Texas State Board of Pharmacy

Board Rules
September 1, 2026

TEXAS ADMINISTRATIVE CODE
TITLE 22 – EXAMINING BOARDS
PART 15 – TEXAS STATE BOARD OF PHARMACY

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CHAPTER 281 – ADMINISTRATIVE PRACTICE AND PROCEDURES

SUBCHAPTER A – GENERAL PROVISIONS

§281.1 Objective and Scope

The objective of this chapter is to obtain a just, fair, and equitable determination of any matter within the jurisdiction of the board. To the end that this objective may be attained with as great expedition and at the least expense as possible to the parties and the state, the provisions of this chapter shall be given a liberal construction. The provisions of this chapter govern the procedure for the institution, conduct, and determination of all proceedings before the board. All actions taken by the board shall be in accordance with the Act, the Government Code, the Occupations Code, the board's rules and any other applicable laws or rules.

§281.2 Definitions

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

(1) Act--The Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code, as amended.
(2) Administrative law judge--A judge employed by the State Office of Administrative Hearings.
(3) Agency--The Texas State Board of Pharmacy, and its divisions, departments, and employees.
(4) Administrative Procedure Act (APA)--Government Code, Chapter 2001, as amended.
(5) Board--The Texas State Board of Pharmacy.
(6) Confidential address of record--The home address required to be provided by each individual, who is a licensee, registrant, or pharmacy owner and where service of legal notice will be sent. The address is confidential, as set forth in §555.001(d) of the Act, and not subject to disclosure under the Public Information Act.
(7) Contested case--A proceeding, including but not restricted to licensing, in which the legal rights, duties, or privileges of a party are to be determined by the board after an opportunity for adjudicative hearing.
(8) Diversion of controlled substances--An act or acts which result in the distribution of controlled substances from legitimate pharmaceutical or medical channels in violation of the Controlled Substances Act or rules promulgated pursuant to the Controlled Substances Act or rules relating to controlled substances promulgated pursuant to this Act.
(9) Diversion of dangerous drugs--An act or acts which result in the distribution of dangerous drugs from legitimate pharmaceutical or medical channels in violation of the Dangerous Drug Act or rules promulgated pursuant to the Dangerous Drug Act or rules relating to dangerous drugs promulgated pursuant to this Act.
(10) Executive director/secretary--The secretary of the board and executive director of the agency.
(11) License--The whole or part of any agency permit, certificate, approval, registration, or similar form of permission required by law.
(12) Licensee--Any individual or person to whom the agency has issued any permit, certificate, approved registration, or similar form of permission authorized by law.
(13) Licensing--The agency process relating to the granting, denial, renewal, revocation, suspension, annulment, withdrawal, or amendment of a license.
(14) Official act--Any act performed by the board pursuant to a duty, right, or responsibility imposed or granted by law, rule, or regulation.
(15) Person--An individual, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership, association, or any other legal entity.
(16) President--The president of the Texas State Board of Pharmacy.
(17) Presiding Officer--The president of the Texas State Board of Pharmacy or, in the president's absence, the highest ranking officer present at a board meeting.

(18) Publicly available address of record--The alternate address required to be provided by each licensee, registrant, or pharmacy owner, which will be released to the public, as set forth in §555.001(d) of the Act, and is subject to disclosure under the Public Information Act.
(A) The alternate address must be a business address or other alternate address, such as the home address of the individual's relative, where mail can be received on a regular basis.
(B) A pharmacy must provide the physical address of the pharmacy to be used for this purpose.
(19) Quorum--A majority of the members of the board appointed and serving on the board.
(20) State Office of Administrative Hearings (SOAH)--The agency to which contested cases are referred by the Texas State Board of Pharmacy.
(21) Sample--A prescription drug which is not intended to be sold and is intended to promote the sale of the drug.
(22) Texas Public Information Act--Government Code, Chapter 552.

§281.3 Construction of This Chapter

(a) In the construction of this chapter, a provision of a section referring to the board, or a provision referring to the presiding officer, is construed to apply to the board or the president if the matter is within the jurisdiction of the board.
(b) Unless otherwise provided by law, any duty imposed on the board or the president may be delegated to a duly authorized representative. In such case, the provisions of any section referring to the board or the president shall be construed to also apply to the duly authorized representative(s) of the board or the president.

§281.4 Official Acts in Writing and Open to the Public

(a) All official acts of the board shall be evidenced by a written record. Such writings shall be open to the public in accordance with the Act and the Texas Public Information Act, Government Code Chapter 552. Any hearing and any Board meeting shall be open to the public in accordance with the Texas Open Meetings Act, Government Code, Chapter 551, provided, however, that pursuant to §552.011, Texas Pharmacy Act, the board may, in its discretion, conduct deliberations relative to licensee disciplinary actions in a closed meeting. The board in a closed meeting may conduct disciplinary hearings relating to a pharmacist or pharmacy student who is impaired because of chemical abuse or mental or physical illness. At the conclusion of its deliberations relative to licensee disciplinary action, the board shall vote and announce its decision relative to the licensee in open session. All disciplinary hearings before the State Office of Administrative Hearings shall be open to the public, including those relating to a pharmacist or pharmacy student who is impaired because of chemical abuse or mental or physical illness. Official action of the board shall not be bound or prejudiced by any informal statement or opinion made by any member of the board or the employees of the agency.
(b) The president shall be the chairman and preside over all meetings of the board at which the president is present unless otherwise provided for under this chapter. In the absence of the president, the vice president shall preside. In the vice president's absence, one of the other Board members shall preside as acting chairman. The acting chairman shall be selected by mutual agreement of the board members present or, lacking mutual agreement, shall be the member senior in length of service on the board.

§281.5 Initiating Proceedings Before the Board

(a) Rules. Any interested person may petition the board requesting the adoption of a rule. Petitions shall be sent to the executive director/secretary. Within 60 days after the submission of a petition, the board shall either deny the petition in writing, stating the reasons for the denial, or shall initiate rulemaking proceedings. Petitions shall be deemed sufficient if they contain:
(1) the exact wording of the new, changed, or amended proposed rule;
(2) specific reference to the existing rule which is proposed to be changed or amended in the case of a changed or amended rule; and
(3) a justification for the proposed action set out in narrative form with sufficient particularity to inform the board and any other interested party of the reasons and arguments on which the petitioner is relying.

(b) Other. In any other matter, any person desiring that the board perform some official act permitted or required by law shall request such performance in writing. Such requests shall be directed to the executive director/secretary of the board. Any written request shall be deemed sufficient to initiate the proceedings and present the subject matter to the board for its official determination if the request reasonably gives notice to the board of the act desired. The board may also initiate proceedings on its own motion.

§281.6 Mental or Physical Examination

For the purposes of the Act, §§565.001(a)(4), 565.052, 568.003(a)(5), and 568.0036, shall be applied as follows.

(1) The board may discipline an applicant, licensee, or registrant if the board finds that the applicant, licensee, or registrant has developed an incapacity that in the estimation of the board would prevent a pharmacist from engaging in the practice of pharmacy or a pharmacy technician or pharmacy technician trainee from practicing with a level of skill and competence that ensures the public health, safety, and welfare.

(2) Upon a finding of probable cause, as determined by the board or an authorized agent of the board, that the applicant, licensee, or registrant has developed an incapacity that in the estimation of the board would prevent a pharmacist from engaging in the practice of pharmacy or a pharmacy technician or pharmacy technician trainee from practicing with a level of skill and competence that ensures the public health, safety, and welfare, the following is applicable.

(A) The executive director/secretary, legal counsel of the agency, or other representative of the agency as designated by the executive director/secretary, shall request the applicant, licensee, or registrant to submit to a mental or physical examination by a physician or other healthcare professional designated by the board. The individual providing the examination shall be approved by the board. Such examination shall be coordinated through the entity that contracts with the board to aid impaired pharmacists and pharmacy students. The applicant, licensee, or registrant shall:

(i) provide the entity with written notice of the appointment at least three days prior to the appointment;

(ii) execute and return to the entity an authorization for release of relevant information on the form required by the entity, within ten days of receipt of request for the release from the entity; and

(iii) follow all other procedures of the entity for each examination.

(B) The applicant, licensee, or registrant shall be notified in writing, by either personal service or certified mail with return receipt requested, of the request to submit to the examination.

(C) The applicant, licensee, or registrant shall submit to the examination within 30 days of the date of the receipt of the request.

(D) The applicant, licensee, or registrant shall authorize the release of the results of the examination and the results shall be submitted to the board within 15 days of the date of the examination.

(3) If the applicant, licensee, or registrant does not comply with the provisions of paragraph (2) of this section, the following is applicable.

(A) The executive director/secretary shall cause to be issued an order requiring the applicant, licensee, or registrant to show cause why he/she will not submit to the examination.

(B) The executive director/secretary shall schedule a hearing on the order before a panel of three members of the board appointed by the president of the board, within 30 days after notice is served on the applicant, licensee, or registrant.

(C) The applicant, licensee, or registrant shall be notified of the hearing by either personal service or certified mail with return receipt requested.

(D) At the hearing, the applicant, licensee, or registrant has the burden of proof once probable cause has been established by the board, as required by §565.062 of the Act to rebut the probable cause. The applicant, licensee, or registrant, and if applicable, the applicant's, licensee's, or registrants' attorney, are entitled to present testimony and other evidence to show why probable cause has not been

established requiring the applicant, licensee, or registrant to submit to the examination. An evaluation that has not been approved by the board and coordinated by the entity that contracts with the board to aid impaired pharmacist and pharmacy students according to its procedure cannot be admitted at the hearing in lieu of one that has been properly approved and coordinated.

(E) After the hearing, the panel shall issue an order either requiring the applicant, licensee, or registrant to submit to the examination not later than the 60th day after the date of the order or withdraw the request for examination, as applicable.

§281.7 Grounds for Discipline for a Pharmacist License

(a) For the purposes of the Act, §565.001(a)(2), "unprofessional conduct" is defined as engaging in behavior or committing an act that fails to conform with the standards of the pharmacy profession, including, but not limited to, criminal activity or activity involving moral turpitude, dishonesty, or corruption. This conduct shall include, but not be limited to:

(1) dispensing a prescription drug pursuant to a forged, altered, or fraudulent prescription;

(2) dispensing a prescription drug order pursuant to a prescription from a practitioner as follows:

(A) the dispensing of a prescription drug order not issued for a legitimate medical purpose or in the usual course of professional practice shall include the following:

(i) dispensing controlled substances or dangerous drugs to an individual or individuals in quantities, dosages, or for periods of time which grossly exceed standards of practice, approved labeling of the federal Food and Drug Administration, or the guidelines published in professional literature; or

(ii) dispensing controlled substances or dangerous drugs when the pharmacist knows or reasonably should have known that the controlled substances or dangerous drugs are not necessary or required for the patient's valid medical needs or for a valid therapeutic purpose;

(B) the provisions of subparagraph (A)(i) and (ii) of this paragraph are not applicable for prescriptions dispensed to persons with intractable pain in accordance with the requirements of the Intractable Pain Treatment Act, or to a narcotic drug dependent person in accordance with the requirements of Title 21, Code of Federal Regulations, §1306.07, and the Regulation of Narcotic Drug Treatment Programs Act;

(3) delivering or offering to deliver a prescription drug or device in violation of this Act, the Controlled Substances Act, the Dangerous Drug Act, or rules promulgated pursuant to these Acts;

(4) acquiring or possessing or attempting to acquire or possess prescription drugs in violation of this Act, the Controlled Substances Act, the Dangerous Drug Act, or rules adopted pursuant to these Acts;

(5) distributing prescription drugs or devices to a practitioner or a pharmacy not in the course of professional practice or in violation of this Act, the Controlled Substances Act, Dangerous Drug Act, or rules adopted pursuant to these Acts;

(6) refusing or failing to keep, maintain or furnish any record, notification or information required by this Act, the Controlled Substances Act, the Dangerous Drug Act, or rules adopted pursuant to these Acts;

(7) refusing an entry into any pharmacy for any inspection authorized by the Act;

(8) making false or fraudulent claims to third parties for reimbursement for pharmacy services;

(9) operating a pharmacy in an unsanitary manner;

(10) making false or fraudulent claims concerning any drug;

(11) persistently and flagrantly overcharging for the dispensing of controlled substances;

(12) dispensing controlled substances or dangerous drugs in a manner not consistent with the public health or welfare;

(13) failing to practice pharmacy in an acceptable manner consistent with the public health and welfare;

(14) refilling a prescription upon which there is authorized "prn" refills or words of similar meaning, for a period of time in excess of one year from the date of issuance of such prescription;

(15) engaging in any act, acting in concert with another, or engaging in any conspiracy resulting in a restraint of trade, coercion, or a monopoly in the practice of pharmacy;
(16) sharing or offering to share with a practitioner compensation received from an individual provided pharmacy services by a pharmacist;
(17) obstructing a board employee in the lawful performance of his or her duties of enforcing the Act;
(18) engaging in conduct that subverts or attempts to subvert any examination or examination process required for a license to practice pharmacy. Conduct that subverts or attempts to subvert the pharmacist licensing examination process includes, but is not limited to:

(A) copying, retaining, repeating, or transmitting in any manner the questions contained in any examination administered by the board or questions contained in a question pool of any examination administered by the board;

(B) copying or attempting to copy another candidate's answers to any questions on any examination required for a license to practice pharmacy;

(C) obtaining or attempting to obtain confidential examination materials compiled by testing services or the board;

(D) impersonating or acting as a proxy for another in any examination required for a license to practice pharmacy;

(E) requesting or allowing another to impersonate or act as a proxy in any examination required for a license to practice pharmacy; or

(F) violating or attempting to violate the security of examination materials or the examination process in any manner;

(19) violating the provisions of an agreed board order or board order;
(20) dispensing a prescription drug while not acting in the usual course of professional pharmacy practice;
(21) failing to provide or providing false or fraudulent information on any application, notification, or other document required under this Act, the Dangerous Drug Act, the Controlled Substances Act, or rules adopted pursuant to those Acts;
(22) using abusive, intimidating, or threatening behavior toward a board member or employee during the performance of such member's or employee's lawful duties;
(23) failing to establish or maintain effective controls against the diversion or loss of controlled substances or dangerous drugs, loss of controlled substance or dangerous drug records, or failing to ensure that controlled substances or dangerous drugs are dispensed in compliance with state and federal laws or rules, by a pharmacist who is:

(A) a pharmacist-in-charge of a pharmacy;

(B) a sole proprietor or individual owner of a pharmacy;

(C) a partner in the ownership of a pharmacy; or

(D) a managing officer of a corporation, association, or joint-stock company owning a pharmacy. A pharmacist, as set out in subparagraphs (B) - (D) of this paragraph, is equally responsible with an individual designated as pharmacist-in-charge of such pharmacy to ensure that employee pharmacists and the pharmacy are in compliance with all state and federal laws or rules relating to controlled substances or dangerous drugs;

(24) failing to correct the issues identified in a warning notice by the specified time;
(25) being the subject of civil fines imposed by a federal or state court as a result of violating the Controlled Substances Act or the Dangerous Drug Act;
(26) selling, purchasing, or trading or offering to sell, purchase, or trade prescription drug samples; provided, however, this paragraph does not apply to:

(A) prescription drugs provided by a manufacturer as starter prescriptions or as replacement for such manufacturer's out-dated drugs;

(B) prescription drugs provided by a manufacturer in replacement for such manufacturer's drugs that were dispensed pursuant to written starter prescriptions; or

(C) prescription drug samples possessed by a pharmacy of a health care entity which provides health care primarily to indigent or low income patients at no or reduced cost and if:

(i) the samples are possessed in compliance with the Prescription Drug Marketing Act of 1987;

(ii) the pharmacy is owned by a charitable organization described in the Internal Revenue Code of 1986, §501(c)(3), or by a city, state or county government; and

(iii) the samples are for dispensing or provision at no charge to patients of such health care entity;

(27) selling, purchasing, or trading or offering to sell, purchase, or trade prescription drugs:

(A) sold for export use only;

(B) purchased by a public or private hospital or other health care entity; or

(C) donated or supplied at a reduced price to a charitable organization described in the Internal Revenue Code of 1986, §501(c)(3);

(D) provided that subparagraphs (A) - (C) of this paragraph do not apply to:

(i) the purchase or other acquisition by a hospital or other health care entity which is a member of a group purchasing organization or from other hospitals or health care entities which are members of such organization;

(ii) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by an organization described in subparagraph (C) of this paragraph to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(iii) the sale, purchase or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities which are under common control;

(iv) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons including the transfer of a drug between pharmacies to alleviate temporary shortages of the drug arising from delays in or interruptions of regular distribution schedules; or

(v) the dispensing of a prescription drug pursuant to a valid prescription drug order to the extent otherwise permitted by law;

(28) selling, purchasing, or trading, or offering to sell, purchase, or trade:

(A) misbranded prescription drugs; or

(B) prescription drugs beyond the manufacturer's expiration date;

(29) failing to respond and to provide all requested records within the time specified in an audit of continuing education records under §295.8 of this title (relating to Continuing Education Requirements); or

(30) allowing an individual whose license to practice pharmacy, either as a pharmacist or a pharmacist-intern, or a pharmacy technician/trainee whose registration has been disciplined by the board, resulting in the license or registration being revoked, canceled, retired, surrendered, denied or suspended, to have access to prescription drugs in a pharmacy.

(b) For the purposes of the Act, §565.001(a)(3), the term "gross immorality" shall include, but not be limited to:

(1) conduct which is willful, flagrant, and shameless, and which shows a moral indifference to standards of the community;

(2) engaging in an act which is a felony;

(3) engaging in an act that constitutes sexually deviant behavior; or

(4) being required to register with the Department of Public Safety as a sex offender under Chapter 62, Code of Criminal Procedure.

(c) For the purposes of the Act, §565.001(a)(5), the terms "fraud," "deceit," or "misrepresentation" in the practice of pharmacy or in seeking a license to act as a pharmacist shall be defined as follows:

(1) "Fraud" means an intentional perversion of truth for the purpose of inducing another in reliance upon it to part with some valuable thing belonging to him, or to surrender a legal right, or to issue a license; a false representation of a matter of fact, whether by words or by conduct, by false or misleading allegations, or by concealment of that which should have been disclosed, which deceives or is intended to deceive another.
(2) "Deceit" means the assertion, as a fact, of that which is not true by any means whatsoever to deceive or defraud another.
(3) "Misrepresentation" means a manifestation by words or other conduct which is a false representation of a matter of fact.

§281.8 Grounds for Discipline for a Pharmacy License

(a) For the purposes of §565.002(a)(9) of the Act, a pharmacy fails to establish and maintain effective controls against diversion of prescription drugs when:

(1) there is inadequate security or procedures to prevent unauthorized access to prescription drugs; or
(2) there is inadequate security or procedures to prevent the diversion of prescription drugs.

(b) For the purposes of §565.002(a)(3) of the Act, it is grounds for discipline for a pharmacy license when:

(1) during the time an individual's license to practice pharmacy, either as a pharmacist or a pharmacist-intern, or a pharmacy technician's registration has been disciplined by the Board, resulting in the license or registration being revoked, canceled, retired, surrendered, denied or suspended, the pharmacy employs or allows such individual access to prescription drugs;
(2) the pharmacy possesses or engages in the sale, purchase, or trade or the offer to sell, purchase, or trade prescription drug samples; provided however, this paragraph does not apply to:
(A) prescription drugs provided by a manufacturer as starter prescriptions or as replacement for such manufacturer's outdated drugs;
(B) prescription drugs provided by a manufacturer in replacement for such manufacturer's drugs that were dispensed pursuant to written starter prescriptions; or
(C) prescription drug samples possessed by a pharmacy of a health care entity which provides health care primarily to indigent or low income patients at no or reduced cost and if:
(i) the samples are possessed in compliance with the Prescription Drug Marketing Act of 1987;
(ii) the pharmacy is owned by a charitable organization described in the Internal Revenue Code of 1986, §501(c)(3), or by a city, state or county government; and
(iii) the samples are for dispensing or provision at no charge to patients of such health care entity;
(3) the pharmacy possesses or engages in the sale, purchase, or trade or the offer to sell, purchase, or trade of prescription drugs:
(A) sold for export use only;
(B) purchased by a public or private hospital or other health care entity; or
(C) donated or supplied at a reduced price to a charitable organization described in the Internal Revenue Code of 1986, §501(c)(3), and possessed by a pharmacy other than one owned by the charitable organization;
(D) provided that subparagraphs (A) - (C) of this paragraph do not apply to:
(i) the purchase or other acquisition by a hospital or other health care entity which is a member of a group purchasing organization or from other hospitals or health care entities which are members of such organization;
(ii) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by an organization described in paragraph (2)(C)(ii) of this subsection to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
(iii) the sale, purchase or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities which are under common control;

(iv) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons including the transfer of a drug between pharmacies to alleviate temporary shortages of the drug arising from delays in or interruptions of regular distribution schedules;

(v) the dispensing of a prescription drug pursuant to a valid prescription drug order to the extent otherwise permitted by law;

(4) the pharmacy engages in the sale, purchase, or trade or the offer to sell, purchase, or trade of:

(A) misbranded prescription drugs; or

(B) prescription drugs beyond the manufacturer's expiration date.

(5) the owner or managing officer has previously been disciplined by the board; or

(6) a non-resident pharmacy fails to reimburse the board or its designee for all expenses, including travel, incurred by the board in inspecting the non-resident pharmacy as specified in §556.0551 of the Act;

(7) the owner, managing officer(s), or other pharmacy employee(s) displays abusive, intimidating, or threatening behavior toward a board member or employee during the performance of such member's or employee's lawful duties; or

(8) the pharmacy waived, discounted, or reduced, or offered to waive, discount, or reduce, a patient copayment or deductible for a compounded drug in the absence of:

(A) a legitimate, documented financial hardship of the patient; or

(B) evidence of a good faith effort to collect the copayment or deductible from the patient.

(c) For the purposes of §565.002(a)(10) of the Act, the terms "fraud," "deceit," or "misrepresentation" in operating a pharmacy or in seeking a license to operate shall be defined as follows:

(1) "Fraud" means an intentional perversion of truth for the purpose of inducing another in reliance upon it to part with some valuable thing belonging to him, or to surrender a legal right, or to issue a license; a false representation of a matter of fact, whether by words or by conduct, by false or misleading allegations, or by concealment of that which should have been disclosed, which deceives or is intended to deceive another;

(2) "Deceit" means the assertion, as a fact, of that which is not true by any means whatsoever to deceive or defraud another; and

(3) "Misrepresentation" means a manifestation by words or other conduct which is a false representation of a matter of fact.

§281.9 Grounds for Discipline for a Pharmacy Technician or a Pharmacy Technician Trainee

(a) Pharmacy technicians and pharmacy technician trainees shall be subject to all disciplinary grounds set forth in §568.003 of the Act.

(b) For the purposes of the Act, §568.003(a)(10), "negligent, unreasonable, or inappropriate conduct" shall include, but not be limited to:

(1) delivering or offering to deliver a prescription drug or device in violation of this Act, the Controlled Substances Act, the Dangerous Drug Act, or rules promulgated pursuant to these Acts;

(2) acquiring or possessing or attempting to acquire or possess prescription drugs in violation of this Act, the Controlled Substances Act, or Dangerous Drug Act or rules adopted pursuant to these Acts;

(3) failing to perform the duties of a pharmacy technician or pharmacy technician trainee in an acceptable manner consistent with the public health and welfare, which contributes to a prescription not being dispensed or delivered accurately;

(4) obstructing a board employee in the lawful performance of his duties of enforcing the Act;

(5) violating the provisions of an agreed board order or board order, including accessing prescription drugs with a revoked or suspended pharmacy technician or pharmacy technician trainee registration;

(6) abusive, intimidating, or threatening behavior toward a board member or employee during the performance of such member's or employee's lawful duties; or

(7) failing to respond and to provide all requested records within the time specified in an audit of continuing education records under §297.8 of this title (relating to Continuing Education Requirements).

(c) For the purposes of the Act, §568.003(a)(2), the term "gross immorality" shall include, but not be limited to:

(1) conduct which is willful, flagrant, and shameless, and which shows a moral indifference to standards of the community;

(2) engaging in an act which is a felony;

(3) engaging in an act that constitutes sexually deviant behavior; or

(4) being required to register with the Department of Public Safety as a sex offender under Chapter 62, Code of Criminal Procedure.

(d) For the purposes of the Act, §568.003(a)(3), the terms "fraud," "deceit," or "misrepresentation" shall apply to an individual seeking a registration as a pharmacy technician, as well as making an application to any entity that certifies or registers pharmacy technicians, and shall be defined as follows:

(1) "Fraud" means an intentional perversion of truth for the purpose of inducing the board in reliance upon it to issue a registration; a false representation of a matter of fact, whether by words or by conduct, by false or misleading allegations, or by concealment of that which should have been disclosed, which deceives or is intended to deceive the board.

(2) "Deceit" means the assertion, as a fact, of that which is not true by any means whatsoever to deceive or defraud the board.

(3) "Misrepresentation" means a manifestation by words or other conduct which is a false representation of a matter of fact.

§281.10 Denial of a License

If an applicant's original application or request for renewal of a license is denied, he shall have 30 days from the date of denial to make a written request for a hearing. If so requested, the hearing will be granted and the provisions of APA and this chapter with regard to a contested case shall apply.

§281.11 Criminal History Evaluation Letter

(a) A person, who is enrolled or planning to enroll in an educational program that prepares the person for a license as a pharmacist or a registration as a pharmacy technician or trainee, or planning to take an examination required for such a license or registration, and who has reason to believe that he or she may be ineligible due to a conviction or deferred adjudication for a felony or misdemeanor offense, may request a criminal history evaluation letter regarding his or her eligibility for a license or registration.

(b) The person must submit an application for the criminal history evaluation letter on a form provided by the board which includes:

(1) a statement indicating the reasons and basis for potential ineligibility, including each criminal offense for which the person was arrested, charged, convicted, or received deferred adjudication;

(2) all legal documents related to the reasons and basis for potential ineligibility including, but not limited to, police reports, indictments, orders of deferred adjudication, judgments, probation records and evidence of completion of probation, if applicable;

(3) all requirements necessary in order for the Board to access the criminal history record information, including submitting fingerprint information and paying the required fees; and

(4) a non-refundable fee of $150 for processing the application.

(c) The application is considered complete when all documents and other information supporting the potential reasons and basis for potential ineligibility has been received by the board. If such documentation is not received within 120 days of the initial receipt of the application, the application is considered to be expired and must be refilled along with the appropriate fees.

(d) The board shall conduct an investigation of the application and the person's eligibility for a license or registration.

(e) The person or the Board may amend the application to include additional grounds for potential ineligibility at any time before a final determination is made.
(f) A determination of eligibility will be made by the Board or its designees. Notification of the determination will be provided to the person in writing.

(1) If no grounds for ineligibility are identified, the notification shall address the determination regarding each ground of potential ineligibility.

(2) If grounds for ineligibility exist, the notification shall set out each basis for potential ineligibility and the corresponding determination.

(g) The board shall mail the determination of eligibility no later than the 90th day after the complete application, as required by subsections (b) and (c) of this section, has been received by the board.
(h) The determination of eligibility shall be made based on the law in effect on the date of receipt of a complete application.
(i) Any information the person fails to disclose on the application or any information determined to be inaccurate or incomplete shall invalidate the determination of eligibility on the basis of the information, in the discretion of the board.
(j) The administrative rules regarding disciplinary guidelines and regarding considerations and sanctions for criminal conduct apply in making the determination regarding eligibility.
(k) If a person submits an application for license or registration at the same time or within 90 days after the receipt of a complete application for criminal history evaluation letter, board will process only the application for license or registration and will not issue a separate determination of eligibility.

§281.12 Rules Governing Cooperating Practitioners

For the purposes of the Act, §565.063, a person acting under the supervision of a Board employee engaged in the lawful enforcement of the Act shall include, but not be limited to, a practitioner who provides prescriptions for use in investigations of licensees when such prescriptions are issued by a practitioner at the request of and under the supervision of a Board investigator.

§281.13 Official Action by Majority

Any official act or decision of the board shall be concurred in by a majority of its members present at a meeting. Such act or decision shall be based upon information presented to members present at official meetings of the board. There shall be at least a quorum of the board members present at any official meeting of the board. Private solicitation of individual members in an effort to in any way influence their official actions through information or arguments not simultaneously presented to other members of the board is improper.

§281.14 Vendor Protest Procedures

(a) The purpose of this section is to establish procedures for resolving vendor protests relating to purchasing issues.
(b) A vendor who submitted a written response to a solicitation may file a protest with the executive director for actions taken by the board on the following:

(1) the solicitation documents or actions associated with the publication of solicitation documents;

(2) the evaluation or method of evaluation for a solicitation; or

(3) the award of a contract.

(c) Filing requirements.

(1) To be considered, a protest must be:

(A) in writing and contain:

(i) the specific rule, statute or regulation the protesting vendor alleges the solicitation, contract award, or tentative award violated;

(ii) a specific description of each action by the board that the protesting vendor alleges is a violation of the statutory or regulatory provision the protesting vendor identified in subparagraph (A)(i) of this paragraph;

(iii) a precise statement of the relevant facts including:

(I) sufficient documentation to establish that the protest has been timely filed;

(II) a description of the adverse impact to the board and the state; and

(III) a description of the resulting adverse impact to the protesting vendor;

(iv) a statement of the argument and authorities that the protesting vendor offers in support of the protest; and

(v) an explanation of the subsequent action the vendor is requesting;

(B) signed by an authorized representative and the signature notarized; and

(C) filed with the board in the time period specified in this section.

(2) To be considered timely, the protest must be filed:

(A) by the end of the posted solicitation period, if the protest concerns the solicitation documents or actions associated with the publication of solicitation documents;

(B) by the day of the award of a contract resulting from the solicitation, if the protest concerns the evaluation or method of evaluation for a solicitation; or

(C) no later than 10 days after the notice of award, if the protest concerns the award.

(d) Timeliness of Protest.

(1) If a timely protest of a solicitation or contract award is filed under this section, the executive director may delay the solicitation or award of the contract if the executive director makes a determination that the contract must be awarded without delay to protect the best interests of the state.

(2) A protest that is filed untimely under this section shall not be considered unless the executive director determines that good cause for delay is shown or that a protest raises issues that are significant to the agency's procurement practices or procedures in general.

(e) Authority of the Executive Director to Settle the Protest.

(1) Upon receipt of a protest, the executive director may dismiss the protest if it is not timely or does not meet the requirements of this section.

(2) The executive director shall have the authority to settle and resolve the protest. The executive director may solicit written responses to the protest from other interested parties.

(3) If the protest is not resolved through mutual agreement, the executive director shall issue a written determination responding to the protest.

(f) Appeal.

(1) If a protest is based on a solicitation or contract award, the protesting party may appeal a determination of a protest by the executive director to the general counsel. An appeal of the executive director's determination must be in writing and received not later than 10 days after the date the executive director sent written notice of the executive director's determination. The scope of the appeal shall be limited to review of the executive director's determination. The protesting party must mail or deliver to all other interested parties a copy of the appeal, which must contain a certified statement that such copies have been provided.

(2) The general counsel may refer the matter to the board for consideration or may issue a written decision that resolves the protest.

(3) An appeal that is not filed timely shall not be considered unless good cause for delay is shown or the general counsel determines that an appeal raises issues that are significant to the agency's procurement practices or procedures in general.

(4) A written decision issued by the general counsel or the board shall be the final administrative action of the board.

(g) The board shall maintain all documentation on the purchasing process that is the subject of a protest or appeal in accordance with the board's records retention schedule.

§281.15 Negotiated Rulemaking

(a) The board's policy is to encourage the use of negotiated rulemaking for the adoption of board rules in appropriate situations.

(b) The board's general counsel or the designee of the general counsel shall be the board's negotiated rulemaking coordinator (NRC). The NRC shall perform the following functions, as required:

(1) coordinate the implementation of the policy set out in subsection (a) of this section and in accordance with the Negotiated Rulemaking Act, Chapter 2008, Government Code;

(2) serve as a resource for any staff training or education needed to implement negotiated rulemaking procedures; and

(3) collect data to evaluate the effectiveness of negotiated rulemaking procedures implemented by the board.

(c) The board or the executive director may direct the NRC to begin negotiated rulemaking procedures on a specified subject.

§281.16 Alternative Dispute Resolution

(a) The board's policy is to encourage the resolution and early settlement of internal and external disputes, including contested cases, through voluntary settlement processes, which may include any procedure or combination of procedures described by Chapter 154, Civil Practice and Remedies Code. Any ADR procedure used to resolve disputes before the board shall comply with the requirements of Chapter 2009, Government Code, and any model guidelines for the use of ADR issued by the State Office of Administrative Hearings.

(b) The board's general counsel or the designee of the general counsel shall be the board's dispute resolution coordinator (DRC). The DRC shall perform the following functions, as required:

(1) coordinate the implementation of the policy set out in subsection (a) of this section;

(2) serve as a resource for any staff training or education needed to implement the ADR procedures; and

(3) collect data to evaluate the effectiveness of ADR procedures implemented by the board.

(c) The board, a committee of the board, a respondent in a disciplinary matter pending before the board, the executive director, or a board employee engaged in a dispute with the executive director or another employee, may request that the contested matter be submitted to ADR. The request must be in writing, be addressed to the DRC, and state the issues to be determined. The person requesting ADR and the DRC will determine which method of ADR is most appropriate. If the person requesting ADR is the respondent in a disciplinary proceeding, the executive director shall determine if the board will participate in ADR or proceed with the board's normal disciplinary processes.

(d) Any costs associated with retaining an impartial third party mediator, moderator, facilitator, or arbitrator, shall be borne by the party requesting ADR.

(e) Agreements of the parties to ADR must be in writing and are enforceable in the same manner as any other written contract. Confidentiality of records and communications related to the subject matter of an ADR proceeding shall be governed by §154.073 of the Civil Practice and Remedies Code.

(f) If the ADR process does not result in an agreement, the matter shall be referred to the board for other appropriate disposition.

§281.17 Historically Underutilized Businesses

The Texas State Board of Pharmacy adopts by reference the rules promulgated by the Texas Building and Procurement Commission, which are set forth in Subchapter B of 1 TAC §111.11, et al. regarding Historically Underutilized Business Certification Program.

§281.18 Reporting Professional Liability Claims

(a) Reporting responsibilities.

(1) Every insurer or other entity providing pharmacist's professional liability insurance, pharmacy technician professional and supplemental liability insurance, or druggist's professional liability insurance covering a

pharmacist, pharmacy technician, or pharmacy license holder in this state shall submit to the board the information described in subsection (b) of this section at the time prescribed.

(2) The information shall be provided with respect to a notice of claim letter or complaint filed against an insured in a court, if the notice or complaint seeks damages relating to the insured's conduct in providing or failing to provide appropriate service within the scope of pharmaceutical care or services, and with respect to settlement of a claim or lawsuit made on behalf of the insured.

(3) If a pharmacist, pharmacy technician, or a pharmacy licensed in this state does not carry or is not covered by pharmacist's professional liability insurance, pharmacy technician professional and supplemental liability insurance, or druggist's professional liability insurance, or if a pharmacist, pharmacy technician, or a pharmacy licensed in this state is insured by a non-admitted carrier or other entity providing pharmacy professional liability insurance that does not report under this Act, the duty to report information under subsection (b) of this section is the responsibility of the particular pharmacist, pharmacy technician, or pharmacy license holder.

(4) For the purposes of this section a professional liability claim or complaint shall be defined as a cause of action against a pharmacist, pharmacy, or pharmacy technician for conduct in providing or failing to provide appropriate service within the scope of pharmaceutical care or services, which proximately results in injury to or death of the patient, whether the patient's claim or cause of action sounds in tort or contract, to include pharmacist's interns, pharmacy residents, supervising pharmacists, on-call pharmacists, consulting pharmacists.

(b) Information to be reported and due dates. The following reports are required for claims initiated or resolved on or after September 1, 1999.

(1) Initial report. Not later than the 30th day after receipt of the notice of claim letter or complaint by the insurer if the insurer has the duty to report, or by the pharmacist, pharmacy technician, or a pharmacy if the license holder has the duty to report, the following information must be furnished to the board on a form provided by the board:

(A) the name and address of the insurer;

(B) the name and address of the insured and type of license or registration held (pharmacist, pharmacy or pharmacy technician):

(C) the insured's Texas pharmacist or pharmacy license number or pharmacy technician registration number;

(D) certification, if applicable;

(E) the policy number;

(F) name(s) of plaintiff(s);

(G) date of injury;

(H) county of injury;

(I) cause of injury, e.g., dispensing error;

(J) nature of injury;

(K) type of action, e.g., claim only or lawsuit;

(L) name and phone number of the person filing the report; and

(M) a copy of the notice of claim letter or the lawsuit filed in court.

(2) Follow-up report. Within 105 days after disposition of the claim, the following information must be provided to the board on a form provided by the board:

(A) the name and address of the insured and type of license or registration held (pharmacist, pharmacy or pharmacy technician):

(B) the insured's Texas pharmacist or pharmacy license number or pharmacy technician registration number;

(C) name(s) of plaintiff(s);

(D) date of disposition;

(E) type of disposition, e.g., settlement, judgment;

(F) amount of disposition;

(G) whether an appeal has been taken and by which party; and

(H) name and phone number of the person filing the report.

(3) Definition. For the purpose of this section, disposition of a claim shall include circumstances where a court order has been entered, a settlement agreement has been reached, or the complaint has been dropped or dismissed.

(c) Report format

(1) Separate reports are required for each defendant licensee or registrant.

(2) The information shall be reported on a form provided by the board.

(3) A court order or settlement agreement may be submitted as an attachment to the follow-up report.

(d) Claims not required to be reported. Examples of claims that are not required to be reported under this section are the following:

(1) product liability claims (i.e., where a licensee invented a medical device which may have injured a patient but the licensee has no personal pharmacist-patient relationship with the specific patient claiming injury by the device);

(2) antitrust allegations;

(3) allegations involving improper peer review activities;

(4) civil rights violations; or

(5) allegations of liability for injuries occurring on a licensee's property, but not involving a breach of duty (i.e., slip and fall accidents).

(e) Liability. An insurer reporting under this section, its agents or employees, or the board or its employees or representatives are not liable for damages in a suit brought by any person or entity for reporting as required by this section or for any other action taken under this section.

(f) Limit on use of information reported.

(1) Information submitted to the board under this section and the fact that the information has been submitted to the board may not be:

(A) offered in evidence or used in any manner in the trial of a suit described in this section; or

(B) used in any manner to determine the eligibility or credentialing of a pharmacy to participate in a health insurance plan defined by the Insurance Code.

(2) A report received by the board under this section is not a complaint for which a board investigation is required except that the board shall review the information relating to a pharmacist, pharmacy technician, or pharmacy license holder against whom at least three professional liability claims have been reported within a five-year period in the same manner as if a complaint against the pharmacist, pharmacy technician, or pharmacy license holder had been made under Chapter 555 of the Act. The board may initiate an investigation of pharmacist, pharmacy technician, or pharmacy license holder based on the information received under this section.

(3) The information received under this section may be used in any board proceedings as the board deems necessary.

(g) Confidentiality. Information submitted under this section is confidential, except as provided in subsection (f)(3) of this section, and is not subject to disclosure under Chapter 552, Government Code.

(h) Penalty. The Texas Department of Insurance may impose on any insurer subject to this Act sanctions authorized by §§82.051-82.055 (formerly §7, Article 1.10) of the Texas Insurance Code, if the insurer fails to report information as required by this section.

§281.19 Vehicles

(a) Vehicle Inscription Information.

(1) Exemption. As specified in §554.009 of the Act and §721.003 of the Transportation Code, vehicles assigned to or used by the compliance or investigation divisions for enforcement of pharmacy laws and rules are exempt from bearing the inscription required by §721.002 of the Transportation Code. These vehicles are to be used

primarily in the inspection of pharmacies and the investigation of violations of state and federal laws and rules relating to the practice of pharmacy. In addition, as specified in §554.009 of the Act, the vehicles may be registered with the Texas Department of Motor Vehicles in an alias name for investigative personnel.

(2) Purpose. The purpose of exempting these vehicles from the inscription requirements of §721.002 of the Transportation Code is to increase the effectiveness of agency field employees in detecting and investigating violations of state and federal laws relating to the practice of pharmacy, thereby allowing compliance and investigative personnel to accomplish their tasks undetected, and to provide a greater degree of safety for these staff and the state property being used in the enforcement and a greater degree of case integrity.

(b) Restrictions on Assignments of Vehicles.

(1) Each agency vehicle will be assigned to an individual field employee.

(2) The agency may assign a vehicle to a board member or an individual administrative or executive employee:

(A) on a temporary basis if field personnel are not available to assume responsibility for the car; or

(B) on a regular basis only if the agency makes a written documented finding that the assignment is critical to the needs and mission of the agency.

SUBCHAPTER B – GENERAL PROCEDURES IN A CONTESTED CASE

§281.20 Application of Other Laws

All disciplinary action shall be taken by the board in accordance with Chapters 2001 and 2003, Government Code, the State Office of Administrative Hearings Rules of Procedure, the board's rules, and any other applicable law or rule.

§281.21 Complaints

Complaints may be filed with the agency in writing or by submitting a completed complaint form to the agency by mail or other method of delivery or through the Internet. A complaint form shall be maintained on the agency's Internet site and at the agency's office for use by a complainant. The complaint form shall request information necessary for the proper processing of the complaint by the agency, including, but not limited to:

(1) complainant's name, address, and phone number;

(2) name, address and phone number of subject of complaint, if known;

(3) date of incident;

(4) description of drug(s) involved, if any; and

(5) description of incident giving rise to complaint.

§281.22 Informal Disposition of a Contested Case

(a) Unless precluded by law, informal disposition may be made of any contested case by stipulation, agreed settlement, consent order, default, or dismissal.

