

## RULE ANALYSIS

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

**Short Title:** Records

**Rule Numbers:** §291.34

**Statutory Authority:** Texas Pharmacy Act, Chapter 551-566 and 568-569, 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 and update the section to be consistent with other sections of this title and DPS and DEA laws/rules; require documentation of a consultation with a prescriber regarding a prescription; add rules regarding auto-refill programs; and update the rules regarding prescription transfers including no longer allowing interns to transfer prescriptions, specifying that the transfer must be confirmed by each pharmacist, and holding both the transferring and receiving pharmacist responsible for a dispensing error involving a transferred prescription.

**Background:** Board staff presents these amendments to update the Class A rules regarding the records of the pharmacy.

**The Board reviewed and voted to propose the amendments during the February 5, 2013, meeting. The proposed amendments were published in the March 8, 2013, issue of the *Texas Register* at 38 *TexReg* 1643.**

(II) a pharmacist checks the accuracy of each original or new prescription drug order.

(ii) the prescription is dispensed, labeled, and made ready for delivery to the patient in compliance with Class A (Community) Pharmacy rules; and

(iii) prior to delivery to the patient:

(I) the automated checking device confirms that the correct drug and strength has been labeled with the correct label for the correct patient; and

(II) a pharmacist performs all other duties required to ensure that the prescription has been dispensed safely and accurately as prescribed.

(B) [(C)] If the final check is accomplished as specified in subparagraph (A) [(B)] of this paragraph, the following additional requirements must be met.

(i) The pharmacy has conducted initial testing of the automated checking device and has a continuous quality assurance program which documents that the automated checking device accurately confirms that the correct drug and strength has been labeled with the correct label for the correct patient.

(ii) The pharmacy documents and maintains:

(I) the name(s), initials, or identification code(s) of each pharmacist responsible for the checks outlined in subparagraph (A) [(B)](i) of this paragraph; and

(II) the name(s) initials, or identification code(s) and specific activity(ies) of each pharmacist or pharmacy technician who perform any other portion of the dispensing process.

(iii) The pharmacy establishes mechanisms and procedures to test the accuracy of the automated checking device at least monthly.

(4) [(5)] Automated storage and distribution device. A pharmacy may use an automated storage and distribution device to deliver a previously verified prescription to a patient or patient's agent when the pharmacy is open or when the pharmacy is closed as specified in subsection (b)(3)(B)(iii) of this section, provided:

(A) the device is used to deliver refills of prescription drug orders and shall not be used to deliver new prescriptions as defined by §291.31(26) of this title (relating to Definitions);

(B) the automated storage and distribution device may not be used to deliver a controlled substance;

(C) drugs stored in the automated storage and distribution device are stored at proper temperatures;

(D) the patient or patient's agent is given the option to use the system;

(E) the patient or patient's agent has access to a pharmacist for questions regarding the prescription at the pharmacy where the automated storage and distribution device is located, by a telephone available at the pharmacy that connects directly to another pharmacy, or by a telephone available at the pharmacy and a posted telephone number to reach another pharmacy;

(F) the pharmacist-in-charge is responsible for the supervision of the operation of the system;

(G) the automated storage and distribution device has been tested by the pharmacy and found to dispense prescriptions accurately.

The pharmacy shall make the results of such testing available to the board upon request;

(H) the automated storage and distribution device may be loaded with previously verified prescriptions only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist;

(I) the pharmacy will make the automated storage and distribution device available for inspection by the board;

(J) the automated storage and distribution device is located within the pharmacy building whereby pharmacy staff has access to the device from within the prescription department and patients have access to the device from outside the prescription department. The device may not be located on an outside wall of the pharmacy and may not be accessible from a drive-thru;

(K) the automated storage and distribution device is secure from access and removal of prescription drug orders by unauthorized individuals;

(L) the automated storage and distribution device has adequate security system to prevent unauthorized access and to maintain patient confidentiality; and

(M) the automated storage and distribution device records a digital image of the individual accessing the device to pick-up a prescription and such record is maintained by the pharmacy for two years.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on February 25, 2013.

TRD-201300857

Gay Dodson, R.Ph.

Executive Director/Secretary

Texas State Board of Pharmacy

Earliest possible date of adoption: April 7, 2013

For further information, please call: (512) 305-8028



## 22 TAC §291.34

The Texas State Board of Pharmacy proposes amendments to §291.34 concerning Records. The amendments, if adopted, clarify and update the section to be consistent with other sections of this title and DPS and DEA laws/rules; require documentation of a consultation with a prescriber regarding a prescription; add rules regarding auto-refill programs; and update the rules regarding prescription transfers including no longer allowing interns to transfer prescriptions and specifying that the transfer must be confirmed by each pharmacist.

Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year period the rule is in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule.

Ms. Dodson 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 rule will be to clarify and update the Class A rules regarding the records of a pharmacy. There is no fiscal impact for individuals, small or large businesses, or to other entities which are required to comply with this section.

Comments on the proposed amendments may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600, Austin, Texas 78701, FAX (512) 305-8008. Comments must be received by 5:00 p.m., April 30, 2013.

The amendments are proposed under §551.002 and §554.051 of the Texas Pharmacy Act (Chapters 551 - 566 and 568 - 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 - 566 and 568 - 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 [§291.31 of this title (relating to Definitions), §291.32 of this title (relating to Personnel), §291.33 of this title (relating to Operational Standards), §291.34 of this title (relating to Records), and §291.35 of this title (relating to Official Prescription Requirements), contained in] Community Pharmacy (Class A)) shall be:

(A) - (B) (No change.)

(2) - (3) (No change.)

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

(A) - (B) (No change.)

(b) Prescriptions.

(1) (No change.)

(2) Written prescription drug orders.

(A) Practitioner's signature.

(i) Dangerous drug prescriptions. Written [~~Except as noted in clause (ii) of this subparagraph, written~~] prescription drug orders shall be:

(I) (No change.)

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

(-a-) - (-b-) (No change.)

(ii) Controlled substance prescriptions. Prescription drug orders for Schedule 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[, and be manually signed by the practitioner].

(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 or otherwise reproduced signatures may not be used except as authorized in clause (i) of this subparagraph.

(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) (No change.)

(ii) Controlled substance prescription drug orders.

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

(-a-) - (-b-) (No change.)

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

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

(-a-) the prescription drug order is a [~~written, oral, or telephonically or electronically communicated prescription, as allowed by the DEA~~] 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 Schedule III, IV, or V controlled substances in such other state;

(-b-) - (-c-) (No change.)

(C) (No change.)

(D) Prescription drug orders carried out or signed by an advanced practice nurse, physician assistant, or pharmacist.

(i) A pharmacist may dispense a prescription drug order that [~~which~~] is:

(I) - (II) (No change.)

(ii) (No change.)

(E) (No change.)

(3) (No change.)

(4) Electronic prescription drug orders. [~~For the purpose of this subsection, prescription drug orders shall be considered the same as verbal prescription drug orders.~~]

(A) Dangerous drugs.

(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 main-

tain 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) ~~[(C)]~~ Controlled substances. A pharmacist may only dispense an electronic prescription drug order for a Schedule II, III, IV, or V controlled substance in compliance with the federal and state laws and the rules of the Drug Enforcement Administration outlined in Part 1300 of the Code of Federal Regulations and Texas Department of Public Safety.

(C) ~~[(D)]~~ Prescriptions issued by a practitioner licensed in the Dominion of Canada or the United 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) Prescriptions.

(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 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) ~~[(5)]~~ 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) 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.

(C) 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) ~~[(9)]~~ of this subsection relating to accelerated refills.

(D) 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.

(E) Original prescription records other than prescriptions for Schedule II controlled substances may be stored in a ~~[on microfilm, microfiche, or other]~~ system that ~~[which]~~ is capable of producing a direct image of the original prescription record, e.g., 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) ~~[(6)]~~ Prescription drug order information.

(A) All original prescriptions shall bear:

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

(ii) address of the patient, provided, however, 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) 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 ~~[address and]~~ DEA registration number of the practitioner;

(iv) name and strength of the drug prescribed;

(v) 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) intended use for the drug unless the practitioner determines the furnishing of this information is not in the best interest of the patient; ~~[and]~~

(viii) 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 full 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 full 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 the:

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

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

~~{(B) All original electronic prescription drug orders shall bear:}~~

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

~~{(ii) address of the patient, provided, however, 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) name, and if for a controlled substance, the address and DEA registration number of the practitioner;}~~

~~{(iv) name and strength of the drug prescribed;}~~

~~{(v) quantity prescribed;}~~

~~{(vi) directions for use;}~~

~~{(vii) indications for use, unless the practitioner determines the furnishing of this information is not in the best interest of the patient;}~~

~~{(viii) date of issuance;}~~

~~{(ix) if a faxed prescription, a statement which indicates that the prescription has been faxed (e.g., Faxed to);}~~

~~{(x) telephone number of the prescribing practitioner;}~~

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

~~{(xii) if transmitted by a designated agent, the full name of the designated agent.}~~

~~{(C) All original written prescriptions carried out or signed by an advanced practice nurse or physician assistant in accordance with Subtitle B, Chapter 157, Occupations Code, shall bear:}~~

~~{(i) name and address of the patient;}~~

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

~~{(iii) name, original signature, and if the prescription is for a controlled substance, the DEA number of the advanced practice nurse or physician assistant;}~~

