RULE ANALYSIS

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

Short Title: Labeling Requirements

Rule Numbers: §291.93

Statutory Authority: Texas Pharmacy Act, Chapter 551-569, Occupations Code:

(1) Section 551.002 specifies that the purpose of the Act is to protect the public through the effective control and regulation of the practice of pharmacy; and
(2) Section 554.051 gives the Board the authority to adopt rules for the proper administration and enforcement of the Act.

Purpose: The amendments, if adopted, update the rules for Class D pharmacies to be consistent with other sections; and clarify the labeling requirements to allow an auxiliary label to be used for adding certain information to the prescription label.

The Board reviewed and voted to propose the amendments during the November 1, 2016, meeting. The proposed amendments were published in the December 30, 2016, issue of the Texas Register at 41 TexReg10509.
CHAPTER 291. PHARMACIES

SUBCHAPTER E. CLINIC PHARMACY (CLASS D)

22 TAC §291.93

The Texas State Board of Pharmacy proposes amendments to §291.93, concerning Operational Standards. The amendments to §291.93, if adopted, update the rules for Class D pharmacies to be consistent with other sections; and clarify the labeling requirements to allow an auxiliary label to be used for adding certain information to the prescription label.

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 amendments will ensure medications provided by Class D pharmacies are appropriately labeled. There is no fiscal impact for individuals, small or large businesses, or to other entities which are required to comply with this section.

Written comments on the amendments may be submitted to Allison Vordenbaumen 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) 305-6778. Comments must be received by 5:00 p.m., February 6, 2017.

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.

§291.93 Operational Standards.

(a) Registration.

(1) Licensing [General] requirements.

(A) All clinic pharmacies shall register with the board on a pharmacy license application [form] provided by the board, following the procedures specified in §291.1 of this title (relating to Pharmacy License Application).

January 17, 2017
(B) All clinic pharmacies shall provide a copy of their policy and procedure manual, which includes the formulary, to the board with the initial license application.

[(C) The registration form shall be signed by the pharmacist-in-charge of the clinic pharmacy.]

[(D) The owner or managing officer of the clinic shall sign the registration form and shall agree to comply with the rules adopted by the board governing clinic pharmacies.]

[(E) The registration form shall be certified and state whether the clinic pharmacy is a sole ownership and give the name of the owner, or if a partnership, name all the managing partners, or if a corporation, name all the managing officers.]

(C) [(F)] The following fees will be charged.

(i) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for the issuance of a new license and for each renewal.

(ii) A pharmacy operated by the state or a local government that qualifies for a Class D license is not required to pay a fee to obtain a license.

(D) [(G)] A Class D pharmacy which changes ownership shall notify the board within ten days of the change of ownership and apply for a new and separate license as specified in §291.3 of this title (relating to Required Notifications). [When a clinic pharmacy changes ownership, a new and separate license application must be filed with the board and the old license returned to the board's office.]

(E) [(H)] A clinic pharmacy shall notify the board in writing of any change in name or location as specified in §291.3 of this title. [within 10 days.]

(F) [(I)] A separate license is required for each principal place of business and only one pharmacy license may be issued to a specific location.

(G) [(J)] A clinic pharmacy shall notify the board in writing within 10 days of a change of the pharmacist-in-charge or staff pharmacist or consultant pharmacist.

(H) [(K)] A Class D pharmacy shall notify the board in writing within ten days of closing, following the procedures as specified in §291.5 of this title (relating to Closing a Pharmacy). [A clinic pharmacy shall notify the board in writing within 10 days of permanent closing.]