(b) Prior to the imposition of disciplinary sanction(s) against a respondent, the board shall provide the respondent with written notice of the matters asserted, including:

(1) a statement of the legal authority, jurisdiction, and alleged conduct under which the enforcement action is based, with a reference to the particular section(s) of the statutes and rules involved;

(2) information the board staff intends to use at an informal conference;

(3) an offer for the respondent to attend an informal conference at a specified time and place and show compliance with all requirements of law, in accordance with §2001.054(c) of the Administrative Procedure Act;

(4) a statement that the respondent has an opportunity for a hearing before the State Office of Administrative Hearings on the allegations; and

(5) the following statement in capital letters in 12 point boldface type: FAILURE TO RESPOND TO THE ALLEGATIONS, BY EITHER PERSONAL APPEARANCE AT THE INFORMAL CONFERENCE OR IN WRITING, WILL RESULT IN THE ALLEGATIONS BEING ADMITTED AS TRUE AND THE RECOMMENDED SANCTION MADE AT THE INFORMAL CONFERENCE BEING GRANTED BY DEFAULT. The notice shall be served by delivering a copy to the

respondent in person, by courier receipted delivery, by first class mail, or by certified or registered mail, return receipt requested to the respondent's last known address of record as shown by agency records.

(c) The respondent will be provided the opportunity to appear at an informal conference prior to a hearing at the State Office of Administrative Hearings. The notice of the time and place of the informal conference, along with the written notice required in subsection (b) of this section, will be given to the respondent at least 45 days before the date of the informal conference. If such notice is not timely provided, the respondent may reschedule the informal conference.

(d) The respondent shall respond either by personal appearance at the informal conference, or by providing a rebuttal in writing no later than 15 days before the date of the informal conference. If the respondent chooses to respond in writing, the response shall admit or deny each of the allegations. If the respondent intends to deny only a part of an allegation, the respondent shall specify so much of it is true and shall deny only the remainder. The response shall also include any other matter, whether of law or fact, upon which the respondent intends to rely upon as a defense. If the respondent fails to respond to the notice specified in subsection (b) of this section, the matter will be considered as a default case and the respondent will be deemed to have:

(1) admitted all the factual allegations in the notice specified in subsection (b) of this section;

(2) waived the opportunity to show compliance with the law;

(3) waived notice of a hearing;

(4) waived the opportunity for a hearing on the allegations; and

(5) waived objection to the recommended sanctions made at the informal conference.

(e) Default orders.

(1) The informal conference panel may recommend that the board enter a default order, based upon the allegations set out in the notice specified in subsection (b) of this section, adopting the recommended sanctions made at the informal conference. Upon consideration of the case, the board may enter a default order under §2001.056 of the Administrative Procedure Act or direct that the case be set for a hearing at the State Office of Administrative Hearings.

(2) For a contested case before the State Office of Administrative Hearings, the judge may announce a default upon receiving the required showing of proof to support a default, and then recess the hearing, issue an order dismissing the case from the docket of the State Office of Administrative Hearings, and return the file to the board for informal disposition on a default basis in accordance with §2001.056 of the Administrative Procedure Act. The board may then enter a default order or direct the case back to the State Office of Administrative Hearings.

(f) Any default judgment granted under this section will be entered on the basis of the factual allegations in the notice specified in subsection (b) of this section, and upon proof of proper notice to the respondent's address of record. For purposes of this section, proper notice means notice sufficient to meet the provisions of §2001.054 of the Administrative Procedure Act and §281.30 of this title (relating to Pleadings and Notice in a Contested Case).

(g) A motion for rehearing which requests that the board vacate its default order under this section shall be granted if the motion presents convincing evidence that the failure to respond to the notice specified in subsection (b) of this section was not intentional or the result of conscious indifference, but due to accident or mistake, provided that the respondent has a meritorious defense to the factual allegations contained in the notice specified in subsection (b) of this section and the granting thereof will not result in delay or injury to the public or the board.

(h) Informal conferences shall be attended by the executive director/secretary or designated representative, legal counsel of the agency or an attorney employed by the office of the attorney general, and other representative(s) of the agency as the executive director/secretary and legal counsel may deem necessary for proper conduct of the conference. The respondent and/or the respondent's authorized representative(s) may attend the informal conference and shall be provided an opportunity to be heard. All communications from the respondent shall be directed to the legal counsel of the agency.

(i) In any case where charges are based upon information provided by a person (complainant) who filed a complaint with the board, the complainant may attend the informal conference, unless the proceedings are confidential under §564.002 and §564.003 of the Texas Pharmacy Act or other applicable law. A complainant who chooses to attend an

informal conference shall be provided an opportunity to be heard with regard to charges based upon the information provided by the complainant. Nothing herein requires a complainant to attend an informal conference.
(j) Informal conferences shall not be deemed meetings of the board, and no formal record of the proceedings at such conferences shall be made or maintained unless the respondent requests such a recording in writing at least 15 days before the informal conference. Board staff will arrange for the presence of a court reporter to make the recording. The respondent shall be responsible for the cost of the recording. The recording will be part of the board's investigative file and will not be released to a third party unless authorized under §565.055 of the Act. The board will provide a copy of the recording to the respondent upon request.
(k) Any proposed consent order shall be presented to the board in open meeting for its review. At the conclusion of its review, the board shall approve or disapprove the proposed consent order. Should the board approve the proposed consent order, the appropriate notation shall be made in minutes of the board and the proposed consent order shall be entered as an official action of the board. Should the board disapprove the proposed consent order, the matter shall be scheduled for public hearing.

§281.23 Subpoenas
(a) A subpoena issued by the executive director/secretary under the authority of §565.058 of the Act is considered by the board to be a ministerial act. Such subpoena shall be used to obtain information and testimony at the request of board staff.
(b) If a subpoena is requested by an applicant, licensee, or registrant under §2001.089 of the APA, a showing of good cause shall be made to the executive director/secretary. Such a showing shall be by submission of a written request for the subpoena indicating the purpose of the subpoena and indicating that the subpoena is not requested in bad faith. In addition, the requesting party shall aver that the subpoena:
(1) does not request information that is privileged;
(2) requests information relevant to the contested case;
(2) is not an undue burden; and
(3) is sufficiently specific.
(c) Once the requesting party has complied with the requirements in subsection (b) of this section, the executive director/secretary may issue the subpoena.
(d) If the requesting party, the subpoenaed party, any other party to the contested case, or any person or entity affected by the subpoena objects, a challenge to the subpoena shall be filed with the Administrative Law Judge at the State Office of Administrative Hearings.

§281.30 Pleadings and Notice in a Contested Case
(a) The board initiates a contested case hearing at the State Office of Administrative Hearings by filing a complaint with notice of not less than 10 days as specified in subsection (b) of this section to the applicant, licensee, or registrant.
(1) The complaint shall contain the matters asserted by the board, including the alleged conduct under which the enforcement action is based, and a statement of legal authority to the statutes or rules allegedly violated and those establishing jurisdiction.
(2) The following statement in capital letters in 12 point boldface type shall be contained in the complaint: FAILURE TO RESPOND TO THE ALLEGATIONS IN WRITING WILL RESULT IN THE ALLEGATIONS BEING ADMITTED AS TRUE AND AN ORDER BEING ENTERED BY THE BOARD BY DEFAULT.
(b) The board may serve notice of the complaint initiating a contested case hearing at the State Office of Administrative Hearings by sending it to the party's current publicly available address of record and the party's current confidential address of record if the confidential address of record is different from the party's publicly available address of record as shown by the board's records. The notice shall be served by delivering a copy to the party either in person or by certified or registered mail, return receipt requested.
(c) The applicant, licensee, or registrant shall file a written answer with the State Office of Administrative Hearings in response to the complaint with service to the board within 23 days after the date of service of the complaint. The

answer shall admit or deny each of the allegations. If the party intends to deny only a part of an allegation, the party shall specify so much of it is true and shall deny only the remainder. The response shall also include any other matter, whether of law or fact, upon which the licensee or registrant intends to rely for his or her defense. If the party fails to respond by filing a timely answer, the board's attorney files a motion to remand the case to the board for entry of a default order, and the matter will be considered as a default case and the party will be deemed to have:

(1) admitted all the factual allegations in the notice specified in subsection (b) of this section;
(2) waived notice of a hearing;
(3) waived the opportunity for a hearing on the allegations; and
(4) waived objection to the recommended sanctions made at the informal conference.

(d) If the contested case is remanded to the board by the State Office of Administrative Hearings as specified in subsection (c) of this section, the board may enter a default order under §2001.056 of the Administrative Procedure Act.
(e) Any default judgment granted under this section will be entered on the basis of the factual allegations in the notice specified in subsection (b) of this section, and upon proof of proper notice to the party's address of record.
(f) The party may file a motion for rehearing to set aside the default order. The motion, which requests that the Board vacate its default order under this section, shall be granted if the motion presents convincing evidence that the failure to respond to the notice specified in subsection (b) of this section was not intentional or the result of conscious indifference, but due to accident or mistake, provided that the party has a meritorious defense to the factual allegations contained in the notice specified in subsection (b) of this section and the granting thereof will not result in delay or injury to the public or the Board.

§281.31 Burden of Proof

(a) In a contested case hearing at the State Office of Administrative Hearings involving grounds for disciplinary action, the board has the burden to prove that grounds to discipline respondent exist. However, the party that claims any exemption or exception, including mitigating factors as specified in §281.62 of this chapter, has the burden to prove that the exemption or exception should be applied.
(b) In a contested case hearing at the State Office of Administrative Hearings involving a petition for reinstatement or removal of restriction, the petitioner has the burden to prove that the license should be reinstated or that a restriction on the license should be removed in accordance with §281.66 of the chapter.
(c) In a show cause order hearing before a panel of the board involving an applicant, licensee, or registrant who has been previously ordered by the board to submit to a mental or physical examination under §565.052 or §568.0036 of the Act, the applicant, licensee, or registrant has the burden to prove that the applicant, licensee, or registrant should not be required to submit to the examination.

§281.32 Failure to Attend Hearing and Default

(a) If a party who does not have the burden of proof fails to appear at a contested case hearing at the State Office of Administrative Hearings, the administrative law judge may announce a default upon receiving the required showing of proof to support a default, and then recess the hearing, issue an order dismissing the case from the docket of the State Office of Administrative Hearings, and return the file to the board for informal disposition on a default basis in accordance with §2001.056 of the Administrative Procedure Act. In the alternative, the judge may issue a default proposal for decision, rather than continuing or dismissing the case and requiring the board to dispose of the case on a default basis as an informal disposition.
(b) If a party who does have the burden of proof fails to appear at a contested case hearing at the State Office of Administrative Hearings, the administrative law judge shall dismiss the case for want of prosecution, any relevant application will be withdrawn, and the board may not consider a subsequent petition from the party until the first anniversary of the date of dismissal of the case.

§281.33 Proposal for Decision

(a) The administrative law judge shall submit a proposal for decision to the agency, and the board shall render the final decision in the contested case. The board may request that the proposal for decision be presented to the board by the administrative law judge at the next board meeting.

(b) If a party submitted proposed findings of fact, the proposal for decision shall include a ruling on each proposed finding by the administrative law judge.

(c) The parties may submit to the board for consideration, prior to the final decision, an alternative proposed board order with changes to the proposal for decision in compliance with the APA.

§281.34 Record of Hearing

(a) The board shall arrange for a stenographic recording of all contested case hearings before the State Office of Administrative Hearings on a regular basis. The administrative law judge may waive the requirement as authorized by the State Office of Administrative Hearings Rules of Procedure. Any party may request a written transcript of all or part of the hearing. The cost of a transcript shall be paid by the requesting party.

(b) A party who appeals a final decision in a hearing shall pay the cost of preparation of the original or a certified copy of the record of the board proceeding that is required to be sent to the reviewing court. A charge imposed under this section is a court cost and may be assessed by the court in accordance with the Texas Rules of Civil Procedure.

§281.35 Temporary Suspension or Restriction.

(a) In accordance with §§565.059 and 568.0037 of the Act, and §2001.081 of the Administrative Procedure Act, Title 10, Chapter 2001, Government Code, the determination of the disciplinary panel may be based not only on evidence admissible under the Texas Rules of Evidence, but may be based on information necessary to ascertain facts not reasonably susceptive of proof under those rules, not precluded by statute, and of a type on which a reasonably prudent person commonly relies in the conduct of the person's affairs.

(b) Questioning of witnesses by the parties or panel members shall be permitted in the discretion of the chair of the disciplinary panel with due consideration being given to the need to obtain accurate information and prevent the harassment or undue embarrassment of witnesses.

(c) In receiving information on which to base its determination of a continuing threat to the public welfare, the disciplinary panel may accept the testimony of witnesses by telephone in the discretion of the chair of the disciplinary panel.

(d) Hearings before disciplinary panels convened under §§565.059(b)(1) and 568.0037(b)(1) of the Act are not recorded unless the respondent requests such a recording in writing at least 5 days before the hearing. If requested in a timely manner, the board will arrange for the presence of a court reporter to make the recording. The respondent shall be responsible for the cost of the court reporter, the recording, and any written transcript requested by the respondent.

(e) Minutes of the hearing will be made and maintained by the board. The board will provide a copy of the minutes to the respondent upon request.

SUBCHAPTER C – DISCIPLINARY GUIDELINES

§281.60 General Guidance

(a) This subchapter is promulgated to:

(1) promote consistency and guidance in the exercise of sound discretion by the agency in licensure and disciplinary matters;

(2) provide notice as to the types of conduct that constitute violations of the Act and as to the disciplinary action that may be imposed; and

(3) provide a framework of analysis for administrative law judges in making recommendations in licensure and disciplinary matters.

(b) Board's role. The board shall render the final decision in a contested case and has the responsibility to assess sanctions against licensees who are found to have violated the Act. The board welcomes recommendations of administrative law judges as to the sanctions to be imposed, but the board is not bound by such recommendations. A sanction should be consistent with sanctions imposed in other similar cases and should reflect the board's determination of the seriousness of the violation and the sanction required to deter future violations. A determination of the appropriate sanction is reserved to the board. The appropriate sanction is not a proper finding of fact or conclusion of law. This subchapter shall be construed and applied so as to preserve board member discretion in the imposition of sanctions and remedial measures pursuant to the APA and the Act's provisions related to types of discipline and administrative penalties. This subchapter shall be further construed and applied so as to be consistent with the Act, and shall be limited to the extent as otherwise proscribed by statute and board rule.
(c) Purpose of guidelines. These guidelines are designed to provide guidance in assessing sanctions for violations of the Act. The ultimate purpose of disciplinary sanctions is to protect and inform the public, deter future violations, offer opportunities for rehabilitation, if appropriate, punish violators, and deter others from violations. These guidelines are intended to promote consistent sanctions for similar violations, facilitate timely resolution of cases, and encourage settlements.

(1) The standard sanctions outlined in the subchapter apply to cases involving a single violation of the Act, and in which there are no aggravating factors that apply. The board may impose more restrictive sanctions when there are multiple violations of the Act. In cases which do not have standard sanctions outlined in the subchapter, the board may consider any aggravating and/or mitigating factors listed in §281.62 of this title (relating to Aggravating and Mitigating Factors) that are found to apply in a particular case.
(2) The standard and minimum sanctions outlined in the subchapter are applicable to first time violators. The board shall consider revoking the person's license if the person is a repeat offender.
(3) The maximum sanction in all cases is revocation of the licensee's license, which may be accompanied by an administrative penalty of up to $5,000 per violation. Each day the violation continues is a separate violation.
(4) Each statutory violation constitutes a separate offense, even if arising out of a single act.

§281.61 Definitions of Discipline Authorized

For the purpose of the Act, §565.051 and §568.0035:

(1) "Probation" means a period of supervision by the board imposed against a license or registration for a term and under conditions as determined by the board, including a probation fee.
(2) "Reprimand" means a public and formal censure against a license or registration.
(3) "Restrict" means to limit, confine, abridge, narrow, or restrain a license or registration for a term and under conditions determined by the board.
(4) "Revoke" means a license or registration is void and may not be reissued; provided, however, upon the expiration of 12 months from and after the effective date of the order revoking a license or registration, the license or registration may be reinstated by the board upon the successful completion of any requirements determined by the board.
(5) "Suspend" means a license or registration is of no further force and effect for a period of time as determined by the board.
(6) "Retire" means a license or registration has been withdrawn and is of no further force and effect.

§281.62 Aggravating and Mitigating Factors

The following factors may be considered in determining the disciplinary sanctions imposed by the board if the factors are applicable to the factual situation alleged. The factors are not applicable in situations involving criminal actions (in which case §281.63 of this title (relating to Considerations for Criminal Offenses) applies).

(1) Aggravation. The following may be considered as aggravating factors so as to merit an increase in the severity of disciplinary sanction(s) to be imposed:

(A) extent and gravity of personal, economic, or public damage or harm;
(B) vulnerability of the patient(s);
(C) willful or reckless conduct, or as a result of a knowingly made professional omission, as opposed to negligent conduct;
(D) pattern of misconduct that serves as a basis of discipline;
(E) prior disciplinary action(s);
(F) attempted concealment of the conduct which serves as a basis for disciplinary action under the Act; and
(G) violation of a board order.

(2) Extenuation and Mitigation. The following may be considered as extenuating and mitigating factors so as to merit a reduction in the severity of disciplinary sanction(s) to be imposed:
(A) isolated incident that serves as a basis for disciplinary action;
(B) remorse for conduct;
(C) interim implementation of remedial measures to correct or mitigate harm from the conduct which serves as a basis for disciplinary action under the Act;
(D) remoteness of misconduct, when not based on delay attributable to actions by the respondent;
(E) extent to which respondent cooperated with board investigation;
(F) treatment and/or monitoring of an impairment;
(G) self-reported and voluntary admissions of the conduct which serves as a basis for disciplinary action under section 565.001(a)(4) and (7) of the Act; and
(H) if acting as pharmacist-in-charge, respondent did not personally engage, either directly or indirectly, in the conduct that serves as the basis for disciplinary action; did not permit or encourage, either by professional oversight or extreme negligence, the conduct that serves as the basis for disciplinary action; promptly reported the conduct to the board or other state or federal regulatory authorities or law enforcement upon identifying the conduct that serves as the basis for disciplinary action; and took all reasonable steps to mitigate or remediate the conduct that serves as the basis for disciplinary action.

§281.63 Considerations for Criminal Offenses

(a) The purpose of this section is to establish guidelines and criteria on the eligibility of persons with criminal backgrounds to obtain a license or registration from the board and on the disciplinary actions taken by the board. The section applies to all criminal convictions and to all deferred adjudication community supervisions or deferred dispositions, as authorized by the Act, for all types of licenses and registrations.

(b) The board may suspend, revoke, or impose other authorized disciplinary action on a current license or registration, disqualify a person from receiving a license or registration, or deny to a person the opportunity to be examined for a license or registration because of a person's conviction or deferred adjudication of a crime that serves as a ground for discipline under the Act, and that the board determines directly relates to the duties and responsibilities of a licensee, a registrant, or of an owner of a pharmacy. This subsection applies to persons who are not imprisoned at the time the board considers the conviction or deferred adjudication.

(c) The board may revoke a license or registration upon the imprisonment of the licensee, the registrant, or the owner of a pharmacy following a felony conviction or deferred adjudication. The board shall revoke a license or registration upon the imprisonment of the licensee, the registrant, or the owner of a pharmacy following a:

(1) felony conviction or deferred adjudication for:
(A) an offense that directly relates to the occupation of a licensee or registrant, or the operation of a pharmacy;
(B) an offense listed in Article 42.054, Code of Criminal Procedure; or
(C) a sexually violent offense, as defined by Article 62.001, Code of Criminal Procedure;

(2) felony community supervision revocation;

(3) revocation of parole; or

(4) revocation of mandatory supervision.

(d) A person in prison is not eligible for a license or registration.

(e) An applicant for a license or registration from the board shall disclose in writing to the board any conviction or deferred adjudication against him or her at the time of application. A current licensee or registrant shall disclose in writing to the board any conviction or deferred adjudication against him or her at the time of renewal.

(f) The board has determined that the criminal offenses listed in subsection (i) of this section directly relate to the occupation of a licensee or registrant, or the operation of a pharmacy. For all other offenses not listed in this section, in considering whether a criminal conviction or deferred adjudication directly relates to the duties and responsibilities of a licensee, a registrant, or of an owner of a pharmacy, the board shall consider the following factors:

(1) the nature and seriousness of the crime;

(2) the relationship of the crime to the purposes for requiring a license or registration to engage in the occupation of the licensee or registrant, or the operation of a pharmacy;

(3) the extent to which a license or registration might afford the licensee or registrant an opportunity to repeat the criminal activity in which the person had been involved;

(4) the relationship of the crime to the ability, capacity, or fitness required to perform the duties and discharge the responsibilities of the licensee or registrant.

(5) any correlation between the elements of the crime and the duties and responsibilities of the license or registration.

(g) The board has the authority to impose disciplinary action as authorized by the Act, for those criminal offenses that provide grounds for discipline under the Act. In reaching a decision regarding the severity of the disciplinary sanction to impose on a license or registration, the board shall, in its discretion and unless otherwise specified in §281.64 of this title (relating to Sanctions for Criminal Offenses), also determine the person's fitness to perform the duties and discharge the responsibilities of a licensee or registrant by evaluating and balancing these factors in the following priority with the first being the highest priority:

(1) the extent and nature of the person's past criminal activity;

(2) the amount of time that has elapsed since the person's last criminal activity;

(3) the person's rehabilitation or rehabilitative effort while incarcerated or following release as corroborated by extrinsic evidence;

(4) the age of the person at the time of the commission of the crime, if younger than 21 years of age at the time of the crime;

(5) the conduct and work activity of the person prior to and following the criminal activity; and

(6) evidence of the person's compliance with any conditions of community supervision, parole, or mandatory supervision; and

(7) other evidence of the person's present fitness, including letters of recommendation.

(h) In order to establish the factors in subsection (g) of this section, a person with a conviction or deferred adjudication shall:

(1) to the extent possible, secure and provide to the board the recommendations specified in subsection (g)(7) of this section;

(2) cooperate with the board by providing the information required by this section, including proof that he or she has:

(A) maintained a record of steady employment, as evidenced by salary stubs, income tax records or other employment records for the time since the conviction or deferred adjudication and/or release from imprisonment;

(B) supported his or her dependents, as evidenced by salary stubs, income tax records or other employment records for the time since the conviction or deferred adjudication and/or release from imprisonment, and a recommendation from the spouse or either parent;

(C) maintained a record of good conduct as evidenced by recommendations, absence of other criminal activity or documentation of community service since conviction or deferred adjudication;

(D) paid all outstanding court costs, supervision fees, fines, and restitution as may have been ordered in all criminal cases in which he or she has been convicted, as evidenced by certified copies of a court release or other documentation from the court system that all monies have been paid; and

(E) obtained appropriate treatment and/or counseling, if applicable.

(i) The board has determined that the following crimes directly relate to duties and responsibilities of board licensees or registrants. The commission of each indicates an inability or a tendency for the person to be unable to perform or to be unfit for licensure or registration, because commission of such crimes indicates a lack of integrity and respect for one's fellow human being and the community at large. Even if the commission of these crimes did not occur while the licensee or registrant was on-duty or employed at a pharmacy, the board has determined that the crimes directly relate to the practice of pharmacy based on a lack of integrity and good moral character exhibited by the commission of the crimes. In addition, the direct relationship to a license or registration is presumed when any crime occurs in connection with the practice of pharmacy or the operation of a pharmacy. The crimes are as follows:

(1) practicing or operating a pharmacy without a license or registration and other violations of the Pharmacy Act;

(2) deceptive business practices under the Texas Penal Code;

(3) Medicare or Medicaid fraud;

(4) a misdemeanor or felony offense under the Texas Penal Code involving:

(A) murder;

(B) assault;

(C) burglary;

(D) robbery;

(E) theft;

(F) sexual assault;

(G) injury to a child;

(H) injury to an elderly person;

(I) child abuse or neglect;

(J) tampering with a governmental record;

(K) forgery;

(L) perjury;

(M) failure to report abuse;

(N) bribery;

(O) harassment;

(P) insurance claim fraud;

(Q) driving while intoxicated;

(R) solicitation of professional employment under the Penal Code §38.12(d) or Occupations Code, Chapter 102;

(S) mail fraud; or

(T) any criminal offense which requires the individual to register with the Department of Public Safety as a sex offender under Chapter 62, Code of Criminal Procedure.

(5) any crime of moral turpitude;

(6) a misdemeanor or felony offense under Chapters 431 and 481 through 486, Health and Safety Code and the Comprehensive Drug Abuse Prevention and Control Act of 1970; or

(7) other misdemeanors or felonies which serve as grounds for discipline under the Act, including violations of the Penal Code, Titles 4, 5, 6, 7, 8, 9, and 10, which indicate an inability or tendency for the person to be unable to perform as a licensee or registrant, or to be unfit for licensure or registration, if action by the board will promote the intent of the Pharmacy Act, board rules including this chapter, and Occupations Code, Chapter 53.

§281.64 Sanctions for Criminal Offenses

(a) The guidelines for disciplinary sanctions apply to criminal convictions and to deferred adjudication community supervisions or deferred dispositions, as authorized by the Act, for all types of licensees and registrants including applicants for such licenses and registrations issued by the board. The board considers criminal behavior to be highly relevant to an individual's fitness to engage in pharmacy practice and has determined that the sanctions imposed by these guidelines promote the intent of §551.002 of the Act. The "date of disposition," when referring to the number of years used to calculate the application of disciplinary sanctions, refers to the date a conviction, a deferred adjudication, or a deferred disposition is entered by the court. The use of the term "currently on probation" is construed to refer to individuals currently serving community supervision or any other type of probationary term imposed by an order of a court for a conviction, deferred adjudication, or deferred disposition.

(b) The sanctions imposed by the guidelines can be used in conjunction with other types of disciplinary actions, including administrative penalties, as outlined in this section.

(c) The board has determined that the nature and seriousness of certain crimes outweigh other factors to be considered in §281.63(g) of this title (relating to Considerations for Criminal Offenses) and necessitate the disciplinary action listed in paragraphs (1) - (3) of this subsection. In regard to the crimes enumerated in this rule, the board has weighed the factors, which are required to be considered from §281.63(g) of this title, in a light most favorable to the individual, and even if these factors were present, the board has concluded that the following sanctions apply to individuals with the criminal offenses as described in paragraphs (1) - (3) of this subsection:

(1) Criminal offenses which require the individual to register with the Department of Public Safety as a sex offender under Chapter 62, Code of Criminal Procedure--denial or revocation;

(2) Felony offenses:

(A) Drug-related offenses, such as those listed in Chapter 481 or 483, Health and Safety Code:

(i) Offenses involving manufacture, delivery, possession with intent to deliver, or illegal dispensing:

(I) Currently on probation--denial or revocation;

(II) 0-5 years since date of disposition--denial or revocation;

(III) 6-10 years since date of disposition--denial or revocation;

(IV) 11-20 years since date of disposition--5 years probation;

(V) Over 20 years since date of disposition--3 years probation;

(ii) Offenses involving possession of drugs, fraudulent prescriptions, theft of drugs, or alcohol:

(I) If the offense involved only the personal use of the drugs or alcohol and/or chemical impairment:

(-a-) Currently on probation--90-day to one-year suspension followed by 5 years probation;

(-b-) 0-5 years since date of disposition--5 years probation;

(-c-) 6-10 years since date of disposition--3 years probation;

(-d-) 11-20 years since date of disposition--1 year probation; or

(II) Otherwise:

(-a-) Currently on probation--denial or revocation;

(-b-) 0-5 years since date of disposition--denial or one-year suspension followed by 5 years probation;

(-c-) 6-10 years since date of disposition--180-day suspension followed by 5 years probation;

(-d-) 11-20 years since date of disposition--3 years probation;

(-e-) Over 20 years since date of disposition--1 year probation;

(B) Offenses involving sexual contact or violent acts, or offenses considered to be felonies of the first degree under the Texas Penal Code:

(i) Currently on probation--denial or revocation;

(ii) 0-5 years since date of disposition--denial or revocation;
(iii) 6-10 years since date of disposition--denial or revocation;
(iv) 11-20 years since date of disposition--5 years probation;
(v) Over 20 years since date of disposition--1 year probation;
(C) Other felony offenses:
(i) Currently on probation--denial, revocation, or 30- to 180-day suspension followed by 5 years probation;
(ii) 0-5 years since date of disposition--5 years probation;
(iii) 6-10 years since date of disposition--3 years probation;
(iv) 11-20 years since date of disposition--1 year probation;
(3) Misdemeanor offenses:
(A) Drug-related offenses, such as those listed in Chapter 481 or 483, Health and Safety Code:
(i) Offenses involving manufacture, delivery, or possession with intent to deliver:
(I) Currently on probation--denial or revocation;
(II) 0-10 years since date of disposition--30- to 180-day suspension followed by 5 years probation;
(III) 11-20 years since date of disposition--1 year probation;
(ii) Offenses involving possession of drugs, fraudulent prescriptions, or theft of drugs:
(I) Pharmacists:
(-a-) 0-5 years since date of disposition--5 years probation;
(-b-) 6-10 years since date of disposition--3 years probation;
(II) Pharmacy Technicians and Pharmacy Technician Trainees:
(-a-) 0-5 years since date of disposition and offense determined to be in violation of §568.003(a)(5) or (9) of the Act--5 years probation;
(-b-) 0-5 years since date of disposition and determined not to be in violation of §568.003(a)(5) or (9) of the Act--1 year probation;
(-c-) 6-10 years since date of disposition and offense determined to be in violation of §568.003(a)(5) or (9) of the Act--3 years probation;
(II) Pharmacy Technicians and Pharmacy Technician Trainees:
(-a-) 0-5 years since date of disposition and offense determined to be in violation of §568.003(a)(5) or (9) of the Act--5 years probation;
(-b-) 0-5 years since date of disposition and determined not to be in violation of §568.003(a)(5) or (9) of the Act--1 year probation;
(-c-) 6-10 years since date of disposition and offense determined to be in violation of §568.003(a)(5) or (9) of the Act--3 years probation;
(III) If 0-5 years since date of disposition, and the offense did not involve only personal use of the drugs and/or chemical impairment, an additional 30- to 90-day suspension will be imposed preceding the probation for the offenses in this clause;
(B) Intoxication and alcoholic beverage offenses as defined in the Texas Penal Code, if two such offenses involving intoxication due to ingestion of alcohol occurred in the previous five years or if one such offense involving intoxication due to ingestion of controlled substances or dangerous drugs occurred in the previous five years:
(i) Pharmacists: 0-5 years since date of disposition and offense determined to be in violation of §565.001(a)(4) or (7) of the Act--5 years probation;
(ii) Pharmacy Technicians and Pharmacy Technician Trainees: 0-5 years since date of disposition and offense determined to be in violation of §568.003(a)(5) or (9) of the Act--5 years probation;
(C) Other misdemeanor offenses involving moral turpitude: 0-5 years since date of disposition--reprimand.

(d) When an individual has multiple criminal offenses or other violations, the board shall consider imposing additional more severe types of disciplinary sanctions, as deemed necessary.
(e) An individual who suffers from an impairment as described by §565.001(a)(4) or (7) or §568.003(a)(5) or (9), may provide mitigating information including treatment, counseling, and monitoring in order to mitigate the sanctions imposed.

§281.65 Schedule of Administrative Penalties

The board has determined that the assessment of an administrative penalty promotes the intent of §551.002 of the Act. In disciplinary matters, the board may assess an administrative penalty in addition to any other disciplinary action in the circumstances and amounts as follows:

(1) The following violations by a pharmacist may be appropriate for disposition with an administrative penalty with or without additional sanctions or restrictions:

(A) failing to provide patient counseling: $1,000;
(B) failing to conduct a drug regimen review or inappropriate drug regimen reviews provided by §291.33(c)(2)(A) of this title (relating to Operational Standards): $1,000;
(C) failing to clarify a prescription with the prescriber: $1,000;
(D) failing to properly supervise or improperly delegating a duty to a pharmacy technician: $1,000;
(E) failing to identify the dispensing pharmacist on required pharmacy records: $500;
(F) failing to maintain records of prescriptions: $500;
(G) failing to respond or failing to provide all requested records within the time specified in a board audit of continuing education records: $100 per hour of continuing education credit not provided;
(H) failing to provide or providing false or fraudulent information on any application, notification, or other document required under this Act, the Dangerous Drug Act, or Controlled Substances Act, or rules adopted pursuant to those Acts: $1,000;
(I) dispensing a prescription drug pursuant to a forged, altered, or fraudulent prescription: up to $5,000;
(J) dispensing unauthorized prescriptions: up to $5,000;
(K) dispensing controlled substances or dangerous drugs to an individual or individuals in quantities, dosages, or for periods of time which grossly exceed standards of practice, approved labeling of the federal Food and Drug Administration, or the guidelines published in professional literature: up to $5,000;
(L) violating a disciplinary order of the Board or a contract under the program to aid impaired pharmacists or pharmacy students under Chapter 564 of the Act: $500;
(M) failing to report or to assure the report of a malpractice claim: $1,000;
(N) practicing pharmacy with a delinquent license: $500;
(O) operating a pharmacy with a delinquent license: $1,000;
(P) allowing an individual to perform the duties of a pharmacy technician without a valid registration: $1,000;
(Q) aiding and abetting the unlicensed practice of pharmacy, if the pharmacist knew or reasonably should have known that the person was unlicensed at the time: $2,500;
(R) unauthorized substitutions: $1,000;
(S) submitting false or fraudulent claims to third parties for reimbursement of pharmacy services: $1,000;
(T) selling, purchasing, or trading, or offering to sell, purchase, or trade of misbranded prescription drugs or prescription drugs beyond the manufacturer's expiration date: $1,000;
(U) selling, purchasing, or trading, or offering to sell, purchase, or trade of prescription drug samples as provided by §281.7(a)(26) of this title (relating to Grounds for Discipline for a Pharmacist License): $1,000;

(V) failing to keep, maintain or furnish an annual inventory as required by §291.17 of this title (relating to Inventory Requirements): $1,000;
(W) failing to obtain training on the preparation of sterile pharmaceutical compounding: $1,000;
(X) failing to maintain the confidentiality of prescription records: $1,000;
(Y) failing to inform the board of any notification or information required to be reported by the Act or rules: $500;
(Z) failing to operate a pharmacy as provided by §291.11 of this title (relating to Operation of a Pharmacy): $1,000;
(AA) accessing information submitted to the Prescription Monitoring Program in violation of §481.076 of the Controlled Substances Act: $1,000 - $2,500; and
(BB) failing to access the Prescription Monitoring Program for a patient's information before dispensing opioids, benzodiazepines, barbiturates, or carisoprodol: $500.

(2) The following violations by a pharmacy may be appropriate for disposition with an administrative penalty with or without additional sanctions or restrictions:
(A) failing to provide patient counseling: $1,500;
(B) failing to conduct a drug regimen review or inappropriate drug regimen reviews provided by §291.33(c)(2)(A) of this title: $1,500;
(C) failing to clarify a prescription with the prescriber: $1,500;
(D) failing to properly supervise or improperly delegating a duty to a pharmacy technician: $1,500;
(E) failing to identify the dispensing pharmacist on required pharmacy records: $500;
(F) failing to maintain records of prescriptions: $500;
(G) failing to provide or providing false or fraudulent information on any application, notification, or other document required under this Act, the Dangerous Drug Act, or Controlled Substances Act, or rules adopted pursuant to those Acts: $1,000;
(H) following an accountability audit, shortages of prescription drugs: dependent on the quantity involved with a minimum of $1,000;
(I) dispensing a prescription drug pursuant to a forged, altered, or fraudulent prescription: up to $5,000;
(J) dispensing unauthorized prescriptions: up to $5,000;
(K) dispensing controlled substances or dangerous drugs to an individual or individuals in quantities, dosages, or for periods of time which grossly exceed standards of practice, approved labeling of the federal Food and Drug Administration, or the guidelines published in professional literature: up to $5,000;
(L) violating a disciplinary order of the Board: $1,000;
(M) failing to report or to assure the report of a malpractice claim: $1,500;
(N) allowing a pharmacist to practice pharmacy with a delinquent license: $1,000;
(O) operating a pharmacy with a delinquent license: $1,000;
(P) allowing an individual to perform the duties of a pharmacy technician without a valid registration: $3,000;
(Q) failing to comply with the reporting requirements to the Prescription Monitoring Program: $1,000;
(R) aiding and abetting the unlicensed practice of pharmacy, if an employee of the pharmacy knew or reasonably should have known that the person engaging in the practice of pharmacy was unlicensed at the time: $5,000;
(S) unauthorized substitutions: $1,000;
(T) submitting false or fraudulent claims to third parties for reimbursement of pharmacy services: $1,000;
(U) possessing or engaging in the sale, purchase, or trade or the offer to sell, purchase, or trade of misbranded prescription drugs or prescription drugs beyond the manufacturer's expiration date: $1,000;

(V) possessing or engaging in the sale, purchase, or trade or the offer to sell, purchase, or trade of prescription drug samples as provided by §281.8(b)(2) of this title (relating to Grounds for Discipline for a Pharmacy License): $1,000;
(W) failing to keep, maintain or furnish an annual inventory as required by §291.17 of this title: $2,500;
(X) failing to obtain training on the preparation of sterile pharmaceutical compounding: $2,000;
(Y) failing to maintain the confidentiality of prescription records: $1,000;
(Z) failing to inform the board of any notification or information required to be reported by the Act or rules: $1,000;
(AA) failing to operate a pharmacy as specified in §291.11 of this title: $3,000; and
(BB) operating a Class E or Class E-S pharmacy without a Texas licensed pharmacist-in-charge: $1,000.

(3) The following violations by a pharmacy technician may be appropriate for disposition with an administrative penalty with or without additional sanctions or restrictions:
(A) failing to respond or failing to provide all requested records within the time specified in a board audit of continuing education records: $30 per hour of continuing education credit not provided;
(B) failing to provide or providing false or fraudulent information on any application, notification, or other document required under this Act, the Dangerous Drug Act, or Controlled Substances Act, or rules adopted pursuant to those Acts: $500;
(C) violating a disciplinary Order of the Board: $250;
(D) performing the duties of a pharmacy technician without a valid registration: $250;
(E) failing to obtain training on the preparation of sterile pharmaceutical compounding: $500;
(F) failing to maintain the confidentiality of prescription records: $500;
(G) failing to inform the board of any notification or information required to be reported by the Act or rules: $250; and
(H) accessing information submitted to the Prescription Monitoring Program in violation of §481.076 of the Controlled Substances Act: $500 - $2,000.

(4) Any of the violations listed in this section may be appropriate for disposition by the administrative penalties in this section in conjunction with any other penalties in §281.61 of this title (relating to Definitions of Discipline Authorized).

(5) Each day a violation continues or occurs is a separate violation for purposes of imposing a penalty or fine.

(6) The amount, to the extent possible, shall be based on:
(A) the seriousness of the violation, including the nature, circumstances, extent, and gravity of any prohibited act, and the hazard or potential hazard created to the health, safety, or economic welfare of the public;
(B) the aggravating and mitigating factors in §281.62 of this title (relating to Aggravating and Mitigating Factors);
(C) the amount necessary to deter a future violation; and
(D) any other matter that justice may require.

§281.66 Application for Reissuance or Removal of Restrictions of a License or Registration

(a) A person whose pharmacy license, pharmacy technician registration, or license or registration to practice pharmacy has been canceled, revoked, or restricted, whether voluntary or by action of the board, may, after 12 months from the effective date of such cancellation, revocation, or restriction, apply to the board for reinstatement or removal of the restriction of the license or registration.

(1) The application shall be given under oath and on the form prescribed by the board.

(2) A person applying for reinstatement or removal of restrictions may be required to meet all requirements necessary in order for the board to access the criminal history record information, including submitting fingerprint information and being responsible for all associated costs.

(3) A person applying for reinstatement or removal of restrictions has the burden of proof.

(4) On investigation and hearing, the board may in its discretion grant or deny the application or it may modify its original finding to reflect any circumstances that have changed sufficiently to warrant the modification.

(5) If such application is denied by the board, a subsequent application may not be considered by the board until 12 months from the date of denial of the previous application.

(6) The board in its discretion may require a person to pass an examination or examinations to reenter the practice of pharmacy.

(7) The fee for reinstatement of a license or registration shall be $100 which is to be paid to the Texas State Board of Pharmacy and includes the processing of the reinstatement application.

(b) In reinstatement cases not involving criminal offenses, the board may consider the following items in determining the reinstatement of an applicant's previously revoked or canceled license or registration:

(1) moral character in the community;

(2) employment history;

(3) financial support to his/her family;

(4) participation in continuing education programs or other methods of maintaining currency with the practice of pharmacy;

(5) criminal history record;

(6) offers of employment in pharmacy;

(7) involvement in public service activities in the community;

(8) failure to comply with the provisions of the board order revoking or canceling the applicant's license or registration;

(9) action by other state or federal regulatory agencies;

(10) any physical, chemical, emotional, or mental impairment;

(11) the gravity of the offense for which the applicant's license or registration was canceled, revoked, or restricted and the impact the offense had upon the public health, safety and welfare;

(12) the length of time since the applicant's license or registration was canceled, revoked or restricted, as a factor in determining whether the time period has been sufficient for the applicant to have rehabilitated himself/herself to be able to practice pharmacy in a manner consistent with the public health, safety and welfare;

(13) competency to engage in the practice of pharmacy; or

(14) other rehabilitation actions taken by the applicant.

(c) If a reinstatement case involves criminal offenses, the sanctions specified in §281.64 of this chapter (relating to Sanctions for Criminal Offenses) apply.

(d) If an application for reinstatement of a license to practice pharmacy is granted by the board, the applicant, in addition to any sanctions or other requirements imposed by the board, shall complete approved continuing education and board-approved internship requirements according to the following schedule:

(1) if the license has been revoked or canceled for at least one year but less than two years, complete 15 contact hours of approved continuing education;

(2) if the license has been revoked or canceled for at least two years but less than three years, complete 30 contact hours of approved continuing education and 100 hours of internship in a board-approved internship program;

(3) if the license has been revoked or canceled for at least three years but less than four years, complete 45 contact hours of approved continuing education and 300 hours of internship in a board-approved internship program;

(4) if the license has been revoked or canceled for at least four years but less than five years, complete 45 contact hours of approved continuing education and 500 hours of internship in a board-approved internship program;

(5) if the license has been revoked or canceled for at least five years but less than six years, complete 45 contact hours of approved continuing education and 700 hours of internship in a board-approved internship program;

(6) if the license has been revoked or canceled for at least six years but less than seven years, complete 45 contact hours of approved continuing education and 900 hours of internship in a board-approved internship program;
(7) if the license has been revoked or canceled for at least seven years but less than eight years, complete 45 contact hours of approved continuing education and 1,100 hours of internship in a board-approved internship program;
(8) if the license has been revoked or canceled for at least eight years but less than nine years, complete 45 contact hours of approved continuing education and 1,300 hours of internship in a board-approved internship program;
(9) if the license has been revoked or canceled for at least nine years but less than ten years, complete 45 contact hours of approved continuing education and 1,500 hours of internship in a board-approved internship program; and
(10) if the license has been revoked or canceled for ten years or more, complete 45 contact hours of approved continuing education and the number of internship hours required by the Accreditation Council for Pharmacy Education (ACPE) for licensure in a board-approved internship program.

