22 TAC §§291.91 - 291.94

The Texas State Board of Pharmacy proposes amendments to §291.91, concerning Definitions, §291.92, concerning Personnel, §291.93, concerning Operational Standards, and §291.94, concerning Records. The amendments, if adopted, incorporate the recommendations of the Task Force on Clinic Pharmacies (Class D). Specifically, the amendments, if adopted, update the definition of "practitioner" to be consistent with the Texas Pharmacy Act; update formulary requirements to allow Class D pharmacies with expanded formularies to have antipsychotic drugs; prohibit Class D pharmacies from having Carisoprodal or drugs used to treat erectile dysfunction; allow Class D pharmacies with expanded formularies including drugs requiring special monitoring to submit policies and procedures regarding the provision of such drugs; clarify that Class D pharmacies wishing to add drugs to an expanded formulary must make such a request in writing to the Board prior to adding the drugs; require pharmacists to conduct retrospective drug reviews on a quarterly basis in Class D pharmacies with expanded formularies; require an initial order by a physician for antipsychotic drugs provided in a Class D pharmacy, followed by monitored therapy and at least yearly physical exams by the physician; and require a licensed nurse or practitioner to provide verbal and written information to the patient.

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

Ms. Dodson has determined that, for each year of the first five-year period the rules will be in effect, the public benefit anticipated as a result of enforcing the rules will be to ensure patients receiving medications at Class D pharmacies are appropriate and safe. There is no fiscal impact for individuals, small or large businesses or to other entities which are required to comply with the sections.

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) 305-8082. Comments must be received by 5:00 p.m., July 21, 2008.

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 the amendments: Texas Pharmacy Act, Chapters 551 - 566 and 568 - 569, Texas Occupations Code.

§291.91.Definitions.

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) - (15) (No change.)

(16) Practitioner--

(A) a person licensed or registered to prescribe, distribute, administer, or dispense a prescription drug or device in the course of professional practice in this state, including a physician, dentist, podiatrist, or veterinarian but excluding a person licensed under the Act;

(B) a person licensed by another state, Canada, or the United Mexican States in a health field in which, under the law of this state, a license holder in this state may legally prescribe a dangerous drug;

(C) a person practicing in another state and licensed by another state as a physician, dentist, veterinarian, or podiatrist, who has a current federal Drug Enforcement Administration registration number and who may legally prescribe a Schedule II, III, IV, or V controlled substance, as specified under Chapter 481, Health and Safety Code, in that other state; or

(D) an advanced practice nurse or physician assistant to whom a physician has delegated the authority to carry out or sign prescription drug orders under §§157.0511, 157.052, 157.053, 157.054, 157.0541, or 157.0542, Occupations Code.

~~[(16) Practitioner--]~~

~~[(A) a physician, dentist, podiatrist, veterinarian, or other person licensed or registered to distribute or dispense a prescription drug or device in the course of professional practice in this state;]~~

~~[(B) a person licensed by another state in a health field in which, under Texas law, licensees in this state may legally prescribe dangerous drugs or a person practicing in another state and licensed by another state as a physician, dentist, veterinarian, or podiatrist, having a current federal Drug Enforcement Administration registration number, and who may legally prescribe Schedule II, III, IV, or V controlled substances in such other state; or]~~

~~[(C) a person licensed in the Dominion of Canada or the United Mexican States in a health field in which, under the laws of this state, a licensee may legally prescribe dangerous drugs;]~~

~~[(D) does not include a person licensed under the Act.]~~

(17) - (22) (No change.)

§291.92.Personnel.

(a) Pharmacist-in-charge.

(1) (No change.)