(2) Registration requirements for facilities that operate at temporary clinic sites. A facility that operates a clinic at one or more temporary locations may be licensed as a Class D [(clinic)] pharmacy and provide dangerous drugs from these temporary locations provided:

(A) the Class D [(clinic)] pharmacy complies with the registration requirements in paragraph (1) of this subsection;
(B) the Class D [clinic] pharmacy has a permanent location where all dangerous drugs and records are stored;

(C) no dangerous drugs are stored or left for later pickup by the patient at the temporary location(s), and all drugs are returned to the permanent location each day and stored:

(i) within the Class D [clinic] pharmacy; or

(ii) within the pharmacy's mobile unit provided the mobile clinic is parked at the location of the clinic pharmacy in a secure area with adequate measures to prevent unauthorized access, and the drugs are maintained at proper temperatures;

(D) the permanent location is the address of record for the pharmacy;

(E) the facility has no more than six temporary locations in operation simultaneously;

(F) the Class D [clinic] pharmacy notifies the board of the locations of the temporary locations where drugs will be provided and the schedule for operation of such clinics; and

(G) the Class D [clinic] pharmacy notifies the board within 10 days of a change in address or closing of a temporary location or a change in schedule of operation of a clinic.

(b) Environment.

(1) General requirements.

(A) The Class D [clinic] pharmacy shall have a designated area(s) for the storage of dangerous drugs and/or devices.

(B) No person may operate a pharmacy which is unclean, unsanitary, or under any condition which endangers the health, safety, or welfare of the public.

(C) The Class D pharmacy shall comply with all federal, state, and local health laws and ordinances.

(D) A sink with hot and cold running water shall be available to all pharmacy personnel and shall be maintained in a sanitary condition at all times.

(2) Security.

(A) Only authorized personnel may have access to storage areas for dangerous drugs and/or devices.

(B) All storage areas for dangerous drugs and/or devices shall be locked by key, combination, or other mechanical or electronic means, so as to prohibit access by unauthorized individuals.
(C) The pharmacist-in-charge shall be responsible for the security of all storage areas for dangerous drugs and/or devices including provisions for adequate safeguards against theft or diversion of dangerous drugs and devices, and records for such drugs and devices.

(D) The pharmacist-in-charge shall consult with clinic personnel with respect to security of the pharmacy, including provisions for adequate safeguards against theft or diversion of dangerous drugs and/or devices, and records for such drugs and/or devices.

(E) Housekeeping and maintenance duties shall be carried out in the pharmacy, while the pharmacist-in-charge, consultant pharmacist, staff pharmacist, or supportive personnel is on the premises.

(c) Equipment. Each Class D [clinic] pharmacy shall maintain the following equipment and supplies:

1. if the Class D [clinic] pharmacy prepackages drugs for provision:
   (A) a typewriter or comparable equipment; and
   (B) an adequate supply of child-resistant, moisture-proof, and light-proof containers and prescription, poison, and other applicable identification labels used in dispensing and providing of drugs;

2. if the Class D [clinic] pharmacy maintains dangerous drugs requiring refrigeration and/or freezing, a refrigerator and/or freezer;

3. if the Class D [clinic] pharmacy compounds prescription drug orders, a properly maintained Class A prescription balance (with weights) or equivalent analytical balance. It is the responsibility of the pharmacist-in-charge to have such balance inspected at least every three years by the appropriate authority as prescribed by local, state, or federal law or regulations.

(d) Library. A reference library shall be maintained which includes the following in hard copy or electronic format:

1. current copies of the following:
   (A) Texas Pharmacy Act and rules; and
   (B) Texas Dangerous Drug Act;

2. current copies of at least two of the following references:
   (A) Facts and Comparisons with current supplements;
   (B) AHFS Drug Information;
(C) United States Pharmacopeia Dispensing Information (USPDI);

(D) Physician's Desk Reference (PDR);

(E) American Drug Index;

(F) a reference text on drug interactions, such as Drug Interaction Facts. A separate reference is not required if other references maintained by the pharmacy contain drug interaction information including information needed to determine severity or significance of the interaction and appropriate recommendations or actions to be taken;

(G) reference texts in any of the following subjects: toxicology, pharmacology, or drug interactions; or

(H) reference texts pertinent to the major function(s) of the clinic.

e) Drugs and devices.

(1) Formulary.

(A) Each Class D pharmacy shall have a formulary which lists all drugs and devices that are administered, dispensed, or provided by the Class D pharmacy.

