout shall be available within 72 hours with a certification by the individual providing the printout, stating that the printout is true and correct as of the date of entry and such information has not been altered, amended, or modified.

(G) The pharmacist-in-charge is responsible for the proper maintenance of such records, for ensuring that such data processing system can produce the records outlined in this section, and that such system is in compliance with this subsection.

(H) The data processing system shall be capable of producing a hard copy printout of an audit trail for all dispensing (original and refill) of any specified strength and dosage form of a drug (by either brand or generic name or both) during a specified time period.

(i) Such audit trail shall contain all of the information required on the daily printout as set out in subparagraph (C) of this paragraph.

(ii) The audit trail required in this subparagraph shall be supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy.

(I) 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.

(J) The data processing system shall provide online retrieval (via computer display or hard copy printout) of the information set out in subparagraph (C) of this paragraph of:

(i) the original controlled substance prescription drug orders currently authorized for refilling; and

(ii) the current refill history for Schedules III, IV, and V controlled substances for the immediately preceding six-month period.

(K) In the event that a pharmacy using a data processing system experiences system downtime, the following is applicable:

(i) an auxiliary procedure shall ensure that refills are authorized by the original prescription drug order and that the maximum number of refills has not been exceeded, or authorization from the prescribing practitioner shall be obtained prior to dispensing a refill; and

(ii) all of the appropriate data shall be retained for online data entry as soon as the system is available for use again.

(3) Authorization of refills. Practitioner authorization for additional refills of a prescription drug order shall be noted as follows:

(A) on the hard copy prescription drug order;

(B) on the daily hard copy printout; or

(C) via the computer display.

(f) Limitation to one type of recordkeeping system. When filing prescription drug order information a pharmacy may use only one of the two systems described in subsection (d) or (e) of this section.

(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 Schedules III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only. However, pharmacies electronically sharing a real-time, online 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:

(A) directly by a pharmacist or pharmacist-intern to another pharmacist or pharmacist-intern for prescription drug order information for controlled substances; or

(B) directly by a pharmacist, pharmacist-intern, or pharmacy technician to another pharmacist, pharmacist-intern, or pharmacy technician for prescription drug order information for dangerous drugs.

(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:

(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, and 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, the name, address, 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 indicate in the prescription record that 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 the following:

(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, the 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, that 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; and

(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 store all the information as specified in paragraphs (5) and (6) of this subsection;

(ii) Pharmacies not owned by the same entity 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; and

(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 within four business hours of the request.

(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) 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 subsection 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 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.

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

(3) If the distribution is for a Schedule III, IV, or V controlled substance, a record shall be maintained that 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.** [~~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; 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.

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

(1) a 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 (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 forms (DEA 222) that have been properly dated, initialed, and filed, 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 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 substances 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 copy of inventories required by §291.17 of this title (relating to Inventory Requirements);

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

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

(7) [~~(9)~~] a 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 the 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 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) 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 the Drug Enforcement Administration 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 the Drug Enforcement Administration 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 that 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 on microfilm, computer media, or in any form requiring special equipment to render the records easily readable, the pharmacy shall provide access to such equipment with the records; and

(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.

(k) Ownership of pharmacy records. For the purposes of these sections, a pharmacy licensed under the Act is the only entity that may legally own and maintain prescription drug records.

(l) Documentation of consultation. When a pharmacist, pharmacist-intern, or pharmacy technician consults a prescriber as described in this section, the individual shall document such occurrences on the hard copy or in the pharmacy's data processing system associated with the prescription and shall include the following information:

(1) date the prescriber was consulted;

(2) name of the person communicating the prescriber's instructions;

(3) any applicable information pertaining to the consultation; and

(4) initials or identification code of the pharmacist, pharmacist-intern, or pharmacy technician performing the consultation clearly recorded for the purpose of identifying the individual who performed the consultation if the information is recorded on the hard copy prescription.