~~{(iv) address and telephone number of the clinic at which the prescription drug order was carried out or signed;}~~

~~{(v) name, strength, and quantity of the drug;}~~

~~{(vi) directions for use;}~~

~~{(vii) indications for use, if appropriate;}~~

~~{(viii) date of issuance; and}~~

~~{(ix) number of refills authorized.}~~

~~(B) [(D)] At the time of dispensing, a pharmacist is responsible for documenting the following information on either the original hard copy [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 product actually dispensed, if the drug was prescribed by generic name or if a drug product other than the one prescribed was dispensed pursuant to the provisions of the Act, Chapters 562 and 563.~~

~~(8) [(7)] 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) [(9)] of this subsection relating to accelerated refills.~~

~~(ii) [(B)] 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) [(C)] 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) [(D)] 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) [(E)] 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 professional judgment in refilling a prescription drug order for a drug, other than a controlled substance listed in Schedule II, 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; and

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

(I) the patient has the prescription container, label, receipt or other documentation from the other pharmacy ~~that~~ which 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 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) ~~[(F)]~~ Natural or manmade disasters. If a natural or manmade disaster has occurred that prohibits the pharmacist from being able to contact the practitioner, a pharmacist may exercise his professional judgment in refilling a prescription drug order for a drug, other than a controlled substance listed in Schedule II, 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 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 professional judgment in refilling the prescription provided:

(I) the patient has the prescription container, label, receipt or other documentation from the other pharmacy ~~that~~ which 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 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 patients, and patients must affirmatively indicate that they wish to enroll in such a program and the pharmacy shall document such indication.

(ii) Patients shall have the option to withdraw from such a program at any time.

(iii) Prescription refills for 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) ~~[(8)]~~ Records Relating to Dispensing Errors.

~~[(A) For purposes of this subsection, a dispensing error is defined as an action committed by a pharmacist or other pharmacy personnel that causes the patient or patient's agent to take possession of a dispensed prescription drug and an individual subsequently discovers that the patient has received an incorrect drug product, which includes incorrect strength, incorrect dosage form, and/or incorrect directions for use.]~~

~~[(B) 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)~~ ~~[(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)~~ ~~[(9)]~~ 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) (No change.)

(2) The patient medication record system shall provide for the immediate retrieval of information for the previous 12 months that [which] 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) - (5) (No change.)

(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)~~ ~~[(b)(5)(D)]~~ of this section.

(2) Refills.

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

~~(i)~~ (No change.)

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

~~(I) - (VII)~~ (No change.)

(B) (No change.)

(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 (1) of this section.

~~[(4) Transfer of prescription drug order information. For the purpose of refill or initial dispensing, the transfer of original prescription drug order information is permissible between pharmacies, subject to the following requirements:]~~

~~[(A) 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:]~~

~~[(B) 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:]~~

~~[(C) the transfer is communicated directly between pharmacists and/or pharmacist interns:]~~

~~[(D) both the original and the transferred prescription drug order are maintained for a period of two years from the date of last refill:]~~

~~[(E) the pharmacist or pharmacist intern transferring the prescription drug order information shall:]~~

~~[(i) write the word "void" on the face of the invalidated prescription drug order; and]~~

~~[(ii) record on the reverse of the invalidated prescription drug order the following information:]~~

~~[(I) the name, address, and if a controlled substance, the DEA registration number of the pharmacy to which such prescription drug order is transferred:]~~

~~[(II) the name of the pharmacist or pharmacist intern receiving the prescription drug order information:]~~

~~[(III) the name of the pharmacist or pharmacist intern transferring the prescription drug order information; and]~~

~~[(IV) the date of the transfer:]~~

~~[(F) the pharmacist or pharmacist intern receiving the transferred prescription drug order information shall:]~~

~~[(i) write the word "transfer" on the face of the transferred prescription drug order; and]~~

~~[(ii) record on the transferred prescription drug order the following information:]~~

~~[(I) original date of issuance and date of dispensing or receipt, if different from date of issuance:]~~

~~[(II) original prescription number and the number of refills authorized on the original prescription drug order:]~~

~~[(III) number of valid refills remaining and the date of last refill, if applicable;~~

~~[(IV) name, address, and if a controlled substance, the DEA registration number of the pharmacy from which such prescription information is transferred; and]~~

~~[(V) name of the pharmacist or pharmacist intern transferring the prescription drug order information.]~~

~~[(5) A pharmacist or pharmacist intern may not refuse to transfer original prescription information to another pharmacist or pharmacist intern who is acting on behalf of a patient and who is making a request for this information as specified in paragraph (4) of this subsection.]~~

~~(4) [(6)] 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 [~~community~~] pharmacy's data processing system is not in compliance with this subsection, the pharmacy must maintain a manual recordkeeping 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) [~~(b)(5)(D)~~] of this section.