(B) The formulary shall be limited to the following types of drugs and devices, exclusive of injectable drugs for administration in the clinic and nonprescription drugs, except as provided in subparagraph (D) of this paragraph:

(i) anti-infective drugs;

(ii) musculoskeletal drugs;

(iii) vitamins;

(iv) obstetrical and gynecological drugs and devices;

(v) topical drugs; and

(vi) serums, toxoids, and vaccines.

(C) The formulary shall not contain the following drugs or types of drugs:

(i) Nalbuphine (Nubain);

(ii) drugs used to treat erectile dysfunction; and

(iii) Schedule I - V controlled substances.
Clinics with a patient population which consists of at least 80% indigent patients may petition the board to operate with a formulary which includes types of drugs and devices, other than those listed in subparagraph (B) of this paragraph based upon documented objectives of the clinic, under the following conditions.

(i) Such petition shall contain an affidavit with the notarized signatures of the medical director, the pharmacist-in-charge, and the owner/chief executive officer of the clinic, and include the following documentation:

(I) the objectives of the clinic;

(II) the total number of patients served by the clinic during the previous fiscal year or calendar year;

(III) the total number of indigent patients served by the clinic during the previous fiscal year or calendar year;

(IV) the percentage of clinic patients who are indigent, based upon the patient population during the previous fiscal year or calendar year;

(V) the proposed formulary and the need for additional types of drugs based upon objectives of the clinic; and

(VI) if the provision of any drugs on the proposed formulary require special monitoring, the clinic pharmacy shall submit relevant sections of the clinic’s policy and procedure manual regarding the provision of drugs that require special monitoring.

(ii) Such petition shall be resubmitted every two years in conjunction with the application for renewal of the pharmacy license.

(I) Such renewal petition shall contain the documentation required in clause (i) of this subparagraph.

(II) If at the time of renewal of the pharmacy license, the patient population for the previous fiscal year or calendar year is below 80% indigent patients, the clinic shall be required to submit an application for a Class A pharmacy license or shall limit the clinic formulary to those types of drugs and devices listed in subparagraph (B) of this paragraph.

(iii) If a Class D [clinic] pharmacy wishes to add additional drugs to the expanded formulary, the pharmacy shall petition the board in writing prior to adding such drugs to the formulary. The petition shall identify drugs to be added and the need for the additional drugs based upon objectives of the clinic as specified in clause (i) of this subparagraph.

(iv) The following additional requirements shall be satisfied for clinic pharmacies with expanded formularies.
(I) Supportive personnel who are providing drugs shall be licensed nurses or practitioners.

(II) The pharmacist-in-charge, consultant pharmacist, or staff pharmacist shall make on-site visits to the clinic at least monthly.

(III) If the pharmacy provides drugs which require special monitoring (i.e., drugs which require follow-up laboratory work or drugs which should not be discontinued abruptly), the pharmacy shall have policies and procedures for the provision of the prescription drugs to patients and the monitoring of patients who receive such drugs.

(IV) The pharmacist-in-charge, consultant pharmacists, or staff pharmacists shall conduct retrospective drug regimen reviews of a random sample of patients of the clinic on at least a quarterly basis. The pharmacist-in-charge shall be responsible for ensuring that a report regarding the drug regimen review, including the number of patients reviewed, is submitted to the clinic's medical director and the pharmacy and therapeutics committee of the clinic.

(V) If a pharmacy provides antipsychotic drugs:

(-a-) a physician of the clinic shall initiate the therapy;

(-b-) a practitioner shall monitor and order ongoing therapy; and

(-c-) the patient shall be physically examined by the physician at least on a yearly basis.

(v) The board may consider the following items in approving or disapproving a petition for an expanded formulary:

(I) the degree of compliance on past compliance inspections;

(II) the size of the patient population of the clinic;

(III) the number and types of drugs contained in the formulary; and

(IV) the objectives of the clinic.

(2) Storage.

(A) Drugs and/or devices which bear the words "Caution, Federal Law Prohibits Dispensing without prescription" or "Rx only" shall be stored in secured storage areas.

(B) All drugs shall be stored at the proper temperatures, as defined in §291.15 of this title (relating to Storage of Drugs).