§281.67 Sanctions for Out-of-State Disciplinary Actions

(a) When determining the appropriate sanction for a disciplinary action taken by a regulatory board of another state under §565.001(a)(16), §565.002(a)(13), or §568.003(a)(13), the board has determined that the following shall be applicable for all types of licensees and registrants for such licenses and registrations issued by the board.

(1) If the other state's disciplinary action resulted in the license or registration being restricted, suspended, revoked, or surrendered, the appropriate sanction shall be the same as the sanction imposed by the other state, such that the licensee or registrant has the same restriction against practice in Texas.

(2) If the license or registration is subject to any other type of disciplinary sanctions, the appropriate sanction shall be equivalent to or less than that imposed by the other state unless contrary to board policy.

(b) The sanctions imposed by this chapter can be used in conjunction with other types of disciplinary actions, including administrative penalties, as outlined in this chapter.

(c) When a licensee or registrant has additional violations of the Texas Pharmacy Act, the board shall consider imposing additional more severe types of disciplinary sanctions, as deemed necessary.

§281.68 Remedial Plan

(a) The board may issue a remedial plan by agreement with the respondent to resolve the investigation of a complaint relating to the Act unless the complaint involves:

(1) a death;
(2) a hospitalization;
(3) the commission of a felony;
(4) the unlicensed practice of a licensee or registrant;
(5) audit shortages;
(6) diversion of controlled substances;
(7) impairment by chemical abuse or mental or physical illness of a licensee or registrant;
(8) unauthorized dispensing of a prescription drug;
(9) gross immorality as defined by the board;
(10) engaging in fraud, deceit, or misrepresentation as defined by board rule;
(11) disciplinary action by another regulatory board of this state or another state; or
(12) any other matter determined by the board.

(b) The board shall not impose a remedial plan if the appropriate resolution of the complaint involves a restriction on the manner in which a license holder practices pharmacy.

(c) The board may not issue a remedial plan to resolve a complaint against a license holder if the license holder has entered into a remedial plan with the board in the preceding 24 months for the resolution of a different complaint relating to this subtitle.
(d) If a license holder complies with and successfully completes the terms of a remedial plan, the board shall remove all records of the remedial plan from the board's records at the end of the fiscal year in which the fifth anniversary of the date the board issued the terms of the remedial plan occurs in accordance with §565.060 of the Act.
(e) The board may assess a fee against a license holder participating in a remedial plan in the amount of $1,000 to recover the costs of administering the plan.

§281.69 Automatic Denial or Revocation

(a) Notwithstanding subsection (c) of this section, as required in Texas Occupations Code, §§108.052 and 108.053, the board shall deny an application for licensure as a pharmacist or immediately upon receiving notification as specified in §108.053(b) revoke the pharmacist license of a person who:

(1) is required to register as a sex offender under Chapter 62, Code of Criminal Procedure;

(2) has been previously convicted of or placed on deferred adjudication community supervision for the commission of a felony offense involving the use or threat of force; or

(3) has been previously convicted of or placed on deferred adjudication community supervision for the commission of an offense:

(A) under Penal Code, §§22.011, 22.02, 22.021, or 22.04, or an offense under the laws of another state or federal law that is equivalent to an offense under one of those sections;

(B) committed:

(i) when the applicant held a license as a health care professional in this state or another state; and

(ii) in the course of providing services within the scope of the applicant's license; and

(C) in which the victim of the offense was a patient of the applicant.

(b) As specified in Texas Occupations Code, §108.054, a person whose license application is denied under this subsection:

(1) based on a conviction or placement on deferred adjudication community supervision for an offense described by subsections (a)(2) or (3) of this section may reapply for a license if the conviction or deferred adjudication is reversed, set aside, or vacated on appeal; or

(2) based on a requirement to register as a sex offender under Chapter 62, Code of Criminal Procedure, may reapply for a license after the expiration of the period for which the person is required to register.

(c) As specified in Texas Occupations Code, §108.055, a person whose license is revoked under this subsection:

(1) based on a conviction or placement on deferred adjudication community supervision for an offense described by subsections (a)(2) or (3) of this section may apply for reinstatement of the license if the conviction or deferred adjudication is reversed, set aside, or vacated on appeal; or

(2) based on a requirement to register as a sex offender under Chapter 62, Code of Criminal Procedure, may apply for reinstatement of the license after the expiration of the period for which the person is required to register.

§281.70 Surety Bond

The Board may require a surety bond if an investigation of a pharmacy involves §565.002(a)(7) or (10) of the Act.

CHAPTER 283 – LICENSING REQUIREMENTS FOR PHARMACISTS

§283.1 Purpose

The purpose of this chapter is to provide a comprehensive, coherent regulatory scheme for the licensing of individuals wishing to engage in the practice of pharmacy in this state. The provisions of this chapter govern in conjunction with the Texas Pharmacy Act (Chapters 551 - 566, and 568 - 569, Occupations Code, as amended) the method for the issuance of a certificate to act as a pharmacist in Texas. This chapter also provides a framework for any board-approved internship program.

§283.2 Definitions

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

(1) ACPE--Accreditation Council for Pharmacy Education.

(2) Applicant--An individual having applied for licensure to act as a pharmacist in Texas.

(3) Approved continuing education--Continuing education which meets the requirements of §295.8 of this title (relating to Continuing Education Requirements).

(4) Board--The Texas State Board of Pharmacy; all members, divisions, departments, sections, and employees thereof.

(5) College/School of pharmacy--A college/school of pharmacy whose professional degree program has been approved by the board and is either accredited by:

(A) ACPE; or

(B) the Canadian Council for Accreditation of Pharmacy Programs for 1993 - 2004 graduates.

(6) Competency--A demonstrated state of preparedness for the realities of professional pharmacy practice.

(7) Didactic--Systematic classroom instruction.

(8) Direct supervision--A pharmacist preceptor or healthcare professional preceptor is physically present and on-site at the licensed location of the pharmacy where the pharmacist-intern is performing pharmacist-intern duties.

(9) Extended-intern--An intern, registered with the board, who has:

(A) applied to the board for licensure by examination and has successfully passed the NAPLEX and Texas Pharmacy Jurisprudence Examination but lacks the required number of hours of internship for licensure; or

(B) applied to the board to take the NAPLEX and Texas Pharmacy Jurisprudence Examinations within six calendar months after graduation and has either:

(i) graduated and received a professional degree from a college/school of pharmacy; or

(ii) completed all of the requirements for graduation and for receipt of a professional degree from a college/school of pharmacy; or

(C) applied to the board to take the NAPLEX and Texas Pharmacy Jurisprudence Examinations within six calendar months after obtaining full certification from the Foreign Pharmacy Graduate Equivalency Commission; or

(D) applied to the Board for re-issuance of a pharmacist license which has been expired for more than two years but less than ten years and has successfully passed the Texas Pharmacy Jurisprudence Examination, but lacks the required number of hours of internship or continuing education required for licensure; or

(E) been ordered by the Board to complete an internship.

(10) Foreign pharmacy graduate--An individual whose pharmacy degree was conferred by a pharmacy school whose professional degree program has not been accredited by ACPE and approved by the board. An individual whose pharmacy degree was conferred by a pharmacy school that was accredited by the Canadian Council for

Accreditation of Pharmacy Programs between 1993 and 2004, inclusively, is not considered a foreign pharmacy graduate.
(11) FPGEC--The Foreign Pharmacy Graduate Equivalency Commission.
(12) Healthcare Professional--An individual licensed as:
(A) a physician, dentist, podiatrist, veterinarian, advanced practice registered nurse, or physician assistant in Texas or another state; or
(B) a pharmacist in a state other than Texas but not licensed in Texas.
(13) Healthcare Professional Preceptor--A healthcare professional serving as an instructor for a Texas college/school-based internship program who is recognized by a Texas college/school of pharmacy to supervise and be responsible for the activities and functions of a student-intern in the internship program.
(14) Internship--A practical experience program that is approved by the board.
(15) MPJE--Multistate Pharmacy Jurisprudence Examination.
(16) NABP--The National Association of Boards of Pharmacy.
(17) NAPLEX--The North American Pharmacy Licensing Examination, or its predecessor, the National Association of Boards of Pharmacy Licensing Examination.
(18) Pharmaceutical care--The provision of drug therapy and other pharmaceutical services defined in the rules of the board and intended to assist in the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process.
(19) Pharmacist Preceptor--A pharmacist licensed in Texas to practice pharmacy who meets the requirements under board rules and is recognized by the board to supervise and be responsible for the activities and functions of a pharmacist-intern in an internship program.
(20) Pharmacist-intern--A student-intern, a resident-intern, or an extended-intern who is participating in a board approved internship program.
(21) Preceptor--A pharmacist preceptor or a healthcare professional preceptor.
(22) Professional degree--A bachelor of science degree in pharmacy or a doctorate of pharmacy degree.
(23) Resident-intern--An individual who is registered with the board and:
(A) has graduated from a college/school of pharmacy; and
(B) is completing a residency program in the state of Texas.
(24) State--One of the 50 United States of America, the District of Columbia, and Puerto Rico.
(25) Student-intern--An individual registered with the board who is enrolled in the professional sequence of a college/school of pharmacy and is participating in a board-approved internship program.
(26) Texas Pharmacy Jurisprudence Examination--A licensing exam developed or approved by the Board which evaluates an applicant's knowledge of the drug and pharmacy requirements to practice pharmacy legally in the state of Texas.

§283.3 Educational and Age Requirements

An applicant for licensure as a pharmacist shall provide satisfactory evidence that the age of 18 years has been obtained and shall meet one of the following requirements:
(1) have graduated and received a professional degree from a college of pharmacy; or
(2) have graduated from a foreign college of pharmacy and obtained full certification from the FPGEC.

§283.4 Internship Requirements

(a) Goals and competency objectives of internship.
(1) The goal of internship is for the pharmacist-intern to attain the knowledge, skills, and abilities to safely, efficiently, and effectively provide pharmacist-delivered patient care to a diverse patient population and practice pharmacy under the laws and regulations of the State of Texas.
(2) The following competency objectives are necessary to accomplish the goal of internship in paragraph (1) of this subsection:

(A) Provides drug products. The pharmacist-intern shall demonstrate competence in determining the appropriateness of prescription drug orders and medication orders; evaluating and selecting products; and assuring the accuracy of the product/prescription dispensing process.
(B) Communicates with patients and patients' agents about prescription drugs. The pharmacist-intern shall demonstrate competence in interviewing and counseling patients, and patients' agents on drug usage, dosage, packaging, routes of administration, intended drug use, and storage; discussing drug cautions, adverse effects, and patient conditions; explaining policies on fees and services; relating to patients in a professional manner; and interacting to confirm patient understanding.
(C) Communicates with patients and patients' agents about nonprescription products, devices, dietary supplements, diet, nutrition, traditional nondrug therapies, complementary and alternative therapies, and diagnostic aids. The pharmacist-intern shall demonstrate competence in interviewing and counseling patients and patients' agents on conditions, intended drug use, and adverse effects; assisting in and recommending drug selection; triaging and assessing the need for treatment or referral, including referral for a patient seeking pharmacist-guided self-care; providing information on medical/surgical devices and home diagnostic products; and providing poison control treatment information and referral.
(D) Communicates with healthcare professionals, patients and patients' agents. The pharmacist-intern shall demonstrate competence in obtaining and providing accurate and concise information in a professional manner and using appropriate oral, written, and nonverbal language.
(E) Practices as a member of the patient's interdisciplinary healthcare team. The pharmacist-intern shall demonstrate competence in collaborating with physicians, other healthcare professionals, patients, and patients' agents to formulate a therapeutic plan. The pharmacist-intern shall demonstrate competence in establishing and interpreting databases, identifying drug-related problems and recommending appropriate pharmacotherapy specific to patient needs, monitoring and evaluating patient outcomes, and devising follow-up plans.
(F) Maintains professional-ethical standards. The pharmacist-intern is required to comply with laws and regulations pertaining to pharmacy practice; to apply professional judgment; to exhibit reliability and credibility in dealing with others; to deal professionally and ethically with colleagues and patients; to demonstrate sensitivity and empathy for patients/care givers; and to maintain confidentiality.
(G) Compounds. The pharmacist-intern shall demonstrate competence in using acceptable professional procedures; selecting appropriate equipment and containers; appropriately preparing compounded non-sterile and sterile preparations; and documenting calculations and procedures. Pharmacist-interns engaged in compounding non-sterile preparations shall meet the training requirements for pharmacists specified in §291.131 of this title (relating to Pharmacies Compounding Non-sterile Preparations). Pharmacist-interns engaged in compounding sterile preparations shall meet the training requirements for pharmacists specified in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).
(H) Retrieves and evaluates drug information. The pharmacist-intern shall demonstrate competence in retrieving, evaluating, managing, and using the best available clinical and scientific publications for answering a drug-related request in a timely fashion and assessing, evaluating, and applying evidence based information to promote optimal health care. The pharmacist-intern shall perform investigations on relevant topics in order to promote inquiry and problem-solving with dissemination of findings to the healthcare community and the public.
(I) Manages general pharmacy operations. The pharmacist-intern shall develop a general understanding of planning, personnel and fiscal management, leadership skills, and policy development. The pharmacist-intern shall have an understanding of drug security, storage and control procedures and the regulatory requirements associated with these procedures, and maintaining quality assurance and performance improvement. The pharmacist-intern shall observe and document discrepancies and

irregularities, keep accurate records and document actions. The pharmacist-intern shall attend meetings requiring pharmacy representation.

(J) Participates in public health, community service or professional activities. The pharmacist-intern shall develop basic knowledge and skills needed to become an effective healthcare educator and a responsible participant in civic and professional organizations.

(K) Demonstrates scientific inquiry. The pharmacist-intern shall develop skills to expand and refine knowledge in the areas of pharmaceutical and medical sciences or pharmaceutical services. This may include data analysis of scientific, clinical, sociological, or economic impacts of pharmaceuticals (including investigational drugs), pharmaceutical care, and patient behaviors, with dissemination of findings to the scientific community and the public.

(b) Hours requirement.

(1) The board requires the number of hours of internship required by ACPE for licensure. These hours may be obtained through one or more of the following methods:

(A) in a board-approved student internship program, as specified in subsection (c) of this section;

(B) in a board-approved extended-internship program as specified in subsection (d) of this section;

(C) graduation from a college/school of pharmacy. Persons graduating from such programs shall be credited the number of hours obtained and reported by the college; or

(D) internship hours approved and certified to the board by another state board of pharmacy.

(2) Pharmacist-interns participating in an internship may be credited no more than 50 hours per week of internship experience.

(3) Internship hours may be used for the purpose of licensure for no longer than three years from the date the internship is completed.

(c) College-/School-Based Internship Programs.

(1) Internship experience acquired by student-interns.

(A) An individual may be designated a student-intern provided he/she:

(i) submits an application to the board that includes the following information:

(I) name;

(II) addresses, phone numbers, date of birth, and social security number;

(III) college of pharmacy and expected graduation date; and

(IV) any other information requested on the application;

(ii) is enrolled in the professional sequence of a college/school of pharmacy; and

(iii) has met all requirements necessary for the board to access the criminal history records information, including submitting fingerprint information and being responsible for all associated costs.

(B) The terms of the student internship shall be as follows.

(i) The student internship shall be gained concurrent with college attendance, which may include:

(I) partial semester breaks such as spring breaks;

(II) between semester breaks; and

(III) whole semester breaks provided the student-intern attended the college/school in the immediate preceding semester and is scheduled with the college/school to attend in the immediate subsequent semester.

(ii) The student internship shall be obtained in pharmacies licensed by the board, federal government pharmacies, or in a board-approved program.

(iii) The student internship shall be in the presence of and under the supervision of a healthcare professional preceptor or a pharmacist preceptor.

(C) None of the internship hours acquired outside of a school-based program may be substituted for any of the hours required in a college/school of pharmacy internship program.

(2) Expiration date for student-intern designation.

(A) The student-internship expires if:

(i) the student-intern voluntarily or involuntarily ceases enrollment, including suspension, in a college/school of pharmacy;

(ii) the student-intern fails more than once either the NAPLEX or Texas Pharmacy Jurisprudence Examination specified in this section; or

(iii) the student-intern fails to take either the NAPLEX or Texas Pharmacy Jurisprudence Examination or both within six calendar months after graduation.

(B) The executive director of the board, in his/her discretion, may extend the term of the student internship if administration of the NAPLEX or Texas Pharmacy Jurisprudence Examination is suspended or delayed.

(3) Texas colleges/schools of pharmacy internship programs.

(A) Student-interns completing a board-approved Texas college/school-based structured internship shall be credited the number of hours actually obtained and reported by the college. No credit shall be awarded for didactic experience.

(B) No more than 600 hours of the required number of hours may be obtained under a healthcare professional preceptor except when a pharmacist-intern is working in a federal government pharmacy.

(d) Extended-internship program.

(1) A person may be designated an extended-intern provided he/she has met one of the following requirements:

(A) passed the NAPLEX and Texas Pharmacy Jurisprudence Examination but lacks the required number of internship hours for licensure;

(B) applied to the board to take the NAPLEX and Texas Pharmacy Jurisprudence Examination within six calendar months after graduation and has:

(i) graduated and received a professional degree from a college/school of pharmacy; or

(ii) completed all of the requirements for graduation and receipt of a professional degree from a college/school of pharmacy.

(C) applied to the board to take the NAPLEX and Texas Pharmacy Jurisprudence Examination within six calendar months after obtaining full certification from the Foreign Pharmacy Graduate Equivalency Commission;

(D) applied to the board for re-issuance of a pharmacist license which has expired for more than two years but less than ten years and has successfully passed the Texas Pharmacy Jurisprudence Examination, but lacks the required number of hours of internship or continuing education required for licensure;

(E) is a resident in a residency program in the state of Texas and has not previously failed more than once either the NAPLEX or Texas Pharmacy Jurisprudence Examination; or

(F) been ordered by the Board to complete an internship.

(2) In addition to meeting one of the requirements in paragraph (1) of this subsection, an applicant for an extended-internship must:

(A) submit an application to the board that includes the following information:

(i) name;

(ii) addresses, phone numbers, date of birth, and social security number; and

(iii) any other information requested on the application; and

(B) meet all requirements necessary for the board to access the criminal history records information, including submitting fingerprint information and being responsible for all associated costs.

(3) The terms of the extended-internship shall be as follows.

(A) The extended-internship shall be board-approved and gained in a pharmacy licensed by the board, or a federal government pharmacy participating in a board-approved internship program.

(B) The extended-internship shall be in the presence of and under the direct supervision of a pharmacist preceptor.

(4) The extended internship remains in effect for two years. However, the internship expires immediately upon:

(A) the failure of the extended-intern to take the NAPLEX and Texas Pharmacy Jurisprudence Examination within six calendar months after graduation or FPGEC certification;

(B) the extended-intern failing more than once either the NAPLEX or Texas Pharmacy Jurisprudence Examination specified in this section;

(C) termination of the residency program; or

(D) obtaining a Texas pharmacist license.

(5) The executive director of the board, in his/her discretion, may extend the term of the extended internship if administration of the NAPLEX or Texas Pharmacy Jurisprudence Examination is suspended or delayed.

(6) An applicant for licensure who has completed less than 500 hours of internship at the time of application shall complete the remainder of the required number of hours of internship and have the preceptor certify that the applicant has met the objectives listed in subsection (a) of this section.

(e) Pharmacist-intern identification.

(1) Pharmacist-interns shall keep documentation of designation as a pharmacist-intern with them at all times they are serving as a pharmacist-intern and make it available for inspection by board agents.

(2) All pharmacist-interns shall wear an identification tag or badge which bears the person's name and identifies him or her as a pharmacist-intern.

(f) Change of address or name.

(1) Change of address. A pharmacist-intern shall notify the board electronically or in writing within 10 days of a change of address, giving the old and new address.

(2) Change of name. A pharmacist-intern shall notify the board in writing within 10 days of a change of name by sending a copy of the official document reflecting the name change (e.g., marriage certificate, divorce decree).

§283.5 Pharmacist-Intern Duties

(a) A pharmacist-intern participating in a board-approved internship program may perform any duty of a pharmacist provided the duties are delegated by and under the supervision of:

(1) a pharmacist licensed by the board and approved as a preceptor by the board; or

(2) a healthcare professional preceptor.

(b) When not under the supervision of a pharmacist preceptor, a pharmacist-intern may function as a pharmacy technician and perform all of the duties of a pharmacy technician without registering as a pharmacy technician provided the pharmacist-intern:

(1) is registered with the board as a pharmacist-intern;

(2) is under the direct supervision of a pharmacist;

(3) has completed the pharmacy's on-site technician training program;

(4) has completed the training required for pharmacists in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations) if the pharmacist-intern is involved in compounding sterile preparations; and

(5) is not counted as a pharmacy technician in the ratio of pharmacists to pharmacy technicians.

(c) A pharmacist-intern may not:

(1) present or identify himself/herself as a pharmacist;

(2) sign or initial any document which is required to be signed or initialed by a pharmacist unless a preceptor cosigns the document; or

(3) independently supervise pharmacy technicians or pharmacy technician trainees.

§283.6 Preceptor Requirements and Ratio of Preceptors to Pharmacist-Interns

(a) Preceptor requirements.

(1) Preceptors shall be:

(A) a pharmacist whose license to practice pharmacy in Texas is current and not on inactive status with the board; or

(B) a healthcare professional preceptor.

(2) To be recognized as a pharmacist preceptor, a pharmacist must:

(A) have at least:

(i) one year of experience as a licensed pharmacist; or

(ii) six months of residency training if the pharmacy resident is completing a residency program;

(B) have completed:

(i) for initial certification, three hours of pharmacist preceptor training provided by an ACPE approved provider within the previous two years. Such training shall be:

(I) developed by a Texas college/school of pharmacy; or

(II) approved by:

(-a-) a committee comprised of the Texas college/schools of pharmacy; or

(-b-) the board; or

(ii) to continue certification, three hours of pharmacist preceptor training provided by an ACPE approved provider within the pharmacist's current license renewal period. Such training shall be:

(I) developed by a Texas college/school of pharmacy; or

(II) approved by:

(-a-) a committee comprised of the Texas college/schools of pharmacy; or

(-b-) the board; and

(C) meet the requirements of subsection (c) of this section.

(3) A pharmacist preceptor must be certified by the board.

(b) Ratio of preceptors to pharmacist-interns.

(1) A preceptor may supervise only one pharmacist-intern at any given time (1:1 ratio) except as provided in paragraph (2) of this subsection.

(2) The following is applicable to Texas college/school of pharmacy internship programs only.

(A) Supervision. Supervision of a pharmacist-intern shall be:

(i) direct supervision when the student-intern is engaged in functions associated with the preparation and delivery of prescription or medication drug orders; and

(ii) general supervision when the student-intern is engaged in functions not associated with the preparation and delivery of prescription or medication drug orders.

(B) Exceptions to the 1:1 ratio. There is no ratio requirement for preceptors supervising student-interns as a part of a Texas college/school of pharmacy program.

(c) No pharmacist may serve as a pharmacist preceptor if his or her license to practice pharmacy has been the subject of an order of the board imposing any penalty set out in §565.051 of the Act during the period he or she is serving as a pharmacist preceptor or within the three-year period immediately preceding application for approval as a pharmacist preceptor. Provided, however, a pharmacist who has been the subject of such an order of the board may petition the board, in writing, for approval to act as a pharmacist preceptor. The board may consider the following items in approving a pharmacist's petition to act as a pharmacist preceptor:

(1) the type and gravity of the offense for which the pharmacist's license was disciplined;

(2) the length of time since the action that caused the order;

(3) the length of time the pharmacist has previously served as a preceptor;

(4) the availability of other preceptors in the area;

(5) the reason(s) the pharmacist believes he/she should serve as a preceptor;

(6) a letter of recommendation from a Texas college/school of pharmacy if the pharmacist will be serving as a pharmacist preceptor for a Texas college/school of pharmacy; and

(7) any other factor presented by the pharmacist demonstrating good cause why the pharmacist should be allowed to act as a pharmacist preceptor.

§283.7 Examination Requirements

Each applicant for licensure by examination shall pass the Texas Pharmacy Jurisprudence Examination and the NAPLEX. The examination requirements shall be as follows:

(1) Prior to taking the required examination, the applicant shall:

(A) except as provided in paragraph (3) of this section, meet the educational and age requirements as set forth in §283.3 of this title (relating to Educational and Age Requirements);

(B) meet all requirements necessary in order for the Board to access the criminal history record information, including submitting fingerprint information and being responsible for all associated costs; and

(C) submit an application to the board that includes the following information:

(i) name;

(ii) addresses, phone numbers, date of birth, and social security number; and

(iii) any other information requested on the application.

(2) All applicants shall pass NAPLEX, which includes, at a minimum, the following subject areas:

(A) chemistry;

(B) mathematics;

(C) pharmacy;

(D) pharmacology; and

(E) practice of pharmacy.

(3) An applicant who has completed the three didactic years of pharmacy education (i.e., P1 through P3 years) may take the Texas Pharmacy Jurisprudence Examination a maximum of one time prior to graduation from a college/school of pharmacy.

(4) The following examination requirements apply.

(A) To pass the NAPLEX, an applicant shall make a minimum scaled score of 75.

(B) Should the applicant fail to achieve a minimum scaled score of 75 in the NAPLEX, such applicant, in order to be licensed, shall retake the NAPLEX, as specified in §283.11 of this title (relating to Examination Retake Requirements) until such time as a minimum scaled score of 75 is achieved.

(5) To pass the Texas Pharmacy Jurisprudence Examination, an applicant shall make a minimum grade of 75. Should the applicant fail to achieve a minimum grade of 75 on the Texas Pharmacy Jurisprudence Examination, such applicant, in order to be licensed, shall retake the Texas Pharmacy Jurisprudence Examination as specified in §283.11 of this title until such time as a minimum average grade of 75 is achieved.

(6) A passing grade on an examination may be used for the purpose of licensure for a period of two years from the date of passing the examination.

(7) Each applicant for licensure by examination utilizing NAPLEX scores transferred from another state shall meet the following requirements for licensure in addition to the requirements set out in paragraphs (1) - (6) of this section.

(A) The applicant shall request NABP to transfer NAPLEX scores to the board. Such request shall be in accordance with NABP policy.

(B) The applicant shall pay the fee set out in §283.9 of this title.

(8) The NAPLEX and Texas Pharmacy Jurisprudence Examination shall be administered in compliance with the Americans with Disabilities Act of 1990 (42 U.S.C. Section 12101 et seq.) and in accordance with NABP policy.

(9) The board, in accordance with NABP policy, shall provide reasonable accommodations for an applicant diagnosed as having dyslexia, as defined in §51.970, Texas Education Code. The applicant shall provide:

(A) written documentation from a licensed physician which indicates that the applicant has been diagnosed as having dyslexia; and

(B) a written request outlining the reasonable accommodations requested.

§283.8 Reciprocity Requirements

(a) All applicants for licensure by reciprocity shall:

(1) meet the educational and age requirements specified in §283.3 of this title (relating to Educational and Age Requirements);

(2) meet all requirements necessary in order for the board to access the criminal history record information, including submitting fingerprint information and being responsible for all associated costs;

(3) complete the Texas and NABP applications for reciprocity. Any fraudulent statement made in the application for reciprocity is grounds for denial of the application; if such application is granted, any fraudulent statement is grounds for suspension, revocation, and/or cancellation of any license so granted by the board. The Texas application includes the following information:

(A) name;

(B) addresses, phone numbers, dates of birth, and social security numbers; and

(C) any other information requested on the application.

(4) shall present to the board proof of initial licensing by examination and proof that their current license and any other license or licenses granted to the applicant by any other state have not been suspended, revoked, canceled, surrendered, or otherwise restricted for any reason; and

(5) shall pass the Texas Pharmacy Jurisprudence Examination with a minimum grade of 75. (The passing grade may be used for the purpose of licensure by reciprocity for a period of two years from the date of passing the examination.) Should the applicant fail to achieve a minimum grade of 75 on the Texas Pharmacy Jurisprudence Examination, such applicant, in order to be licensed, shall retake the Texas Pharmacy Jurisprudence Examination as specified in §283.11 of this title (relating to Examination Retake Requirements) until such time as a minimum grade of 75 is achieved.

(b) A reciprocity applicant originally licensed after January 1, 1978, and who has graduated and received a professional degree from a college of pharmacy, shall show proof such applicant has passed the NAPLEX or equivalent examination based on criteria no less stringent than the criteria in force in Texas.

(c) A reciprocity applicant who is a foreign pharmacy graduate shall provide written documentation that such applicant has:

(1) obtained full certification from the FPGEC; and

(2) passed NAPLEX or equivalent examination based on criteria no less stringent than the criteria in force in Texas.

(d) An applicant is not eligible for licensing by reciprocity unless the state in which the applicant is currently or was initially licensed as a pharmacist also grants reciprocal licensing to pharmacists duly licensed by examination in this state, under like circumstances and conditions.

§283.9 Fee Requirements for Licensure by Examination, Score Transfer and Reciprocity

(a) The fees for licensure by examination, score transfer, and reciprocity shall include one exam administration. The fees are as follows:

(1) Examination Fee. The fee to submit an application for licensure by examination will include:

(A) An examination processing fee of $103, which is to be paid to the Texas State Board of Pharmacy and includes the processing of the Texas application.

(B) NAPLEX administrative and examination fees as determined by NABP, which are to be paid to NABP in accordance with NABP policy.

(C) MPJE administrative and examination fees as determined by NABP, which are to be paid to NABP in accordance with NABP policy.

(2) Reciprocity Fee. The fee to submit an application for licensure by reciprocity will include:

(A) A reciprocity fee of $255, which is to be paid to the Texas State Board of Pharmacy.

(B) MPJE administrative and examination fees as determined by NABP, which are to be paid to NABP in accordance with NABP policy.

(C) A license verification fee as determined by NABP, which is to be paid to NABP in accordance with NABP policy.

(3) Score Transfer Fee. The fees to transfer a score to Texas, using the NAPLEX Score Transfer system will include:

(A) An examination processing fee of $103, which is to be paid to the Texas State Board of Pharmacy and includes the processing of the Texas application.

(B) MPJE administrative and examination fees as determined by NABP, which are to be paid to NABP in accordance with NABP policy.

(C) A score transfer fee as determined by NABP, which is to be paid to NABP in accordance with NABP policy.

(b) If an applicant fails an examination or is required to take an examination by the Board, the application fee is $103 for each examination the applicant is required to take.

(c) Rescheduling or canceling an examination appointment.

(1) Refunds for fees charged by NABP for the administration of the NAPLEX and MPJE are in accordance with NABP policy. Rescheduling of an examination appointment shall be in accordance with NABP policy.

(2) The Board may refund fifty percent of an examination fee paid to the Board by an applicant if the applicant:

(A) provides advance notice of their inability to take the examination prior to the board providing authorization to take the examination; or

(B) is unable to take the examination due to an emergency situation including but not limited to a manmade or natural disaster, documented serious medical illness, or other circumstance deemed an emergency by the Executive Director of the Board.

(d) A person who takes the NAPLEX or the Texas Pharmacy Jurisprudence Examination will be notified of the results of the examination(s) within two weeks of receipt of the results of the examination(s) from the testing service. If both the NAPLEX and Texas Pharmacy Jurisprudence Examination are taken, the applicant will not be notified until the results of both examinations have been received. Such notification will be made within two weeks after receipt of the results of both examinations.

(e) Once an applicant has successfully completed all requirements of licensure, the applicant will be notified of licensure as a pharmacist and of his or her pharmacist license number and the following is applicable.

(1) An initial license will be issued by the board authorizing the person to practice pharmacy in Texas for a period of 30 days.

(2) The applicant shall complete a pharmacist license application and pay the initial license fee specified in §295.5 of this title (relating to Pharmacist License or Renewal Fees).

(3) If application and payment of the initial license fee are not received by the board within 30 days from the initial license was issued, the person's license to practice pharmacy shall expire. A person may not practice pharmacy with an expired license. The license may be renewed according to the following schedule.

(A) If the initial license has been expired for 90 days or less, the person may become licensed by making application and paying to the board one initial license fee and a fee that is one-half of a renewal fee.

(B) If the initial license has been expired for more than 90 days but less than one year, the person may become licensed by making application and paying to the board once initial license fee and a fee that is equal to a renewal fee.

(C) If the initial license has been expired for one year or more, the person shall apply for a new license.

§283.10 Requirements for Application for a Pharmacist License Which Has Expired

(a) Expired less than 90 days. If a person's license has been expired for 90 days or less, the person may renew the license by:

(1) paying to the board a renewal fee that is equal to one and one-half times the renewal fee for the license as specified in §295.5 of this title (relating to Pharmacist License Renewal Fees); and

(2) reporting completion of the required number of contact hours of approved continuing education.

(b) Expired more than 90 days. If a person's license has been expired for more than 90 days but less than one year, the person may renew the license by:

(1) paying to the board all unpaid renewal fees and a renewal fee that is equal to two times the renewal fee for the license as specified in §295.5 of this title; and

(2) reporting completion of the required number of contact hours of approved continuing education.

(c) Expired for one year or more. If a person's license to practice pharmacy in Texas has been expired for one year or more, the person may not renew the license and shall apply for a new license.

(d) Reexamination. The board may issue a new license to a person if the person submits to reexamination and complies with the requirements and procedures for obtaining an original license as specified in §283.7 of this title (relating to Examination Requirements).

(e) Alternatives to reexamination. In lieu of reexamination as specified in subsection (d) of this section, the board may issue a license to a person whose license has been expired for one year or more, if the person meets the requirements of subsection (f) or (g) of this section and has not had a license granted by any other state suspended, revoked, canceled, surrendered, or otherwise restricted for any reason.

(f) Persons practicing pharmacy in another state. Beginning January 1, 2002, the board may issue a license to a person who was licensed as a pharmacist in Texas, moved to another state, is licensed in the other state, and has been engaged in the practice of pharmacy in the other state for the two years preceding the application if the person meets the following requirements:

(1) makes application for licensure to the board on a form prescribed by the board;

(2) submits to the board certification that the applicant:

(A) is licensed as a pharmacist in another state and that such license is in good standing;

(B) has been continuously employed as a pharmacist in that state for the two years preceding the application; and

(C) has completed a minimum of 30 contact hours of approved continuing education during the preceding two license years;

(3) passes the Texas Pharmacy Jurisprudence Examination with a grade of 75 (the passing grade may be used for the purpose of licensure for a period of two years from the date of passing the examination); and

(4) pays to the board the examination fee set out in §283.9 of this title (relating to Fee Requirements for Licensure by Examination, Score Transfer and Reciprocity).

(g) Persons not practicing pharmacy. Beginning January 1, 2002, the board may issue a license to a person who was licensed as a pharmacist in this state, but has not practiced pharmacy for the two years preceding application for licensure under the following conditions.

(1) The person's Texas pharmacist license has been expired for less than 10 years, the person shall:

(A) make application for licensure to the board on a form prescribed by the board;

(B) pass the Texas Pharmacy Jurisprudence Examination with a grade of 75 (the passing grade may be used for the purpose of licensure for a period of two years from the date of passing the examination);

(C) pay the examination fee set out in §283.9 of this title; and

(D) complete approved continuing education and/or board-approved internship requirements according to the following schedule:

(i) if the Texas pharmacist license has been expired for more than one year but less than two years, the applicant shall complete 15 contact hours of approved continuing education;

(ii) if the Texas pharmacist license has been expired for more than two years but less than three years, the applicant shall complete 30 contact hours of approved continuing education;

(iii) if the Texas pharmacist license has been expired for more than three years but less than four years, the applicant shall complete 45 contact hours of approved continuing education;

(iv) if the Texas pharmacist license has been expired for more than four years but less than five years, the applicant shall complete 45 contact hours of approved continuing education and 500 hours of internship in a board-approved internship program;
(v) if the Texas pharmacist license has been expired for more than five years but less than six years, the applicant shall complete 45 contact hours of approved continuing education and 700 hours of internship in a board-approved internship program;
(vi) if the Texas pharmacist license has been expired for more than six years but less than seven years, the applicant shall complete 45 contact hours of approved continuing education and 900 hours of internship in a board-approved internship program;
(vii) if the Texas pharmacist license has been expired for more than seven years but less than eight years, the applicant shall complete 45 contact hours of approved continuing education and 1,100 hours of internship in a board-approved internship program;
(viii) if the Texas pharmacist license has been expired for more than eight years but less than nine years, the applicant shall complete 45 contact hours of approved continuing education and 1,300 hours of internship in a board-approved internship program; and
(ix) if the Texas pharmacist license has been expired for more than nine years but less than 10 years, the applicant shall complete 45 contact hours of approved continuing education and 1,500 hours of internship in a board-approved internship program.

(2) Any hours of approved continuing education earned within two years prior to the applicant successfully passing the Texas Pharmacy Jurisprudence Examination may be applied towards the continuing education requirement.

(3) Any hours worked as a licensed pharmacist in another state during the two years prior to the applicant successfully passing the Texas Pharmacy Jurisprudence examination may be applied towards the internship requirement.

(4) All requirements for licensure shall be completed within two years from the date the applicant successfully passes the Texas Pharmacy Jurisprudence Examination.

(5) If the person's Texas pharmacist license has been expired for 10 years or more, the applicant shall apply for licensure by examination as specified in §283.7 of this title and §283.4 of this title (relating to Internship Requirements).

§283.11 Examination Retake Requirements

(a) Licensing by examination. Should an applicant fail to achieve the minimum grade on the NAPLEX or Texas Pharmacy Jurisprudence Examination or both, the following is applicable.

(1) If the applicant fails to achieve the minimum grade on NAPLEX as specified in §283.7 of this title (relating to Examination Requirements), the applicant may retake NAPLEX four additional times for a total of five exam administrations. Prior to any subsequent retakes of NAPLEX, the applicant must:

(A) complete course work in subject areas recommended by the board;

(B) submit documentation to the board which specifies that the applicant has successfully completed the course work specified; and

(C) comply with the requirements of §283.7 of this title (relating to Examination Requirements).

(2) If the applicant fails to achieve the minimum grade on the Texas Pharmacy Jurisprudence Examination as specified in §283.7 of this title (relating to Examination Requirements), the applicant may retake the examination four additional times for a total of five exam administrations. Prior to any subsequent retake of the Texas Pharmacy Jurisprudence Examination, the applicant must:

(A) complete course work recommended by the board;

(B) submit documentation to the board which specifies that the applicant has successfully completed the recommended course work; and

(C) comply with the requirements of §283.7 of this title (relating to Examination Requirements).

(3) If the applicant fails to achieve the minimum grade on both NAPLEX and the Texas Pharmacy Jurisprudence Examination, the applicant shall retake the examinations until a passing grade is achieved on one of the examinations. Such retakes shall be as specified in paragraphs (1) and (2) of this subsection.

(b) Licensing by reciprocity. If an applicant fails to achieve the minimum grade on the Texas Pharmacy Jurisprudence Examination as specified in §283.8 of this title (relating to Reciprocity Requirements), the applicant may retake the examination four additional times for a total of five exam administrations. Prior to any subsequent retake of the Texas Pharmacy Jurisprudence Examination, the applicant must:

(1) complete course work recommended by the board;

(2) submit documentation to the board which specifies that the applicant has successfully completed the recommended course work; and

(3) comply with the requirements of §283.8 of this title (relating to Reciprocity Requirements).

(c) Course work. For the purpose of this subsection, course work shall be one or more standard courses or self-paced work offered in a college of pharmacy's academic program.

§283.12 Licenses for Military Service Members, Military Veterans, and Military Spouses

(a) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Active duty--Current full-time military service in the armed forces of the United States or active duty military service as a member of the Texas military forces, or similar military service of another state.

(2) Armed forces of the United States--The army, navy, air force, space force, coast guard, or marine corps of the United States or a reserve unit of one of those branches of the armed forces.

(3) Military service member--A person who is on active duty.

(4) Military spouse--A person who is married to a military service member.

(5) Military veteran--A person who has served on active duty and who was discharged or released from active duty.

(b) Alternative licensing procedure. For the purpose of §55.004, Occupations Code, a military service member, military veteran, or military spouse may complete the following alternative procedures to apply for a pharmacist license if the applicant holds a current license issued by another state that is similar in scope of practice to the license in this state and is in good standing with that state's licensing authority or within the five years preceding the application date held a pharmacist license in this state.

(1) Provisional license. On receipt by the board of an application for a pharmacist license in accordance with this subsection, the board shall issue a provisional license to the applicant while the board processes the application. A provisional license issued under this subsection expires on the earlier of:

(A) the date the board approves or denies the provisional license holder's application for the license; or

(B) the 180th date after the date the provisional license is issued.

(2) Requirements for licensing by reciprocity. An applicant for licensing by reciprocity who meets all of the following requirements may be granted a temporary license as specified in this subsection prior to completing the NABP application for pharmacist license by reciprocity, and taking and passing the Texas Pharmacy Jurisprudence Examination. The applicant shall:

(A) complete the Texas application for pharmacist license by reciprocity that includes the following:

(i) name;

(ii) addresses, phone numbers, date of birth, and social security number; and

(iii) any other information requested on the application;

(B) meet the educational and age requirements as set forth in §283.3 of this title (relating to Educational and Age Requirements);

(C) present to the board proof of initial licensing by examination and proof that any current licenses and any other licenses granted to the applicant by any other state have not been suspended, revoked, canceled, surrendered, or otherwise restricted for any reason;

(D) meet all requirements necessary for the board to access the criminal history records information, including submitting fingerprint information, and such criminal history check does not reveal any disposition for a crime specified in §281.64 of this title (relating to Sanctions for Criminal Offenses) indicating a sanction of denial, revocation, or suspension;

(E) be exempt from the application and examination fees paid to the board set forth in §283.9(a)(2)(A) and (b) of this title (relating to Fee Requirements for Licensure by Examination, Score Transfer and Reciprocity); and

(F) provide documentation of eligibility, including:

(i) military identification indicating that the applicant is a military service member, military veteran, or military dependent, if a military spouse; and

(ii) marriage certificate, if a military spouse.