(C) Requirements for backup systems.

(i) (No change.)

(ii) Data processing systems shall have a workable (electronic) data retention system that [~~which~~] 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) (No change.)

(II) purge the records of dispensing to a printout that [~~which~~] contains the same information required on the daily printout as specified in paragraph (2)(C) of this subsection. The information on this hard copy [~~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) (No change.)

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

(iii) (No change.)

(E) (No change.)

(2) Records of dispensing.

(A) (No change.)

(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 [~~hard-copy~~] prescription.

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

(i) - (viii) (No change.)

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

(I) - (VI) (No change.)

(x) (No change.)

(D) The daily hard copy [~~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 noncontrolled substances.

(E) Each individual pharmacist who dispenses or refills a prescription drug order shall verify that the data indicated on the daily hard copy [~~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 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 [~~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 [~~hard-copy~~] printout shall be available within 72 hours with a certification by the individual providing the printout, that [~~which~~] states that the printout is true and correct as of the date of entry and such information has not been altered, amended, or modified.

(G) (No change.)

(H) The data processing system shall be capable of producing a hard copy [~~hard-copy~~] printout of an audit trail for all dispensings (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) - (ii) (No change.)

(I) (No change.)

(J) The data processing system shall provide on-line retrieval (via computer [~~CRT~~] display or hard copy [~~hard-copy~~] printout) of the information set out in subparagraph (C) of this paragraph of:

(i) - (ii) (No change.)

(K) In the event that a pharmacy that [~~which~~] uses a data processing system experiences system downtime, the following is applicable:

(i) - (ii) (No change.)

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

(A) on the hard copy [~~hard-copy~~] prescription drug order;

(B) on the daily hard copy [~~hard-copy~~] printout; or

(C) via the computer [~~CRT~~] display.

~~(4) Transfer of prescription drug order information. For the purpose of refill or initial dispensing, the transfer of original pre-~~

scription drug order information is permissible between pharmacies, subject to the following requirements.}]

[(A) 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.}]

[(B) 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.}]

[(C) The transfer is communicated directly between pharmacists and/or pharmacist interns orally by telephone or via facsimile or as authorized in paragraph (5) of this subsection. A transfer completed as authorized in paragraph (5) of this subsection may be initiated by a pharmacy technician or pharmacy technician trainee acting under the direct supervision of a pharmacist.}]

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

[(E) The pharmacist or pharmacist intern transferring the prescription drug order information shall ensure the following occurs:}]

[(i) the prescription is voided in the data processing system; and}]

[(ii) the following information is stored with the invalidated prescription drug order in the data processing system:}]

[(I) the name, address, and if a controlled substance, the DEA registration number of the pharmacy to which such prescription is transferred;}]

[(II) the name of the pharmacist or pharmacist intern receiving the prescription drug order information;}]

[(III) the name of the pharmacist or pharmacist intern transferring the prescription drug order information; and}]

[(IV) the date of the transfer.}]

[(F) The pharmacist or pharmacist intern receiving the transferred prescription drug order information shall ensure the following occurs:}]

[(i) the prescription record indicates the prescription was a transfer; and}]

[(ii) the following information is stored with the prescription drug order in the data processing system:}]

[(I) original date of issuance and date of dispensing or receipt, if different from date of issuance;}]

[(II) original prescription number and the number of refills authorized on the original prescription drug order;}]

[(III) number of valid refills remaining and the date of last refill, if applicable;}]

[(IV) name, address, and if a controlled substance, the DEA registration number of the pharmacy from which such prescription drug order information is transferred; and}]

[(V) name of the pharmacist or pharmacist intern transferring the prescription drug order information.}]

[(G) 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, a pharmacist or pharmacist intern, and the prescription may be read to a pharmacist or pharmacist intern by telephone.}]

[(H) 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.}]

[(I) If the data processing system does not have the capacity to store all the information required in subparagraphs (E) and (F) of this paragraph, the pharmacist is required to record this information on the original or transferred prescription drug order.}]

[(J) The data processing system shall have a mechanism to prohibit the transfer or refilling of controlled substance prescription drug orders which have been previously transferred.}]

[(5) Electronic transfer of prescription drug order information between pharmacies. Pharmacies electronically accessing the same prescription drug order records may electronically transfer prescription information if the following requirements are met.}]

[(A) The original prescription is voided and the following information is documented in the records of the transferring pharmacy:}]

[(i) the name, address, and if a controlled substance, the DEA registration number of the pharmacy to which such prescription is transferred;}]

[(ii) the name of the pharmacist or pharmacist intern receiving the prescription drug order information; and}]