(2) Responsibilities. The pharmacist-in-charge shall have at a minimum, the responsibility for the following:

(A) continuous supervision of registered nurses, licensed vocational nurses, physician assistants, pharmacy technicians , pharmacy technician trainees, and assistants carrying out the pharmacy related aspects of provision;

(B) documented periodic on-site visits as specified in §291.93(h) and §291.94(b) [~~§291.94(a)~~] of this title (relating to Operational Standards and Records), either personally or by the consultant pharmacist or staff pharmacist, to insure that the clinic is following set policies and procedures; documentation shall be as specified in §291.94(b) [~~§291.94(a) ~~] of this title;

(C) development of a formulary for the clinic, in conjunction with the clinic's pharmacy and therapeutics committee, consisting of drugs and/or devices needed to meet the objectives of the clinic;

(D) procurement and storage of drugs and/or devices, but he or she may receive input from other appropriate staff of the clinic;

(E) determining specifications of all drugs and/or devices procured by the clinic;

(F) maintenance of records of all transactions of the pharmacy as may be required by applicable law and as may be necessary to maintain accurate control over and accountability for all drugs and/or devices;

(G) development and at least annual [~~periodic~~] review of a policy and procedure manual for the pharmacy in conjunction with the clinic's pharmacy and therapeutics committee;

(H) meeting inspection and other requirements of the Texas Pharmacy Act and these sections;

(I) dispensing of prescription orders; and

(J) conducting inservice training at least annually for supportive personnel who provide drugs; such training shall be related to actions, contraindications, adverse reactions, and pharmacology of drugs contained in the formulary.

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

(d) Supportive personnel.

(1) Qualifications.

(A) Supportive personnel shall possess education and training necessary to carry out their responsibilities.

(B) Supportive personnel shall be qualified to perform the pharmacy tasks assigned to them.

(2) Duties. Duties may include:

~~[(A) provision of drugs and/or devices 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 §291.93(e)(6)(F) of this title (relating to Operational Standards);]~~

(A) [~~(B)~~] prepackaging and labeling unit of use packages, under the direct supervision of a pharmacist with the pharmacist conducting in-process and final checks and affixing his or her signature to the appropriate quality control records;

(B) [~~(C)~~] maintaining inventories of drugs and/or devices; and

(C) [~~(D)~~] maintaining pharmacy records.

(3) Absence of the pharmacist. The pharmacist-in-charge shall designate from among the supportive personnel a person to supervise the day-to-day pharmacy-related operations of the clinic.

(e) Owner. The owner of a Class D pharmacy shall have responsibility for all administrative and operational functions of the pharmacy. The pharmacist-in-charge may advise the owner on administrative and operational concerns. The owner shall have responsibility for, at a minimum, the following, and if the owner is not a Texas licensed pharmacist, the owner shall consult with the pharmacist-in-charge or another Texas licensed pharmacist:

(1) - (4) (No change.)

§291.93.Operational Standards.

(a) Registration.

(1) General requirements.

(A) - (G) (No change.)

(H) A clinic [~~Class D (clinic)~~] pharmacy shall notify the board in writing of any change in name or location within 10 days.

(I) - (K) (No change.)

(2) (No change.)

(b) Environment.

(1) (No change.)

(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, [~~or~~] combination, or other mechanical or electronic means, so as to prohibit access by unauthorized individuals [~~ so as to prevent access by unauthorized personnel~~].

(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) (No change.)

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

(1) current copies of the following [~~laws~~]:

(A) Texas Pharmacy Act and rules; and

(B) Texas Dangerous Drug Act [~~Law~~];

(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; [~~ Hansten's and Horn's Drug Interactions Analysis and Management;~~]

(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 [~~and/or~~] devices, exclusive of injectable drugs for administration in the clinic and nonprescription drugs, except as provided in subparagraph (D) of this paragraph:

(i) - (vi) (No change.)

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

(i) Nalbuphine (Nubain);

(ii) Carisoprodal (Soma); [~~antipsychotics; and~~]

(iii) drugs used to treat erectile dysfunction; and

(iv) [~~(iii)~~] Schedule I-V controlled substances.

(D) 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 [~~and/or~~] 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; [~~and~~]

(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 [~~and/or~~] devices listed in subparagraph [~~subparagraphs~~] (B) [~~and (C)~~] of this paragraph.

(iii) If a 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) [~~(iii)~~] 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 [~~physician assistants~~].