(3) Requirements for an applicant whose Texas pharmacist license has expired. An applicant whose Texas pharmacist license has expired within five years preceding the application date:

(A) shall complete the Texas application for licensing that includes the following:

(i) name;

(ii) addresses, phone numbers, date of birth, and social security number; and

(iii) any other information requested on the application;

(B) shall provide documentation of eligibility, including:

(i) military identification indicating that the applicant is a military service member, military veteran, or military dependent, if a military spouse; and

(ii) marriage certificate, if a military spouse;

(C) shall pay the renewal fee specified in §295.5 of this title (relating to Pharmacist License or Renewal Fees); however, the applicant shall be exempt from the fees specified in §295.7(3) of this title (relating to Pharmacist License Renewal);

(D) shall complete approved continuing education requirements according to the following schedule:

(i) if the Texas pharmacist license has been expired for more than one year but less than two years, the applicant shall complete 15 contact hours of approved continuing education;

(ii) if the Texas pharmacist license has been expired for more than two years but less than three years, the applicant shall complete 30 contact hours of approved continuing education; or

(iii) if the Texas pharmacist license has been expired for more than three years but less than five years, the applicant shall complete 45 contact hours of approved continuing education; and

(E) is not required to take the Texas Pharmacy Jurisprudence Examination.

(4) A temporary license issued under this subsection is valid for no more than six months and may be extended, if disciplinary action is pending, or upon request, as otherwise determined reasonably necessary by the executive director of the board.

(5) A temporary license issued under this subsection expires within six months of issuance if the individual fails to pass the Texas Pharmacy Jurisprudence Examination within six months or fails to take the Texas Pharmacy Jurisprudence Examination within six months.

(6) An individual may not serve as pharmacist-in-charge of a pharmacy with a temporary license issued under this subsection.

(c) Expedited licensing procedure. For the purpose of §55.005, Occupations Code, a military service member, military veteran, or military spouse may complete the following expedited procedures to apply for a pharmacist license if the applicant holds a current license issued by another state that is similar in scope of practice to the license in this state and is in good standing with that state's licensing authority or within the five years preceding the application date held a pharmacist license in this state. The applicant shall:

(1) meet the educational and age requirements specified in §283.3 of this title (relating to Educational and Age Requirements);

(2) meet all requirements necessary in order for the board to access the criminal history record information, including submitting fingerprint information and being responsible for all associated costs;

(3) complete the Texas and NABP applications for reciprocity. Any fraudulent statement made in the application for reciprocity is grounds for denial of the application. If such application is granted, any fraudulent statement is grounds for suspension, revocation, and/or cancellation of any license so granted by the board. The Texas application includes the following information:

(A) name;

(B) addresses, phone numbers, date of birth, and social security number; and

(C) any other information requested on the application;

(4) present to the board proof of initial licensing by examination and proof that their current license and any other license or licenses granted to the applicant by any other state have not been suspended, revoked, canceled, surrendered, or otherwise restricted for any reason;

(5) pass the Texas Pharmacy Jurisprudence Examination with a minimum grade of 75. (The passing grade may be used for the purpose of licensure by reciprocity for a period of two years from the date of passing the examination.) Should the applicant fail to achieve a minimum grade of 75 on the Texas Pharmacy Jurisprudence Examination, such applicant, in order to be licensed, shall retake the Texas Pharmacy Jurisprudence Examination as specified in §283.11 of this title (relating to Examination Retake Requirements) until such time as a minimum grade of 75 is achieved; and

(6) be exempt from the application and examination fees paid to the board set forth in §283.9(a)(2)(A) and (b) of this title.

(d) License renewal. As specified in §55.003, Occupations Code, a military service member who holds a pharmacist license is entitled to two years of additional time to complete any requirements related to the renewal of the military service member's license.

(1) A military service member who fails to renew their pharmacist license in a timely manner because the individual was serving as a military service member shall submit to the board:

(A) name, address, and license number of the pharmacist;

(B) military identification indicating that the individual is a military service member; and

(C) a statement requesting up to two years of additional time to complete the renewal.

(2) A military service member specified in paragraph (1) of this subsection shall be exempt from fees specified in §295.7(3) of this title (relating to Pharmacist License Renewal).

(3) A military service member specified in paragraph (1) of this subsection is entitled to two additional years of time to complete the continuing education requirements specified in §295.8 of this title (relating to Continuing Education Requirements).

(e) Inactive status. The holder of a pharmacist license who is a military service member, a military veteran, or a military spouse who holds a pharmacist license and who is not engaged in the practice of pharmacy in this state may place the license on inactive status as specified in §295.9 of this title (relating to Inactive License). The inactive license holder:

(1) shall provide documentation to include:

(A) military identification indicating that the pharmacist is a military service member, military veteran, or military dependent, if a military spouse; and

(B) marriage certificate, if a military spouse;

(2) shall be exempt from the fees specified in §295.9(a)(1)(C) and §295.9(a)(2)(C) of this title;

(3) shall not practice pharmacy in this state; and

(4) may reactivate the license as specified in §295.9 of this title (relating to Inactive License).

(f) Interim license for military service member or military spouse. In accordance with §55.0041, Occupations Code, a military service member or military spouse may be issued an interim pharmacist license if the member or spouse currently holds a license similar in scope of practice issued by the licensing authority of another state and is in good standing with that licensing authority as specified in §55.0042, Occupations Code.

(1) Before engaging in the practice of pharmacy, the military service member or military spouse shall submit an application that includes:

(A) a copy of the member's military orders showing relocation to this state;

(B) if the applicant is a military spouse, a copy of the military spouse's marriage certificate; and

(C) a notarized affidavit affirming under penalty of perjury that:

(i) the applicant is the person described and identified in the application;

(ii) all statements in the application are true, correct, and complete;

(iii) the applicant understands the scope of practice for a pharmacist license in this state and will not perform outside of that scope of practice; and

(iv) the applicant is in good standing in each state in which the applicant holds or has held a pharmacist license.

(2) A military service member or military spouse applying for an interim license under this subsection may not practice pharmacy in this state until issued an interim pharmacist license.

(3) For a military service member or military spouse applying for an interim license under this subsection, the board shall:

(A) determine whether the state in which the applicant is licensed issues licenses similar in scope of practice to a pharmacist license issued by the board; and

(B) notify the applicant that:

(i) the board is issuing the interim license;

(ii) the application is incomplete; or

(iii) the board is unable to issue the interim license because a pharmacist license issued by the board is not similar in scope of practice to the applicant's license.

(4) A military service member or military spouse may engage in the practice of pharmacy under an interim license issued under this subsection only for the period during which the military service member or, with respect to a military spouse, the military service member to whom the spouse is married is stationed at a military installation in this state.

(5) In the event of a divorce or similar event that affects a person's status as a military spouse, the former spouse may continue to engage in the practice of pharmacy under an interim license issued under this subsection until the third anniversary of the date the spouse submitted the application required under paragraph (1) of this subsection.

(6) While engaged in the practice of pharmacy in this state, the military service member or military spouse shall comply with all other laws and regulations applicable to the practice of pharmacy in this state.

(g) Relationship to federal law. This section establishes requirements and procedures authorized or required by Texas Occupations Code, Chapter 55, and does not modify or alter rights that may be provided under federal law.

CHAPTER 291 – PHARMACIES

SUBCHAPTER A – ALL CLASSES OF PHARMACIES

§291.1 Pharmacy License Application

(a) To qualify for a pharmacy license, the applicant must submit an application which includes any information requested on the application and, as required by §560.052(b) of the Act, a sworn disclosure statement as specified in §291.4 of this title (relating to Sworn Disclosure Statement).
(b) The applicant may be required to meet all requirements necessary in order for the Board to access the criminal history record information, including submitting fingerprint information and being responsible for all associated costs. The criminal history information may be required for each individual owner, or if the pharmacy is owned by a partnership or a closely held corporation for each managing officer.
(c) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for the issuance of a pharmacy license.
(d) For the purposes of this section, managing officers are defined as the top four executive officers, including the corporate officer in charge of pharmacy operations, who are designated by the partnership or corporation to be jointly responsible for the legal operation of the pharmacy.
(e) Prior to the issuance of a license for a pharmacy located in Texas, the board shall conduct an on-site inspection of the pharmacy in the presence of the pharmacist-in-charge and owner or representative of the owner, to ensure that the pharmacist-in-charge and owner can meet the requirements of the Texas Pharmacy Act and Board Rules.
(f) If the applicant holds an active pharmacy license in Texas on the date of application for a new pharmacy license or for other good cause shown as specified by the board, the board may waive the pre-inspection as set forth in subsection (e) of this section.

§291.2 Definitions

Any term not defined in this chapter shall have the definition set out in the Act, §551.003.

§291.3 Required Notifications

(a) Change of Location.
(1) When a pharmacy changes location, the following is applicable:
(A) A new completed pharmacy application containing the information outlined in §291.1 of this title (relating to Pharmacy License Application) must be filed with the board not later than 30 days before the date of the change of location of the pharmacy;
(B) An amended license reflecting the new location of the pharmacy will be issued by the board; and
(C) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for processing the application for change of location.
(2) At least 14 days prior to the change of location of a pharmacy that dispenses prescription drug orders, the pharmacist-in-charge shall post a sign in a conspicuous place indicating that the pharmacy is changing locations. Such sign shall be in the front of the prescription department and at all public entrance doors to the pharmacy and shall indicate the date the pharmacy is changing locations.
(3) Disasters, accidents, and emergencies which require the pharmacy to change location shall be immediately reported to the board. If a pharmacy changes location suddenly due to disasters, accidents, or other emergency circumstances and the pharmacist-in-charge cannot provide notification 14 days prior to the change of location, the pharmacist-in-charge shall comply with the provisions of paragraph (2) of this subsection as far in advance of the change of location as allowed by the circumstances.
(4) When a Class A-S, C-S, or E-S pharmacy changes location, the pharmacy's classification will revert to a Class A, Class C, or Class E unless or until the board or its designee has inspected the new location to ensure the

pharmacy meets the requirements as specified in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).

(5) When a Class B pharmacy changes location, the board shall inspect the pharmacy at the new location to ensure the pharmacy meets the requirements as specified in subchapter C of this title (relating to Nuclear Pharmacy (Class B)) prior to the pharmacy becoming operational.

(b) Change of Name. When a pharmacy changes its name, the following is applicable:

(1) A new completed pharmacy application containing the information outlined in §291.1 of this title (relating to Pharmacy License Application) must be filed with the board within 10 days of the change of name of the pharmacy;

(2) An amended license reflecting the new name of the pharmacy will be issued by the board; and

(3) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for processing the application for change of name.

(c) Change of Managing Officers.

(1) The owner of a pharmacy shall notify the board in writing within 10 days of a change of any managing officer of a partnership or corporation which owns a pharmacy. The written notification shall include the effective date of such change, an updated sworn disclosure statement as required by §560.052(b) of the Act and as specified in §291.4 of this title (relating to Sworn Disclosure Statement), and the following information for all managing officers:

(A) name and title;

(B) home address and telephone number;

(C) date of birth;

(D) a copy of social security card or other official document showing the social security number as approved by the board; and

(E) a copy of current driver's license, state issued photo identification card, or passport.

(2) For purposes of this subsection, managing officers are defined as the top four executive officers, including the corporate officer in charge of pharmacy operations, who are designated by the partnership or corporation to be jointly responsible for the legal operation of the pharmacy.

(d) Change of Ownership.

(1) When a pharmacy changes ownership, a new pharmacy application must be filed with the board following the procedures as specified in §291.1 of this title (relating to Pharmacy License Application), including, as required by §560.052(b) of the Act, the submission of a sworn disclosure statement as specified in §291.4 of this title (relating to Sworn Disclosure Statement). In addition, a copy of the purchase contract or mutual agreement between the buyer and seller must be submitted.

(2) A fee as specified in §291.6 of this title will be charged for issuance of a new license.

(e) Change of Pharmacist Employment.

(1) Change of pharmacist employed in a pharmacy. When a change in pharmacist employment occurs, the pharmacist shall report such change in writing to the board within 10 days.

(2) Change of pharmacist-in-charge of a pharmacy. The incoming pharmacist-in-charge shall be responsible for notifying the board within 10 days in writing on a form provided by the board that a change of pharmacist-in-charge has occurred. The notification shall include the following:

(A) the name and license number of the departing pharmacist-in-charge;

(B) the name and license number of the incoming pharmacist-in-charge;

(C) the date the incoming pharmacist-in-charge became the pharmacist-in-charge; and

(D) a statement signed by the incoming pharmacist-in-charge attesting that:

(i) an inventory, as specified in §291.17 of this title (relating to Inventory Requirements), has been conducted by the departing and incoming pharmacists-in-charge; if the inventory was not taken by both pharmacists, the statement shall provide an explanation; and

(ii) the incoming pharmacist-in-charge has read and understands the laws and rules relating to this class of pharmacy.

(f) Notification of Theft or Loss of a Controlled Substance or a Dangerous Drug.

(1) Controlled substances. For the purposes of the Act, §562.106, the theft or significant loss of any controlled substance by a pharmacy shall be reported in writing to the board immediately on discovery of such theft or loss. A pharmacy shall be in compliance with this subsection by submitting to the board a copy of the Drug Enforcement Administration (DEA) report of theft or loss of controlled substances, DEA Form 106, or by submitting a list of all controlled substances stolen or lost.

(2) Dangerous drugs. A pharmacy shall report in writing to the board immediately on discovery the theft or significant loss of any dangerous drug by submitting a list of the name and quantity of all dangerous drugs stolen or lost.

(g) Fire, Flood or Natural Disaster. If a pharmacy experiences a fire, flood or natural disaster that may have affected the strength, purity, or labeling of drugs, medications, devices, or other materials used in the diagnosis or the treatment of injury, illness, and disease, the following requirements are applicable.

(1) Responsibilities of the pharmacist-in-charge.

(A) The pharmacist-in-charge shall be responsible for reporting the date of the fire, flood or natural disaster to the board within 10 days from the date of the fire, flood or natural disaster.

(B) The pharmacist-in-charge or designated agent shall comply with the following procedures.

(i) If controlled substances, dangerous drugs, or Drug Enforcement Administration (DEA) order forms are lost or destroyed in the disaster, the pharmacy shall:

(I) notify the DEA and the board of the loss of the controlled substances or order forms immediately upon discovery; and

(II) notify the board in writing of the loss of the dangerous drugs by submitting a list of the dangerous drugs lost.

(ii) If the extent of the loss of controlled substances or dangerous drugs is not able to be determined, the pharmacy shall:

(I) take a new, complete inventory of all remaining drugs specified in §291.17(c) of this title (relating to Inventory Requirements);

(II) submit to the DEA a statement attesting that the loss of controlled substances is indeterminable and that a new, complete inventory of all remaining controlled substances was conducted and state the date of such inventory; and

(III) submit to the board a statement attesting that the loss of controlled substances and dangerous drugs is indeterminable and that a new, complete inventory of the drugs specified in §291.17(c) of this title was conducted and state the date of such inventory.

(C) If the pharmacy changes to a new, permanent location, the pharmacist-in-charge shall comply with subsection (a) of this section.

(D) If the pharmacy moves to a temporary location, the pharmacist shall comply with subsection (a) of this section. If the pharmacy returns to the original location, the pharmacist-in-charge shall again comply with subsection (a) of this section.

(E) If the pharmacy closes due to a fire, flood, or natural disaster and timely notifies the board under subparagraph (A) of this paragraph, the pharmacy may be closed for not longer than 90 days.

(F) If the pharmacy discontinues business (ceases to operate as a pharmacy), the pharmacist-in-charge shall comply with §291.5 of this title (relating to Closing a Pharmacy).

(G) The pharmacist-in-charge shall maintain copies of all inventories, reports, or notifications required by this section for a period of two years.

(2) Drug stock.

(A) Any drug which has been exposed to excessive heat, smoke, moisture or other conditions which may have caused deterioration shall not be dispensed.

(B) Any potentially adulterated or damaged drug shall only be sold, transferred, or otherwise distributed pursuant to the provisions of the Texas Food Drug and Cosmetics Act (Chapter 431, Health and Safety Code) administered by the Bureau of Food and Drug Safety of the Texas Department of State Health Services.

(h) Notification to Consumers.

(1) Pharmacy.

(A) Every licensed pharmacy shall provide notification to consumers of the name, mailing address, Internet site address, and telephone number of the board for the purpose of directing complaints concerning the practice of pharmacy to the board. Such notification shall be provided as follows.

(i) If the pharmacy serves walk-in customers, the pharmacy shall either:

(I) post in a prominent place that is in clear public view where prescription drugs are dispensed:

(-a-) a sign which notifies the consumer that complaints concerning the practice of pharmacy may be filed with the board and list the board's name, mailing address, Internet site address, telephone number, and a toll-free telephone number for filing complaints; or

(-b-) an electronic messaging system in a type size no smaller than ten-point Times Roman which notifies the consumer that complaints concerning the practice of pharmacy may be filed with the board and list the board's name, mailing address, Internet site address, telephone number, and a toll-free number for filing complaints; or

(II) provide with each dispensed prescription a written notification in a type size no smaller than ten-point Times Roman which states the following: "Complaints concerning the practice of pharmacy may be filed with the Texas State Board of Pharmacy at: (list the mailing address, Internet site address, telephone number of the board, and a toll-free telephone number for filing complaints)."

(ii) If the prescription drug order is delivered to patients at their residence or other designated location, the pharmacy shall provide with each dispensed prescription a written notification in type size no smaller than ten-point Times Roman which states the following: "Complaints concerning the practice of pharmacy may be filed with the Texas State Board of Pharmacy at: (list the mailing address, Internet site address, telephone number, and a toll-free telephone number for filing complaints)." If multiple prescriptions are delivered to the same location, only one such notice shall be required.

(iii) The provisions of this subsection do not apply to prescriptions for patients in facilities where drugs are administered to patients by a person required to do so by the laws of the state (i.e., nursing homes).

(B) A pharmacy that maintains a generally accessible site on the Internet that is located in Texas or sells or distributes drugs through this site to residents of this state shall post the following information on the pharmacy's initial home page and on the page where a sale of prescription drugs occurs.

(i) Information on the ownership of the pharmacy, to include at a minimum, the:

(I) owner's name or if the owner is a partnership or corporation, the partnership's or corporation's name and the name of the chief operating officer;

(II) owner's address;

(III) owner's telephone number; and state.

(IV) year the owner began operating pharmacies in the United States.

(ii) The Internet address and toll free telephone number that a consumer may use to:

(I) report medication/device problems to the pharmacy; and

(II) report business compliance problems.

(iii) Information about each pharmacy that dispenses prescriptions for this site, to include at a minimum, the:

(I) pharmacy's name, address, and telephone number;

(II) name of the pharmacist responsible for operation of the pharmacy;

(III) Texas pharmacy license number for the pharmacy and a link to the Internet site maintained by the Texas State Board of Pharmacy; and

(IV) the names of all other states in which the pharmacy is licensed, the license number in that state, and a link to the Internet site of the entity that regulates pharmacies in that state, if available.

(C) A pharmacy whose Internet site has been verified by the National Association of Boards of Pharmacy to be in compliance with the laws of this state, as well as in all other states in which the pharmacy is licensed shall be in compliance with subparagraph (B) of this paragraph.

(2) Texas State Board of Pharmacy. The board shall establish a pharmacy profile system as specified in §2054.2606, Government Code.

(A) The board shall make the pharmacy profiles available to the public on the agency's Internet site.

(B) A pharmacy profile shall contain at least the following information:

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

(ii) pharmacy license number, licensure status, and expiration date of the license;

(iii) the class and type of the pharmacy;

(iv) ownership information for the pharmacy;

(v) names and license numbers of all pharmacists working at the pharmacy;

(vi) whether the pharmacy has had prior disciplinary action by the board;

(vii) whether the pharmacy's consumer service areas are accessible to persons with disabilities as defined by law;

(viii) the type of language translating services, including translating services for persons who are deaf or hard of hearing, that the pharmacy provides for consumers; and

(ix) insurance information including whether the pharmacy participates in the state Medicaid program.

(C) The board shall gather this information on initial licensing and update the information in conjunction with the license renewal for the pharmacy.

(i) Notification of Licensees or Registrants Obtaining Controlled Substances or Dangerous Drugs by Forged Prescriptions. If a licensee or registrant obtains controlled substances or dangerous drugs from a pharmacy by means of a forged prescription, the pharmacy shall report in writing to the board immediately on discovery of such forgery. A pharmacy shall be in compliance with this subsection by submitting to the board the following:

(1) name of licensee or registrant obtaining controlled substances or dangerous drugs by forged prescription;

(2) date(s) of forged prescription(s);

(3) name(s) and amount(s) of drug(s); and

(4) copies of forged prescriptions.

(j) Notification of Disciplinary Action. For the purpose of the Act, §562.106, a pharmacy shall report in writing to the board not later than the 10th day after the date of:

(1) a final order against the pharmacy license holder by the regulatory or licensing agency of the state in which the pharmacy is located if the pharmacy is located in another state; or

(2) a final order against a pharmacist who is designated as the pharmacist-in-charge of the pharmacy by the regulatory or licensing agency of the state in which the pharmacy is located if the pharmacy is located in another state.

(k) Temporary Closing for Loss of Pharmacist-in-Charge. A pharmacy that temporarily closes for loss of a pharmacist-in-charge as provided by §291.5(d)(2) of this title shall notify the board in writing on a form provided by the board. The

pharmacy shall submit the notification not later than the next business day after the date of departure of the pharmacist-in-charge.

(l) Loss of Data. As provided by §§291.34(e), 291.55(a), 291.75(c), 291.104(a), and 291.151(e) of this title (relating to Records; Records; Records; Operational Standards; Pharmacies Located in a Freestanding Emergency Medical Care Facility (Class F)), when a Class A, Class B, Class C, Class E, or Class F pharmacy experiences a significant loss of information from its data processing system, the pharmacist-in-charge shall report the loss to the board in writing within 10 days of discovery of the loss.

§291.4 Sworn Disclosure Statement

(a) The following words and terms, when used in this section, shall have the following meanings:

(1) Publicly traded company--a company with a class of securities registered under section 12 of the Securities Exchange Act of 1934 (15 U.S.C. § 78l) or that is required to file reports under section 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. § 78o(d)).

(2) Retail grocery store chain--ten or more stores under the same ownership which primarily sell produce, food, and beverage products that are intended for off premises consumption.

(b) To qualify for a pharmacy license, a sworn disclosure statement form must be submitted to the board, unless:

(1) the pharmacy for which the application is made is operated by a publicly traded company;

(2) the pharmacy for which the application is made is wholly owned by a retail grocery store chain; or

(3) the applicant is applying for a Class B or Class C pharmacy license.

(c) The sworn disclosure statement form must be notarized and must include any information requested on the form, including:

(1) the name of the pharmacy;

(2) the name of each person who has a direct financial investment in the pharmacy;

(3) the name of each person who:

(A) is not an individual;

(B) has any financial investment in the pharmacy; and

(C) is not otherwise disclosed under paragraph (2) of this subsection;

(4) the total amount or percentage of the financial investment made by each person described by paragraph (2) of this subsection; and

(5) the name of each of the following persons, if applicable, connected to the pharmacy if the person is not otherwise disclosed under paragraph (2) or (3) of this subsection:

(A) a partner;

(B) an officer;

(C) a director;

(D) a managing employee;

(E) an owner or person who controls the owner; and

(F) a person who acts as a controlling person of the pharmacy through the exercise of direct or indirect influence or control over the management of the pharmacy, the expenditure of money by the pharmacy, or a policy of the pharmacy, including:

(i) a management company, landlord, marketing company, or similar person who operates or contracts for the operation of a pharmacy and, if the pharmacy is a publicly traded corporation or is controlled by a publicly traded corporation, an officer or director of the corporation but not a shareholder or lender of the corporation;

(ii) an individual who has a personal, familial, or other relationship with an owner, manager, landlord, tenant, or provider of a pharmacy that allows the individual to exercise actual control of the pharmacy; and

(iii) any other person the board by rule requires to be included based on the person's exercise of direct or indirect influence or control.

§291.5 Closing a Pharmacy

(a) Prior to closing. At least 14 days prior to the closing of a pharmacy that dispenses prescription drug orders the pharmacist-in-charge shall:

(1) post a closing notice sign in a conspicuous place in the front of the prescription department and at all public entrance doors to the pharmacy. Such closing notice sign shall contain the following information:

(A) the date of closing; and

(B) the name, address, and telephone number of the pharmacy acquiring the prescription drug orders, including refill information and patient medication records of the pharmacy.

(2) notify DEA of any controlled substances being transferred to another registrant as specified in 21 CFR 1301.52(d).

(b) Closing day. On the date of closing, the pharmacist-in-charge shall comply with the following:

(1) take an inventory as specified in §291.17 of this title (relating to Inventory Requirements);

(2) remove all prescription drugs from the pharmacy by one or a combination of the following methods:

(A) return prescription drugs to manufacturer or supplier (for credit/disposal);

(B) transfer (sell or give away) prescription drugs to a person who is legally entitled to possess drugs, such as a hospital, or another pharmacy; and

(C) destroy the prescription drugs following procedures specified in §303.2 of this title (relating to Disposal of Stock Prescription Drugs); and

(3) if the pharmacy dispenses prescription drug orders:

(A) transfer the prescription drug order files, including refill information, and patient medication records to a licensed pharmacy; and

(B) remove all signs or notify the landlord or owner of the property that it is unlawful to use the word "pharmacy" either in English or any other language, or any other word or combination of words of the same or similar meaning, or any graphic representation that would mislead or tend to mislead the public that a pharmacy is located at the address.

(c) After closing.

(1) Within ten days after the closing of the pharmacy, the pharmacist-in-charge shall forward to the board a written notice of the closing which includes the following information:

(A) the actual date of closing;

(B) the license issued to the pharmacy;

(C) a statement attesting:

(i) that an inventory as specified in §291.17 of this title (relating to Inventory Requirements) has been conducted; and

(ii) the manner by which the dangerous drugs and controlled substances possessed by the pharmacy were transferred or disposed; and

(D) if the pharmacy dispenses prescription drug orders, the name and address of the pharmacy to which the prescription drug orders, including refill information, and patient medication records were transferred.

(2) If the pharmacy is registered to possess controlled substances, send notification to the appropriate DEA divisional office explaining that the pharmacy has closed and include the following items:

(A) DEA registration certificate; and

(B) all unused DEA order forms (222) with the word VOID written on the face of each order form.

(3) Once the pharmacy has notified the board that the pharmacy is closed, the license may not be renewed. The pharmacy may apply for a new license as specified in §291.1 of this title (relating to Pharmacy License Application).

(d) Emergency or temporary closing.

(1) If pharmacy is closed suddenly due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, or other emergency circumstances and the pharmacist-in-charge cannot provide notification 14 days prior to the closing, the pharmacist-in-charge shall comply with the provisions of subsection (a) of this section as far in advance of the closing as allowed by the circumstances.

(2) A pharmacy may temporarily close for lack of a pharmacist-in-charge for no more than 30 days. If a pharmacy temporarily closes for lack of a pharmacist-in-charge, the pharmacy shall:

(A) only allow access to the prescription department if a pharmacist is present;

(B) send notification to the board as specified in §291.3(k) of this title (relating to Required Notifications); and

(C) either:

(i) reopen within 48 hours under the supervision of a new pharmacist-in-charge who has been reported to the board as specified in §291.3(e)(2) of this title; or

(ii) comply with the provisions of subsection (a) of this section as far in advance of the closing as allowed by the circumstances.

(e) Joint responsibility. If the pharmacist-in-charge is not available to comply with the requirements of this section, the owner shall be responsible for compliance with the provisions of this section.

§291.6 Pharmacy License Fees

(a) Initial License Fee. The fee for an initial license shall be $610 for the initial registration period.

(b) Biennial License Renewal. The Texas State Board of Pharmacy shall require biennial renewal of all pharmacy licenses provided under the Act §561.002.

(c) Renewal Fee. The fee for biennial renewal of a pharmacy license shall be $607 for the renewal period.

(d) Fee for Change of Location/Name/Rank. The application fee for a change of name, location, or rank shall be $100.

(e) Remote Pharmacy Services Fee. The application fee for an initial or renewed certificate to provide remote pharmacy services under §291.121 of this title (relating to Remote Pharmacy Services) shall be:

(1) for a certificate to provide remote pharmacy services using automated pharmacy systems under §291.121(a) of this title: $100;

(2) for a certificate to provide remote pharmacy services using emergency medication kits under §291.121(b) of this title: $50;

(3) for a certificate to provide remote pharmacy services using telepharmacy systems under §291.121(c) of this title: $150; and

(4) for a certificate to provide remote pharmacy services using automated dispensing and delivery systems under §291.121(d) of this title: $100.

§291.7 Prescription Drug Recalls by the Manufacturer

(a) The pharmacist-in-charge shall develop and implement a written procedure for proper management of drug recalls by the manufacturer. Such procedures shall include, where appropriate, contacting patients to whom the recalled drug products have been dispensed.

(b) The written procedure shall include, but not be limited to, the following:

(1) the pharmacist-in-charge shall reasonably ensure that a recalled drug has been removed from inventory no more than 24 hours after receipt of the recall notice, and quarantined until proper disposal or destruction of the drug; and

(2) if the drug that is the subject to a recall is maintained by the pharmacy in a container without a lot number, the pharmacist-in-charge shall consider this drug included in the recall.

§291.8 Return of Prescription Drugs

(a) General prohibition on return of prescription drugs. A pharmacist may not accept an unused prescription or drug, in whole or in part, for the purpose of resale or re-dispensing to any person, after the prescription or drug has been

originally dispensed, or sold except as provided in subsection (b) of this section or Subchapter M, Chapter 431, Health and Safety Code, or Chapter 442, Health and Safety Code.

(b) Return of prescription drugs from health care facilities.

(1) Purpose. The purpose of this subsection is to outline procedures for the return of unused drugs from a health care facility or a penal institution to a dispensing pharmacy as specified in the §562.1085 of the Occupations Code. Nothing in this section shall require a consultant pharmacist, health care facility, penal institution, or pharmacy to participate in the return of unused drugs.

(2) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(A) Consultant pharmacist--A pharmacist who practices in or serves as a consultant for a health care facility in this state.

(B) Health care facility--A facility regulated under Chapter 242, Health and Safety Code.

(C) Licensed health care professional--A person licensed by the Texas Medical Board, Texas Board of Nursing, or the Texas State Board of Pharmacy.

(D) Penal institution--A place designated by law for confinement of persons arrested for, charged with, or convicted of an offense. A penal institution includes a city, county or state jail or prison.

(3) Responsibilities. A licensed health care professional in a penal institution or a consultant pharmacist may return to a pharmacy certain unused drugs, other than a controlled substance as defined by Chapter 481, Health and Safety Code, purchased from the pharmacy.

(A) The unused drugs must:

(i) be approved by the federal Food and Drug Administration and be:

(I) sealed in unopened tamper-evident packaging and either individually packaged or packaged in unit-dose packaging;

(II) oral or parenteral medication in sealed single-dose containers approved by the federal Food and Drug Administration;

(III) topical or inhalant drugs in sealed unit-of-use containers approved by the federal Food and Drug Administration; or

(IV) parenteral medications in sealed multiple-dose containers approved by the federal Food and Drug Administration from which doses have not been withdrawn.

(ii) not be the subject of a mandatory recall by a state or federal agency or a voluntary recall by a drug seller or manufacturer; and

(iii) have not been in the physical possession of the person for whom it was prescribed.

(B) A healthcare facility or penal institution may not return any drug product that:

(i) has been compounded;

(ii) appears on inspection to be adulterated;

(iii) requires refrigeration; or

(iv) has less than 120 days until the expiration date or end of the shelf life.

(C) The consultant pharmacist or licensed health care professional in a penal institution shall be responsible for assuring an inventory of the drugs to be returned to a pharmacy is completed. The following information shall be included on this inventory:

(i) name and address of the facility or institution;

(ii) name and pharmacist license number of the consultant pharmacist or name and license number of the licensed health care professional;

(iii) date of return;

(iv) date the prescription was dispensed;

(v) unique identification number assigned to the prescription by the pharmacy;

(vi) name of dispensing pharmacy;

(vii) name, strength, and quantity of drug;

(viii) signature of consultant pharmacist or licensed healthcare professional responsible for the administration of drugs in a penal institution.

(D) The health care facility/penal institution shall send a copy of the inventory specified in subparagraph (C) of this paragraph to:

(i) the pharmacy with the drugs returned; and

(ii) the Health and Human Services Commission.

(4) Dispensing/Receiving pharmacy responsibilities. If a pharmacy accepts the return of unused drugs from a health care facility/penal institution, the following is applicable.

(A) A pharmacist employed by the pharmacy shall examine the drugs to ensure the integrity of the drug product.

(B) The pharmacy shall reimburse or credit the entity that paid for the drug including the state Medicaid program for an unused drug returned to the pharmacy. The pharmacy shall maintain a record of the credit or reimbursement containing the following information:

(i) name and address of the facility or institution which returned the drugs;

(ii) date and amount of the credit or reimbursement was issued;

(iii) name of the person or entity to whom the credit or reimbursement was issued;

(iv) date the prescription was dispensed;

(v) unique identification number assigned to the prescription by the pharmacy;

(vi) name, strength, and quantity of drug;

(vii) signature of the pharmacist responsible for issuing the credit.

(C) After the pharmacy has issued credit or reimbursement, the pharmacy may restock and re-dispense the unused drugs returned under this section.

(5) Limitation on Liability.

(A) A pharmacy that returns unused drugs and a manufacturer that accepts the unused drugs under §562.1085, Occupations Code, and the employees of the pharmacy or manufacturer are not liable for harm caused by the accepting, dispensing, or administering of drugs returned in strict compliance with §562.1085, Occupations Code, unless the harm is caused by:

(i) wilful or wanton acts of negligence;

(ii) conscious indifference or reckless disregard for the safety of others; or

(iii) intentional conduct.

(B) This section does not limit, or in any way affect or diminish, the liability of a drug seller or manufacturer under Chapter 82, Civil Practice and Remedies Code.

(C) This section does not apply if harm results from the failure to fully and completely comply with the requirements of §562.1085, Occupations Code.

(D) This section does not apply to a pharmacy or manufacturer that fails to comply with the insurance provisions of Chapter 84, Civil Practice and Remedies Code.

§291.9 Prescription Pick Up Locations

(a) No person, firm, or business establishment may have, participate in, or permit an arrangement, branch, connection or affiliation whereby prescriptions are solicited, collected, picked up, or advertised to be picked up, from or at any location other than a pharmacy which is licensed and in good standing with the board.

(b) A pharmacist or pharmacy by means of its employee or by use of a common or contract carrier, at the request of the patient, may:

(1) pick up prescription orders at the:

(A) office or home of the prescriber;

(B) residence or place of employment of the person for whom the prescription was issued; or

(C) hospital or medical care facility in which the patient is receiving treatment; and

(2) deliver prescription drugs to the:

(A) office of the prescriber if the prescription is:

(i) for a dangerous drug; or

(ii) for a single dose of a controlled substance that is for administration to the patient in the prescriber's office;

(B) residence of the person for whom the prescription was issued;

(C) place of employment of the person for whom the prescription was issued, if the person is present to accept delivery; or

(D) hospital or medical care facility in which the patient is receiving treatment.

(c) A pharmacist or pharmacy by use of unmanned aircraft systems (i.e., "drones"), at the request of a patient or patient's agent, may deliver prescription drugs, excluding controlled substances or sterile compounded preparations, to a selected delivery location mutually agreed upon by the patient and the pharmacist using the pharmacist's professional judgment.

§291.10 Pharmacy Balance Registration/Inspection

(a) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise. Pharmacy balance--An instrument for weighing including balances and scales.

(b) Registration.

(1) A pharmacy shall annually or biennially register each pharmacy balance. The fee for the annual registration shall be $12.50 per pharmacy balance. The fee for the biennial registration shall be $25.00 per pharmacy balance.

(2) The expiration date for pharmacy balance registrations shall coincide with the pharmacy license expiration date.

(c) Inspection.

(1) The Board shall periodically inspect pharmacy balances to verify accuracy.

(2) If a pharmacy balance fails the accuracy inspection, the following is applicable.

(A) The pharmacy balance may not be used until it is repaired by an authorized repair person.

(B) A tag indicating that the pharmacy balance failed the inspection and may not be used shall be placed on the pharmacy balance.

§291.11 Operation of a Pharmacy

(a) For the purposes of §565.002(a)(7) of the Texas Pharmacy Act, the following words and terms shall be defined as follows.

(1) "Failure to engage in the business described in the application for a license" means the holder of a pharmacy license has not commenced operating the pharmacy within six months of the date of issuance of the license.

(2) "Ceased to engage in the business described in the application for a license" means the holder of a pharmacy license, once it has been in operation, discontinues operating the pharmacy for a period of 30 days or longer, except as provided in paragraph (3) of this subsection.

(3) A pharmacy may discontinue operating for not longer than 90 days if the pharmacy experiences a fire, flood, or natural disaster that may have affected the strength, purity, or labeling of drugs, medications, devices, or other materials used in the diagnosis or the treatment of injury, illness, and disease and timely notifies the board under §291.3(g) of this title (relating to Required Notifications).

(b) For the purposes of this section, the term "operating the pharmacy" means the pharmacy shall demonstrate observable pharmacy business activity on a regular, routine basis, including a sufficient number of transactions of receiving, processing, or dispensing prescription drug orders or medication drug orders.

(c) No person may operate a pharmacy in a personal residence.

§291.12 Delivery of Prescription Drugs

(a) Applicability. This section applies to the delivery of prescription drugs by a pharmacy licensed by the board as a Class A, Class A-S, Class E, or Class E-S pharmacy.

(b) Definitions.

(1) Common carrier--A person or entity who holds out to the general public a willingness to provide transportation of property from place to place for compensation in the normal course of business.

(2) Contract carrier--A person or entity who provides to industrial customers, pursuant to the terms of a bilateral agreement, the transportation of property for compensation in the normal course of business.

(c) Delivery by common or contract carrier. A pharmacy may deliver prescription drugs by use of a common or contract carrier as provided in §291.9 of this title (relating to Prescription Pick Up Locations) on request of the patient or patient's agent. A pharmacy that delivers prescription drugs by use of a common or contract carrier providing a same-day courier service is not subject to subsection (c) of this section and shall comply with subsection (d) of this section.

(1) Standards. The pharmacy shall ensure that all prescription drugs are delivered to the patient or patient's agent in accordance with nationally recognized standards, such as those of the manufacturer or the United States Pharmacopeia. The pharmacy is responsible for any problems in the delivery of a prescription drug by a contract carrier.

(2) Packaging. The pharmacy shall ensure that prescription drugs are packaged in commercially available tamper evident packaging.

(3) Temperature. The pharmacy shall ensure that any prescription drug delivered by a common or contract carrier is packaged in a manner that maintains a temperature range appropriate for the drug. This may include, without limitation, use of temperature tags, time temperature strips, insulated packaging, gel ice packs, or a combination of these as necessary.

(4) Irregularity in delivery. The pharmacy shall provide a method by which a patient or patient's agent can notify the pharmacy as to any irregularity in the delivery of the patient's prescription, to include but not be limited to:

(A) timeliness of delivery;

(B) condition of the prescription drug upon delivery; and

(C) failure to receive the proper prescription drug.

(5) Refusal to deliver. The pharmacy shall refuse to deliver by common or contract carrier a prescription drug which in the professional opinion of the dispensing pharmacist may be clinically compromised by delivery by common or contract carrier.

(d) Delivery by pharmacy employee or common or contract carrier providing a same-day courier service. A pharmacy may deliver prescription drugs by means of its employee or a common or contract carrier providing a same-day courier service as provided in §291.9 of this title on request of the patient or patient's agent.

(1) Standards. The pharmacy is responsible for any problems in the delivery of the prescription drug.

(2) Temperature. The prescription drug shall be maintained within the temperature range allowed by the United States Pharmacopeia or recommended by the manufacturer until the delivery has been received by the patient or patient's agent.

(e) Delivery by unmanned aircraft systems (i.e., "drones"). A pharmacy may deliver prescription drugs, excluding controlled substances or sterile compounded preparations, by use of a common or contract carrier providing an unmanned aircraft system delivery service as provided in §291.9 of this title on request of the patient or patient's agent.

(1) Standards. Unmanned aircraft systems shall maintain appropriate federal registration and comply with all state and federal laws and rules. The pharmacy shall ensure that all prescription drugs are delivered to the patient or patient's agent in accordance with nationally recognized standards, such as those of the manufacturer or the United States Pharmacopeia. The pharmacy is responsible for any problems in the delivery of the prescription drug.

(2) The pharmacist-in-charge is responsible for developing written policies and procedures regarding prescription drug delivery in accordance with this subsection to be used by pharmacy personnel to include, but not be limited to, the following:

(A) training pharmacy personnel engaged in preparing and packaging prescription drugs for delivery;
(B) packaging prescription drugs for delivery;
(C) verification of the correct recipient and delivery address;
(D) maintaining the confidentiality of prescription records;
(E) secure transfer of prescription drugs from the pharmacy;
(F) provision of patient counseling;
(G) remediation of errors in delivery or adverse events; and
(H) recordkeeping.

(3) Packaging. The pharmacy shall ensure that prescription drugs are packaged in commercially available tamper evident packaging.

(4) Temperature. The pharmacy shall ensure that any prescription drug delivered by a common or contract carrier providing an unmanned aircraft system delivery service is packaged in a manner that maintains a temperature range appropriate for the drug. This may include, without limitation, use of temperature tags, time temperature strips, insulated packaging, gel ice packs, or a combination of these as necessary.

(5) Records. The pharmacy shall document each change in the chain of custody of a prescription drug, including departure of the prescription drug from the pharmacy, transfer to the person or entity fulfilling delivery, and delivery to the patient.

(6) Confirmation of presence at selected delivery location. The pharmacy shall receive confirmation from the patient or patient's agent that the patient or patient's agent is present at the selected delivery location before unmanned aircraft system delivery is initiated.

(7) Security. The pharmacy must ensure that delivery is made to a reasonably secure location at the selected delivery location that minimizes the opportunity for unauthorized access to prescription drugs and confidential prescription records.