[(iii) the date of the transfer.}]

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

[(C) An electronic transfer between pharmacies may be initiated by a pharmacy technician or pharmacy technician trainee acting under the direct supervision of a pharmacist.}]

[(6) A pharmacist or pharmacist intern may not refuse to transfer original prescription information to another pharmacist or pharmacist intern who is acting on behalf of a patient and who is making a request for this information as specified in paragraphs (4) and (5) of this subsection.}]

(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 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 directly between pharmacists orally by telephone or via facsimile or as authorized in paragraph (8)(E) of this subsection. A transfer completed as authorized in paragraph (8)(E) of this subsection may be initiated by a pharmacy technician or pharmacy technician trainee acting under the direct supervision of a 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 pharmacist 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; and

(B) the following information is recorded on the reverse of the invalidated prescription drug order or stored with the invalidated prescription drug order in the data processing system:

(i) the name, address, and if a controlled substance, the DEA registration number of the pharmacy to which such prescription is transferred;

(ii) the name of the pharmacist receiving the prescription drug order information;

(iii) the name of the pharmacist transferring the prescription drug order information; and

(iv) the date of the transfer.

(6) The pharmacist receiving the transferred prescription drug order information shall ensure the following occurs:

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

(B) the following information if recorded on the prescription drug order or is stored with the prescription drug order in the data processing system:

(i) original date of issuance and date of dispensing or receipt, if different from date of issuance;

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

(iii) number of valid refills remaining and the date of last refill, if applicable;

(iv) name, address, and if a controlled substance, the DEA registration number of the pharmacy from which such prescription drug order information is transferred; and

(v) name of the pharmacist transferring the prescription drug order information.

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

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

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

(8) Pharmacies using a data processing system 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, 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 required 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 required in paragraphs (5) and (6) of this subsection.

(ii) Pharmacies not owned by the same 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 pharmacy technician or pharmacy technician trainee acting under the direct supervision of a pharmacist.

(9) A pharmacist may not refuse to transfer original prescription information to another pharmacist who is acting on behalf of a patient and who is making a request for this information as specified in this subsection.

(h) [(g)] 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 [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) 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) [~~(DEA 222C)~~] to the distributing pharmacy.

(B) The distributing pharmacy shall:

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

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

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

(i) [~~(h)~~] Other records. Other records to be maintained by a pharmacy:

(1) a permanent log of the initials or identification codes that [which] will identify each pharmacist, pharmacy technician, and pharmacy technician trainee 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);

(2) Copy 3 of DEA order form (DEA 222) that [~~(DEA 222C)~~ which] 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 [~~(DEA 222C)~~] 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 [~~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 [which] 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) [~~(h)~~] 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 Texas State Board of Pharmacy. 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.

(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 [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 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.

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

(l) Documentation of consultation. When a pharmacist consults a prescriber as described in this section, the pharmacist shall document on the hard copy or in the pharmacy's data processing system associated with the prescription such occurrences 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 performing the consultation clearly recorded for the purpose of identifying

the pharmacist who performed the consultation if on the information is recorded on the hard copy prescription.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on February 25, 2013.

TRD-201300858

Gay Dodson, R.Ph.

Executive Director/Secretary

Texas State Board of Pharmacy

Earliest possible date of adoption: April 7, 2013

For further information, please call: (512) 305-8028



## CHAPTER 297. PHARMACY TECHNICIANS AND PHARMACY TECHNICIAN TRAINEES

### 22 TAC §297.8

The Texas State Board of Pharmacy proposes amendments to §297.8 concerning Continuing Education Requirements. The amendments, if adopted, require the law portion of the continuing education requirements for pharmacy technicians to relate to Texas pharmacy law.

Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year period the rule is in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule.

Ms. Dodson 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 rule will be to update the law portion of the requirements for pharmacy technicians to be consistent with the pharmacists' requirements. There is no fiscal impact for individuals, small or large businesses, or to other entities which are required to comply with this section.

Comments on the proposed amendments may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600, Austin, Texas 78701, FAX (512) 305-8008. Comments must be received by 5:00 p.m., April 30, 2013.

The amendments are proposed under §551.002 and §554.051 of the Texas Pharmacy Act (Chapters 551 - 566 and 568 - 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 - 566 and 568 - 569, Texas Occupations Code.

§297.8. *Continuing Education Requirements.*

(a) (No change.)

(b) Pharmacy Technicians.

(1) - (2) (No change.)

(3) For renewals received after January 1, 2015, one [One] hour specified in paragraph (2) of this subsection [subsection (a)] of this

section] shall be related to Texas pharmacy laws or rules [pharmacy law].

(4) - (5) (No change.)