(C) Any drug or device bearing an expiration date may not be provided, dispensed, or administered beyond the expiration date of the drug or device.
(D) Outdated drugs or devices shall be removed from stock and shall be quarantined together until such drugs or devices are disposed.

(E) Controlled substances may not be stored at the Class D [clinic] pharmacy.

(3) Drug samples.

(A) Drug samples of drugs listed on the Class D [clinic] pharmacy's formulary and supplied by manufacturers shall be properly stored, labeled, provided, or dispensed by the Class D [clinic] pharmacy in the same manner as prescribed by these sections for dangerous drugs.

(B) Samples of controlled substances may not be stored, provided, or dispensed in the Class D [clinic] pharmacy.

(4) Prepackaging and labeling for provision.

(A) Drugs may be prepackaged and labeled for provision in the Class D [clinic] pharmacy. Such prepackaging shall be performed by a pharmacist or supportive personnel under the direct supervision of a pharmacist and shall be for the internal use of the clinic.

(B) Drugs must be prepackaged in suitable containers.

(C) The label of the prepackaged unit shall bear:

(i) the name, address, and telephone number of the clinic;

(ii) directions for use, which may include incomplete directions for use provided:

(I) labeling with incomplete directions for use has been authorized by the pharmacy and therapeutics committee;

(II) precise requirements for completion of the directions for use are developed by the pharmacy and therapeutics committee and maintained in the pharmacy policy and procedure manual; and

(III) the directions for use are completed by practitioners, pharmacists, licensed nurses or physician assistants in accordance with the precise requirements developed under subclause (II) of this clause;

(iii) name and strength of the drug--if generic name, the name of the manufacturer or distributor of the drug;

(iv) quantity;

(v) lot number and expiration date; and

(vi) appropriate ancillary label(s).
(D) Records of prepackaging shall be maintained according to §291.94(c) of this title (relating to Records).

(5) Labeling for provision of drugs and/or devices in an original manufacturer's container.

(A) Drugs and/or devices in an original manufacturer's container shall be labeled prior to provision with the information set out in paragraph (4)(C) of this subsection.

(B) Drugs and/or devices in an original manufacturer's container may be labeled by:

(i) a pharmacist in a pharmacy licensed by the board; or

(ii) supportive personnel in a Class D pharmacy, provided the drugs and/or devices and control records required by §291.94(d) of this title are quarantined together until checked and released by a pharmacist.

(C) Records of labeling for provision of drugs and/or devices in an original manufacturer's container shall be maintained according to §291.94(d) of this title.

(6) Provision.

(A) Drugs and devices may only be provided to patients of the clinic.

(B) At the time of the initial provision, a licensed nurse or practitioner shall provide verbal and written information to the patient or patient's agent on side effects, interactions, and precautions concerning the drug or device provided. If the provision of subsequent drugs is delivered to the patient at the patient's residence or other designated location, the following is applicable:

(i) Written information as specified in subparagraph (B) of this paragraph shall be delivered with the medication.

(ii) The pharmacy shall maintain and use adequate storage or shipment containers and use shipping processes to ensure drug stability and potency. Such shipping processes shall include the use of appropriate packaging material and/or devices to ensure that the drug is maintained at an appropriate temperature range to maintain the integrity of the medication throughout the delivery process.

(iii) The pharmacy shall use a delivery system which is designed to ensure that the drugs are delivered to the appropriate patient.

(C) The provision of drugs or devices shall be under the continuous supervision of a pharmacist according to standing delegation orders or standing medical orders and in accordance with written policies and procedures and completion of the label as specified in subparagraph (G) of this paragraph.
(D) Drugs and/or devices may only be provided in accordance with the system of control and accountability for drugs and/or devices provided by the clinic; such system shall be developed and supervised by the pharmacist-in-charge.

(E) Only drugs and/or devices listed in the clinic formulary may be provided.

(F) Drugs and/or devices may only be provided in prepackaged quantities in suitable containers and/or original manufacturer's containers which are appropriately labeled as set out in paragraphs (4) and (5) of this subsection.