(f) All deliveries. A pharmacy that delivers prescription drugs by common or contract carrier, by pharmacy employee or common or contract carrier providing a same-day courier service, or by common or contract carrier providing an unmanned aircraft system delivery service shall also comply with the following:

(1) Counseling information. The pharmacy shall comply with the requirements of §291.33(c)(1)(F) of this title (relating to Operational Standards).

(2) Notification of delivery. The pharmacy shall notify the patient or patient's agent of the delivery of a prescription drug.

(3) Compromised delivery. If a pharmacist determines a prescription drug is in any way compromised during delivery, the pharmacy shall replace the drug or arrange for the drug to be replaced, either by promptly delivering a replacement to the patient or by promptly contacting the prescriber to arrange for the drug to be dispensed to the patient by a pharmacy of the patient's or patient's agent's choice.

(4) Records. The pharmacy shall maintain records for two years on the following events:
(A) when a prescription drug was sent and delivered to the patient or patient's agent; and
(B) patient complaints regarding compromised deliveries, which may be documented in the patient profile.

(5) Controlled substances. A pharmacy shall comply with all state and federal laws and rules relating to the delivery of controlled substances.

§291.13 Telehealth Services Provided by a Pharmacist

(a) "Telehealth service" shall have the meaning defined by Texas Occupations Code §111.001(3).

(b) The requirements of subsection (c) of this section apply to a telehealth service regardless of whether the patient interaction occurs in a video or audio-only format.

(c) A pharmacist who provides a telehealth service shall ensure that the informed consent of the patient, or of another individual authorized to make health care treatment decisions for the patient, is obtained before the telehealth service is provided. The informed consent may be obtained either in writing or verbally.

(1) The informed consent shall include the patient's consent to:
(A) treatment;
(B) data collection; and
(C) data sharing.
(2) The informed consent shall be documented in:
(A) the pharmacy's data processing system;
(B) an electronic logbook; or
(C) a hard-copy log.
(3) If obtained verbally, the informed consent shall be documented by recording the initials or identification code of the pharmacist or agent who obtained the consent.
(4) Documentation of informed consent shall be:
(A) kept by the pharmacy at the pharmacy's licensed location and be available, for at least two years from the date of such record, for inspection 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 board. Failure to provide the records, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

§291.14 Pharmacy License Renewal

(a) Renewal requirements.
(1) A license to operate a pharmacy expires on the last day of the assigned expiration month.
(2) The provision of the Act, §561.005, shall apply if the completed application and a renewal fee is not received in the board's office on or before the last day of the assigned expiration month.
(3) An expired license may be renewed according to the following schedule:
(A) If the license has been expired for 90 days or less, the license may be renewed by paying to the board a renewal fee that is equal to one and one-half times the required renewal fee as specified in §291.6 of this title (relating to Pharmacy License Fees).
(B) If the license has been expired for 91 days or more, the license may not be renewed. The pharmacy may apply for a new license as specified in §291.1 of this title (relating to Pharmacy License Application), including, as required by §560.052(b) of the Act, the submission of a sworn disclosure statement as specified in §291.4 of this title (relating to Sworn Disclosure Statement).
(b) If the board determines on inspection at the pharmacy's address on or after the expiration date of the license that no pharmacy is located or exists at the pharmacy's address (e.g., the building is vacated or for sale or lease, or another business is operating at the location), the board shall not renew the license.
(c) Additional renewal requirements for Class E pharmacies. In addition to the renewal requirements in subsection (a) of this section, a Class E pharmacy shall have on file with the board an inspection report issued:
(1) not more than three years before the date the renewal application is received; and
(2) by the pharmacy licensing board in the state of the pharmacy's physical location except as provided in §291.104 of this title (relating to Operational Standards).

§291.15 Storage of Drugs

All drugs shall be stored at the proper temperature and conditions as defined by the following terms:
(1) Freezer--A place in which the temperature is maintained thermostatically between minus 25 degrees Celsius and minus 10 degrees Celsius (minus 13 degrees Fahrenheit and 14 degrees Fahrenheit).
(2) Cold--Any temperature not exceeding 8 degrees Celsius (46 degrees Fahrenheit). A refrigerator is a cold place in which the temperature is maintained thermostatically between 2 degrees Celsius and 8 degrees Celsius (36 degrees Fahrenheit and 46 degrees Fahrenheit).

(3) Cool--Any temperature between 8 degrees Celsius and 15 degrees Celsius (46 degrees Fahrenheit and 59 degrees Fahrenheit). An article for which storage in a cool place is directed may, alternatively, be stored and distributed in a refrigerator, unless otherwise specified by the individual monograph.
(4) Room temperature--The temperature prevailing in a working area.
(5) Controlled room temperature--A temperature maintained thermostatically between 15 degrees Celsius and 30 degrees Celsius (59 degrees Fahrenheit and 86 degrees Fahrenheit).
(6) Warm--Any temperature between 30 degrees Celsius and 40 degrees Celsius (86 degrees Fahrenheit and 104 degrees Fahrenheit).
(7) Excessive heat--Any temperature above 40 degrees Celsius (104 degrees Fahrenheit).
(8) 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.
(9) Dry place--A place that does not exceed 40% average relative humidity at controlled room temperature or the equivalent water vapor pressure at other temperatures.

§291.16 Samples

Unless otherwise specified, a pharmacy may not sell, purchase, trade or possess prescription drug samples, unless the pharmacy meets all of the following conditions:

(1) the pharmacy is owned by a charitable organization described in the Internal Revenue Code of 1986, or by a city, state or county government;
(2) the pharmacy is a part of a health care entity which provides health care primarily to indigent or low income patients at no or reduced cost;
(3) the samples are for dispensing or provision at no charge to patients of such health care entity; and
(4) the samples are possessed in compliance with the federal Prescription Drug Marketing Act of 1987.

§291.17 Inventory Requirements

(a) General requirements.

(1) The pharmacist-in-charge shall be responsible for taking all required inventories, but may delegate the performance of the inventory to another person(s).
(2) The inventory shall be maintained in a written, typewritten, or printed form. An inventory taken by use of an oral recording device must be promptly transcribed.
(3) The inventory shall be kept in the pharmacy and shall be available for inspection for two years.
(4) The inventory shall be filed separately from all other records.
(5) The inventory shall be in a written, typewritten, or printed form and include all stocks of all controlled substances on hand on the date of the inventory (including any which are out-of-date).
(6) The inventory may be taken either as of the opening of business or as of the close of business on the inventory date.
(7) The inventory record shall indicate whether the inventory is taken as of the opening of business or as of the close of business on the inventory date. If the pharmacy is open 24 hours a day, the inventory record shall indicate the time that the inventory was taken.
(8) The person(s) taking the inventory shall make an exact count or measure of all controlled substances listed in Schedule II.
(9) The person(s) taking the inventory shall make an estimated count or measure of all controlled substances listed in Schedules III, IV, and V, unless the container holds more than 1,000 tablets or capsules in which case, an exact count of the contents must be made.
(10) The inventory of Schedule II controlled substances shall be listed separately from the inventory of Schedules III, IV, and V controlled substances.

(11) If the pharmacy maintains a perpetual inventory of any of the drugs required to be inventoried, the perpetual inventory shall be reconciled on the date of the inventory.

(b) Initial inventory.

(1) A new Class A, Class A-S, Class C, Class C-S, or Class F pharmacy shall take an inventory on the opening day of business. Such inventory shall include all stocks of all controlled substances (including any out-of-date drugs).

(2) In the event the Class A, Class A-S, Class C, Class C-S, or Class F pharmacy commences business with no controlled substances on hand, the pharmacy shall record this fact as the initial inventory.

(3) The initial inventory shall serve as the pharmacy's inventory until the next May 1, or until the pharmacy's regular general physical inventory date, at which time the Class A, Class A-S, Class C, Class C-S, or Class F pharmacy shall take an annual inventory as specified in subsection (c) of this section.

(c) Annual inventory.

(1) A Class A, Class A-S, Class C, Class C-S, or Class F pharmacy shall take an inventory on May 1 of each year, or on the pharmacy's regular general physical inventory date. Such inventory may be taken within four days of the specified inventory date and shall include all stocks of all controlled substances (including out-of-date drugs).

(2) A Class A, Class A-S, Class C, Class C-S, or Class F pharmacy applying for renewal of a pharmacy license shall include as a part of the pharmacy license renewal application a statement attesting that an annual inventory has been conducted, the date of the inventory, and the name of the person(s) taking the inventory.

(3) The person(s) taking the annual inventory and the pharmacist-in-charge shall indicate the time the inventory was taken (as specified in subsection (a)(7) of this section) and shall sign and date the inventory with the date the inventory was taken.

(d) Change of ownership.

(1) A Class A, Class A-S, Class C, Class C-S, or Class F pharmacy that changes ownership shall take an inventory on the date of the change of ownership. Such inventory shall include all stocks of all controlled substances (including any out-of-date drugs).

(2) Such inventory shall constitute, for the purpose of this section, the closing inventory for the seller and the initial inventory for the buyer.

(3) Transfer of any controlled substances listed in Schedule II shall require the use of official DEA order forms (Form 222).

(4) The person(s) taking the inventory and the pharmacist-in-charge shall indicate the time the inventory was taken (as specified in subsection (a)(7) of this section) and shall sign and date the inventory with the date the inventory was taken.

(e) Closed pharmacies.

(1) The pharmacist-in-charge of a Class A, Class A-S, Class C, Class C-S, or Class F pharmacy that ceases to operate as a pharmacy shall forward to the board, within 10 days of the cessation of operation, a statement attesting that an inventory of all controlled substances on hand has been conducted, the date of closing, and a statement attesting the manner by which the dangerous drugs and controlled substances possessed by such pharmacy were transferred or disposed.

(2) The person(s) taking the inventory and the pharmacist-in-charge shall indicate the time the inventory was taken (as specified in subsection (a)(7) of this section) and shall sign and date the inventory with the date the inventory was taken.

(f) Additional requirements for Class C and Class C-S pharmacies.

(1) Perpetual inventory.

(A) A Class C or Class C-S pharmacy shall maintain a perpetual inventory of all Schedule II controlled substances.

(B) The perpetual inventory shall be reconciled on the date of the annual inventory.

(2) Annual inventory. The inventory of the Class C or Class C-S pharmacy shall be maintained in the pharmacy. The inventory shall include all controlled substances located in the pharmacy and, if applicable, all controlled

substances located in other departments within the institution. If an inventory is conducted in other departments within the institution, the inventory of the pharmacy shall be listed separately, as follows:

(A) the inventory of drugs on hand in the pharmacy shall be listed separately from the inventory of drugs on hand in the other areas of the institution; and

(B) the inventory of drugs on hand in all other departments shall be identified by department.

(g) Change of pharmacist-in-charge of a pharmacy.

(1) On the date of the change of the pharmacist-in-charge of a Class A, Class A-S, Class C, Class C-S, or Class F pharmacy, an inventory shall be taken. Such inventory shall include all stocks of all controlled substances (including any out-of-date drugs).

(2) This inventory shall constitute, for the purpose of this section, the closing inventory of the departing pharmacist-in-charge and the beginning inventory of the incoming pharmacist-in-charge.

(3) If the departing and the incoming pharmacists-in-charge are unable to conduct the inventory together, a closing inventory shall be conducted by the departing pharmacist-in-charge and a new and separate beginning inventory shall be conducted by the incoming pharmacist-in-charge.

(4) The incoming pharmacist-in-charge shall be responsible for notifying the board within 10 days, as specified in §291.3 of this title (relating to Required Notifications), that a change of pharmacist-in-charge has occurred.

§291.18 Time Limit for Filing a Complaint

For the purposes of the Act, §556.055, the board determines that a "reasonable time" to be no less than 10 days from the date of an inspection giving rise to a possible complaint; provided, however, in situations presenting imminent danger to the public health and safety, the board may obtain an injunction under the Act, §566.051, to restrain or enjoin a person from continuing to violate the Act or rules promulgated pursuant to the Act without waiting the 10-day period set out in this section.

§291.19 Administrative Actions as a Result of a Compliance Inspection

As a result of a compliance inspection or compliance reinspection of a pharmacy wherein violations of the Texas Pharmacy Act, Controlled Substances Act, Dangerous Drug Act, Texas Food, Drug and Cosmetic Act, or rules adopted pursuant to such acts are observed an agent of the board:

(1) may issue a written warning notice listing specific violations and providing a reasonable amount of time to comply with the laws and rules; or

(2) may recommend the institution of action against a licensee if such agent determines that:

(A) previously cited violations are continuing to occur; or

(B) violations observed are of a nature that a written warning notice would not be in the best interest of the public.

§291.22 Petition to Establish an Additional Class of Pharmacy

(a) Purpose. The purpose of this section is to specify the procedures to be followed in petitioning the board to establish an additional class of pharmacy as authorized by §560.053 of the Texas Pharmacy Act (Chapters 551 - 566 and 568 - 569, Texas Occupations Code). In reviewing petitions, the board will only consider petitions that provide pharmaceutical care services which contribute to positive patient outcomes. The board will not consider any petition intended only to provide a competitive advantage.

(b) Procedures for petitioning the board to establish an additional class of pharmacy. A person who wishes the board to consider establishing an additional class of pharmacy shall submit to the board a petition that contains at least the following information:

(1) name, address, telephone number, and pharmacist's license number of the pharmacist responsible for submitting the petition;

(2) a detailed summary of the additional class of pharmacy which includes:

(A) a description of the type of pharmacy and the pharmaceutical care services provided to the public;
(B) if a pharmacy of this type currently exists, the name, address, and license number of the pharmacy;
(C) a full explanation of the reasons:
(i) the existing classifications of pharmacy licenses are not appropriate for this practice setting; and
(ii) that establishment of a new classification of pharmacy license is necessary to protect the public health, safety, and welfare.

(c) Review and approval or denial of the petition.

(1) On receipt of a petition to establish an additional class of pharmacy, board staff shall initially review the petition for completeness and appropriateness. If the petition is incomplete or inappropriate for board consideration for any reason, board staff shall return the petition with a letter of explanation. Such review shall be completed within 30 working days of receipt of the petition.

(2) Once board staff has determined that the petition is complete and appropriate, a task force composed of board staff, at least one board member and, if deemed necessary, resource personnel appointed by the board president, shall review the petition and make a written recommendation to the board regarding approval. Such recommendation shall be presented to the board at the next regularly scheduled meeting of the board that occurs at least three weeks after completion of the review and written recommendation.

(3) A copy of the recommendation shall be provided to the petitioner and the board at least two weeks prior to the board meeting.

(4) Both the petitioner and a representative of the task force shall be given equal time for presentations to the board.

(5) Upon hearing the presentations, the board shall approve or deny the petition. If the board approves the petition, the board shall direct staff to develop rules for the new class of pharmacy or appoint a task force to work with the staff to assist in developing rules for the new class of pharmacy. The board shall approve or deny any petition to establish an additional class of pharmacy not later than the board meeting following the meeting at which the petition is heard.

§291.23 Pilot or Demonstration Research Projects for Innovative Applications in the Practice of Pharmacy

(a) Purpose. The purpose of this section is to specify the procedures to be followed in applying for approval of a pilot or demonstration research project for innovative applications in the practice of pharmacy as authorized by §554.011 of the Texas Pharmacy Act (Chapters 551- 566 and 568 - 569, Texas Occupations Code). In reviewing projects, the board will only consider projects that expand pharmaceutical care services which contribute to positive patient outcomes. The board will not consider any project intended only to provide a competitive advantage.

(b) Scope of pilot or demonstration research projects and the board's approval of such projects.

(1) Pilot or demonstration research projects may not:
(A) expand the definition of the practice of pharmacy as provided in the Act; or
(B) include therapeutic substitution or substitution of medical devices used in patient care.

(2) The board's approval of pilot or demonstration research projects may include the granting of an exception to the rules adopted under the Texas Pharmacy Act, but may not include an exception from any law relating to the practice of pharmacy. Such exception to the rules shall be for a specified period of time and such period may not exceed 18 months.

(3) The board may extend the time an exception to a rule is granted as necessary for the board to adopt an amendment or modification of the rule.

(c) Procedures for applying for approval of pilot or demonstration research projects. A person who wishes the board to consider approval of a pilot or demonstration research project shall submit to the board a petition for approval which contains at least the following information:

(1) name, address, telephone number, and pharmacist's license number of the pharmacist responsible for overseeing the project;

(2) specific location and, if a pharmacy, the pharmacy license number where the proposed pilot or demonstration project will be conducted;
(3) a detailed summary of the proposed pilot or demonstration project which includes:
(A) the goals, hypothesis, and/or objectives of the proposed project;
(B) a full explanation of the project and how it will be conducted;
(C) the time frame for the project including the proposed start date and length of study. Such time frame may not exceed 18 months;
(D) background information and/or literature review to support the proposal;
(E) the rule(s) that will have to be waived in order to complete the project and a request to waive the rule(s);
(F) procedures to be used during the project to ensure that the public's health and safety are not compromised as a result of the rule waiver.

(d) Review and approval or denial of the proposed projects.
(1) On receipt of a petition for approval of a pilot or demonstration research project, board staff shall initially review the petition for completeness and appropriateness. If the petition is incomplete or inappropriate for board consideration for any reason, staff shall return the petition with a letter of explanation. Such review shall be completed within 30 working days of receipt of the petition.
(2) Once board staff has determined that the petition is complete and appropriate, a task force composed of board staff, at least one board member and, if deemed necessary, resource personnel appointed by the board president, shall review the petition and make a written recommendation to the board regarding approval. Such recommendation shall be presented to the board at the next regularly scheduled meeting of the board that occurs at least three weeks after completion of the review and written recommendation.
(3) A copy of the recommendation shall be provided to the petitioner and the board at least two weeks prior to the board meeting.
(4) Both the petitioner and a representative of the task force shall be given equal time for presentations to the board.
(5) Upon hearing the presentations, the board shall either approve or deny the petition. If the board approves the petition, the approval:
(A) shall be specific for that project and for a specific time period; and
(B) may include conditions or qualifications, if deemed appropriate by the board.
(6) The board or its representatives shall be allowed to inspect and review the project documentation and site at any time during the review process and after the project is approved.

(e) Presentation of results to the board.
(1) The pharmacist responsible for overseeing the project shall forward to the board a summary of the results of the project and conclusions drawn from the results within three months after completion of the project.
(2) A task force composed of board staff, at least one board member and, if deemed necessary, resource personnel appointed by the board president, shall review the results and make written recommendations to the board regarding the results of the project.
(3) The board will receive the report of the task force at the next regularly scheduled meeting of the board that occurs at least three weeks after the task force has completed its review and issued written recommendations.
(4) A copy of the task force recommendation shall be provided to the petitioner and the board at least two weeks prior to the board meeting.
(5) Both the petitioner and a representative of the task force shall be given equal time for presentations to the board.

§291.27 Confidentiality

(a) A pharmacist shall provide adequate security of prescription drug orders, medication orders, and patient medication records to prevent indiscriminate or unauthorized access to confidential health information. If prescription drug orders,

requests for refill authorization, or other confidential health information are not transmitted directly between a pharmacy and a physician but are transmitted through a data communication device, confidential health information may not be accessed or maintained by the operator of the data communication device unless specifically authorized to obtain the confidential information by this section.

(b) Confidential records are privileged and may be released only to:

(1) the patient or the patient's agent;

(2) a practitioner or another pharmacist if, in the pharmacist's professional judgement, the release is necessary to protect the patient's health and well being;

(3) the board or to a person or another state or federal agency authorized by law to receive the confidential record;

(4) a law enforcement agency engaged in investigation of a suspected violation of Chapter 481 or 483, Health and Safety Code, or the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. Section 801 et seq.);

(5) a person employed by a state agency that licenses a practitioner, if the person is performing the person's official duties; or

(6) an insurance carrier or other third party payor authorized by a patient to receive such information.

(c) A pharmacy shall provide written policies and procedures to prohibit the unauthorized disclosure of confidential records.

§291.28 Access to Confidential Records

(a) Access to confidential records. A pharmacy shall comply with the request of a patient or a patient's agent to inspect or obtain a copy of the patient's confidential records maintained by the pharmacy, as defined in §551.003(10) of the Act. A pharmacy shall comply with all relevant state and federal laws regarding release of confidential records to third party requestors.

(b) Form of request. The pharmacy may require a patient or a patient's agent or any authorized third party to make requests for confidential records in writing, provided such a requirement has been communicated to the requestor.

(c) Timely action by pharmacy. The pharmacy must respond to a request for confidential records in a timely manner.

(1) The pharmacy must respond to a request for confidential records no later than fifteen days after receipt of the request by providing a copy of the records or, with the consent of the requestor, a summary or explanation of such information.

(2) The pharmacy must provide confidential records as requested in a mutually agreed upon format.

(3) Access to confidential records may be expedited at the request of a patient or a patient's agent if there is a medical emergency. The pharmacy must respond to a request for expedited access to confidential records within 24 hours if the records are maintained at the pharmacy or within 72 hours if the records are stored off-site. The pharmacy may charge a reasonable fee, in addition to the fees outlined in subsection (d) of this section, of no more than $25.00 for expediting a request for access to confidential records.

(d) Fees. The pharmacy may charge a reasonable, cost-based fee for providing a copy of confidential records or a summary or explanation of such information.

(1) A reasonable fee shall be a charge of no more than $50.00 for the first twenty pages and $0.50 per page for every page thereafter. A reasonable fee shall include only the cost of:

(A) copying, including the cost of supplies for and labor of copying;

(B) postage, when the individual has requested the records be mailed; and

(C) preparing an explanation or summary of the protected health information, if appropriate and consented to by the patient or patient's agent.

(2) If an affidavit is requested certifying that the information is a true and correct copy of the records, a reasonable fee of no more than $15.00 may be charged for executing the affidavit.

(3) If an affidavit or questionnaire accompanies the request, the pharmacy may charge a reasonable fee of no more than $50.00 to complete the written response.

§291.29 Professional Responsibility of Pharmacists

(a) A pharmacist shall exercise sound professional judgment with respect to the accuracy and authenticity of any prescription drug order dispensed. If the pharmacist questions the accuracy or authenticity of a prescription drug order, the pharmacist shall verify the order with the practitioner prior to dispensing.

(b) A pharmacist shall make every reasonable effort to ensure that any prescription drug order, regardless of the means of transmission, has been issued for a legitimate medical purpose by a practitioner in the course of medical practice. A pharmacist shall not dispense a prescription drug if the pharmacist knows or should have known that the order for such drug was issued without a valid pre-existing patient-practitioner relationship as defined by the Texas Medical Board in 22 Texas Administrative Code (TAC) §190.8 (relating to Violation Guidelines) or without a valid prescription drug order.

(1) A prescription drug order may not be dispensed or delivered by means of the Internet unless pursuant to a valid prescription that was issued for a legitimate medical purpose in the course of medical practice by a practitioner, or practitioner covering for another practitioner.

(2) A prescription drug order may not be dispensed or delivered if the pharmacist has reason to suspect that the prescription drug order may have been authorized in the absence of a valid patient-practitioner relationship, or otherwise in violation of the practitioner's standard of practice to include that the practitioner:

(A) did not establish a diagnosis through the use of acceptable medical practices for the treatment of patient's condition;

(B) prescribed prescription drugs that were not necessary for the patient due to a lack of a valid medical need or the lack of a therapeutic purpose for the prescription drugs; or

(C) issued the prescriptions outside the usual course of medical practice.

(3) Notwithstanding the provisions of this subsection and as authorized by the Texas Medical Board in 22 TAC §190.8, a pharmacist may dispense a prescription when a physician has not established a professional relationship with a patient if the prescription is for medications for:

(A) sexually transmitted diseases for partners of the physician's established patient; or

(B) 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.

(c) If a pharmacist has reasons to suspect that a prescription was authorized solely based on the results of a questionnaire and/or in the absence of a documented patient evaluation including a physical examination, the pharmacist shall ascertain if that practitioner's standard of practice allows that practitioner to authorize a prescription under such circumstances. Reasons to suspect that a prescription may have been authorized in the absence of a valid patient-practitioner relationship or in violation of the practitioner's standard of practice include:

(1) the number of prescriptions authorized on a daily basis by the practitioner;

(2) a disproportionate number of patients of the practitioner receive controlled substances;

(3) the manner in which the prescriptions are authorized by the practitioner or received by the pharmacy;

(4) the geographical distance between the practitioner and the patient or between the pharmacy and the patient;

(5) knowledge by the pharmacist that the prescription was issued solely based on answers to a questionnaire;

(6) knowledge by the pharmacist that the pharmacy he/she works for directly or indirectly participates in or is otherwise associated with an Internet site that markets prescription drugs to the public without requiring the patient to provide a valid prescription order from the patients practitioner; or

(7) knowledge by the pharmacist that the patient has exhibited doctor-shopping or pharmacy-shopping tendencies.

(d) A pharmacist shall ensure that prescription drug orders for the treatment of chronic pain have been issued in accordance with the guidelines set forth by the Texas Medical Board in 22 TAC §170.3 (relating to Guidelines), prior to dispensing or delivering such prescriptions.

(e) A prescription drug order may not be dispensed or delivered if issued by a practitioner practicing at a pain management clinic that is not in compliance with the rules of the Texas Medical Board in 22 TAC §§195.1 - 195.4

(relating to Pain Management Clinics). A prescription drug order from a practitioner practicing at a certified pain management clinic is not automatically valid and does not negate a pharmacist's responsibility to determine that the prescription is valid and has been issued for a legitimate or appropriate medical purpose.
(f) A pharmacist shall not dispense a prescription drug if the pharmacist knows or should know the prescription drug order is fraudulent or forged. A pharmacist shall make every reasonable effort to prevent inappropriate dispensing due to fraudulent, forged, invalid, or medically inappropriate prescriptions in violation of a pharmacist's corresponding responsibility. The following patterns (i.e., red flag factors) are relevant to preventing the non-therapeutic dispensing of controlled substances and shall be considered by evaluating the totality of the circumstances rather than any single factor:

(1) the pharmacy dispenses a reasonably discernible pattern of substantially identical prescriptions for the same controlled substances, potentially paired with other drugs, for numerous persons, indicating a lack of individual drug therapy in prescriptions issued by the practitioner;
(2) the pharmacy operates with a reasonably discernible pattern of overall low prescription dispensing volume, maintaining relatively consistent 1:1 ratio of controlled substances to dangerous drugs and/or over-the-counter products dispensed as prescriptions;
(3) prescriptions by a prescriber presented to the pharmacy are routinely for controlled substances commonly known to be abused drugs, including opioids, benzodiazepines, muscle relaxants, psychostimulants, and/or cough syrups containing codeine, or any combination of these drugs;
(4) prescriptions for controlled substances by a prescriber presented to the pharmacy contain nonspecific or no diagnoses, or lack the intended use of the drug;
(5) prescriptions for controlled substances are commonly for the highest strength of the drug and/or for large quantities (e.g., monthly supply), indicating a lack of individual drug therapy in prescriptions issued by the practitioner;
(6) dangerous drugs or over-the-counter products (e.g., multi-vitamins or laxatives) are consistently added by the prescriber to prescriptions for controlled substances presented to the pharmacy, indicating a lack of individual drug therapy in prescriptions issued by the practitioner;
(7) upon contacting the practitioner's office regarding a controlled substance prescription, the pharmacist is unable to engage in a discussion with the actual prescribing practitioner; the practitioner fails to appropriately address based on a reasonable pharmacist standard the pharmacist's concerns regarding the practitioner's prescribing practices with regard to the prescription; and/or the practitioner is unwilling to provide additional information, such as treatment goals and/or prognosis with prescribed drug therapy;
(8) the practitioner's clinic is not registered as, and not exempted from registration as, a pain management clinic by the Texas Medical Board, despite prescriptions by the practitioner presented to the pharmacy indicating that the practitioner is mostly prescribing opioids, benzodiazepines, barbiturates, or carisoprodol, but not including suboxone, or any combination of these drugs;
(9) the controlled substance(s) or the quantity of the controlled substance(s) prescribed are inconsistent with the practitioner's area of medical practice;
(10) the Texas Prescription Monitoring Program indicates the person presenting the prescriptions is obtaining similar drugs from multiple practitioners, and/or that the persons is being dispensed similar drugs at multiple pharmacies;
(11) multiple persons with the same address present substantially similar controlled substance prescriptions from the same practitioner;
(12) persons consistently pay for controlled substance prescriptions with cash or cash equivalents more often than through insurance;
(13) persons presenting controlled substance prescriptions are doing so in such a manner that varies from the manner in which persons routinely seek pharmacy services (e.g., persons arriving in the same vehicle with prescriptions from same practitioner; one person seeking to pick up prescriptions for multiple others; drugs referenced by street names;

(14) the pharmacy charges and persons are willing to pay significantly more for controlled substances relative to nearby pharmacies;
(15) the pharmacy routinely orders controlled substances from more than one drug supplier;
(16) the pharmacy has been discontinued by a drug supplier related to controlled substance orders;
(17) the pharmacy has a sporadic and inconsistent dispensing volume (including zero dispensing);
(18) the pharmacy does not maintain normal operational hours each week from Monday through Friday; and
(19) the pharmacy has been previously warned or disciplined by the Texas State Board of Pharmacy for inappropriate dispensing of controlled substances.

(g) Prescriptions issued as a result of telemedicine medical services or teledentistry dental services.

(1) The validity of a prescription issued as a result of telemedicine medical services or teledentistry dental services is determined by the same standards that would apply to the issuance of the prescription in an in-person setting.

(2) A valid prescription issued as a result of telemedicine medical services or teledentistry dental services must:

(A) be issued for a legitimate medical purpose by a practitioner as part of a practitioner-patient relationship as set out in Texas Occupations Code §111.005; and

(B) meet all other applicable laws before prescribing, dispensing, delivering, or administering a dangerous drug or controlled substance.

SUBCHAPTER B – COMMUNITY PHARMACY (CLASS A)

§291.31 Definitions

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

(1) Accurately as prescribed--Dispensing, delivering, and/or distributing a prescription drug order:

(A) to the correct patient (or agent of the patient) for whom the drug or device was prescribed;

(B) with the correct drug in the correct strength, quantity, and dosage form ordered by the practitioner; and

(C) with correct labeling (including directions for use) as ordered by the practitioner. Provided, however, that nothing herein shall prohibit pharmacist substitution if substitution is conducted in strict accordance with applicable laws and rules, including Chapter 562 of the Texas Pharmacy Act.

(2) Act--The Texas Pharmacy Act, Chapters 551 - 569, Occupations Code, as amended.

(3) Advanced practice registered nurse--A registered nurse licensed by the Texas Board of Nursing to practice as an advanced practice registered nurse on the basis of completion of an advanced education program. The term includes nurse practitioner, nurse midwife, nurse anesthetist, and clinical nurse specialist. The term is synonymous with advanced nurse practitioner and advanced practice nurse.

(4) Automated checking device--A device that confirms that the correct drug and strength has been labeled with the correct label for the correct patient prior to delivery of the drug to the patient.

(5) Automated counting device--An automated device that is loaded with bulk drugs and counts and/or packages (i.e., fills a vial or other container) a specified quantity of dosage units of a designated drug product.

(6) Automated pharmacy dispensing system--A system that automatically performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, and labeling for dispensing and delivery of medications, and that collects, controls, and maintains all transaction information. "Automated pharmacy dispensing system" does not mean "Automated compounding or counting device" or "Automated medication supply device."

(7) Beyond use date--The date beyond which a product should not be used.

(8) Board--The Texas State Board of Pharmacy.

(9) Common ownership--Two or more pharmacies with an identical owner of record with the board or that have owners of record with the board that are a parent, subsidiary, or affiliate of one another under §1.002, Business Organizations Code.
(10) Confidential record--Any health-related record that contains information that identifies an individual and that is maintained by a pharmacy or pharmacist, such as a patient medication record, prescription drug order, or medication order.
(11) Controlled substance--A drug, immediate precursor, or other substance listed in Schedules I - V or Penalty Groups 1 - 4 of the Texas Controlled Substances Act, as amended (Chapter 481, Health and Safety Code), or a drug, immediate precursor, or other substance included in Schedules I, II, III, IV, or V of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public Law 91-513).
(12) Dangerous drug--A drug or device that:
(A) is not included in Penalty Groups 1 - 4 of the Texas Controlled Substances Act, as amended, (Chapter 481, Health and Safety Code), and is unsafe for self-medication; or
(B) bears or is required to bear the legend:
(i) "Caution: federal law prohibits dispensing without prescription" or "Rx only" or another legend that complies with federal law; or
(ii) "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian."
(13) Data communication device--An electronic device that receives electronic information from one source and transmits or routes it to another (e.g., bridge, router, switch or gateway).
(14) Deliver or delivery--The actual, constructive, or attempted transfer of a prescription drug or device or controlled substance from one person to another, whether or not for a consideration.
(15) Designated agent--
(A) a licensed nurse, physician assistant, pharmacist, or other individual designated by a practitioner to communicate prescription drug orders to a pharmacist;
(B) a licensed nurse, physician assistant, or pharmacist employed in a health care facility to whom the practitioner communicates a prescription drug order;
(C) an advanced practice registered nurse or physician assistant authorized by a practitioner to prescribe or order drugs or devices under Chapter 157 of the Medical Practice Act (Subtitle B, Occupations Code); or
(D) a person who is a licensed vocational nurse or has an education equivalent to or greater than that required for a licensed vocational nurse designated by the practitioner to communicate prescriptions for an advanced practice registered nurse or physician assistant authorized by the practitioner to sign prescription drug orders under Chapter 157 of the Medical Practice Act (Subtitle B, Occupations Code).
(16) Dispense--Preparing, packaging, compounding, or labeling for delivery a prescription drug or device in the course of professional practice to an ultimate user or his agent by or pursuant to the lawful order of a practitioner.
(17) Dispensing error--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.
(18) Dispensing pharmacist--The pharmacist responsible for the final check of the dispensed prescription before delivery to the patient.
(19) Distribute--The delivery of a prescription drug or device other than by administering or dispensing.
(20) Downtime--Period of time during which a data processing system is not operable.
(21) Drug regimen review--An evaluation of prescription drug orders and patient medication records for:
(A) known allergies;
(B) rational therapy-contraindications;
(C) reasonable dose and route of administration;

(D) reasonable directions for use;
(E) duplication of therapy;
(F) drug-drug interactions;
(G) drug-food interactions;
(H) drug-disease interactions;
(I) adverse drug reactions; and
(J) proper utilization, including overutilization or underutilization.

(22) Electronic prescription drug order--A prescription drug order that is generated on an electronic application and transmitted as an electronic data file.

(23) Electronic signature--A unique security code or other identifier which specifically identifies the person entering information into a data processing system. A facility which utilizes electronic signatures must:

(A) maintain a permanent list of the unique security codes assigned to persons authorized to use the data processing system; and

(B) have an ongoing security program which is capable of identifying misuse and/or unauthorized use of electronic signatures.

(24) Electronic verification process--An electronic verification, bar code verification, weight verification, radio frequency identification (RFID), or similar electronic process or system that accurately verifies that medication has been properly dispensed and labeled by, or loaded into, an automated pharmacy dispensing system.

(25) Full-time pharmacist--A pharmacist who works in a pharmacy from 30 to 40 hours per week or, if the pharmacy is open less than 60 hours per week, one-half of the time the pharmacy is open.

(26) Hard copy--A physical document that is readable without the use of a special device.

(27) Hot water--The temperature of water from the pharmacy's sink maintained at a minimum of 105 degrees F (41 degrees C).

(28) Medical Practice Act--The Texas Medical Practice Act, Subtitle B, Occupations Code, as amended.

(29) Medication order--A written order from a practitioner or an oral order from a practitioner or his authorized agent for administration of a drug or device.

(30) New prescription drug order--A prescription drug order that has not been dispensed to the patient in the same strength and dosage form by this pharmacy within the last year.

(31) Original prescription--The:

(A) original written prescription drug order; or

(B) original oral or electronic prescription drug order reduced to writing either manually or electronically.

(32) Owner of record--The direct owner of the pharmacy provided on the pharmacy's application for a pharmacy license or most recent approved change of ownership form.

(33) Part-time pharmacist--A pharmacist who works less than full-time.

(34) Patient counseling--Communication by the pharmacist of information to the patient or patient's agent in order to improve therapy by ensuring proper use of drugs and devices.

(35) Patient med-pak--A package prepared by a pharmacist for a specific patient comprised of a series of containers and containing two or more prescribed solid oral dosage forms. The patient med-pak is so designed or each container is so labeled as to indicate the day and time, or period of time, that the contents within each container are to be taken.

(36) Pharmaceutical care--The provision of drug therapy and other pharmaceutical services intended to assist in the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process.

(37) Pharmacist-in-charge--The pharmacist designated on a pharmacy license as the pharmacist who has the authority or responsibility for a pharmacy's compliance with laws and rules pertaining to the practice of pharmacy.

(38) Pharmacy technician--An individual who is registered with the board as a pharmacy technician and whose responsibility in a pharmacy is to provide technical services that do not require professional judgment regarding preparing and distributing drugs and who works under the direct supervision of and is responsible to a pharmacist.
(39) Pharmacy technician trainee--An individual who is registered with the board as a pharmacy technician trainee and is authorized to participate in a pharmacy's technician training program.
(40) Physician assistant--A physician assistant recognized by the Texas Medical Board as having the specialized education and training required under Subtitle B, Chapter 157, Occupations Code, and issued an identification number by the Texas Medical Board.
(41) 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 this 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 registered nurse or physician assistant to whom a physician has delegated the authority to prescribe or order drugs or devices under Chapter 157 of the Medical Practice Act (Subtitle B, Occupations Code) or, for the purpose of this subchapter, a pharmacist who practices in a hospital, hospital-based clinic, or an academic health care institution and to whom a physician has delegated the authority to sign a prescription for a dangerous drug under §157.101, Occupations Code.

(42) Prepackaging--The act of repackaging and relabeling quantities of drug products from a manufacturer's original commercial container into a prescription container, unit-dose packaging, or multi-compartment container for dispensing by a pharmacist to the ultimate consumer, including dispensing through the use of an automated pharmacy dispensing system or automated checking device.
(43) Prescription department--The area of a pharmacy that contains prescription drugs.
(44) Prescription drug--

(A) a substance for which federal or state law requires a prescription before the substance may be legally dispensed to the public;
(B) a drug or device that under federal law is required, before being dispensed or delivered, to be labeled with the statement:

(i) "Caution: federal law prohibits dispensing without prescription" or "Rx only" or another legend that complies with federal law; or
(ii) "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian"; or

(C) a drug or device that is required by federal or state statute or regulation to be dispensed on prescription or that is restricted to use by a practitioner only.

(45) Prescription drug order--

(A) a written order from a practitioner or an oral order from a practitioner or his authorized agent to a pharmacist for a drug or device to be dispensed; or
(B) a written order or an oral order pursuant to Subtitle B, Chapter 157, Occupations Code.

(46) Prospective drug use review--A review of the patient's drug therapy and prescription drug order or medication order prior to dispensing or distributing the drug.
(47) State--One of the 50 United States of America, a U.S. territory, or the District of Columbia.

(48) Texas Controlled Substances Act--The Texas Controlled Substances Act, Health and Safety Code, Chapter 481, as amended.
(49) Written protocol--A physician's order, standing medical order, standing delegation order, or other order or protocol as defined by rule of the Texas Medical Board under the Texas Medical Practice Act.

§291.32 Personnel

(a) Pharmacist-in-charge.

(1) General.

(A) Each Class A pharmacy shall have one pharmacist-in-charge who is employed on a full-time basis and who may be the pharmacist-in-charge for only one such pharmacy; provided, however, such pharmacist-in-charge may be the pharmacist-in-charge of:

(i) more than one Class A pharmacy, if the additional Class A pharmacies are not open to provide pharmacy services simultaneously; or

(ii) during an emergency, up to two Class A pharmacies open simultaneously if the pharmacist-in-charge works at least 10 hours per week in each pharmacy for no more than a period of 30 consecutive days.

(B) The pharmacist-in-charge shall comply with the provisions of §291.17 of this title (relating to Inventory Requirements).

(C) The pharmacist-in-charge of a Class A pharmacy may not serve as the pharmacist-in-charge of a Class B pharmacy or a Class C pharmacy with 101 beds or more.

(2) Responsibilities. The pharmacist-in-charge shall have responsibility for the practice of pharmacy at the pharmacy for which he or she is the pharmacist-in-charge. The pharmacist-in-charge may advise the owner on administrative or operational concerns. The pharmacist-in-charge shall have responsibility for, at a minimum, the following:

(A) educating and training of pharmacy technicians and pharmacy technician trainees;

(B) supervising a system to assure appropriate procurement of prescription drugs and devices and other products dispensed from the Class A pharmacy;

(C) disposing of and distributing drugs from the Class A pharmacy;

(D) storing all materials, including drugs, chemicals, and biologicals;

(E) maintaining records of all transactions of the Class A pharmacy necessary to maintain accurate control over and accountability for all pharmaceutical materials required by applicable state and federal laws and sections;

(F) supervising a system to assure maintenance of effective controls against the theft or diversion of prescription drugs, and records for such drugs;

(G) adhering to policies and procedures regarding the maintenance of records in a data processing system such that the data processing system is in compliance with Class A (community) pharmacy requirements;

(H) legally operating the pharmacy, including meeting all inspection and other requirements of all state and federal laws or sections governing the practice of pharmacy; and

(I) if the pharmacy uses an automated pharmacy dispensing system, shall be responsible for the following:

(i) consulting with the owner concerning and adherence to the policies and procedures for system operation, safety, security, accuracy and access, patient confidentiality, prevention of unauthorized access, and malfunction;

(ii) inspecting medications in the automated pharmacy dispensing system, at least monthly, for expiration date, misbranding, physical integrity, security, and accountability;

(iii) assigning, discontinuing, or changing personnel access to the automated pharmacy dispensing system;

(iv) ensuring that pharmacy technicians, pharmacy technician trainees, and licensed healthcare professionals performing any services in connection with an automated pharmacy dispensing system have been properly trained on the use of the system and can demonstrate comprehensive knowledge of the written policies and procedures for operation of the system; and

(v) ensuring that the automated pharmacy dispensing system is stocked accurately and an accountability record is maintained in accordance with the written policies and procedures of operation.