(6) Pharmacy technicians who are certified by the Pharmacy Technician Certification Board and maintain this certification shall be considered as having met the continuing education requirements of this section and shall not be subject to audit by the board provided one hour of continuing education is related to Texas pharmacy law or rules.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on February 25, 2013.

TRD-201300859

Gay Dodson, R.Ph.

Executive Director/Secretary

Texas State Board of Pharmacy

Earliest possible date of adoption: April 7, 2013

For further information, please call: (512) 305-8028



## PART 21. TEXAS STATE BOARD OF EXAMINERS OF PSYCHOLOGISTS

### CHAPTER 463. APPLICATIONS AND EXAMINATIONS

#### 22 TAC §463.2

The Texas State Board of Examiners of Psychologists proposes an amendment to §463.2, concerning Application Process. The proposed amendment will describe the exclusive method for obtaining an application for licensure from the Board and remove the dated reference to a non-existent fee for obtaining an application packet from the Board by mail. The fee referenced in paragraph (1) was found in §473.5 but has been deleted. The proposed amendment also clarifies the point from which the 90-day period begins to run during which an application file remains active. Lastly, the proposed amendment will clarify paragraphs (3) and (4), so that they accurately reflect the application review process.

Darrel D. Spinks, Executive Director, has determined that for the first five-year period the proposed amendment will be in effect there will be no fiscal implications for state or local government as a result of enforcing or administering the amendment.

Mr. Spinks also has determined that for each year of the first five years the rule is in effect the public benefit anticipated as a result of enforcing the rule will be to help the Board protect the public. There will be no effect on small businesses. There is no anticipated economic cost to persons who are required to comply with the rule as proposed.

Comments on the proposed amendment may be submitted to Brenda Skiff, Texas State Board of Examiners of Psychologists, 333 Guadalupe, Suite 2-450, Austin, Texas 78701, (512) 305-7700 or email [brenda@tsbep.state.tx.us](mailto:brenda@tsbep.state.tx.us) within 30 days of publication of this proposal in the *Texas Register*.

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

5  
6 §291.34 Records

7  
8 XXX

9  
10 (b) Prescriptions.

11  
12 XXX

13  
14 **(8)** ~~[(7)]~~ Refills.

15  
16 XXX

17  
18 **(F) Auto-Refill Programs. A pharmacy may use a program that automatically refills**  
19 **prescriptions that have existing refills available in order to improve patient compliance**  
20 **with and adherence to prescribed medication therapy. The following is applicable in**  
21 **order to enroll patients into an auto-refill program.**

22  
23 **(i) Notice of the availability of an auto-refill program shall be given to the patient or**  
24 **patient's agent, and the patient or patient's agent must affirmatively indicate that**  
25 **they wish to enroll in such a program and the pharmacy shall document such**  
26 **indication.**

27  
28 **(ii) The patient or patient's agent shall have the option to withdraw from such a**  
29 **program at any time.**

30  
31 **(iii) Prescription refills for controlled substances may not be dispensed by an**  
32 **auto-refill program.**

33  
34 **(iv) As is required for all prescriptions, a drug regimen review shall be completed**  
35 **on all prescriptions filled as a result of the auto-refill program. Special attention**  
36 **shall be noted for drug regimen review warnings of duplication of therapy and all**  
37 **such conflicts shall be resolved with the prescribing practitioner prior to refilling**  
38 **the prescription.**

39

----- Original Message -----

Subject:

From: "Halverson, Roberta" <[REDACTED]>

To: Gay Dodson <[gay.dodson@tsbp.state.tx.us](mailto:gay.dodson@tsbp.state.tx.us)>

CC:

Dear Ms. Dotson,

The proposed language for the Class A revision on lines 550-566 on Auto-Refill Programs was discussed at your last Board of Pharmacy meeting in February. I understood some of the language was going to be revised. In the long term care setting, it is not always practical to obtain *patient* consent in a cycle-fill program for a facility. Omnicare has established Standard Operating Procedures regarding Cycle Fill prescriptions to participating facilities. Each prescription dispensed as part of a Cycle Fill must have a corresponding authorization to refill from the facility (or customer). Is it possible to exclude health care facility patients from the notice and enrollment documentation portion of this rule, as this piece is handled at the facility level?

Respectfully,

Roberta Halverson, RPh, CGP

*Roberta Halverson, RPh, CGP  
General Manager  
American Pharmaceutical Services  
An Omnicare Company  
9210 Cameron Road, Suite 800  
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April 8, 2013

Allison Benz, RPh, MS  
Texas State Board of Pharmacy  
William P. Hobby Building  
333 Guadalupe Street, Suite 3-600  
Austin, TX 78701-3942

RE: Comments to Proposed Rules for Adoption

Dear Ms. Benz:

On behalf of HEB, I appreciate the opportunity to submit comments regarding the proposed new rules under §291.33 (Class A Pharmacy Operational Standards) and §291.34 (Class A Pharmacy Records).