(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) [~~(iv)~~] 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). [~~by the following terms.~~]

[~~(i) Cold--Any temperature not exceeding 8 degrees Centigrade (46 degrees Fahrenheit). A refrigerator is a cold place in which the temperature is maintained thermostatically between 2 degrees and 8 degrees Centigrade (36 degrees and 46 degrees Fahrenheit). A freezer is a cold place in which the temperature is maintained thermostatically between -20 degrees and -10 degrees Centigrade (-4 degrees and 14 degrees Fahrenheit).~~]

[~~(ii) Cool--Any temperature between 8 degrees and 15 degrees Centigrade (46 degrees and 59 degrees Fahrenheit). An article for which storage in a cool place is directed may, alternatively, be stored in a refrigerator, unless otherwise specified in the individual monograph.~~]

[~~(iii) Room temperature--The temperature prevailing in a working area. Controlled room temperature is a temperature maintained thermostatically between 15 degrees and 30 degrees Centigrade (59 degrees and 86 degrees Fahrenheit).~~]

[~~(iv) Warm--Any temperature between 30 degrees and 40 degrees Centigrade (86 degrees and 104 degrees Fahrenheit).~~]

[~~(v) Excessive heat--Temperature above 40 degrees Centigrade (104 degrees Fahrenheit).~~]

[~~(vi) Protection from freezing--Where, in addition to the risk of breakage of the container, freezing subjects a product to loss of strength or potency, or to destructive alteration of the dosage form, the container label bears an appropriate instruction to protect the product from freezing.~~]

(C) Any drug or [~~and/or~~] device bearing an expiration date may not be provided, dispensed, or administered beyond the expiration date of the drug or [~~and/or~~] device.

(D) Outdated drugs or [~~and/or~~] devices shall be removed from stock and shall be quarantined together until such drugs or [~~and/or~~] devices are disposed.

(E) Controlled substances may not be stored at the clinic pharmacy.

(3) Drug samples.

(A) Drug samples of drugs listed on the clinic pharmacy's formulary and supplied by manufacturers shall be properly stored, labeled, provided, or dispensed by the 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 clinic pharmacy.

(4) Prepackaging and labeling for provision.

(A) Drugs may be prepackaged and labeled for provision in the 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 [~~and address~~] 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 [~~and/or~~] devices may only be provided to patients of the clinic.

(B) At the time of 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. [~~the patient shall be provided verbal and/or written information on side effects, interactions, and precautions concerning the drug and/or device provided.~~]

(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) [~~(C)~~] 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) [~~(D)~~] Only drugs and/or devices listed in the clinic formulary may be provided.

(F) [~~(E)~~] 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) [~~(F)~~] 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:

(i) patient's name;

(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) [~~(G)~~] Records of provision shall be maintained according to §291.94(e) of this title.

(I) [~~(H)~~] 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. [~~§§291.31 - 291.36 of this title (relating to Community Class A Pharmacy).~~]

(f) Pharmacy and therapeutics committee.

(1) The clinic pharmacy shall have a pharmacy and therapeutics committee, which [~~pharmacy and therapeutics committee~~] 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 [~~and/or~~] 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: [~~review and update the policy and procedure manual.~~]

(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 [~~and addresses~~] of the pharmacist-in-charge, consultant-pharmacist, staff pharmacist(s), supportive personnel designated to provide drugs or [~~and/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) [~~(x)~~] supervision;

(xii) [~~(xi)~~] labeling-relabeling;

(xiii) [~~(xii)~~] samples;

(xiv) [~~(xiii)~~] drug destruction and returns;

(xv) [~~(xiv)~~] drug and [~~and/or~~] device procuring;

(xvi) [~~(xv)~~] receiving of drugs and [~~ and/or~~] devices;

(xvii) [~~(xvi)~~] delivery of drugs and [~~ and/or~~] devices;

(xviii) [~~(xvii)~~] recordkeeping; and

(xix) [~~(xviii)~~] 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) The pharmacist-in-charge, consultant pharmacist, or staff pharmacist shall be in contact with the clinic on at least a monthly basis, either through written memos, documented telephonic conferences, or on-site visits.]~~