(b) Owner. The owner of a Class A 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) establishing policies for procurement of prescription drugs and devices and other products dispensed from the Class A pharmacy;

(2) establishing policies and procedures for the security of the prescription department including the maintenance of effective controls against the theft or diversion of prescription drugs;

(3) if the pharmacy uses an automated pharmacy dispensing system, reviewing and approving all policies and procedures for system operation, safety, security, accuracy and access, patient confidentiality, prevention of unauthorized access, and malfunction;

(4) providing the pharmacy with the necessary equipment and resources commensurate with its level and type of practice; and

(5) establishing policies and procedures regarding maintenance, storage, and retrieval of records in a data processing system such that the system is in compliance with state and federal requirements.

(c) Pharmacists.

(1) General.

(A) The pharmacist-in-charge shall be assisted by sufficient number of additional licensed pharmacists as may be required to operate the Class A pharmacy competently, safely, and adequately to meet the needs of the patients of the pharmacy.

(B) All pharmacists shall assist the pharmacist-in-charge in meeting his or her responsibilities in ordering, dispensing, and accounting for prescription drugs.

(C) Pharmacists are solely responsible for the direct supervision of pharmacy technicians and pharmacy technician trainees and for designating and delegating duties, other than those listed in paragraph (2) of this subsection, to pharmacy technicians and pharmacy technician trainees. Each pharmacist shall be responsible for any delegated act performed by pharmacy technicians and pharmacy technician trainees under his or her supervision.

(D) Pharmacists shall directly supervise pharmacy technicians and pharmacy technician trainees who are entering prescription data into the pharmacy's data processing system by one of the following methods.

(i) Physically present supervision. A pharmacist shall be physically present to directly supervise a pharmacy technician or pharmacy technician trainee who is entering prescription data into the data processing system. Each prescription entered into the data processing system shall be verified at the time of data entry. If the pharmacist is not physically present due to a temporary absence as specified in §291.33(b)(3) of this title (relating to Operational Standards), on return the pharmacist must:

(I) conduct a drug regimen review for the prescriptions data entered during this time period as specified in §291.33(c)(2) of this title; and

(II) verify that prescription data entered during this time period was entered accurately.

(ii) Electronic supervision. A pharmacist may electronically supervise a pharmacy technician or pharmacy technician trainee who is entering prescription data into the data processing system provided the pharmacist:

(I) has the ability to immediately communicate directly with the technician/trainee;

(II) has immediate access to any original document containing prescription information or other information related to the dispensing of the prescription. Such access may be through imaging technology provided the pharmacist has the ability to review the original, hardcopy documents if needed for clarification; and

(III) verifies the accuracy of the data entered information prior to the release of the information to the system for storage and/or generation of the prescription label.

(iii) Electronic verification of data entry by pharmacy technicians or pharmacy technician trainees. A pharmacist may electronically verify the data entry of prescription information into a data processing system provided:

(I) the pharmacist has the ability to immediately communicate directly with the technician/trainee;

(II) the pharmacist electronically conducting the verification is either a:

(-a-) Texas licensed pharmacist; or

(-b-) pharmacist employed by a Class E pharmacy that:

(-1-) has the same owner as the Class A pharmacy where the pharmacy technicians/trainees are located; or

(-2-) has entered into a written contract or agreement with the Class A pharmacy, which outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations;

(III) the pharmacy establishes controls to protect the privacy and security of confidential records; and

(IV) the pharmacy keeps permanent records of prescriptions electronically verified for a period of two years.

(E) All pharmacists, while on duty, shall be responsible for the legal operation of the pharmacy and for complying with all state and federal laws or rules governing the practice of pharmacy.

(F) A dispensing pharmacist shall be responsible for and ensure that the drug is dispensed and delivered safely and accurately as prescribed, unless the pharmacy's data processing system can record the identity of each pharmacist involved in a specific portion of the dispensing processing. If the system can track the identity of each pharmacist involved in the dispensing process, each pharmacist involved in the dispensing process shall be responsible for and ensure that the portion of the process the pharmacist is performing results in the safe and accurate dispensing and delivery of the drug as prescribed. The dispensing process shall include, but not be limited to, drug regimen review and verification of accurate prescription data entry, including prescriptions placed on hold, packaging, preparation, compounding, transferring, labeling, and performance of the final check of the dispensed prescription. An intern has the same responsibilities described in this subparagraph as a pharmacist but must perform his or her duties under the supervision of a pharmacist.

(2) Duties. Duties which may only be performed by a pharmacist are as follows:

(A) receiving oral prescription drug orders for controlled substances and reducing these orders to writing, either manually or electronically;

(B) interpreting prescription drug orders;

(C) selecting drug products;

(D) performing the final check of the dispensed prescription before delivery to the patient to ensure that the prescription has been dispensed accurately as prescribed;

(E) communicating to the patient or patient's agent information about the prescription drug or device which in the exercise of the pharmacist's professional judgment, the pharmacist deems significant, as specified in §291.33(c) of this title;

(F) communicating to the patient or the patient's agent on his or her request information concerning any prescription drugs dispensed to the patient by the pharmacy;

(G) assuring that a reasonable effort is made to obtain, record, and maintain patient medication records;

(H) interpreting patient medication records and performing drug regimen reviews;

(I) performing a specific act of drug therapy management for a patient delegated to a pharmacist by a written protocol from a physician licensed in this state in compliance with the Medical Practice Act;

(J) verifying that controlled substances listed on invoices are received by clearly recording his/her initials and date of receipt of the controlled substances; and

(K) transferring or receiving a transfer of original prescription information for a controlled substance on behalf of a patient.

(3) Special requirements for compounding. All pharmacists engaged in compounding non-sterile preparations shall meet the training requirements specified in §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

(d) Pharmacy Technicians and Pharmacy Technician Trainees.

(1) General.

(A) All pharmacy technicians and pharmacy technician trainees shall meet the training requirements specified in §297.6 of this title (relating to Pharmacy Technician and Pharmacy Technician Trainee Training).

(B) Special requirements for compounding. All pharmacy technicians and pharmacy technician trainees engaged in compounding non-sterile preparations shall meet the training requirements specified in §291.131 of this title.

(2) Duties.

(A) Pharmacy technicians and pharmacy technician trainees may not perform any of the duties listed in subsection (c)(2) of this section.

(B) A pharmacist may delegate to pharmacy technicians and pharmacy technician trainees any nonjudgmental technical duty associated with the preparation and distribution of prescription drugs provided:

(i) unless otherwise provided under §291.33 of this subchapter, a pharmacist verifies the accuracy of all acts, tasks, and functions performed by pharmacy technicians and pharmacy technician trainees;

(ii) pharmacy technicians and pharmacy technician trainees are under the direct supervision of and responsible to a pharmacist; and

(iii) only pharmacy technicians and pharmacy technician trainees who have been properly trained on the use of an automated pharmacy dispensing system and can demonstrate comprehensive knowledge of the written policies and procedures for the operation of the system may be allowed access to the system.

(C) Pharmacy technicians and pharmacy technician trainees may perform only nonjudgmental technical duties associated with the preparation and distribution of prescription drugs, as follows:

(i) initiating and receiving refill authorization requests;

(ii) entering prescription data into a data processing system;

(iii) taking a stock bottle from the shelf for a prescription;

(iv) preparing and packaging prescription drug orders (i.e., counting tablets/capsules, measuring liquids and placing them in the prescription container);

(v) affixing prescription labels and auxiliary labels to the prescription container;

(vi) reconstituting medications;

(vii) prepackaging and labeling prepackaged drugs;
(viii) loading bulk unlabeled drugs into an automated dispensing system provided a pharmacist verifies that the system is properly loaded prior to use;
(ix) loading prepackaged containers previously verified by a pharmacist or manufacturer's unit of use packages into an automated dispensing system in accordance with §291.33(i)(2)(D)(III) of this subchapter;
(x) compounding non-sterile prescription drug orders; and
(xi) compounding bulk non-sterile preparations.

(D) In addition to the duties listed above in subparagraph (C) of this paragraph, pharmacy technicians may perform the following nonjudgmental technical duties associated with the preparation and distribution of prescription drugs:

(i) receiving oral prescription drug orders for dangerous drugs and reducing these orders to writing, either manually or electronically;
(ii) transferring or receiving a transfer of original prescription information for a dangerous drug on behalf of a patient; and
(iii) contacting a prescriber for information regarding an existing prescription for a dangerous drug.

(3) Ratio of on-site pharmacists to pharmacy technicians and pharmacy technician trainees.

(A) Except as provided in subparagraphs (B) and (C) of this paragraph, the ratio of on-site pharmacists to pharmacy technicians and pharmacy technician trainees may be 1:6, provided the pharmacist is on-site and a maximum of three of the six are pharmacy technician trainees. The ratio of pharmacists to pharmacy technician trainees may not exceed 1:3.

(B) Subparagraph (A) of this paragraph does not apply to a central fill pharmacy, as defined in §291.125 of this title (relating to Centralized Prescription Dispensing), that has no patient-facing contact. For purposes of this subparagraph, patient-facing contact means any direct interaction between a pharmacy employee and a patient or patient's agent.

(C) As specified in §568.006 of the Act, a Class A pharmacy may have a ratio of on-site pharmacists to pharmacy technicians/pharmacy technician trainees of 1:5 provided:

(i) the Class A pharmacy:

(I) dispenses no more than 20 different prescription drugs; and
(II) does not produce sterile preparations including intravenous or intramuscular drugs on-site; and

(ii) the following conditions are met:

(I) at least four are pharmacy technicians and not pharmacy technician trainees; and
(II) The pharmacy has written policies and procedures regarding the supervision of pharmacy technicians and pharmacy technician trainees, including requirements that the pharmacy technicians and pharmacy technician trainees included in a 1:5 ratio may be involved only in one process at a time. For example, a technician/trainee who is compounding non-sterile preparations or who is involved in the preparation of prescription drug orders may not also call physicians for authorization of refills.

(e) Identification of pharmacy personnel. All pharmacy personnel shall be identified as follows.

(1) Pharmacy technicians. All pharmacy technicians shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacy technician, or a certified pharmacy technician, if the technician maintains current certification with the Pharmacy Technician Certification Board or any other entity providing an examination approved by the board.

(2) Pharmacy technician trainees. All pharmacy technician trainees shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacy technician trainee.

(3) Pharmacist interns. All pharmacist interns shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacist intern.
(4) Pharmacists. All pharmacists shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacist.

§291.33 Operational Standards

(a) Licensing requirements.

(1) A Class A pharmacy shall register annually or biennially with the board on a pharmacy license application provided by the board, following the procedures as specified in §291.1 of this title (relating to Pharmacy License Application).
(2) A Class A 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).
(3) A Class A pharmacy which changes location and/or name shall notify the board as specified in §291.3 of this title.
(4) A Class A pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within ten days of the change, following the procedures as specified in §291.3 of this title.
(5) A Class A 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).
(6) A separate license is required for each principal place of business and only one pharmacy license may be issued to a specific location.
(7) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for the issuance and renewal of a license and the issuance of an amended license.
(8) A Class A pharmacy, licensed under the provisions of the Act, §560.051(a)(1), which also operates another type of pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(2) concerning Nuclear Pharmacy (Class B), is not required to secure a license for such other type of pharmacy; provided, however, such licensee is required to comply with the provisions of Subchapter C of this chapter (relating to Nuclear Pharmacy (Class B)), to the extent such sections are applicable to the operation of the pharmacy.
(9) A Class A pharmacy engaged in the compounding of non-sterile preparations shall comply with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).
(10) A Class A pharmacy shall not compound sterile preparations.
(11) A Class A pharmacy engaged in the provision of remote pharmacy services, including storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of this title (relating to Remote Pharmacy Services).
(12) Class A pharmacy engaged in centralized prescription dispensing and/or prescription drug or medication order processing shall comply with the provisions of §291.123 of this title (relating to Central Prescription Drug or Medication Order Processing) and/or §291.125 of this title (relating to Centralized Prescription Dispensing)

(b) Environment.

(1) General requirements.

(A) The pharmacy shall be arranged in an orderly fashion and kept clean. All required equipment shall be clean and in good operating condition.
(B) A Class A pharmacy shall have a sink with hot and cold running water within the pharmacy, exclusive of restroom facilities, available to all pharmacy personnel and maintained in a sanitary condition.
(C) A Class A pharmacy which serves the general public shall contain an area which is suitable for confidential patient counseling.

(i) Such counseling area shall be:

(I) easily accessible to both patient and pharmacists and not allow patient access to prescription drugs; and

(II) designed to maintain the confidentiality and privacy of the pharmacist/patient communication.

(ii) In determining whether the area is suitable for confidential patient counseling and designed to maintain the confidentiality and privacy of the pharmacist/patient communication, the board may consider factors such as the following:

(I) the proximity of the counseling area to the check-out or cash register area;

(II) the volume of pedestrian traffic in and around the counseling area;

(III) the presence of walls or other barriers between the counseling area and other areas of the pharmacy; and

(IV) any evidence of confidential information being overheard by persons other than the patient or patient's agent or the pharmacist or agents of the pharmacist.

(D) The pharmacy shall be properly lighted and ventilated.

(E) The temperature of the pharmacy shall be maintained within a range compatible with the proper storage of drugs. The temperature of the refrigerator shall be maintained within a range compatible with the proper storage of drugs requiring refrigeration.

(F) Animals, including birds and reptiles, shall not be kept within the pharmacy and in immediately adjacent areas under the control of the pharmacy. This provision does not apply to fish in aquariums, service animals accompanying disabled persons, or animals for sale to the general public in a separate area that is inspected by local health jurisdictions.

(G) If the pharmacy has flammable materials, the pharmacy shall have a designated area for the storage of flammable materials. Such area shall meet the requirements set by local and state fire laws.

(2) Security.

(A) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of prescription drugs, and records for such drugs.

(B) The prescription department shall be locked by key, combination or other mechanical or electronic means to prohibit unauthorized access when a pharmacist is not on-site except as provided in subparagraphs (C) and (D) of this paragraph and paragraph (3) of this subsection. The following is applicable:

(i) If the prescription department is closed at any time when the rest of the facility is open, the prescription department must be physically or electronically secured. The security may be accomplished by means such as floor to ceiling walls; walls, partitions, or barriers at least 9 feet 6 inches high; electronically monitored motion detectors; pull down sliders; or other systems or technologies that will secure the pharmacy from unauthorized entrance when the pharmacy is closed. Pharmacies licensed prior to June 1, 2009, shall be exempt from this provision unless the pharmacy changes location. Change of location shall include the relocation of the pharmacy within the licensed address. A pharmacy licensed prior to June 1, 2009 that files a change of ownership but does not change location shall be exempt from the provisions.

(ii) The pharmacy's key, combination, or other mechanical or electronic means of locking the pharmacy may not be duplicated without the authorization of the pharmacist-in-charge or owner.

(iii) At a minimum, the pharmacy must have a basic alarm system with off-site monitoring and perimeter and motion sensors. The pharmacy may have additional security by video surveillance camera systems.

(C) Prior to authorizing individuals to enter the prescription department, the pharmacist-in-charge or owner may designate persons who may enter the prescription department to perform functions, other

than dispensing functions or prescription processing, documented by the pharmacist-in-charge including access to the prescription department by other pharmacists, pharmacy personnel and other individuals. The pharmacy must maintain written documentation of authorized individuals other than individuals employed by the pharmacy who accessed the prescription department when a pharmacist is not on-site.

(D) Only persons designated either by name or by title including such titles as "relief" or "floater" pharmacist, in writing by the pharmacist-in-charge may unlock the prescription department except in emergency situations. An additional key to or instructions on accessing the prescription department may be maintained in a secure location outside the prescription department for use during an emergency or as designated by the pharmacist-in-charge.

(E) Written policies and procedures for the pharmacy's security shall be developed and implemented by the pharmacist-in-charge and/or the owner of the pharmacy. Such policies and procedures may include quarterly audits of controlled substances commonly abused or diverted; perpetual inventories for the comparison of the receipt, dispensing, and distribution of controlled substances; monthly reports from the pharmacy's wholesaler(s) of controlled substances purchased by the pharmacy; opening and closing procedures; product storage and placement; and central management oversight.

(3) Temporary absence of pharmacist.

(A) On-site supervision by pharmacist.

(i) If a pharmacy is staffed by only one pharmacist, the pharmacist may leave the prescription department for short periods of time without closing the prescription department and removing pharmacy technicians, pharmacy technician trainees, and other pharmacy personnel from the prescription department provided the following conditions are met:

(I) at least one pharmacy technician remains in the prescription department;

(II) the pharmacist remains on-site at the licensed location of the pharmacy and is immediately available;

(III) the pharmacist reasonably believes that the security of the prescription department will be maintained in his or her absence. If in the professional judgment of the pharmacist, the pharmacist determines that the prescription department should close during his or her absence, then the pharmacist shall close the prescription department and remove the pharmacy technicians, pharmacy technician trainees, and other pharmacy personnel from the prescription department during his or her absence; and

(IV) a notice is posted which includes the following information:

(-a-) the pharmacist is on a break and the time the pharmacist will return; and

(-b-) pharmacy technicians may begin the processing of prescription drug orders or refills brought in during the pharmacist's absence, but the prescription or refill may not be delivered to the patient or the patient's agent until the pharmacist verifies the accuracy of the prescription.

(ii) During the time a pharmacist is absent from the prescription department, only pharmacy technicians who have completed the pharmacy's training program may perform the following duties, provided a pharmacist verifies the accuracy of all acts, tasks, and functions performed by the pharmacy technicians prior to delivery of the prescription to the patient or the patient's agent:

(I) initiating and receiving refill authorization requests;

(II) entering prescription data into a data processing system;

(III) taking a stock bottle from the shelf for a prescription;

(IV) preparing and packaging prescription drug orders (e.g., counting tablets/capsules, measuring liquids, or placing them in the prescription container);

(V) affixing prescription labels and auxiliary labels to the prescription container;

(VI) prepackaging and labeling prepackaged drugs;

(VII) receiving oral prescription drug orders for dangerous drugs and reducing these orders to writing, either manually or electronically;
(VIII) transferring or receiving a transfer of original prescription information for dangerous drugs on behalf of a patient; and
(IX) contacting a prescriber for information regarding an existing prescription for a dangerous drug.

(iii) Upon return to the prescription department, the pharmacist shall:
(I) conduct a drug regimen review as specified in subsection (c)(2) of this section; and
(II) verify the accuracy of all acts, tasks, and functions performed by the pharmacy technicians prior to delivery of the prescription to the patient or the patient's agent.

(iv) An agent of the pharmacist may deliver a previously verified prescription to the patient or his or her agent provided a record of the delivery is maintained containing the following information:
(I) date of the delivery;
(II) unique identification number of the prescription drug order;
(III) patient's name;
(IV) patient's phone number or the phone number of the person picking up the prescription; and
(V) signature of the person picking up the prescription.

(v) Any prescription delivered to a patient when a pharmacist is not in the prescription department must meet the requirements for a prescription delivered to a patient as described in subsection (c)(1)(F) of this section.

(vi) During the times a pharmacist is absent from the prescription department a pharmacist intern shall be considered a registered pharmacy technician and may perform only the duties of a registered pharmacy technician.

(vii) In pharmacies with two or more pharmacists on duty, the pharmacists shall stagger their breaks and meal periods so that the prescription department is not left without a pharmacist on duty.

(B) Pharmacist is off-site.

(i) The prescription department must be secured with procedures for entry during the time that a pharmacy is not under the continuous on-site supervision of a pharmacist and the pharmacy is not open for pharmacy services.

(ii) Pharmacy technicians and pharmacy technician trainees may not perform any duties of a pharmacy technician or pharmacy technician trainee during the time that the pharmacist is off-site.

(iii) A pharmacy may use an automated dispensing and delivery system as specified in §291.121(d) of this title for pick-up of a previously verified prescription by a patient or patient's agent.

(iv) An agent of the pharmacist may deliver a previously verified prescription to a patient or patient's agent during short periods of time when a pharmacist is off-site, provided the following conditions are met:
(I) short periods of time may not exceed two consecutive hours in a 24 hour period;
(II) a notice is posted which includes the following information:
(-a-) the pharmacist is off-site and not present in the pharmacy;
(-b-) no new prescriptions may be prepared at the pharmacy but previously verified prescriptions may be delivered to the patient or the patient's agent; and
(-c-) the date/time when the pharmacist will return;

(III) the pharmacy must maintain documentation of the absences of the pharmacist(s); and

(IV) the prescription department is locked and secured to prohibit unauthorized entry.

(v) During the time a pharmacist is absent from the prescription department and is off-site, a record of prescriptions delivered must be maintained and contain the following information:

(I) date and time of the delivery;

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

(III) patient's name;

(IV) patient's phone number or the phone number of the person picking up the prescription; and

(V) signature of the person picking up the prescription.

(vi) Any prescription delivered to a patient when a pharmacist is not on-site at the pharmacy must meet the requirements for a prescription delivered to a patient as described in subsection (c)(1)(F) of this section.

(c) Prescription dispensing and delivery.

(1) Patient counseling and provision of drug information.

(A) To optimize drug therapy, a pharmacist shall communicate to the patient or the patient's agent information about the prescription drug or device which in the exercise of the pharmacist's professional judgment the pharmacist deems significant, such as the following:

(i) name and description of the drug or device;

(ii) dosage form, dosage, route of administration, and duration of drug therapy;

(iii) special directions and precautions for preparation, administration, and use by the patient;

(iv) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(v) techniques for self-monitoring of drug therapy;

(vi) proper storage;

(vii) refill information; and

(viii) action to be taken in the event of a missed dose.

(B) Such communication shall be:

(i) provided to new and existing patients of a pharmacy with each new prescription drug order. A new prescription drug order is one that has not been dispensed by the pharmacy to the patient in the same dosage and strength within the last year;

(ii) provided for any prescription drug order dispensed by the pharmacy on the request of the patient or patient's agent;

(iii) communicated orally unless the patient or patient's agent is not at the pharmacy or a specific communication barrier prohibits such oral communication;

(iv) documented by recording the initials or identification code of the pharmacist providing the counseling in the prescription dispensing record as follows:

(I) on the original hard-copy prescription, provided the counseling pharmacist clearly records his or her initials on the prescription for the purpose of identifying who provided the counseling;

(II) in the pharmacy's data processing system;

(III) in an electronic logbook; or

(IV) in a hard-copy log; and

(v) reinforced with written information relevant to the prescription and provided to the patient or patient's agent. The following is applicable concerning this written information:

(I) Written information must be in plain language designed for the patient and printed in an easily readable font size comparable to but no smaller than ten-point Times Roman.

This information may be provided to the patient in an electronic format, such as by e-mail, unless the patient or patient's agent requests the information in a hard-copy format.

(II) When a compounded preparation is dispensed, information shall be provided for the major active ingredient(s), if available.

(III) For new drug entities, if no written information is initially available, the pharmacist is not required to provide information until such information is available, provided:

(-a-) the pharmacist informs the patient or the patient's agent that the product is a new drug entity and written information is not available;

(-b-) the pharmacist documents the fact that no written information was provided; and

(-c-) if the prescription is refilled after written information is available, such information is provided to the patient or patient's agent.

(IV) The written information accompanying the prescription or the prescription label shall contain the statement "Do not flush unused medications or pour down a sink or drain." A drug product on a list developed by the Federal Food and Drug Administration of medicines recommended for disposal by flushing is not required to bear this statement.

(C) Only a pharmacist may verbally provide drug information to a patient or patient's agent and answer questions concerning prescription drugs. Non-pharmacist personnel and/or the pharmacy's computer system may not ask questions of a patient or patient's agent which are intended to screen and/or limit interaction with the pharmacist.

(D) Nothing in this subparagraph shall be construed as requiring a pharmacist to provide consultation when a patient or patient's agent refuses such consultation. The pharmacist shall document such refusal for consultation.

(E) In addition to the requirements of subparagraphs (A) - (D) of this paragraph, if a prescription drug order is delivered to the patient at the pharmacy, the following is applicable:

(i) So that a patient will have access to information concerning his or her prescription, a prescription may not be delivered to a patient unless a pharmacist is in the pharmacy, except as provided in subsection (b)(3) of this section.

(ii) Any prescription delivered to a patient when a pharmacist is not in the pharmacy must meet the requirements described in subparagraph (F) of this paragraph.

(F) In addition to the requirements of subparagraphs (A) - (D) of this paragraph, if a prescription drug order is delivered to the patient or his or her agent at the patient's residence or other designated location, the following is applicable:

(i) The information as specified in subparagraph (A) of this paragraph shall be delivered with the dispensed prescription in writing.

(ii) If prescriptions are routinely delivered outside the area covered by the pharmacy's local telephone service, the pharmacy shall provide a toll-free telephone line which is answered during normal business hours to enable communication between the patient and a pharmacist.

(iii) The pharmacist shall place on the prescription container or on a separate sheet delivered with the prescription container in both English and Spanish the local and, if applicable, toll-free telephone number of the pharmacy and the statement: "Written information about this prescription has been provided for you. Please read this information before you take the medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions at (insert the pharmacy's local and toll-free telephone numbers)."

(iv) 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.

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

(G) The provisions of this paragraph do not apply to patients in facilities where drugs are administered to patients by a person required to do so by the laws of the state (i.e., nursing homes).

(2) Pharmaceutical care services.

(A) Drug regimen review.

(i) For the purpose of promoting therapeutic appropriateness, a pharmacist shall, prior to or at the time of dispensing a prescription drug order, review the patient's medication record. Such review shall at a minimum identify clinically significant:

(I) known allergies;

(II) rational therapy-contraindications;

(III) reasonable dose and route of administration;

(IV) reasonable directions for use;

(V) duplication of therapy;

(VI) drug-drug interactions;

(VII) drug-food interactions;

(VIII) drug-disease interactions;

(IX) adverse drug reactions; and

(X) proper utilization, including overutilization or underutilization.

(ii) Upon identifying any clinically significant conditions, situations, or items listed in clause (i) of this subparagraph, the pharmacist shall take appropriate steps to avoid or resolve the problem including consultation with the prescribing practitioner. The pharmacist shall document such occurrences as specified in subparagraph (C) of this paragraph.

(iii) The drug regimen review may be conducted by remotely accessing the pharmacy's electronic database from outside the pharmacy by:

(I) an individual Texas licensed pharmacist employee of the pharmacy provided the pharmacy establishes controls to protect the privacy of the patient and the security of confidential records; or

(II) a pharmacist employed by a Class E pharmacy provided the pharmacies have entered into a written contract or agreement which outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations.

(iv) Prior to dispensing, 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.

(B) Other pharmaceutical care services which may be provided by pharmacists include, but are not limited to, the following:

(i) managing drug therapy as delegated by a practitioner as allowed under the provisions of the Medical Practice Act;

(ii) administering immunizations and vaccinations under written protocol of a physician;

(iii) managing patient compliance programs;

(iv) providing preventative health care services; and

(v) providing case management of patients who are being treated with high-risk or high-cost drugs, or who are considered "high risk" due to their age, medical condition, family history, or related concern.

(C) Documentation of consultation. When a pharmacist consults a prescriber as described in subparagraph (A) of this paragraph, the pharmacist shall document on the prescription or in the pharmacy's data processing system associated with the prescription such occurrences and shall include the following information:

(i) date the prescriber was consulted;

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

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

(iv) initials or identification code of the pharmacist performing the consultation clearly recorded for the purpose of identifying the pharmacist who performed the consultation.

(3) Substitution of generically equivalent drugs or interchangeable biological products. A pharmacist may dispense a generically equivalent drug or interchangeable biological product and shall comply with the provisions of §309.3 of this title (relating to Substitution Requirements).

(4) Substitution of dosage form.

(A) As specified in §562.012 of the Act, a pharmacist may dispense a dosage form of a drug product different from that prescribed, such as a tablet instead of a capsule or liquid instead of tablets, provided:

(i) the patient consents to the dosage form substitution; and

(ii) the dosage form so dispensed:

(I) contains the identical amount of the active ingredients as the dosage prescribed for the patient;

(II) is not an enteric-coated or time release product; and

(III) does not alter desired clinical outcomes.

(B) Substitution of dosage form may not include the substitution of a product that has been compounded by the pharmacist unless the pharmacist contacts the practitioner prior to dispensing and obtains permission to dispense the compounded product.

(5) Therapeutic Drug Interchange. A switch to a drug providing a similar therapeutic response to the one prescribed shall not be made without prior approval of the prescribing practitioner. This paragraph does not apply to generic substitution. For generic substitution, see the requirements of paragraph (3) of this subsection.

(A) The patient shall be notified of the therapeutic drug interchange prior to, or upon delivery of, the dispensed prescription to the patient. Such notification shall include:

(i) a description of the change;

(ii) the reason for the change;

(iii) whom to notify with questions concerning the change; and

(iv) instructions for return of the drug if not wanted by the patient.

(B) The pharmacy shall maintain documentation of patient notification of therapeutic drug interchange which shall include:

(i) the date of the notification;

(ii) the method of notification;

(iii) a description of the change; and

(iv) the reason for the change.

(C) The provisions of this paragraph do not apply to prescriptions for patients in facilities where drugs are administered to patients by a person required to do so by the laws of this state if the practitioner issuing the prescription has agreed to use of a formulary that includes a listing of therapeutic interchanges that the practitioner has agreed to allow. The pharmacy must maintain a copy of the formulary including a list of the practitioners that have agreed to the formulary and the signatures of these practitioners.

(6) Prescription containers.

(A) A drug dispensed pursuant to a prescription drug order shall be dispensed in a child-resistant container unless:

(i) the patient or the practitioner requests the prescription not be dispensed in a child-resistant container; or

(ii) the product is exempted from requirements of the Poison Prevention Packaging Act of 1970.

(B) A drug dispensed pursuant to a prescription drug order shall be dispensed in an appropriate container as specified on the manufacturer's container.

(C) Prescription containers or closures shall not be re-used. However, if a patient or patient's agent has difficulty reading or understanding a prescription label, a prescription container may be reused provided:

(i) the container is designed to provide audio-recorded information about the proper use of the prescription medication;

(ii) the container is reused for the same patient;

(iii) the container is cleaned; and

(iv) a new safety closure is used each time the prescription container is reused.

(7) Labeling.

(A) At the time of delivery of the drug, the dispensing container shall bear a label in plain language and printed in an easily readable font size, unless otherwise specified, with at least the following information:

(i) name, address and phone number of the pharmacy;

(ii) unique identification number of the prescription that is printed in an easily readable font size comparable to but no smaller than ten-point Times Roman;

(iii) date the prescription is dispensed;

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

(v) name of the prescribing practitioner;

(vi) if the prescription was signed by a pharmacist, the name of the pharmacist who signed the prescription for a dangerous drug under delegated authority of a physician as specified in Subtitle B, Chapter 157, Occupations Code;

(vii) name of the patient or if such drug was prescribed for an animal, the species of the animal and the name of the owner that is printed in an easily readable font size comparable to but no smaller than ten-point Times Roman. The name of 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;

(viii) instructions for use that are printed in an easily readable font size comparable to but no smaller than ten-point Times Roman;

(ix) quantity dispensed;

(x) appropriate ancillary instructions such as storage instructions or cautionary statements such as warnings of potential harmful effects of combining the drug product with any product containing alcohol;

(xi) if the prescription is for a Schedule II - IV controlled substance, the statement "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed";

(xii) if the pharmacist has selected a generically equivalent drug or interchangeable biological product pursuant to the provisions of the Act, Chapter 562, the statement "Substituted for

Brand Prescribed" or "Substituted for 'Brand Name'" where "Brand Name" is the actual name of the brand name product prescribed;

(xiii) the name and strength of the actual drug or biological product dispensed that is printed in an easily readable size comparable to but no smaller than ten-point Times Roman, unless otherwise directed by the prescribing practitioner;

(I) The name shall be either:

(-a-) the brand name; or

(-b-) if no brand name, then the generic drug or interchangeable biological product name and name of the manufacturer or distributor of such generic drug or interchangeable biological product. (The name of the manufacturer or distributor may be reduced to an abbreviation or initials, provided the abbreviation or initials are sufficient to identify the manufacturer or distributor. For combination drug products or non-sterile compounded drug preparations having no brand name, the principal active ingredients shall be indicated on the label.)

(II) Except as provided in clause (xii) of this subparagraph, the brand name of the prescribed drug or biological product shall not appear on the prescription container label unless it is the drug product actually dispensed.

(xiv) if the drug is dispensed in a container other than the manufacturer's original container, the date after which the prescription should not be used or beyond-use-date. Unless otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date the drug is dispensed or the manufacturer's expiration date, whichever is earlier. The beyond-use-date may be placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is not required on the label of a prescription dispensed to a person at the time of release from prison or jail if the prescription is for not more than a 10-day supply of medication; and

(xv) either on the prescription label or the written information accompanying the prescription, the statement "Do not flush unused medications or pour down a sink or drain." A drug product on a list developed by the Federal Food and Drug Administration of medicines recommended for disposal by flushing is not required to bear this statement.

(B) If the prescription label required in subparagraph (A) of this paragraph is printed in a type size smaller than ten-point Times Roman, the pharmacy shall provide the patient written information containing the information as specified in subparagraph (A) of this paragraph in an easily readable font size comparable to but no smaller than ten-point Times Roman.

(C) The label is not required to include the initials or identification code of the dispensing pharmacist as specified in subparagraph (A) of this paragraph if the identity of the dispensing pharmacist is recorded in the pharmacy's data processing system. The record of the identity of the dispensing pharmacist shall not be altered in the pharmacy's data processing system.

(D) The dispensing container is not required to bear the label as specified in subparagraph (A) of this paragraph if:

(i) the drug is prescribed for administration to an ultimate user who is institutionalized in a licensed health care institution (e.g., nursing home, hospice, hospital);

(ii) no more than a 90-day supply is dispensed at one time;

(iii) the drug is not in the possession of the ultimate user prior to administration;

(iv) the pharmacist-in-charge has determined that the institution:

(I) maintains medication administration records which include adequate directions for use for the drug(s) prescribed;

(II) maintains records of ordering, receipt, and administration of the drug(s); and

(III) provides for appropriate safeguards for the control and storage of the drug(s); and

(v) the dispensing container bears a label that adequately:

(I) identifies the:

(-a-) pharmacy by name and address;

(-b-) unique identification number of the prescription;

(-c-) name and strength of the drug dispensed;

(-d-) name of the patient; and

(-e-) name of the prescribing practitioner or, if applicable, the name of the pharmacist who signed the prescription drug order;

(II) if the drug is dispensed in a container other than the manufacturer's original container, specifies the date after which the prescription should not be used or beyond-use-date. Unless otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date the drug is dispensed or the manufacturer's expiration date, whichever is earlier. The beyond-use-date may be placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is not required on the label of a prescription dispensed to a person at the time of release from prison or jail if the prescription is for not more than a 10-day supply of medication; and

(III) sets forth the directions for use and cautionary statements, if any, contained on the prescription drug order or required by law.

(8) Returning Undelivered Medication to Stock.

(A) A pharmacist may not accept an unused prescription or drug, in whole or in part, for the purpose of resale or re-dispensing to any person after the prescription or drug has been originally dispensed or sold, except as provided in §291.8 of this title (relating to Return of Prescription Drugs) or Subchapter M, Chapter 431, Health and Safety Code, or Chapter 442, Health and Safety Code. Prescriptions that have not been picked up by or delivered to the patient or patient's agent may be returned to the pharmacy's stock for dispensing.

(B) A pharmacist shall evaluate the quality and safety of the prescriptions to be returned to stock.

(C) Prescriptions returned to stock for dispensing shall not be mixed within the manufacturer's container.

(D) Prescriptions returned to stock for dispensing should be used as soon as possible and stored in the dispensing container. The expiration date of the medication shall be the lesser of one year from the dispensing date on the prescription label or the manufacturer's expiration date if dispensed in the manufacturer's original container.

(E) At the time of dispensing, the prescription medication shall be placed in a new prescription container and not dispensed in the previously labeled container unless the label can be completely removed. However, if the medication is in the manufacturer's original container, the pharmacy label must be removed so that no confidential patient information is released.

(9) Redistribution of Donated Prepackaged Prescription Drugs.

(A) A participating provider may dispense to a recipient donated prescription drugs that are prepackaged and labeled in accordance with §442.0515, Health and Safety Code, and this paragraph.

(B) Drugs may be prepackaged in quantities suitable for distribution to a recipient only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist.

(C) The label of a prepackaged prescription drug a participating provider dispenses to a recipient shall indicate:

(i) brand name and strength of the drug; or if no brand name, then the generic name, strength, and name of the manufacturer or distributor;

(ii) participating provider’s lot number;

(iii) participating provider's beyond use date; and (iv) quantity of the drug, if the quantity is greater than one.

(D) Records of prepackaged prescription drugs dispensed to a recipient shall be maintained to show:

(i) name of the drug, strength, and dosage form;
(ii) participating provider's lot number;
(iii) manufacturer or distributor;
(iv) manufacturer's lot number;
(v) manufacturer's expiration date;
(vi) quantity per prepackaged unit;
(vii) number of prepackaged units; (viii) date packaged;
(ix) name, initials, or written or electronic signature of the prepacker; and
(x) written, or electronic signature of the responsible pharmacist.

(E) Stock packages, repackaged units, and control records shall be quarantined together until checked/released by the pharmacist.

(d) Equipment and supplies. Class A pharmacies dispensing prescription drug orders shall have the following equipment and supplies:

(1) data processing system including a printer or comparable equipment;
(2) refrigerator;
(3) adequate supply of child-resistant, light-resistant, tight, and if applicable, glass containers;
(4) adequate supply of prescription, poison, and other applicable labels;
(5) appropriate equipment necessary for the proper preparation of prescription drug orders; and
(6) metric-apothecary weight and measure conversion charts.

(e) 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;
(B) Texas Dangerous Drug Act and rules;
(C) Texas Controlled Substances Act and rules; and
(D) Federal Controlled Substances Act and rules (or official publication describing the requirements of the Federal Controlled Substances Act and rules);

(2) at least one current or updated reference from each of the following categories:

(A) a patient prescription drug information reference text or leaflets which are designed for the patient and must be available to the patient;
(B) at least one current or updated general drug information reference which is required to contain drug interaction information including information needed to determine severity or significance of the interaction and appropriate recommendations or actions to be taken; and
(C) if the pharmacy dispenses veterinary prescriptions, a general reference text on veterinary drugs; and

(3) basic antidote information and the telephone number of the nearest Regional Poison Control Center.

(f) Drugs.

(1) Procurement and storage.

(A) The pharmacist-in-charge shall have the responsibility for the procurement and storage of drugs, but may receive input from other appropriate staff relative to such responsibility.
(B) Prescription drugs and devices and nonprescription Schedule V controlled substances shall be stored within the prescription department or a locked storage area.
(C) All drugs shall be stored at the proper temperature, as defined in the USP/NF and §291.15 of this title (relating to Storage of Drugs).

(2) Out-of-date drugs or devices.

(A) Any drug or device bearing an expiration date shall not be dispensed beyond the expiration date of the drug or device.

(B) Outdated drugs or devices shall be removed from dispensing stock and shall be quarantined together until such drugs or devices are disposed of properly.

(3) Nonprescription Schedule V controlled substances.

(A) Schedule V controlled substances containing codeine, dihydrocodeine, or any of the salts of codeine or dihydrocodeine may not be distributed without a prescription drug order from a practitioner.

(B) A pharmacist may distribute nonprescription Schedule V controlled substances which contain no more than 15 milligrams of opium per 29.5729 ml or per 28.35 Gm provided:

(i) such distribution is made only by a pharmacist; a nonpharmacist employee may not distribute a nonprescription Schedule V controlled substance even if under the supervision of a pharmacist; however, after the pharmacist has fulfilled professional and legal responsibilities, the actual cash, credit transaction, or delivery may be completed by a nonpharmacist:

(ii) not more than 240 ml (eight fluid ounces), or not more than 48 solid dosage units of any substance containing opium, may be distributed to the same purchaser in any given 48-hour period without a prescription drug order;

(iii) the purchaser is at least 18 years of age; and

(iv) the pharmacist requires every purchaser not known to the pharmacist to furnish suitable identification (including proof of age where appropriate).

(C) A record of such distribution shall be maintained by the pharmacy in a bound record book. The record shall contain the following information:

(i) true name of the purchaser;

(ii) current address of the purchaser;

(iii) name and quantity of controlled substance purchased;

(iv) date of each purchase; and

(v) signature or written initials of the distributing pharmacist.

(4) Class A Pharmacies may not sell, purchase, trade or possess prescription drug samples, unless the pharmacy meets the requirements as specified in §291.16 of this title (relating to Samples).

(g) Prepackaging of drugs.

(1) Drugs may be prepackaged in quantities suitable for internal distribution only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist.

(2) The label of a prepackaged unit shall indicate:

(A) brand name and strength of the drug; or if no brand name, then the generic name, strength, and name of the manufacturer or distributor;

(B) facility's lot number;

(C) facility's beyond use date; and

(D) quantity of the drug, if the quantity is greater than one.

(3) Records of prepackaging shall be maintained to show:

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

(B) facility's lot number;

(C) manufacturer or distributor;

(D) manufacturer's lot number;

(E) manufacturer's expiration date;

(F) quantity per prepackaged unit;

(G) number of prepackaged units;

(H) date packaged;

(I) name, initials, or electronic signature of the prepacker; and

(J) signature, or electronic signature of the responsible pharmacist.

(4) Stock packages, repackaged units, and control records shall be quarantined together until checked/released by the pharmacist.

(h) Customized patient medication packages.

(1) Purpose. In lieu of dispensing two or more prescribed drug products in separate containers, a pharmacist may, with the consent of the patient, the patient's caregiver, or the prescriber, provide a customized patient medication package (patient med-pak).

(2) Label.

(A) The patient med-pak shall bear a label stating:

(i) the name of the patient;

(ii) the unique identification number for the patient med-pak itself and a separate unique identification number for each of the prescription drug orders for each of the drug products contained therein;

(iii) the name, strength, physical description or identification, and total quantity of each drug product contained therein;

(iv) the directions for use and cautionary statements, if any, contained in the prescription drug order for each drug product contained therein;

(v) if applicable, a warning of the potential harmful effect of combining any form of alcoholic beverage with any drug product contained therein;

(vi) any storage instructions or cautionary statements required by the official compendia;

(vii) the name of the prescriber of each drug product;

(viii) the name, address, and telephone number of the pharmacy;

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

(x) the date after which the prescription should not be used or beyond-use-date. Unless otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date the med-pak is dispensed or the earliest manufacturer's expiration date for a product contained in the med-pak if it is less than one-year from the date dispensed. The beyond-use-date may be placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is not required on the label of a prescription dispensed to a person at the time of release from prison or jail if the prescription is for not more than a 10-day supply of medication;

(xi) either on the prescription label or the written information accompanying the prescription, the statement "Do not flush unused medications or pour down a sink or drain." A drug product on a list developed by the Federal Food and Drug Administration of medicines recommended for disposal by flushing is not required to bear this statement; and

(xii) any other information, statements, or warnings required for any of the drug products contained therein.