H-E-B currently operates 231 pharmacies in the state of Texas and employs over 700 pharmacists, 1400 registered pharmacy technicians and pharmacy technician trainees, and 400 non-registered individuals. Our pharmacies provide prescription services along with other healthcare services such as immunizations, medication therapy management, disease state management, and health screenings to the citizens of Texas.

#### §291.33 Operational Standards

(iv) **Prior to dispensing, any** [Any] questions regarding a prescription drug order must be resolved with the prescriber and written documentation of these discussions made and maintained **as specified in subparagraph (C) of this paragraph.**

I wish to commend the Board for taking an active role dictating that all questionable prescriptions, as part of the Drug Regimen Review process, must be clarified and verified accordingly prior to dispensing. This requirement will mitigate the potential for possible medication errors when the prescription is unclear or has contraindications from the beginning in addition to increasing the level of patient safety in our pharmacies.

#### §291.34 Records

##### **(F) Auto-Refill Programs.**

**(iii) Prescription refills for controlled substances may not be dispensed by an auto-refill program.**

Recognizing the current epidemic of prescription drug abuse, the complete prohibition of controlled substances for auto-refill programs may not serve in a patient's best interest. There are several controlled substances which patients must utilize on a monthly basis which do not carry the same scrutiny as others (for example, patients who take Phenobarbital for seizure control or Lyrica for neuropathic pain control). Although the above-mentioned items are Schedule IV controlled substances, the abuse potential is relatively minimal when compared to high-profile items such as hydrocodone or alprazolam. We believe the decision to add a controlled substance medication to an auto-refill program should not be prohibited but rather be up to the professional judgment of the pharmacist.

(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.

(3) The transfer is communicated directly between pharmacists orally by telephone or via facsimile or as authorized in paragraph (9)(E) of this subsection.

(ii) the name of the pharmacist receiving the prescription drug order information

(iii) the name of the pharmacist transferring the prescription drug order information

I appreciate the Board and its willingness to promote patient safety as it relates to the transfers of prescription information. Such proposals above, however, do not include the "pharmacist intern" as an individual who is authorized to transfer prescriptions or receive prescription transfers. Such exclusion would not allow the intern to prepare for his/her full responsibilities as a Registered Pharmacist as it pertains to transfer of prescriptions. We can completely understand the safety concerns during the transfer process when there is an intern on the transferring end and the receiving end. One possible solution would be to dictate that at least one pharmacy employee, during the prescription transfer process, must be a pharmacist.

Thank you for the consideration of our comments.

Please do not hesitate to contact me with any questions, concerns, or further assistance.

Respectfully,



Doug Read, Pharm.D.  
Director of Pharmacy Compliance and Regulatory Affairs  
H-E-B Pharmacy  
3481 Fredericksburg Rd, Suite #2  
San Antonio, TX 78201



NATIONAL ASSOCIATION OF  
CHAIN DRUG STORES

April 26, 2013

Allison Benz, R.Ph., M.S.  
Director of Professional Services  
Texas State Board of Pharmacy  
333 Guadalupe Street, Suite 3-600  
Austin, Texas 78701

Re: Proposed Rules Changes under 22 TAC §291.34

Dear Ms. Benz:

On behalf of the approximately 2,798 chain pharmacies operating in the state of Texas, the National Association of Chain Drug Stores (“NACDS”) thanks the Texas State Board of Pharmacy (“TSBP”) for the opportunity to submit comments on proposed rules under 22 TAC §291.34 pertaining to community pharmacy records. While we are generally supportive of the proposed rule changes, there are two issues under the rules that we ask TSBP to further address:

Auto-Refill Programs

Under 22 TAC §291.34 (a)(8)(F), TSBP has proposed new language outlining the parameters for auto-refill programs implemented and employed by community pharmacies, including limitations on which medications can be dispensed in this manner. TSBP has proposed to establish that no controlled substance prescription be dispensed by an auto-refill program. Chain pharmacy strongly supports appropriate monitoring and dispensing of controlled substances, especially given the ongoing problems with prescription drug abuse in our country. However, we are concerned that while well-intended, the proposed prohibition against dispensing any controlled substance prescription by an auto-refill program would not be warranted in all instances. For example, there are certain controlled substance prescriptions commonly taken as maintenance medications by epileptics and individuals with neuropathic pain that have a relatively low potential for abuse. In these cases, it would not be inappropriate to dispense these prescriptions through an auto-refill program. For this reason, we ask the Board to consider revising 22 TAC §291.34 (a)(8)(F) to allow pharmacists to exercise professional judgment with respect to whether a certain controlled substance prescription would be appropriately dispensed by an auto-refill program.