~~[(2) The pharmacist-in-charge, consultant pharmacist, or staff pharmacist shall personally visit the clinic every three months to ensure that the clinic is following set policies and procedures, provided, however, that clinics who are operated by state or local governments and clinics who are funded by public money may petition the board for an alternative visitation schedule under the following conditions.]~~

(1) [~~(A)~~] 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) [~~(B)~~] The board may consider the following items in determining an alternative schedule:

(A) [~~(i)~~] the degree of compliance on past compliance inspections;

(B) [~~(ii)~~] the size of the patient population of the clinic;

(C) [~~(iii)~~] the number and types of drugs contained in the formulary; and

(D) [~~(iv)~~] the objectives of the clinic.

(3) [~~(C)~~] Such petition shall be resubmitted every two years in conjunction with the application for renewal of the pharmacy license.

§291.94.Records.

(a) Maintenance of records.

(1) Every inventory or other record required to be kept under the provisions of §291.91 of this title (relating to Definitions), §291.92 of this title (relating to Personnel), §291.93 of this title (relating to Operational Standards), and §291.94 of this title (relating to Records), contained in Clinic Pharmacy (Class D) shall be:

(A) kept by the pharmacy and be available, for at least two years from the date of such inventory or record, for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies; and

(B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in a mutually agreeable electronic format if specifically requested by the board or its representative. Failure to provide the records set out in this section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

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

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

(B) the data processing system is capable of producing a hard copy of the record upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.

(3) Invoices and records of receipt may be kept at a location other than the pharmacy. Any such records not kept at the pharmacy shall be supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy.

(b) [~~(a)~~] On-site visits. A record of on-site visits by the pharmacist-in-charge, consultant pharmacist, or staff pharmacist shall be maintained and include the following information:

(1) date of the visit;

(2) pharmacist's evaluation of findings; and

(3) signature of the visiting pharmacist.

~~[(b) Invoices or records of receipt.]~~

~~[(1) Each Class D pharmacy shall maintain invoices and/or records of procurement in accordance with the requirements of the Texas Dangerous Drug Law and the Texas Pharmacy Act and rules.]~~

~~[(2) Invoices and records of receipt may be kept at a location other than the pharmacy. Any such records not kept at the pharmacy shall be available for inspection, upon request, within two business days.]~~

(c) Prepackaging. Records of prepackaging shall include the following:

(1) name, strength, and dosage form [~~and strength~~] of drug;

(2) name of the manufacturer;

(3) manufacturer's lot number;

(4) [~~manufacturer's~~] expiration date;

(5) facility's lot number;

(6) [~~(5)~~] quantity per package and number of packages;

(7) [~~(6)~~] date packaged;

(8) [~~(7)~~] name(s), signatures, or electronic signatures of the supportive personnel who prepackages the drug under direct supervision of a pharmacist; and

(9) [~~(8)~~] name, signature, or electronic signature of the pharmacist who prepackages the drug or supervises the prepackaging and checks and releases the drug.

(d) Labeling. Records of labeling of drugs or [~~and/or~~] devices in original manufacturer's containers shall include the following:

(1) name and strength of the drug or device labeled;

(2) name of the manufacturer;

(3) manufacturer's lot number;

(4) manufacturer's expiration date;

(5) quantity per package and number of packages;

(6) date labeled;

(7) name of the supportive personnel affixing the label; and

(8) the signature of the pharmacist who checks and releases the drug.

(e) Provision. Records of drugs and/or devices provided shall include logs, patient records, or other acceptable methods for documentation. Documentation shall include:

(1) patient name;

(2) name, signature, or electronic signature of the person who provides the drug or device;

(3) date provided; and

(4) the name of the drug or device and quantity provided.

(f) Dispensing. Record-keeping requirements for dangerous drugs dispensed by a pharmacist are the same as for a Class A pharmacy as set out in §291.34 of this title (relating to Records).

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 June 9, 2008.

TRD-200802979

Gay Dodson, R.Ph.

Executive Director/Secretary

Texas State Board of Pharmacy

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