(B) If the patient med-pak allows for the removal or separation of the intact containers therefrom, each individual container shall bear a label identifying each of the drug product contained therein.

(C) The dispensing container is not required to bear the label as specified in subparagraph (A) of this paragraph if:

(i) the drug is prescribed for administration to an ultimate user who is institutionalized in a licensed health care institution (e.g., nursing home, hospice, hospital);

(ii) no more than a 90-day supply is dispensed at one time;

(iii) the drug is not in the possession of the ultimate user prior to administration;

(iv) the pharmacist-in-charge has determined that the institution:

(I) maintains medication administration records which include adequate directions for use for the drug(s) prescribed;

(II) maintains records of ordering, receipt, and administration of the drug(s); and

(III) provides for appropriate safeguards for the control and storage of the drug(s); and

(v) the dispensing container bears a label that adequately:

(I) identifies the:

(-a-) pharmacy by name and address;

(-b-) name and strength of each drug product dispensed;

(-c-) name of the patient; and

(-d-) name of the prescribing practitioner of each drug product, or the pharmacist who signed the prescription drug order;

(II) the date after which the prescription should not be used or beyond-use-date. Unless otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date the med-pak is dispensed or the earliest manufacturer's expiration date for a product contained in the med-pak if it is less than one-year from the date dispensed. The beyond-use-date may be placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is not required on the label of a prescription dispensed to a person at the time of release from prison or jail if the prescription is for not more than a 10-day supply of medication; and

(III) for each drug product sets forth the directions for use and cautionary statements, if any, contained on the prescription drug order or required by law.

(3) Labeling. The patient med-pak shall be accompanied by a patient package insert, in the event that any drug contained therein is required to be dispensed with such insert as accompanying labeling. Alternatively, such required information may be incorporated into a single, overall educational insert provided by the pharmacist for the total patient med-pak.

(4) Packaging. In the absence of more stringent packaging requirements for any of the drug products contained therein, each container of the patient med-pak shall comply with official packaging standards. Each container shall be either not reclosable or so designed as to show evidence of having been opened.

(5) Guidelines. It is the responsibility of the dispensing pharmacist when preparing a patient med-pak, to take into account any applicable compendial requirements or guidelines and the physical and chemical compatibility of the dosage forms placed within each container, as well as any therapeutic incompatibilities that may attend the simultaneous administration of the drugs.

(6) Recordkeeping. In addition to any individual prescription filing requirements, a record of each patient med-pak shall be made and filed. Each record shall contain, as a minimum:

(A) the name and address of the patient;

(B) the unique identification number for the patient med-pak itself and a separate unique identification number for each of the prescription drug orders for each of the drug products contained therein;

(C) the name of the manufacturer or distributor and lot number for each drug product contained therein;

(D) information identifying or describing the design, characteristics, or specifications of the patient med-pak sufficient to allow subsequent preparation of an identical patient med-pak for the patient;

(E) the date of preparation of the patient med-pak and the beyond-use date that was assigned;

(F) any special labeling instructions; and

(G) the initials or an identification code of the dispensing pharmacist.

(7) The patient med-pak label is not required to include the initials or identification code of the dispensing pharmacist as specified in paragraph (2)(A) of this subsection if the identity of the dispensing pharmacist is recorded in the pharmacy's data processing system. The record of the identity of the dispensing pharmacist shall not be altered in the pharmacy's data processing system.

(i) Automated devices and systems in a pharmacy.

(1) Automated counting devices. If a pharmacy uses automated counting devices:

(A) the pharmacy shall have a method to calibrate and verify the accuracy of the automated counting device and document the calibration and verification on a routine basis;

(B) the devices may be loaded with bulk drugs only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist;
(C) the label of an automated counting device container containing a bulk drug shall indicate the brand name and strength of the drug; or if no brand name, then the generic name, strength, and name of the manufacturer or distributor;
(D) records of loading bulk drugs into an automated counting device shall be maintained to show:
(i) name of the drug, strength, and dosage form;
(ii) manufacturer or distributor;
(iii) manufacturer's lot number;
(iv) expiration date;
(v) date of loading;
(vi) name, initials, or electronic signature of the person loading the automated counting device; and
(vii) name, initials, or electronic signature of the responsible pharmacist; and
(E) the automated counting device shall not be used until a pharmacist verifies that the system is properly loaded and affixes his or her name, initials, or electronic signature to the record as specified in subparagraph (D) of this paragraph.
(2) Automated pharmacy dispensing systems.
(A) Authority to use automated pharmacy dispensing systems. A pharmacy may use an automated pharmacy dispensing system to fill prescription drug orders provided that:
(i) the pharmacist-in-charge is responsible for the supervision of the operation of the system;
(ii) the automated pharmacy dispensing system has been tested by the pharmacy and found to dispense accurately. The pharmacy shall make the results of such testing available to the board upon request; and
(iii) the pharmacy will make the automated pharmacy dispensing system available for inspection by the board for the purpose of validating the accuracy of the system.
(B) Automated pharmacy dispensing systems may be stocked or loaded by a pharmacist or by a pharmacy technician or pharmacy technician trainee under the supervision of a pharmacist.
(C) Quality assurance program. A pharmacy which uses an automated pharmacy dispensing system to fill prescription drug orders shall operate according to a quality assurance program of the automated pharmacy dispensing system which:
(i) requires continuous monitoring of the automated pharmacy dispensing system; and
(ii) establishes mechanisms and procedures to test the accuracy of the automated pharmacy dispensing system at least every twelve months and whenever any upgrade or change is made to the system and documents each such activity.
(D) Policies and procedures of operation.
(i) When an automated pharmacy dispensing system is used to fill prescription drug orders, it shall be operated according to written policies and procedures of operation. The policies and procedures of operation shall:
(I) provide for a pharmacist's review, approval, and accountability for the transmission of each original or new prescription drug order to the automated pharmacy dispensing system before the transmission is made;
(II) provide for access to the automated pharmacy dispensing system for stocking and retrieval of medications which is limited to licensed healthcare professionals or pharmacy technicians acting under the supervision of a pharmacist;
(III) require that a pharmacist checks, verifies, and documents that the correct medication and strength of bulk drugs, prepackaged containers, or manufacturer's unit of use packages were properly stocked, filled, and loaded in the automated pharmacy

dispensing system prior to initiating the fill process; alternatively, an electronic verification system may be used for verification of manufacturer's unit of use packages or prepacked medication previously verified by a pharmacist;

(IV) provide for an accountability record to be maintained that documents all transactions relative to stocking and removing medications from the automated pharmacy dispensing system;

(V) require a prospective drug regimen review is conducted as specified in subsection (c)(2) of this section; and

(VI) establish and make provisions for documentation of a preventative maintenance program for the automated pharmacy dispensing system.

(ii) A pharmacy that uses an automated pharmacy dispensing system to fill prescription drug orders shall, at least annually, review its written policies and procedures, revise them if necessary, and document the review.

(E) Recovery Plan. A pharmacy that uses an automated pharmacy dispensing system to fill prescription drug orders shall maintain a written plan for recovery from a disaster or any other situation which interrupts the ability of the automated pharmacy dispensing system to provide services necessary for the operation of the pharmacy. The written plan for recovery shall include:

(i) planning and preparation for maintaining pharmacy services when an automated pharmacy dispensing system is experiencing downtime;

(ii) procedures for response when an automated pharmacy dispensing system is experiencing downtime; and

(iii) procedures for the maintenance and testing of the written plan for recovery.

(F) Final check of prescriptions dispensed using an automated pharmacy dispensing system. For the purpose of §291.32(c)(2)(D) of this title (relating to Personnel), a pharmacist must perform the final check of all prescriptions prior to delivery to the patient to ensure that the prescription is dispensed accurately as prescribed.

(i) This final check shall be considered accomplished if:

(I) a check of the final product is conducted by a pharmacist after the automated pharmacy dispensing system has completed the prescription and prior to delivery to the patient; or

(II) the following checks are conducted:

(-a-) if the automated pharmacy dispensing system contains bulk stock drugs, a pharmacist verifies that those drugs have been accurately stocked as specified in subparagraph (D)(i)(III) of this paragraph;

(-b-) if the automated pharmacy dispensing system contains manufacturer's unit of use packages or prepackaged medication previously verified by a pharmacist, an electronic verification system has confirmed that the medications have been accurately stocked as specified in subparagraph (D)(i)(III) of this paragraph;

(-c-) a pharmacist checks the accuracy of the data entry of each original or new prescription drug order entered into the automated pharmacy dispensing system; and

(-d-) an electronic verification process is used to verify the proper prescription label has been affixed to the correct medication container, prepackaged medication or manufacturer unit of use package for the correct patient.

(ii) If the final check is accomplished as specified in clause (i)(II) of this subparagraph, the following additional requirements must be met:

(I) the dispensing process must be fully automated from the time the pharmacist releases the prescription to the automated pharmacy dispensing system until a completed, labeled prescription ready for delivery to the patient is produced;
(II) the pharmacy has conducted initial testing and has a continuous quality assurance program which documents that the automated pharmacy dispensing system dispenses accurately as specified in subparagraph (C) of this paragraph;
(III) the automated pharmacy dispensing system documents and maintains:
(-a-) the name(s), initials, or identification code(s) of each pharmacist responsible for the checks outlined in clause (i)(II) of this subparagraph; and
(-b-) the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist, pharmacy technician, or pharmacy technician trainee who performs any other portion of the dispensing process; and
(IV) the pharmacy establishes mechanisms and procedures to test the accuracy of the automated pharmacy dispensing system at least every month rather than every twelve months as specified in subparagraph (C) of this paragraph.

(3) Automated checking device.

(A) For the purpose of §291.32(c)(2)(D) of this title, the final check of a dispensed prescription shall be considered accomplished using an automated checking device provided a check of the final product is conducted by a pharmacist prior to delivery to the patient or the following checks are performed:
(i) the drug used to fill the order is checked through the use of an automated checking device which verifies that the drug is labeled and packaged accurately; and
(ii) a pharmacist checks the accuracy of each original or new prescription drug order and is responsible for the final check of the order through the automated checking device.

(B) If the final check is accomplished as specified in subparagraph (A) 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)(i) of this paragraph; and
(II) the name(s) initials, or identification code(s) and specific activity(ies) of each pharmacist, pharmacy technician, or pharmacy technician trainee who performs 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; and
(iv) the pharmacy establishes procedures to ensure that errors identified by the automated checking device may not be overridden by a pharmacy technician and must be reviewed and corrected by a pharmacist.

§291.34 Records

(a) Maintenance of records.

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

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

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

(2) Records of controlled substances listed in Schedule II shall be maintained separately from all other records of the pharmacy.

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

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

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

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

(b) Prescriptions.

(1) Professional responsibility.

(A) Pharmacists shall exercise sound professional judgment with respect to the accuracy and authenticity of any prescription drug order they dispense. If the pharmacist questions the accuracy or authenticity of a prescription drug order, he/she shall verify the order with the practitioner prior to dispensing.

(B) Prior to dispensing a prescription, pharmacists shall determine, in the exercise of sound professional judgment, that the prescription is a valid prescription. A pharmacist may not dispense a prescription drug unless the pharmacist complies with the requirements of §562.056 and §562.112 of the Act, and §291.29 of this title (relating to Professional Responsibility of Pharmacists).

(C) Subparagraph (B) of this paragraph does not prohibit a pharmacist from dispensing a prescription when a valid patient-practitioner relationship is not present in an emergency situation (e.g., a practitioner taking calls for the patient's regular practitioner).

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

(2) Written prescription drug orders.

(A) Practitioner's signature.

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

(I) manually signed by the practitioner; or

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

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

(-b-) the prescription is printed on paper that is designed to prevent unauthorized copying of a completed prescription and to prevent the erasure or modification of information written on the prescription by the prescribing practitioner. (For example, the paper contains security provisions against

copying that results in some indication on the copy that it is a copy and therefore render the prescription null and void.)

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

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

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

(II) Rubber stamped signatures may not be used.

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

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

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

(ii) Controlled substance prescription drug orders.

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

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

(-b-) the prescription drug order is an original written prescription issued by a person practicing in another state and licensed by another state as a physician, dentist, veterinarian, or podiatrist, who has a current federal Drug Enforcement Administration (DEA) registration number, and who may legally prescribe Schedule II controlled substances in such other state; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(3) Oral prescription drug orders.

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

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

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

(4) Electronic prescription drug orders.

(A) Dangerous drug prescription orders.

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

(I) directly to a pharmacy; or

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

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

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

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

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

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

(5) Facsimile (faxed) prescription drug orders.

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

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

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

(6) Original prescription drug order records.

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

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

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

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

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

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

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

(iii) prescriptions for dangerous drugs and nonprescription drugs.

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

(i) the record of refills recorded on the original prescription must also be stored in this system;
(ii) the original prescription records must be maintained in numerical order and separated in three files as specified in subparagraph (D) of this paragraph; and
(iii) the pharmacy must provide immediate access to equipment necessary to render the records easily readable.

(7) Prescription drug order information.

(A) All original prescriptions shall bear:

(i) the name of the patient, or if such drug is for an animal, the species of such animal and the name of the owner;
(ii) the address of the patient; provided, however, that a prescription for a dangerous drug is not required to bear the address of the patient if such address is readily retrievable on another appropriate, uniformly maintained pharmacy record, such as medication records;
(iii) the name, address and telephone number of the practitioner at the practitioner's usual place of business, legibly printed or stamped, and if for a controlled substance, the DEA registration number of the practitioner;
(iv) the name and strength of the drug prescribed;
(v) the quantity prescribed numerically, and if for a controlled substance:

(I) numerically, followed by the number written as a word, if the prescription is written;
(II) numerically, if the prescription is electronic; or
(III) if the prescription is communicated orally or telephonically, as transcribed by the receiving pharmacist;

(vi) directions for use;
(vii) the intended use for the drug unless the practitioner determines the furnishing of this information is not in the best interest of the patient;
(viii) the date of issuance;
(ix) if a faxed prescription:

(I) a statement that indicates that the prescription has been faxed (e.g., Faxed to); and
(II) if transmitted by a designated agent, the name of the designated agent;

(x) if electronically transmitted:

(I) the date the prescription drug order was electronically transmitted to the pharmacy, if different from the date of issuance of the prescription; and
(II) if transmitted by a designated agent, the name of the designated agent; and

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

(I) the name, address, telephone number, and if the prescription is for a controlled substance, the DEA number of the supervising practitioner; and
(II) the address and telephone number of the clinic where the prescription drug order was carried out or signed; and

(xii) if communicated orally or telephonically:

(I) the initials or identification code of the transcribing pharmacist; and
(II) the name of the prescriber or prescriber's agent communicating the prescription information.

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

(i) the unique identification number of the prescription drug order;
(ii) the initials or identification code of the dispensing pharmacist;
(iii) the initials or identification code of the pharmacy technician or pharmacy technician trainee performing data entry of the prescription, if applicable;

(iv) the quantity dispensed, if different from the quantity prescribed;
(v) the date of dispensing, if different from the date of issuance; and
(vi) the brand name or manufacturer of the drug or biological product actually dispensed, if the drug was prescribed by generic name or interchangeable biological name or if a drug or interchangeable biological product other than the one prescribed was dispensed pursuant to the provisions of the Act, Chapters 562 and 563.

(C) Prescription drug orders may be utilized as authorized in Title 26, Part 1, Chapter 554 of the Texas Administrative Code.

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

(I) the full name of the patient;
(II) the date of issuance;
(III) the name, strength, and dosage form of the drug prescribed;
(IV) directions for use; and
(V) the signature(s) required by 26 TAC §554.1506 (relating to Drug Orders).

(ii) Prescription drug orders for dangerous drugs shall not be dispensed following one year after the date of issuance unless the authorized prescriber renews the prescription drug order.
(iii) Controlled substances shall not be dispensed pursuant to a prescription drug order under this subparagraph.

(8) Refills.

(A) General information.

(i) Refills may be dispensed only in accordance with the prescriber's authorization as indicated on the original prescription drug order except as authorized in paragraph (10) of this subsection relating to accelerated refills.
(ii) If there are no refill instructions on the original prescription drug order (which shall be interpreted as no refills authorized) or if all refills authorized on the original prescription drug order have been dispensed, authorization from the prescribing practitioner shall be obtained prior to dispensing any refills and documented as specified in subsection (l) of this section.

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

(i) Prescription drug orders for dangerous drugs or nonprescription drugs may not be refilled after one year from the date of issuance of the original prescription drug order.
(ii) If one year has expired from the date of issuance of an original prescription drug order for a dangerous drug or nonprescription drug, authorization shall be obtained from the prescribing practitioner prior to dispensing any additional quantities of the drug.

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

(i) Prescription drug orders for Schedules III-V controlled substances may not be refilled more than five times or after six months from the date of issuance of the original prescription drug order, whichever occurs first.
(ii) If a prescription drug order for a Schedule III, IV, or V controlled substance has been refilled a total of five times or if six months have expired from the date of issuance of the original prescription drug order, whichever occurs first, a new and separate prescription drug order shall be obtained from the prescribing practitioner prior to dispensing any additional quantities of controlled substances.

(D) Pharmacist unable to contact prescribing practitioner. If a pharmacist is unable to contact the prescribing practitioner after a reasonable effort, a pharmacist may exercise his or her professional

judgment in refilling a prescription drug order for a drug, other than a Schedule II controlled substance, without the authorization of the prescribing practitioner, provided:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(I) the patient has the prescription container, label, receipt or other documentation from the other pharmacy that contains the essential information;
(II) after a reasonable effort, the pharmacist is unable to contact the other pharmacy to transfer the remaining prescription refills or there are no refills remaining on the prescription;
(III) the pharmacist, in his or her professional judgment, determines that such a request for an emergency refill is appropriate and meets the requirements of clause (i) of this subparagraph; and
(IV) the pharmacist complies with the requirements of clauses (ii) - (viii) of this subparagraph.

(F) Emergency Refills of Insulin and Insulin-Related Equipment or Supplies.

(i) A pharmacist may exercise the pharmacist's professional judgment in refilling a prescription for insulin or insulin-related equipment or supplies without the authorization of the prescribing practitioner if the pharmacist:

(I) is unable to contact the practitioner after reasonable effort;
(II) is provided with documentation showing that the patient was previously prescribed insulin or insulin-related equipment or supplies by a practitioner;
(III) assesses the patient to determine whether the emergency refill is appropriate;
(IV) creates a record that documents the patient's visit that includes a notation describing the documentation provided under subclause (II) of this clause; and
(V) makes a reasonable attempt to inform the practitioner of the emergency refill at the earliest reasonable time.

(ii) The quantity of an emergency refill of insulin may not exceed a 30-day supply. The quantity of an emergency refill of insulin-related equipment or supplies may not exceed the lesser of a 30-day supply or the smallest available package.

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

(i) Notice of the availability of an auto-refill program shall be given to the patient or patient's agent, and the patient or patient's agent must affirmatively indicate that they wish to enroll in such a program and the pharmacy shall document such indication.
(ii) The patient or patient's agent shall have the option to withdraw from such a program at any time.
(iii) Auto-refill programs may be used for refills of dangerous drugs, and Schedules IV and V controlled substances. Schedules II and III controlled substances may not be dispensed by an auto-refill program.
(iv) As is required for all prescriptions, a drug regimen review shall be completed on all prescriptions filled as a result of the auto-refill program. Special attention shall be noted for drug regimen review warnings of duplication of therapy and all such conflicts shall be resolved with the prescribing practitioner prior to refilling the prescription.

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

(A) Original prescription drug orders:

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

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

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

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

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

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

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

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

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

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

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

(c) Patient medication records.

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

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

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

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

(B) address and telephone number of the patient;

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

(D) patient's gender;

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

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

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

(i) date dispensed;

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

(iii) prescribing practitioner's name;

(iv) unique identification number of the prescription; and

(v) name or initials of the dispensing pharmacists.

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

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

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

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

(2) Refills.

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

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

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

(I) unique identification number of the prescription;

(II) name and strength of the drug dispensed;

(III) date of each dispensing;

(IV) quantity dispensed at each dispensing;

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

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

(VII) total number of refills for the prescription.

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

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

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

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

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

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

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

(C) Requirements for backup systems.

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

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

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

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

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

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

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

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

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

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

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

(2) Records of dispensing.

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

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

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

(i) unique identification number of the prescription;

(ii) date of dispensing;

(iii) patient name;

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

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

(vi) quantity dispensed;

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

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

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

(I) patient's address;

(II) prescribing practitioner's address;

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

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

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

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

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

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

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

(F) In lieu of the printout described in subparagraph (C) of this paragraph, the pharmacy shall maintain a log book in which each individual pharmacist using the data processing system shall sign or electronically sign a statement each day, attesting to the fact that the information entered into the data processing system that day has been reviewed by him or her and is correct as entered. Such log book shall be maintained at the pharmacy employing such a system for a period of two years after the date of dispensing; provided, however, that the data processing system can produce the hard copy printout on demand by an authorized agent of the Texas State Board of Pharmacy. If no printer is available on site, the hard copy printout shall be available within 72 hours with a certification by the individual providing the printout, stating that the printout is true and correct as of the date of entry and such information has not been altered, amended, or modified.

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

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

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

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

(I) Failure to provide the records set out in this subsection, either on site or within 72 hours constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

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

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

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

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

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

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

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

(A) on the hard copy prescription drug order;
(B) on the daily hard copy printout; or
(C) via the computer display.

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

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

(1) The transfer of original prescription drug order information for controlled substances listed in Schedules III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

(2) The transfer of original prescription drug order information for dangerous drugs is permissible between pharmacies without limitation up to the number of originally authorized refills.

(3) The transfer is communicated orally by telephone or via facsimile:

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

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

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

(5) The individual transferring the prescription drug order information shall:

(A) write the word "void" on the face of the invalidated prescription or the prescription is voided in the data processing system;

(B) record the name, address, and if for a controlled substance, the DEA registration number of the pharmacy to which it was transferred, and the name of the receiving individual on the reverse of the invalidated prescription or stored with the invalidated prescription drug order in the data processing system;

(C) record the date of the transfer and the name of the individual transferring the information; and

(D) if the prescription is transferred electronically, provide the following information:

(i) date of original dispensing and prescription number;

(ii) number of refills remaining and if a controlled substance, the date(s) and location(s) of previous refills;

(iii) name, address, and if a controlled substance, the DEA registration number of the transferring pharmacy;

(iv) name of the individual transferring the prescription; and

(v) if a controlled substance, the name, address, DEA registration number, and prescription number from the pharmacy that originally dispensed the prescription, if different.

(6) The individual receiving the transferred prescription drug order information shall:

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

(B) reduce to writing all of the information required to be on a prescription as specified in subsection (b)(7) of this section, and the following:

(i) date of issuance and prescription number;

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

(iii) date of original dispensing;

(iv) number of valid refills remaining, and if a controlled substance, the date(s) and location(s) of previous refills;

(v) name, address, and if for a controlled substance, the DEA registration number of the transferring pharmacy;
(vi) name of the individual transferring the prescription; and
(vii) name, address, and if for a controlled substance, the DEA registration number, of the pharmacy that originally dispensed the prescription, if different; or

(C) if the prescription is transferred electronically, create an electronic record for the prescription that includes the receiving pharmacist's name and all of the information transferred with the prescription including all of the information required to be on a prescription as specified in subsection (b)(7) of this section, and the following:
(i) date of original dispensing;
(ii) number of refills remaining and if a controlled substance, the prescription number(s), date(s) and location(s) of previous refills;
(iii) name, address, and if for a controlled substance, the DEA registration number;
(iv) name of the individual transferring the prescription; and
(v) name, address, and if for a controlled substance, the DEA registration number, of the pharmacy that originally filled the prescription.

(7) Both the individual transferring the prescription and the individual receiving the prescription must engage in confirmation of the prescription information by such means as:
(A) the transferring individual faxes the hard copy prescription to the receiving individual; or
(B) the receiving individual repeats the verbal information from the transferring individual and the transferring individual verbally confirms that the repeated information is correct.

(8) Pharmacies transferring prescriptions electronically shall comply with the following:
(A) Prescription drug orders may not be transferred by non-electronic means during periods of downtime except on consultation with and authorization by a prescribing practitioner; provided, however, that during downtime, a hard copy of a prescription drug order may be made available for informational purposes only, to the patient or a pharmacist, and the prescription may be read to a pharmacist by telephone;
(B) The original prescription drug order shall be invalidated in the data processing system for purposes of filling or refilling, but shall be maintained in the data processing system for refill history purposes;
(C) If the data processing system does not have the capacity to store all the information as specified in paragraphs (5) and (6) of this subsection, the pharmacist is required to record this information on the original or transferred prescription drug order;
(D) The data processing system shall have a mechanism to prohibit the transfer or refilling of controlled substance prescription drug orders that have been previously transferred; and
(E) Pharmacies electronically accessing the same prescription drug order records may electronically transfer prescription information if the following requirements are met:
(i) The original prescription is voided and the pharmacies' data processing systems store all the information as specified in paragraphs (5) and (6) of this subsection;
(ii) Pharmacies not owned by the same entity may electronically access the same prescription drug order records, provided the owner, chief executive officer, or designee of each pharmacy signs an agreement allowing access to such prescription drug order records; and
(iii) An electronic transfer between pharmacies may be initiated by a pharmacist intern, pharmacy technician, or pharmacy technician trainee acting under the direct supervision of a pharmacist.

(9) An individual may not refuse to transfer original prescription information to another individual who is acting on behalf of a patient and who is making a request for this information as specified in this subsection. The transfer of original prescription information must be completed within four business hours of the request.

(10) When transferring a compounded prescription, a pharmacy is required to provide all of the information regarding the compounded preparation, including the formula, unless the formula is patented or otherwise protected, in which case, the transferring pharmacy shall, at a minimum, provide the quantity or strength of all of the active ingredients of the compounded preparation.

(11) The electronic transfer of multiple or bulk prescription records between two pharmacies is permitted provided:

(A) a record of the transfer as specified in paragraph (5) of this subsection is maintained by the transferring pharmacy;

(B) the information specified in paragraph (6) of this subsection is maintained by the receiving pharmacy; and

(C) in the event that the patient or patient's agent is unaware of the transfer of the prescription drug order record, the transferring pharmacy must notify the patient or patient's agent of the transfer and must provide the patient or patient's agent with the telephone number of the pharmacy receiving the multiple or bulk prescription drug order records.

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

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

(2) The total number of dosage units of controlled substances distributed by a pharmacy may not exceed 5.0% of all controlled substances dispensed and distributed by the pharmacy during the 12-month period in which the pharmacy is registered; if at any time it does exceed 5.0%, the pharmacy is required to obtain an additional registration to distribute controlled substances.

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

(A) the actual date of distribution;

(B) the name, strength, and quantity of controlled substances distributed;

(C) the name, address, and DEA registration number of the distributing pharmacy; and

(D) the name, address, and DEA registration number of the pharmacy, practitioner, or other registrant to whom the controlled substances are distributed.

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

(A) The pharmacy, practitioner, or other registrant who is receiving the controlled substances shall issue Copy 1 and Copy 2 of a DEA order form (DEA 222) to the distributing pharmacy; and

(B) The distributing pharmacy shall:

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

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

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

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

(1) a log of the initials or identification codes that will identify each pharmacist, pharmacy technician, and pharmacy technician trainee who is involved in the dispensing process, in the pharmacy's data processing system (the initials or identification code shall be unique to ensure that each individual can be identified, i.e., identical initials or identification codes shall not be used). Such log shall be maintained at the pharmacy for at least seven years from the date of the transaction;

(2) suppliers' invoices of dangerous drugs and controlled substances; a pharmacist shall verify that the controlled substances listed on the invoices were actually received by clearly recording his/her initials and the actual date of receipt of the controlled substances;

(3) suppliers' credit memos for controlled substances and dangerous drugs;
(4) a copy of inventories required by §291.17 of this title (relating to Inventory Requirements);
(5) reports of surrender or destruction of controlled substances and/or dangerous drugs to an appropriate state or federal agency;
(6) records of distribution of controlled substances and/or dangerous drugs to other pharmacies, practitioners, or registrants; and
(7) a copy of any notification required by the Texas Pharmacy Act or the sections in this chapter, including, but not limited to, the following:
(A) reports of theft or significant loss of controlled substances to the DEA and the board;
(B) notifications of a change in pharmacist-in-charge of a pharmacy; and
(C) reports of a fire or other disaster that may affect the strength, purity, or labeling of drugs, medications, devices, or other materials used in the diagnosis or treatment of injury, illness, and disease.

(j) Permission to maintain central records. Any pharmacy that uses a centralized recordkeeping system for invoices and financial data shall comply with the following procedures.
(1) Controlled substance records. Invoices and financial data for controlled substances may be maintained at a central location provided the following conditions are met:
(A) Prior to the initiation of central recordkeeping, the pharmacy submits written notification by registered or certified mail to the divisional director of the Drug Enforcement Administration as required by Title 21, Code of Federal Regulations, §1304.04(a), and submits a copy of this written notification to the board. Unless the registrant is informed by the divisional director of the Drug Enforcement Administration that permission to keep central records is denied, the pharmacy may maintain central records commencing 14 days after receipt of notification by the divisional director;
(B) The pharmacy maintains a copy of the notification required in subparagraph (A) of this paragraph; and
(C) The records to be maintained at the central record location shall not include executed DEA order forms, prescription drug orders, or controlled substance inventories that shall be maintained at the pharmacy;
(2) Dangerous drug records. Invoices and financial data for dangerous drugs may be maintained at a central location;
(3) Access to records. If the records are kept on microfilm, computer media, or in any form requiring special equipment to render the records easily readable, the pharmacy shall provide access to such equipment with the records; and
(4) Delivery of records. The pharmacy agrees to deliver all or any part of such records to the pharmacy location within two business days of written request of a board agent or any other authorized official.

(k) Ownership of pharmacy records. For the purposes of these sections, a pharmacy licensed under the Act is the only entity that may legally own and maintain prescription drug records.
(l) Documentation of consultation. When a pharmacist, pharmacist-intern, or pharmacy technician consults a prescriber as described in this section, the individual shall document such occurrences on the hard copy or in the pharmacy's data processing system associated with the prescription and shall include the following information:
(1) date the prescriber was consulted;
(2) name of the person communicating the prescriber's instructions;
(3) any applicable information pertaining to the consultation; and
(4) initials or identification code of the pharmacist, pharmacist-intern, or pharmacy technician performing the consultation clearly recorded for the purpose of identifying the individual who performed the consultation if the information is recorded on the hard copy prescription.

§291.35 Official Prescription Requirements

Class A pharmacies are subject to the rules set forth in chapter 315 of this title (relating to Controlled Substances).

§291.36 Pharmacies Compounding Sterile Preparations (Class A-S)

Licensing Requirements. A community pharmacy engaged in the compounding of sterile preparations shall be designated as a Class A-S pharmacy.

(1) A Class A-S pharmacy shall register annually or biennially with the board on a pharmacy license application provided by the board, following the procedures as specified in §291.1 of this title (relating to Pharmacy License Application). A Class A-S license may not be issued unless the pharmacy has been inspected by the board to ensure the pharmacy meets the requirements as specified in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).

(2) A Class A-S pharmacy may not renew a pharmacy license unless the pharmacy has been inspected by the board within the last renewal period.

(3) A Class A-S 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).

(4) A Class A-S pharmacy which changes location and/or name shall notify the board within ten days of the change and file for an amended license as specified in §291.3 of this title.

(5) A Class A-S pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within ten days of the change, following the procedures as specified in §291.3 of this title.

(6) A Class A-S 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).

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

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

(9) A Class A-S pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(1) concerning Community Pharmacy (Class A) is required to comply with the provisions of §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), §291.35 of this title (relating to Official Prescription Requirements), and §291.133 of this title.

(10) A Class A-S pharmacy engaged in the compounding of non-sterile preparations shall comply with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

(11) A Class A-S pharmacy engaged in the provision of remote pharmacy services, including storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of this title (relating to Remote Pharmacy Services).

(12) A Class A-S pharmacy engaged in centralized prescription dispensing and/or prescription drug or medication order processing shall comply with the provisions of §291.123 of this title (relating to Centralized Prescription Drug or Medication Order Processing) and/or §291.125 of this title (relating to Centralized Prescription Dispensing).

SUBCHAPTER C – NUCLEAR PHARMACY (CLASS B)

§291.51 Purpose

The purpose of this subchapter is to provide standards for the preparation, labeling, and distribution of radiopharmaceuticals by licensed nuclear pharmacies, pursuant to a radioactive prescription drug order. The intent of this subchapter is to establish a minimum acceptable level of pharmaceutical care to the patient so that the patient's

health is protected while contributing to positive patient outcomes. The board has determined that this subchapter is necessary to protect the health and welfare of the citizens of this state.

§291.52 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section shall have the definition set forth in the Act, §551.003.

(1) Accurately as prescribed--Dispensing, delivering, and/or distributing a prescription drug order or radioactive prescription drug order:

(A) to the correct patient (or agent of the patient) for whom the drug or device was prescribed;

(B) with the correct drug in the correct strength, quantity, and dosage form ordered by the practitioner; and

(C) with correct labeling (including directions for use) as ordered by the practitioner. Provided, however, that nothing herein shall prohibit pharmacist substitution if substitution is conducted in strict accordance with applicable laws and rules, including Subchapter A, Chapter 562 of the Act.

(2) ACPE--Accreditation Council for Pharmacy Education.

(3) Act--The Texas Pharmacy Act, Chapters 551 - 569, Occupations Code, as amended.

(4) Administer--The direct application of a prescription drug and/or radiopharmaceutical, by injection, inhalation, ingestion, or any other means to the body of a patient by:

(A) a practitioner, an authorized agent under his supervision, or other person authorized by law; or

(B) the patient at the direction of a practitioner.

(5) Authentication of product history--Identifying the purchasing source, the intermediate handling, and the ultimate disposition of any component of a radioactive drug.

(6) Authorized nuclear pharmacist--A pharmacist who:

(A) has completed the specialized training requirements specified by this subchapter for the preparation and distribution of radiopharmaceuticals; and

(B) is named on a Texas radioactive material license, issued by the Texas Department of State Health Services, Radiation Control Program.

(7) Authorized user--Any individual named on a Texas radioactive material license, issued by the Texas Department of State Health Services, Radiation Control Program.

(8) Board--The Texas State Board of Pharmacy.

(9) Common ownership--Two or more pharmacies with an identical owner of record with the board or that have owners of record with the board that are a parent, subsidiary, or affiliate of one another under §1.002, Business Organizations Code.

(10) Component--Any ingredient intended for use in the compounding of a drug preparation, including those that may not appear in such preparation.

(11) Compounding--The preparation, mixing, assembling, packaging, or labeling of a drug or device:

(A) as the result of a practitioner's prescription drug or medication order based on the practitioner-patient-pharmacist relationship in the course of professional practice;

(B) for administration to a patient by a practitioner as the result of a practitioner's initiative based on the practitioner-patient-pharmacist relationship in the course of professional practice;

(C) in anticipation of prescription drug or medication orders based on routine, regularly observed prescribing patterns; or

(D) for or as an incident to research, teaching, or chemical analysis and not for sale or dispensing, except as allowed under §562.154 or Chapter 563 of the Act.

(12) Controlled substance--A drug, immediate precursor, or other substance listed in Schedules I - V or Penalty Groups 1-4 of the Texas Controlled Substances Act, as amended, or a drug, immediate precursor, or other substance included in Schedule I, II, III, IV, or V of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public Law 91-513).

(13) Dangerous drug--A drug or device that:

(A) is not included in Penalty Group 1, 2, 3, or 4, Chapter 481, Health and Safety Code, and is unsafe for self-medication; or

(B) bears or is required to bear the legend:

(i) "Caution: federal law prohibits dispensing without prescription" or "Rx only" or another legend that complies with federal law; or

(ii) "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian."

(14) Data communication device--An electronic device that receives electronic information from one source and transmits or routes it to another (e.g., bridge, router, switch, or gateway).

(15) Deliver or delivery--The actual, constructive, or attempted transfer of a prescription drug or device, radiopharmaceutical, or controlled substance from one person to another, whether or not for a consideration.

(16) Designated agent--

(A) an individual, including a licensed nurse, physician assistant, nuclear medicine technologist, or pharmacist:

(i) who is designated by a practitioner and authorized to communicate a prescription drug order to a pharmacist; and

(ii) for whom the practitioner assumes legal responsibility;

(B) a licensed nurse, physician assistant, or pharmacist employed in a health care facility to whom a practitioner communicates a prescription drug order; or

(C) a registered nurse or physician assistant authorized by a practitioner to administer a prescription drug order for a dangerous drug under Subchapter B, Chapter 157 (Occupations Code).

(17) Device--An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related articles, including any component parts or accessory that is required under federal or state law to be ordered or prescribed by a practitioner.

(18) Diagnostic prescription drug order--A radioactive prescription drug order issued for a diagnostic purpose.

(19) Dispense--Preparing, packaging, compounding, or labeling for delivery a prescription drug or device, or a radiopharmaceutical in the course of professional practice to an ultimate user or his agent by or pursuant to the lawful order of a practitioner.

(20) Dispensing pharmacist--The authorized nuclear pharmacist responsible for the final check of the dispensed prescription before delivery to the patient.

(21) Distribute--The delivering of a prescription drug or device, or a radiopharmaceutical other than by administering or dispensing.

(22) Electronic radioactive prescription drug order--A radioactive prescription drug order which is transmitted by an electronic device to the receiver (pharmacy).

(23) Full-time pharmacist--A pharmacist who works in a pharmacy at least 30 hours per week or, if the pharmacy is open less than 60 hours per week, one-half of the time the pharmacy is open.

(24) Hot water--The temperature of water from the pharmacy's sink maintained at a minimum of 105 degrees F (41 degrees C).

(25) Nuclear pharmacy technique--The mechanical ability required to perform the nonjudgmental, technical aspects of preparing and dispensing radiopharmaceuticals.

(26) Original prescription--The:

(A) original written radioactive prescription drug orders; or

(B) original oral or electronic radioactive prescription drug orders maintained either manually or electronically.

(27) Owner of record--The direct owner of the pharmacy provided on the pharmacy's application for a pharmacy license or most recent approved change of ownership form.

(28) Pharmacist-in-charge--The pharmacist designated on a pharmacy license as the pharmacist who has the authority or responsibility for a pharmacy's compliance with laws and rules pertaining to the practice of pharmacy.
(29) Pharmacy technician--An individual whose responsibility in a pharmacy is to provide technical services that do not require professional judgment regarding preparing and distributing drugs and who works under the direct supervision of and is responsible to a pharmacist.
(30) Pharmacy technician trainee--An individual who is registered with the board as a pharmacy technician trainee and is authorized to participate in a pharmacy's technician training program.
(31) Radioactive drug service--The act of distributing radiopharmaceuticals; the participation in radiopharmaceutical selection and the performance of radiopharmaceutical drug reviews.
(32) Radioactive prescription drug order--An order from a practitioner or a practitioner's designated agent for a radiopharmaceutical to be dispensed.
(33) Radiopharmaceutical--A prescription drug or device that exhibits spontaneous disintegration of unstable nuclei with the emission of a nuclear particle(s) or photon(s), including any nonradioactive reagent kit or nuclide generator that is intended to be used in preparation of any such substance.
(34) Sterile radiopharmaceutical--A dosage form of a radiopharmaceutical free from living micro-organisms.
(35) Therapeutic prescription drug order--A radioactive prescription drug order issued for a specific patient for a therapeutic purpose.
(36) Ultimate user--A person who has obtained and possesses a prescription drug or radiopharmaceutical for administration to a patient by a practitioner.

§291.53 Personnel

(a) Pharmacists-in-Charge.

(1) General.

(A) Every nuclear pharmacy shall have an authorized nuclear pharmacist designated on the nuclear pharmacy license as the pharmacist-in-charge who shall be responsible for a nuclear pharmacy's compliance with laws and regulations, both state and federal, pertaining to the practice of nuclear pharmacy.

(B) The nuclear pharmacy pharmacist-in-charge shall see that directives from the board are communicated to the owner(s), management, other pharmacists, and interns of the nuclear pharmacy.

(C) Each Class B pharmacy shall have one pharmacist-in-charge who is employed on a full-time basis and who may be the pharmacist-in-charge for only one such pharmacy; provided, however, such pharmacist-in-charge may be the pharmacist-in-charge of:

(i) more than one Class B pharmacy, if the additional Class B pharmacies are not open to provide pharmacy services simultaneously; or

(ii) during an emergency, up to two Class B pharmacies open simultaneously if the pharmacist-in-charge works at least 10 hours per week in each pharmacy for no more than a period of 30 consecutive days.

(D) The pharmacist-in-charge of a Class B pharmacy may not serve as the pharmacist-in-charge of a Class A pharmacy or a Class C pharmacy with 101 beds or more.

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

(A) ensuring that radiopharmaceuticals are dispensed and delivered safely and accurately as prescribed;

(B) developing a system to assure that all pharmacy personnel responsible for compounding and/or supervising the compounding of radiopharmaceuticals within the pharmacy receive appropriate education and training and competency evaluation;

determining that all pharmacists involved in compounding sterile radiopharmaceuticals obtain continuing education appropriate for the type of compounding done by the pharmacist;
supervising a system to assure appropriate procurement of drugs and devices and storage of all pharmaceutical materials including radiopharmaceuticals, components used in the compounding of radiopharmaceuticals, and drug delivery devices;
(C) determining that all pharmacists involved in compounding sterile radiopharmaceuticals obtain continuing education appropriate for the type of compounding done by the pharmacist;
(D) supervising a system to assure appropriate procurement of drugs and devices and storage of all pharmaceutical materials, including radiopharmaceuticals, components used in the compounding of radiopharmaceuticals, and drug delivery devices;
(E) assuring that the equipment used in compounding is properly maintained;
(F) developing a system for the disposal and distribution of drugs from the Class B pharmacy;
(G) developing a system for bulk compounding or batch preparation of radiopharmaceuticals;
(H) developing a system for the compounding, sterility assurance, and quality control of sterile radiopharmaceuticals;
(I) maintaining records of all transactions of the Class B pharmacy necessary to maintain accurate control over and accountability for all pharmaceutical materials, including radiopharmaceuticals, required by applicable state and federal laws and rules;
(J) developing a system to assure the maintenance of effective controls against the theft or diversion of prescription drugs, and records for such drugs;
(K) assuring that the pharmacy has a system to dispose of radioactive and cytotoxic waste in a manner so as not to endanger the public health; and
(L) legally operating the pharmacy, including meeting all inspection and other requirements of all state and federal laws or rules governing the practice of pharmacy.