(8) [(7)] Refills.

(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.

...

(iii) Prescription refills for controlled substances may **not** be dispensed by an auto-refill program ***if a pharmacist determines in his or her professional judgment, dispensing a controlled substance prescription by an auto-refill program would be appropriate in that circumstance.***

### Prescription Transfers

Under 22 TAC §291.34 (g), TSBP has proposed to renumber and revise requirements for prescription transfers. Notably, the proposed rule would omit provisions in current rules that now allow pharmacy interns to participate in prescription transfers. As an alternative, we ask TSBP to instead consider the approach taken by numerous other states, allowing interns under the supervision of a pharmacist to participate in the prescription transfer process. To accomplish this, we suggest the following changes to 22 TAC §291.34 (g):

(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.

...

(3) The transfer is communicated ***directly between pharmacists*** orally by telephone or via facsimile or as authorized in paragraph (8)(E) of this subsection ***by one pharmacist to another pharmacist or a pharmacist intern, or by a pharmacist intern under the supervision of a pharmacist to another pharmacist.*** A transfer completed as authorized in paragraph (8)(E) of this subsection may be initiated by a pharmacy technician or pharmacy technician trainee acting under the direct supervision of a pharmacist.

...

(5) The pharmacist ***or pharmacist intern*** transferring the prescription drug order information shall ensure the following occurs:

...

(B) the following information is recorded on the reverse of the invalidated prescription drug order or stored with the invalidated prescription drug order in the data processing system:

...

(ii) the name of the pharmacist ***or pharmacist intern*** receiving the prescription drug order information;

(iii) the name of the pharmacist ***or pharmacist intern*** transferring the prescription drug order information; and ...

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Texas State Board of Pharmacy  
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NACDS appreciates TSBP considering our input on this rulemaking. Please do not hesitate to contact me with any questions or for further assistance. I can be reached at: 817-442-1155 or [mstaples@nacds.org](mailto:mstaples@nacds.org).

Sincerely,

A handwritten signature in black ink that reads "Mary Staples". The signature is written in a cursive, flowing style.

Mary Staples  
Regional Director, State Government Affairs



May 6, 2013

Allison Benz, RPh, MS

Texas State Board of Pharmacy

William P. Hobby Building

333 Guadalupe Street, Suite 3-600

Austin, TX 78701-3942

RE: Comments to Proposed Amendments to Rule 291.34 – Transfer by Interns

Dear Ms. Benz,

On behalf of the Joint Committee on Internship Programs, which represents the experiential programs from the 7 Texas schools/colleges of pharmacy, we would appreciate the opportunity to comment on the proposed amendment to rule 291.34 which would no longer allow interns to transfer prescriptions.

As part of the professional curriculum, great emphasis is placed on patient safety, and students are trained on these processes in a simulated environment prior to experiential learning in practice sites. Although simulation exercises are valuable learning tools for students, practical experience in actual pharmacy practice settings is the optimal way to prepare the interns to practice pharmacy prior to licensure.

JCIP understands that patient safety is of paramount concern, and we understand that errors can occur if transfers are not done properly. Rather than preventing interns from gaining experience in handling transfers, we would propose that procedures be developed that would provide adequate oversight for interns handling the transfer of prescriptions. Specifically, we would like to propose that interns be allowed to give transfers or receive transfers as long as a pharmacist preceptor is included in the process. Ultimately, the pharmacist is responsible for the transfer, but allowing an intern to be included in the process will allow him or her to gain valuable knowledge and experience in order to practice safely and responsibly as a pharmacist in the future.

Thank you for your consideration of our request. Please do not hesitate to contact us with any questions or concerns.

Respectfully,

Joint Committee on Internship Programs

Texas A&M Health Science Center Irma Rangel College of Pharmacy

Anna H. Brozick, Pharm.D., M.M., Director of Introductory Pharmacy Practice Experiences

David Matthews, PharmD, Director of Advanced Pharmacy Practice Experiences



Texas Southern University College of Pharmacy and Health Sciences  
Flora G. Estes, Pharm.D., Assistant Dean, Practice Programs

Texas Tech University Health Sciences Center School of Pharmacy  
Craig Cox, PharmD, BCPS, Vice-Chair of Experiential Programs

The University of Texas at Austin College of Pharmacy  
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University of Houston College of Pharmacy  
Nancy Ordonez, PharmD, BCPS, Assistant Dean for Experiential Programs  
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Jeffrey Copeland, BS, ThM, PharmD, Assistant Dean, Experiential Programs  
Nicole Farrell, Pharm. D., Introductory Pharmacy Practice Experiences Coordinator

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Lisa Killam-Worrall, PharmD, BCPS, Associate Professor, Director of Experiential Education