(G) Such drugs and/or devices shall be labeled by a pharmacist licensed by the board; however, when drugs and/or devices are provided under the supervision of a physician according to standing delegation orders or standing medical orders, supportive personnel may at the time of provision print on the label the following information or affix an ancillary label containing the following information:

(i) patient's name; however, the patient's partner or family member is not required to be on the label of a drug prescribed for a partner for a sexually transmitted disease or for a patient's family members if the patient has an illness determined by the Centers for Disease Control and Prevention, the World Health Organization, or the Governor's office to be pandemic;

(ii) any information necessary to complete the directions for use in accordance with paragraph (4)(C)(ii) of this subsection;

(iii) date of provision; and

(iv) practitioner's name.

(H) Records of provision shall be maintained according to §291.94(e) of this title.

(I) Controlled substances may not be provided or dispensed.

(J) Non-sterile and sterile preparations may only be provided by the clinic pharmacy in accordance with §291.131 and §291.133 of this title (relating to Pharmacies Compounding Non-sterile Preparations and Pharmacies Compounding Sterile Preparations).

(7) Dispensing. Dangerous drugs may only be dispensed by a pharmacist pursuant to a prescription order in accordance with §§291.31 - 291.35 of this title (relating to Community Pharmacy (Class A)) and §291.131 and §291.133 of this title.

(f) Pharmacy and therapeutics committee.

(1) The clinic pharmacy shall have a pharmacy and therapeutics committee, which shall be composed of at least three persons and shall include the pharmacist-in-charge, the medical director of the clinic, and a person who is responsible for provision of drugs and devices.
(2) The pharmacy and therapeutics committee shall develop the policy and procedure manual.

(3) The pharmacy and therapeutics committee shall meet at least annually to:

(A) review and update the policy and procedure manual; and

(B) review the retrospective drug utilization review reports submitted by the pharmacist-in-charge if the clinic pharmacy has an expanded formulary.

(g) Policies and procedures.

(1) Written policies and procedures shall be developed by the pharmacy and therapeutics committee and implemented by the pharmacist-in-charge.

(2) The policy and procedure manual shall include, but not be limited to, the following:

(A) a current list of the names of the pharmacist-in-charge, consultant-pharmacist, staff pharmacist(s), supportive personnel designated to provide drugs or devices, and the supportive personnel designated to supervise the day-to-day pharmacy related operations of the clinic in the absence of the pharmacist;

(B) functions of the pharmacist-in-charge, consultant pharmacist, staff pharmacist(s), and supportive personnel;

(C) objectives of the clinic;

(D) formulary;

(E) a copy of written agreement between the pharmacist-in-charge and the clinic;

(F) date of last review/revision of policy and procedure manual; and

(G) policies and procedures for:

(i) security;

(ii) equipment;

(iii) sanitation;

(iv) licensing;

(v) reference materials;

(vi) storage;
(vii) packaging-repackaging;
(viii) dispensing;
(ix) provision;
(x) retrospective drug regimen review;
(xi) supervision;
(xii) labeling-relabeling;
(xiii) samples;
(xiv) drug destruction and returns;
(xv) drug and device procuring;
(xvi) receiving of drugs and devices;
(xvii) delivery of drugs and devices;
(xviii) recordkeeping; and
(xix) inspection.

(h) Supervision. The pharmacist-in-charge, consultant pharmacist, or staff pharmacist shall personally visit the clinic on at least a monthly basis to ensure that the clinic is following established policies and procedures. However, clinics operated by state or local governments and clinics funded by government sources money may petition the board for an alternative visitation schedule under the following conditions.

(1) Such petition shall contain an affidavit with the notarized signatures of the medical director, the pharmacist-in-charge, and the owner/chief executive officer of the clinic, which states that the clinic has a current policy and procedure manual on file, has adequate security to prevent diversion of dangerous drugs, and is in compliance with all rules governing Class D pharmacies.

(2) The board may consider the following items in determining an alternative schedule:

(A) the degree of compliance on past compliance inspections;
(B) the size of the patient population of the clinic;
(C) the number and types of drugs contained in the formulary; and
(D) the objectives of the clinic.
(3) Such petition shall be resubmitted every two years in conjunction with the application for renewal of the pharmacy license.