(b) Owner. The owner of a Class B 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) establishing policies for procurement of prescription drugs and devices and other products dispensed from the Class B pharmacy;
(2) establishing policies and procedures for the security of the prescription department including the maintenance of effective controls against the theft or diversion of prescription drugs;
(3) if the pharmacy uses an automated pharmacy dispensing system, reviewing and approving all policies and procedures for system operation, safety, security, accuracy and access, patient confidentiality, prevention of unauthorized access, and malfunction;
(4) providing the pharmacy with the necessary equipment and resources commensurate with its level and type of practice; and
(5) establishing policies and procedures regarding maintenance, storage, and retrieval of records in a data processing system such that the system is in compliance with state and federal requirements.

(c) Authorized nuclear pharmacists.

(1) General.

(A) The pharmacist-in-charge shall be assisted by a sufficient number of additional authorized nuclear pharmacists as may be required to operate the pharmacy competently, safely, and adequately to meet the needs of the patients of the pharmacy.
(B) All personnel performing tasks in the preparation and distribution of radiopharmaceuticals shall be under the direct supervision of an authorized nuclear pharmacist. General qualifications for an authorized nuclear pharmacist are the following. A pharmacist shall:

(i) meet minimal standards of training and experience in the handling of radioactive materials in accordance with the requirements of the Texas Regulations for Control of Radiation of the Radiation Control Program, Texas Department of State Health Services;
(ii) be a pharmacist licensed by the board to practice pharmacy in Texas; and
(iii) submit to the board either:
(I) written certification that he or she has current board certification as a nuclear pharmacist by the Board of Pharmaceutical Specialties; or
(II) written certification signed by a preceptor authorized nuclear pharmacist that he or she has achieved a level of competency sufficient to independently operate as an authorized nuclear pharmacist and has satisfactorily completed 700 hours in a structured educational program consisting of both:
(-a-) 200 hours of didactic training in a program accepted by the Radiation Control Program, Texas Department of State Health Services, in the following areas:
(-1-) radiation physics and instrumentation;
(-2-) radiation protection;
(-3-) mathematics pertaining to the use and measurement of radioactivity;
(-4-) radiation biology; and
(-5-) chemistry of radioactive material for medical use; and
(-b-) 500 hours of supervised practical experience in a nuclear pharmacy involving the following:
(-1-) shipping, receiving, and performing related radiation surveys;
(-2-) using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;
(-3-) calculating, assaying, and safely preparing dosages for patients or human research subjects;
(-4-) using administrative controls to avoid adverse medical events in the administration of radioactive material; and
(-5-) using procedures to prevent or minimize contamination and using proper decontamination procedures.

(C) Authorized nuclear pharmacists are solely responsible for the direct supervision of pharmacy technicians and pharmacy technician trainees and for delegating nuclear pharmacy techniques and additional duties, other than those listed in paragraph (3) of this subsection, to pharmacy technicians and pharmacy technician trainees. Each authorized nuclear pharmacist shall:
(i) verify the accuracy of all acts, tasks, or functions performed by pharmacy technicians and pharmacy technician trainees; and
(ii) be responsible for any delegated act performed by pharmacy technicians and pharmacy technician trainees under his or her supervision.

(D) All authorized nuclear pharmacists while on duty, shall be responsible for complying with all state and federal laws or rules governing the practice of pharmacy.

(E) The dispensing pharmacist shall ensure that the drug is dispensed and delivered safely and accurately as prescribed.

(2) Special requirements for compounding.

(A) Non-sterile preparations. All pharmacists engaged in compounding non-sterile preparations, including radioactive preparations, shall meet the training requirements specified in §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

(B) Sterile Preparations. All pharmacists engaged in compounding sterile preparations, including radioactive preparations, shall meet the training requirements specified in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).

(3) Duties. Duties which may only be performed by an authorized nuclear pharmacist are as follows:

(A) receiving oral therapeutic prescription drug orders for controlled substances and reducing these orders to writing, either manually or electronically;

(B) interpreting and evaluating radioactive prescription drug orders;

(C) selecting drug products; and

(D) performing the final check of the dispensed prescription before delivery to the patient to ensure that the radioactive prescription drug order has been dispensed accurately as prescribed.

(d) Pharmacy Technicians and Pharmacy Technician Trainees.

(1) General. All pharmacy technicians and pharmacy technician trainees shall meet the training requirements specified in §297.6 of this title (relating to Pharmacy Technician and Pharmacy Technician Trainee Training).

(2) Special requirements for compounding.

(A) Non-sterile preparations. All pharmacy technicians and pharmacy technician trainees engaged in compounding non-sterile preparations, including radioactive preparations shall meet the training requirements specified in §291.131 of this title.

(B) Sterile Preparations. All pharmacy technicians and pharmacy technician trainees engaged in compounding sterile preparations, including radioactive preparations shall meet the training requirements specified in §291.133 of this title.

(3) Duties.

(A) Pharmacy technicians and pharmacy technician trainees may not perform any of the duties listed in subsection (c)(3) of this section.

(B) An authorized nuclear pharmacist may delegate to pharmacy technicians and pharmacy technician trainees any nuclear pharmacy technique which is associated with the preparation and distribution of radiopharmaceuticals provided:

(i) an authorized nuclear pharmacist verifies the accuracy of all acts, tasks, and functions performed by pharmacy technicians and pharmacy technician trainees; and

(ii) pharmacy technicians and pharmacy technician trainees are under the direct supervision of and responsible to a pharmacist.

(4) Ratio of authorized nuclear pharmacist to pharmacy technicians and pharmacy technician trainees.

(A) The ratio of authorized nuclear pharmacists to pharmacy technicians and pharmacy technician trainees may be 1:6, provided at least three of the six are pharmacy technicians and are trained in the handling of radioactive materials.

(B) The ratio of authorized nuclear pharmacists to pharmacy technician trainees may not exceed 1:3.

§291.54 Operational Standards

(a) Licensing requirements.

(1) It is unlawful for a person to provide radioactive drug services unless such provision is performed by a person licensed to act as an authorized nuclear pharmacist, as defined by the board, or is a person acting under the direct supervision of an authorized nuclear pharmacist acting in accordance with the Act and its rules, and the regulations of the Texas Department of State Health Services, Radiation Control Program. Subsection (a) of this section does not apply to:

(A) a licensed practitioner or his or her designated agent for administration to his or her patient, provided no person may receive, possess, use, transfer, own, acquire, or dispose of

radiopharmaceuticals except as authorized in a specific or a general license as provided in accordance with the requirements of the Texas Department of State Health Services, Radiation Control Program, Texas Administrative Code, Title 25, Part 1, Subchapter F, §289.252 relating to Licensing of Radioactive Material, or the Act;

(B) institutions and/or facilities with nuclear medicine services operated by practitioners and who are licensed by the Texas Department of State Health Services, Radiation Control Program, to prescribe, administer, and dispense radioactive materials (drugs and/or devices).

(2) An applicant for a Class B pharmacy shall provide evidence to the board of the possession of a Texas Department of State Health Services radioactive material license or proof of application for a radioactive material license.

(3) A Class B pharmacy shall register with the board on a pharmacy license application provided by the board, following the procedures specified in §291.1 of this title (relating to Pharmacy License Application).

(4) A Class B 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).

(5) A Class B pharmacy which changes location and/or name shall notify the board within ten days of the change and file for an amended license as specified in §291.3 of this title.

(6) A Class B pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within ten days of the change, following the procedures in §291.3 of this title.

(7) A Class B pharmacy shall notify the board in writing within ten days of closing, following the procedures in §291.5 of this title (relating to Closing a Pharmacy).

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

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

(10) A Class B pharmacy, licensed under the provisions of the Act, §560.051(a)(2), which also operates another type of pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(1), concerning community pharmacy (Class A), is not required to secure a license for such other type of pharmacy; provided, however, such licensee is required to comply with the provisions of §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), to the extent such rules are applicable to the operation of the pharmacy.

(11) A Class B pharmacy engaged in the compounding of non-sterile preparations, including radioactive preparations, shall comply with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

(12) A Class B pharmacy engaged in the compounding of sterile preparations, including radioactive preparations, shall comply with the provisions of §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations) using only radiopharmaceuticals from FDA-approved drug products.

(13) Effective June 1, 2016, a Class B pharmacy may not renew a pharmacy license unless the pharmacy has been inspected by the board within the last renewal period.

(b) Environment.

(1) General requirements.

(A) The pharmacy shall be arranged in an orderly fashion and kept clean. All required equipment shall be clean and in good operating condition.

(B) The pharmacy shall have a sink with hot and cold running water within the pharmacy, exclusive of restroom facilities, available to all pharmacy personnel and maintained in a sanitary condition.

(C) The pharmacy shall be properly lighted and ventilated.

(D) The temperature of the pharmacy shall be maintained within a range compatible with the proper storage of drugs. The temperature of the refrigerator shall be maintained within a range compatible with the proper storage of drugs requiring refrigeration.

(E) If the pharmacy has flammable materials, the pharmacy shall have a designated area for the storage of flammable materials. Such area shall meet the requirements set by local and state fire laws.

(2) Security requirements.

(A) All areas occupied by a pharmacy shall be capable of being locked by key, combination or other mechanical or electronic means to prohibit unauthorized access, when a pharmacist is not on-site except as provided in subparagraph (B) of this paragraph.

(B) The pharmacy may authorize personnel to gain access to that area of the pharmacy containing dispensed radiopharmaceuticals, in the absence of the pharmacist, for the purpose of retrieving the radiopharmaceuticals to be delivered patients. If the pharmacy allows such after-hours access, the area containing the dispensed radiopharmaceuticals shall be an enclosed and lockable area separate from the area containing undispensed prescription drugs. A list of the authorized personnel having such access shall be in the pharmacy's policy and procedure manual.

(C) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of prescription drugs, and records for such drugs

(c) Prescription dispensing and delivery.

(1) Generic Substitution. A pharmacist may substitute on a prescription drug order issued for a brand name product provided the substitution is authorized and performed in compliance with Chapter 309 of this title (relating to Substitution of Drug Products).

(2) Prescription containers (immediate inner containers).

(A) A drug dispensed pursuant to a radioactive prescription drug order shall be dispensed in an appropriate immediate inner container as follows.

(i) If a drug is susceptible to light, the drug shall be dispensed in a light-resistant container.

(ii) If a drug is susceptible to moisture, the drug shall be dispensed in a tight container.

(iii) The container should not interact physically or chemically with the drug product placed in it so as to alter the strength, quality, or purity of the drug beyond the official requirements.

(B) Immediate inner prescription containers or closures shall not be re-used.

(3) Delivery containers (outer containers).

(A) Prescription containers may be placed in suitable containers for delivery which will transport the radiopharmaceutical safely in compliance with all applicable laws and regulations.

(B) Delivery containers may be re-used provided they are maintained in a manner to prevent cross contamination.

(4) Labeling.

(A) The immediate inner container of a radiopharmaceutical shall be labeled with:

(i) standard radiation symbol;

(ii) the words "caution-radioactive material" or "danger, radioactive material";

(iii) the name of the radiopharmaceutical or its abbreviation; and

(iv) the unique identification number of the prescription.

(B) The outer container of a radiopharmaceutical shall be labeled with:

(i) the name, address, and phone number of the pharmacy;

(ii) the date dispensed;

(iii) the directions for use, if applicable;

(iv) the unique identification number of the prescription;

(v) the name of the patient if known, or the statement, "for physician use" if the patient is unknown;

(vi) the standard radiation symbol;
(vii) the words "caution-radioactive material" or "danger, radioactive material";
(viii) the name of the radiopharmaceutical or its abbreviation;
(ix) the amount of radioactive material contained in millicuries (mCi), microcuries (uCi), or bequerels (Bq) and the corresponding time that applies to this activity, if different from the requested calibration date and time;
(x) the initials or identification codes of the person preparing the product and the authorized nuclear pharmacist who checked and released the final product unless recorded in the pharmacy's data processing system. The record of the identity of these individuals shall not be altered in the pharmacy's data processing system.
(xi) if a liquid, the volume in milliliters;
(xii) the requested calibration date and time; and
(xiii) the expiration date and/or time.

(C) The amount of radioactivity shall be determined by radiometric methods for each individual preparation immediately at the time of dispensing and calculations shall be made to determine the amount of activity that will be present at the requested calibration date and time, due to radioactive decay in the intervening period, and this activity and time shall be placed on the label per requirements set out in paragraph (4) of this subsection.

(d) Equipment. The following minimum equipment is required in a nuclear pharmacy:

(1) vertical laminar flow hood;
(2) dose calibrator;
(3) a calibrated system or device (i.e., thermometer) to monitor the temperature to ensure that proper storage requirements are met, if preparations are stored in the refrigerator;
(4) if applicable, a Class A prescription balance, or analytical balance and weights. Such balance shall be properly maintained and subject to periodic inspection by the board.
(5) scintillation analyzer;
(6) microscope and hemocytometer;
(7) equipment and utensils necessary for the proper compounding of prescription drug or medication orders. Such equipment and utensils used in the compounding process shall be:

(A) of appropriate design, appropriate capacity, and be operated within designed operational limits;
(B) of suitable composition so that surfaces that contact components, in-process material, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond acceptable standards;
(C) cleaned and sanitized immediately prior to each use; and
(D) routinely inspected, calibrated (if necessary), or checked to ensure proper performance;

(8) appropriate disposal containers for used needles, syringes, etc., and if applicable, cytotoxic waste from the preparation of chemotherapeutic agents, and/or biohazardous waste;
(9) all necessary supplies, including:

(A) disposable needles, syringes, and other aseptic mixing;
(B) disinfectant cleaning solutions;
(C) hand washing agents with bactericidal action;
(D) disposable, lint free towels or wipes;
(E) appropriate filters and filtration equipment;
(F) radioactive spill kits, if applicable; and
(G) masks, caps, coveralls or gowns with tight cuffs, shoe covers, and gloves, as applicable.

(10) adequate glassware, utensils, gloves, syringe shields and remote handling devices, and adequate equipment for product quality control;
(11) adequate shielding material;

(12) data processing system including a printer or comparable equipment;
(13) radiation dosimeters for visitors and personnel and log entry book;
(14) exhaust/fume hood with monitor, for storage and handling of all volatile radioactive drugs if applicable, to be determined by the Texas Department of State Health Services, Radiation Control Program; and
(15) adequate radiation monitor(s).

(e) Library. A nuclear pharmacy shall maintain a reference library which shall include the following in hard copy or electronic format current or updated copies of the following:
(1) Texas Pharmacy Act and rules;
(2) Texas Dangerous Drug Act and rules;
(3) Texas Controlled Substances Act and rules; and
(4) Federal Controlled Substances Act and rules (or official publication describing the requirements of the Federal Controlled Substances Act and rules); and
(5) a minimum of one text dealing with nuclear medicine science.

(f) Radiopharmaceuticals and/or radioactive materials.
(1) General requirements.
(A) Radiopharmaceuticals may only be dispensed pursuant to a radioactive prescription drug order.
(B) An authorized nuclear pharmacist may distribute radiopharmaceuticals to authorized users for patient use. A nuclear pharmacy may furnish radiopharmaceuticals for departmental or physicians' use if such authorized users maintain a Texas radioactive materials license.
(C) An authorized nuclear pharmacist may transfer to authorized users radioactive materials not intended for drug use in accordance with the requirements of the Texas Department of State Health Services, Radiation Control Program, Texas Administrative Code, Title 25, Part 1, Subchapter F, §289.252 relating to Licensing of Radioactive Material.
(D) The transportation of radioactive materials from the nuclear pharmacy must be in accordance with current state and federal transportation regulations.
(2) Procurement and storage.
(A) The pharmacist-in-charge shall have the responsibility for the procurement and storage of drugs, but may receive input from other appropriate staff relative to such responsibility.
(B) Prescription drugs and devices shall be stored within the prescription department or a locked storage area.
(C) All drugs shall be stored at the proper temperature, as defined in the USP/NF and §291.15 of this title (relating to Storage of Drugs).
(D) The pharmacy's generator(s) shall be stored and eluted in an ISO Class 7 or ISO Class 8 environment as specified in §291.133 of this title.
(3) Out-of-date and other unusable drugs or devices.
(A) Any drug or device bearing an expiration date shall not be dispensed beyond the expiration date of the drug or device.
(B) Outdated and other unusable drugs or devices shall be removed from dispensing stock and shall be quarantined together until such drugs or devices are disposed of properly.

§291.55 Records

(a) Maintenance of records.
(1) Every inventory or other record required to be kept under this section 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 other authorized local, state, or federal law enforcement agencies; and
(B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the board. If the pharmacy maintains the records in an electronic format, the requested records must be provided in a

mutually agreeable electronic format it specifically requested by the board or its representative. Failure to provide the records set out in this subsection, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(2) Records of controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy.

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

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

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

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

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

(b) Prescriptions.

(1) Professional responsibility. Pharmacists shall exercise sound professional judgment with respect to the accuracy and authenticity of any radioactive prescription drug order they dispense. If the pharmacist questions the accuracy or authenticity of a radioactive prescription drug order, he/she shall verify the order with the practitioner prior to dispensing.

(2) Oral radioactive prescription drug orders.

(A) Only a pharmacist may receive an oral prescription drug order for a controlled substance. Only an authorized nuclear pharmacist, or a pharmacist-intern or pharmacy technician under the direct supervision of an authorized nuclear pharmacist, may receive from a practitioner or a practitioner's designated agent:

(i) an oral therapeutic prescription drug order; or

(ii) an oral diagnostic prescription drug order in instances where patient specificity is required for patient safety (e.g., radiolabeled blood products, radiolabeled antibodies).

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

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

(3) Radioactive prescription drug orders issued by practitioners in another state.

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

(B) Controlled substance prescription drug orders. A pharmacist may dispense radioactive prescription drug orders for controlled substances in Schedule III, IV, or V issued by a practitioner in another state provided:

(i) the radioactive prescription drug order is 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 Drug Enforcement Administration registration number, and who may legally prescribe Schedule III, IV, or V controlled substances in such other state; and

(ii) the radioactive prescription drug order is not dispensed more than six months from the initial date of issuance.

(4) Radioactive prescription drug orders issued by practitioners in the United Mexican States or the Dominion of Canada.

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

(B) Dangerous drug prescription drug orders. A pharmacist may dispense a radioactive prescription drug order for a dangerous drug issued by a person licensed in the Dominion of Canada or the United Mexican States as a physician, dentist, veterinarian, or podiatrist provided the radioactive prescription drug order is an original written prescription.

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

(5) Electronic radioactive prescription drug orders. For the purpose of this paragraph, electronic radioactive prescription drug orders shall be considered the same as oral radioactive prescription drug orders.

(A) An electronic radioactive prescription drug order 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:

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

(II) 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.

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

(C) A pharmacist may not dispense an electronic radioactive prescription drug order for a:

(i) Schedule II controlled substance except as authorized in §481.075, Health and Safety Code; or

(ii) dangerous drug or controlled substance issued by a practitioner licensed in the Dominion of Canada or the United Mexican States unless the practitioner is also licensed in Texas.

(6) Original prescription drug order records.

(A) Original prescriptions shall be maintained and readily retrievable by the pharmacy and remain accessible for a period of two years from the date of filling.

(B) 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.

(C) Original prescriptions shall be maintained in one of the following formats:

(i) 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; or

(ii) within a patient medication record system provided that original prescriptions for controlled substances are maintained separate from original prescriptions for noncontrolled substances and prescriptions for Schedule II controlled substances are maintained separate from all other original prescriptions.

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

(i) The original prescription records must be maintained and readily retrievable as specified in subparagraph (C) of this paragraph.

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

(7) Prescription drug order information.

(A) All original radioactive prescription drug orders shall bear:

(i) the name of the patient, if applicable at the time of the order;

(ii) the name of the institution;

(iii) the name, and if for a controlled substance, the address and DEA registration number of the practitioner;

(iv) the name of the radiopharmaceutical;

(v) the amount of radioactive material contained in millicuries (mCi), microcuries (uCi), or bequerels (Bq) and the corresponding time that applies to this activity, if different than the requested calibration date and time;

(vi) the date and time of calibration; and

(vii) the date of issuance.

(B) At the time of dispensing, a pharmacist is responsible for the addition of the following information to the original prescription:

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

(ii) the initials or identification code of the person who compounded the sterile radiopharmaceutical and the pharmacist who checked and released the product unless maintained in a readily retrievable format;

(iii) the name, quantity, lot number, and expiration date of each product used in compounding the sterile radiopharmaceutical; and

(iv) the date of dispensing, if different from the date of issuance.

(8) Refills. A radioactive prescription drug order must be filled from an original prescription which may not be refilled.

(c) Policy and procedure manual.

(1) All nuclear pharmacies shall maintain a policy and procedure manual. The nuclear pharmacy policy and procedure manual is a compilation of written policy and procedure statements.

(2) A technical operations manual governing all nuclear pharmacy functions shall be prepared. It shall be continually revised to reflect changes in techniques, organizations, etc. All pharmacy personnel shall be familiar with the contents of the manual.

(3) The nuclear pharmacy policies and procedures manual shall be prepared by the pharmacist-in-charge with input from the affected personnel and from other involved staff and committees to govern procurement, preparation, distribution, storage, disposal, and control of all drugs used and the need for policies and procedures relative to procurement of multisource items, inventory, investigational drugs, and new drug applications.

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

(1) a permanent log of the initials or identification codes which identifies each dispensing pharmacist by name (the initials or identification codes shall be unique to ensure that each pharmacist can be identified, i.e., identical initials or identification codes shall not be used);
(2) copy 3 of DEA order forms (DEA 222) which have been properly dated, initialed, and filed, and all copies of each unaccepted or defective order form and any attached statements or other documents;
(3) a hard copy of the power of attorney to sign DEA 222 order forms (if applicable);
(4) suppliers' invoices of 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 reports of surrender or destruction of controlled substances and/or dangerous drugs to an appropriate state or federal agency;
(8) records of distribution of controlled substances and/or dangerous drugs to other pharmacies, practitioners, or registrants; and
(9) a hard copy of any notification required by the Texas Pharmacy Act or these sections, including, but not limited to, the following:
(A) reports of theft or significant loss of controlled substances to DEA and the board;
(B) notifications of a change in pharmacist-in-charge of a pharmacy; and
(C) reports of a fire or other disaster which may affect the strength, purity, or labeling of drugs, medications, devices, or other materials used in the diagnosis or treatment of injury, illness, and disease.

(e) Permission to maintain central records. Any pharmacy that uses a centralized recordkeeping system for invoices and financial data shall comply with the following procedures.
(1) Controlled substance records. Invoices and financial data for controlled substances may be maintained at a central location provided the following conditions are met.
(A) Prior to the initiation of central recordkeeping, the pharmacy submits written notification by registered or certified mail to the divisional director of DEA as required by the Code of Federal Regulations, Title 21, §1304.04(a), and submits a copy of this written notification to the board. Unless the registrant is informed by the divisional director of DEA that permission to keep central records is denied, the pharmacy may maintain central records commencing 14 days after receipt of notification by the divisional director.
(B) The pharmacy maintains a copy of the notification required in subparagraph (A) of this paragraph.
(C) The records to be maintained at the central record location shall not include executed DEA order forms, prescription drug orders, or controlled substance inventories, which shall be maintained at the pharmacy.
(2) Dangerous drug records. Invoices and financial data for dangerous drugs may be maintained at a central location.
(3) Access to records. If the records are kept 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 an authorized agent of the board or any other authorized official.
(5) Ownership of pharmacy records. For purposes of these sections, a pharmacy licensed under the Act is the only entity which may legally own and maintain prescription drug records.

SUBCHAPTER D – INSTITUTIONAL PHARMACY (CLASS C)

§291.71 Purpose

The purpose of these sections is to provide standards in the conduct, practice activities, and operation of a pharmacy located in a hospital or other inpatient facility that is licensed under the Texas Hospital Licensing Law, the Health and Safety Code, Chapter 241, or the Texas Mental Health Code, Chapter 6, Texas Civil Statutes, Article 5547-1 et seq., or a pharmacy located in a hospital maintained or operated by the state. The intent of these standards is to establish a minimum acceptable level of pharmaceutical care to the patient so that the patient's health is protected while contributing to positive patient outcomes.

§291.72 Definitions

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

(1) Accurately as prescribed--Distributing and/or delivering a medication drug order:

(A) to the correct patient (or agent of the patient) for whom the drug or device was prescribed;

(B) with the correct drug in the correct strength, quantity, and dosage form ordered by the practitioner; and

(C) with correct labeling as ordered by the practitioner and required by rule.

(2) Act--The Texas Pharmacy Act, Chapters 551 - 566 and 568 - 569, Occupations Code, as amended.

(3) Administer--The direct application of a prescription drug by injection, inhalation, ingestion, or any other means to the body of a patient by:

(A) a practitioner, an authorized agent under his supervision, or other person authorized by law; or

(B) the patient at the direction of a practitioner.

(4) Automated compounding or counting device--An automated device that compounds, measures, counts and/or packages a specified quantity of dosage units of a designated drug product.

(5) Automated medication supply system--A mechanical system that performs operations or activities relative to the storage and distribution of medications for administration and which collects, controls, and maintains all transaction information.

(6) Board--The State Board of Pharmacy.

(7) Clinical Pharmacy Program--An ongoing program in which pharmacists are on duty during the time the pharmacy is open for pharmacy services and pharmacists provide direct focused, medication-related care for the purpose of optimizing patients' medication therapy and achieving definite outcomes, which includes the following activities:

(A) prospective medication therapy consultation, selection, and adjustment;

(B) monitoring laboratory values and therapeutic drug monitoring;

(C) identifying and resolving medication-related problems; and

(D) disease state management.

(8) Common ownership--Two or more pharmacies with an identical owner of record with the board or that have owners of record with the board that are a parent, subsidiary, or affiliate of one another under §1.002, Business Organizations Code.

(9) Confidential record--Any health-related record that contains information that identifies an individual and that is maintained by a pharmacy or pharmacist, such as a patient medication record, prescription drug order, or medication drug order.

(10) Consultant pharmacist--A pharmacist retained by a facility on a routine basis to consult with the facility in areas that pertain to the practice of pharmacy.

(11) Controlled substance--A drug, immediate precursor, or other substance listed in Schedules I - V or Penalty Groups 1 - 4 of the Texas Controlled Substances Act, as amended, or a drug, immediate precursor, or other substance included in Schedules I - V of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public Law 91-513).

(12) Dangerous drug--A drug or device that:

(A) is not included in Penalty Group 1, 2, 3, or 4, Chapter 481, Health and Safety Code, and is unsafe for self-medication; or

(B) bears or is required to bear the legend:

(i) "Caution: federal law prohibits dispensing without prescription" or "Rx only" or another legend that complies with federal law; or

(ii) "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian."

(13) Device--An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part or accessory, that is required under federal or state law to be ordered or prescribed by a practitioner.

(14) Direct copy--Electronic copy or carbonized copy of a medication order, including a facsimile (FAX) or digital image.

(15) Dispense--Preparing, packaging, compounding, or labeling for delivery a prescription drug or device in the course of professional practice to an ultimate user or his agent by or pursuant to the lawful order of a practitioner.

(16) Distribute--The delivery of a prescription drug or device other than by administering or dispensing.

(17) Distributing pharmacist--The pharmacist who checks the medication order prior to distribution.

(18) Downtime--Period of time during which a data processing system is not operable.

(19) Drug regimen review--

(A) An evaluation of medication orders and patient medication records for:

(i) known allergies;

(ii) rational therapy--contraindications;

(iii) reasonable dose and route of administration;

(iv) reasonable directions for use;

(v) duplication of therapy;

(vi) drug-drug interactions;

(vii) drug-food interactions;

(viii) drug-disease interactions;

(ix) adverse drug reactions; and

(x) proper utilization, including overutilization or underutilization.

(B) The drug regimen review may be conducted prior to administration of the first dose (prospective) or after administration of the first dose (retrospective).

(20) Electronic signature--A unique security code or other identifier which specifically identifies the person entering information into a data processing system. A facility which utilizes electronic signatures must:

(A) maintain a permanent list of the unique security codes assigned to persons authorized to use the data processing system; and

(B) have an ongoing security program which is capable of identifying misuse and/or unauthorized use of electronic signatures.

(21) Expiration date--The date (and time, when applicable) beyond which a product should not be used.

(22) Facility--

(A) a hospital or other patient facility that is licensed under Chapter 241 or 577, Health and Safety Code;

(B) a hospice patient facility that is licensed under Chapter 142, Health and Safety Code;

(C) an ambulatory surgical center licensed under Chapter 243, Health and Safety Code; or

(D) a hospital maintained or operated by the state.

(23) Floor stock--Prescription drugs or devices not labeled for a specific patient and maintained at a nursing station or other hospital department (excluding the pharmacy) for the purpose of administration to a patient of the facility.

(24) Formulary--List of drugs approved for use in the facility by the committee which performs the pharmacy and therapeutics function for the facility.

(25) Full-time pharmacist--A pharmacist who works in a pharmacy from 30 to 40 hours per week or if the pharmacy is open less than 60 hours per week, one-half of the time the pharmacy is open.
(26) Hard copy--A physical document that is readable without the use of a special device (i.e., data processing system, computer, etc).
(27) Hot water--The temperature of water from the pharmacy's sink maintained at a minimum of 105 degrees F (41 degrees C).
(28) Institutional pharmacy--Area or areas in a facility where drugs are stored, bulk compounded, delivered, compounded, dispensed, and distributed to other areas or departments of the facility, or dispensed to an ultimate user or his or her agent.
(29) Investigational new drug--New drug intended for investigational use by experts qualified to evaluate the safety and effectiveness of the drug as authorized by the Food and Drug Administration.
(30) Medical Practice Act--The Texas Medical Practice Act, Subtitle B, Occupations Code, as amended.
(31) Medication order--A written order from a practitioner or a verbal order from a practitioner or his authorized agent for administration of a drug or device.
(32) Number of beds--The total number of beds is determined by the:

(A) number of beds for which the hospital is licensed by the Texas Department of State Health Services; or

(B) average daily census as calculated by dividing the total number of inpatients admitted during the previous calendar year by 365 (or 366 if the previous calendar year is a leap year).

(33) Owner of record--The direct owner of the pharmacy provided on the pharmacy's application for a pharmacy license or most recent approved change of ownership form.
(34) Part-time pharmacist--A pharmacist either employed or under contract, who routinely works less than full-time.
(35) Patient--A person who is receiving services at the facility (including patients receiving ambulatory procedures and patients conditionally admitted as observation patients), or who is receiving long term care services or Medicare extended care services in a swing bed on the hospital premise or an adjacent, readily accessible facility that is under the authority of the hospital's governing body. For the purposes of this definition, the term "long term care services" means those services received in a skilled nursing facility which is a distinct part of the hospital and the distinct part is not licensed separately or formally approved as a nursing home by the state, even though it is designated or certified as a skilled nursing facility. A patient includes a person confined in any correctional institution operated by the state of Texas.
(36) Perpetual inventory--An inventory which documents all receipts and distributions of a drug product, such that an accurate, current balance of the amount of the drug product present in the pharmacy is indicated.
(37) Pharmaceutical care--The provision of drug therapy and other pharmaceutical services intended to assist in the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process.
(38) Pharmacist-in-charge--Pharmacist designated on a pharmacy license as the pharmacist who has the authority or responsibility for a pharmacy's compliance with laws and rules pertaining to the practice of pharmacy.
(39) Pharmacy and therapeutics function--Committee of the medical staff in the facility which assists in the formulation of broad professional policies regarding the evaluation, selection, distribution, handling, use, and administration, and all other matters relating to the use of drugs and devices in the facility.
(40) Pharmacy technician--An individual who is registered with the board as a pharmacy technician and whose responsibility in a pharmacy is to provide technical services that do not require professional judgment regarding preparing and distributing drugs and who works under the direct supervision of and is responsible to a pharmacist.
(41) Pharmacy technician trainee--An individual who is registered with the board as a pharmacy technician trainee and is authorized to participate in a pharmacy's technician training program.

(42) Pre-packaging--The act of re-packaging and re-labeling quantities of drug products from a manufacturer's original container into unit-dose packaging or a multiple dose container for distribution within the facility except as specified in §291.74(f)(3)(B) of this title (relating to Operational Standards).

(43) Prescription drug--

(A) A substance for which federal or state law requires a prescription before it may be legally dispensed to the public;

(B) A drug or device that under federal law is required, prior to being dispensed or delivered, to be labeled with either of the following statements:

(i) Caution: federal law prohibits dispensing without prescription or "Rx only" or another legend that complies with federal law; or

(ii) Caution: federal law restricts this drug to use by or on order of a licensed veterinarian; or

(C) A drug or device that is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by a practitioner only.

(44) Prescription drug order--

(A) a written order from a practitioner or a verbal order from a practitioner or his authorized agent to a pharmacist for a drug or device to be dispensed; or

(B) a written order or a verbal order pursuant to Subtitle B, Chapter 157, Occupations Code.

(45) Rural hospital--A licensed hospital with 75 beds or fewer that:

(A) is located in a county with a population of 50,000 or less as defined by the United States Census Bureau in the most recent U.S. census; or

(B) has been designated by the Centers for Medicare and Medicaid Services as a critical access hospital, rural referral center, or sole community hospital.

(46) Sample--A prescription drug which is not intended to be sold and is intended to promote the sale of the drug.

(47) Supervision--

(A) Physically present supervision--In a Class C pharmacy, a pharmacist shall be physically present to directly supervise pharmacy technicians or pharmacy technician trainees.

(B) Electronic supervision--In a Class C pharmacy in a facility with 100 beds or less, a pharmacist licensed in Texas may electronically supervise pharmacy technicians or pharmacy technician trainees to perform the duties specified in §291.73(e)(2) of this title (relating to Personnel) provided:

(i) the pharmacy uses a system that monitors the data entry of medication orders and the filling of such orders by an electronic method that shall include the use of one or more the following types of technology:

(I) digital interactive video, audio, or data transmission;

(II) data transmission using computer imaging by way of still-image capture and store and forward; and

(III) other technology that facilitates access to pharmacy services;

(ii) the pharmacy establishes controls to protect the privacy and security of confidential records;

(iii) the pharmacist responsible for the duties performed by a pharmacy technician or pharmacy technician trainee verifies:

(I) the data entry; and

(II) the accuracy of the filled orders prior to release of the order; and

(iv) the pharmacy keeps permanent digital records of duties electronically supervised and data transmissions associated with electronically supervised duties for a period of two years.

(C) If the conditions of subparagraph (B) of this paragraph are met, electronic supervision shall be considered the equivalent of direct supervision for the purposes of the Act.

(48) Tech-Check-Tech--Allowing a pharmacy technician to verify the accuracy of work performed by another pharmacy technician relating to the filling of floor stock and unit dose distribution systems for a patient admitted to the hospital if the patient's orders have previously been reviewed and approved by a pharmacist.
(49) Texas Controlled Substances Act--The Texas Controlled Substances Act, the Health and Safety Code, Chapter 481, as amended.
(50) Unit-dose packaging--The ordered amount of drug in a dosage form ready for administration to a particular patient, by the prescribed route at the prescribed time, and properly labeled with name, strength, and expiration date of the drug.
(51) Unusable drugs--Drugs or devices that are unusable for reasons, such as they are adulterated, misbranded, expired, defective, or recalled.
(52) Written protocol--A physician's order, standing medical order, standing delegation order, or other order or protocol as defined by rule of the Texas Medical Board under the Texas Medical Practice Act Subtitle B, Chapter 157, Occupations Code.

§291.73 Personnel

(a) Requirements for pharmacist services.

(1) A Class C pharmacy in a facility with 101 beds or more shall be under the continuous on-site supervision of a pharmacist during the time it is open for pharmacy services; provided, however, that pharmacy technicians and pharmacy technician trainees may distribute prepackaged and prelabeled drugs from a drug storage area of the facility (e.g., a surgery suite), in the absence of physical supervision of a pharmacist, under the following conditions:

(A) the distribution is under the control of a pharmacist; and

(B) a pharmacist is on duty in the facility.

(2) A Class C pharmacy in a facility with 100 beds or less shall have the services of a pharmacist at least on a part-time or consulting basis according to the needs of the facility except that a pharmacist shall be on-site at least once every seven days.

(3) A pharmacist shall be accessible at all times to respond to other health professional's questions and needs. Such access may be through a telephone which is answered 24 hours a day, e.g., answering or paging service, a list of phone numbers where the pharmacist may be reached, or any other system which accomplishes this purpose.

(b) Pharmacist-in-charge.

(1) General.

(A) Each institutional pharmacy in a facility with 101 beds or more shall have one full-time pharmacist-in-charge, who may be pharmacist-in-charge for only one such pharmacy except as specified in subparagraph (C) of this paragraph.

(B) Each institutional pharmacy in a facility with 100 beds or less shall have one pharmacist-in-charge who is employed or under contract, at least on a consulting or part-time basis, but may be employed on a full-time basis, if desired, and who may be pharmacist-in-charge for no more than three facilities or 150 beds.

(C) A pharmacist-in-charge may be in charge of one facility with 101 beds or more and one facility with 100 beds or less, including a rural hospital, provided the total number of beds does not exceed 150 beds.

(D) The pharmacist-in-charge shall be assisted by additional pharmacists, pharmacy technicians and pharmacy technician trainees commensurate with the scope of services provided.

(E) If the pharmacist-in-charge is employed on a part-time or consulting basis, a written agreement shall exist between the facility and the pharmacist, and a copy of the written agreement shall be made available to the board upon request.

(F) The pharmacist-in-charge of a Class C pharmacy with 101 beds or more, may not serve as the pharmacist-in-charge of a Class A pharmacy or a Class B pharmacy.

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

(A) providing the appropriate level of pharmaceutical care services to patients of the facility;

(B) ensuring that drugs and/or devices are prepared for distribution safely, and accurately as prescribed;

(C) supervising a system to assure maintenance of effective controls against the theft or diversion of prescription drugs, and records for such drugs;

(D) providing written guidelines and approval of the procedure to assure that all pharmaceutical requirements are met when any part of preparing, sterilizing, and labeling of sterile preparations is not performed under direct pharmacy supervision;

(E) participating in the development of a formulary for the facility, subject to approval of the appropriate committee of the facility;

(F) developing a system to assure that drugs to be administered to patients are distributed pursuant to an original or direct copy of the practitioner's medication order;

(G) developing a system for the filling and labeling of all containers from which drugs are to be distributed or dispensed;

(H) assuring that the pharmacy maintains and makes available a sufficient inventory of antidotes and other emergency drugs as well as current antidote information, telephone numbers of regional poison control center and other emergency assistance organizations, and such other materials and information as may be deemed necessary by the appropriate committee of the facility;

(I) maintaining records of all transactions of the institutional pharmacy as may be required by applicable law, state and federal, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials including pharmaceuticals, components used in the compounding of preparations, and participate in policy decisions regarding prescription drug delivery devices;

(J) participating in those aspects of the facility's patient care evaluation program which relate to pharmaceutical utilization and effectiveness;

(K) participating in teaching and/or research programs in the facility;

(L) implementing the policies and decisions of the appropriate committee(s) relating to pharmaceutical services of the facility;

(M) providing effective and efficient messenger or delivery service to connect the institutional pharmacy with appropriate areas of the facility on a regular basis throughout the normal workday of the facility;

(N) developing a system for the labeling, storage, and distribution of investigational new drugs, including access to related drug information for healthcare personnel in the pharmacy and nursing station where such drugs are being administered, concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interactions and symptoms of toxicity of investigational new drugs;

(O) assuring that records in a data processing system are maintained such that the data processing system is in compliance with Class C (Institutional) pharmacy requirements;

(P) assuring that a reasonable effort is made to obtain, record, and maintain patient medication records;

(Q) assuring the legal operation of the pharmacy, including meeting all inspection and other requirements of all state and federal laws or rules governing the practice of pharmacy; and

(R) if the pharmacy uses an automated medication supply system, shall be responsible for the following:

(i) reviewing and approving all policies and procedures for system operation, safety, security, accuracy and access, patient confidentiality, prevention of unauthorized access, and malfunction;

(ii) inspecting medications in the automated medication supply system, at least monthly, for expiration date, misbranding, physical integrity, security, and accountability; except that

inspection of medications in the automated medication supply system may be performed quarterly if:

(I) the facility uses automated medication supply systems that monitors expiration dates of prescription drugs; and

(II) security of the system is checked at regularly defined intervals (e.g., daily or weekly);

(iii) assigning, discontinuing, or changing personnel access to the automated medication supply system;

(iv) ensuring that pharmacy technicians, pharmacy technician trainees, and licensed healthcare professionals performing any services in connection with an automated medication supply system have been properly trained on the use of the system and can demonstrate comprehensive knowledge of the written policies and procedures for operation of the system; and

(v) ensuring that the automated medication supply system is stocked accurately and an accountability record is maintained in accordance with the written policies and procedures of operation.

(c) Consultant pharmacist.

(1) The consultant pharmacist may be the pharmacist-in-charge.

(2) A written agreement shall exist between the facility and any consultant pharmacist, and a copy of the written agreement shall be made available to the board upon request.

(d) Pharmacists.

(1) General.

(A) The pharmacist-in-charge shall be assisted by a sufficient number of additional licensed pharmacists as may be required to operate the institutional pharmacy competently, safely, and adequately to meet the needs of the patients of the facility.

(B) All pharmacists shall assist the pharmacist-in-charge in meeting the responsibilities as outlined in subsection (b)(2) of this section and in ordering, administering, and accounting for pharmaceutical materials.

(C) All pharmacists shall be responsible for any delegated act performed by pharmacy technicians or pharmacy technician trainees under his or her supervision.

(D) All pharmacists while on duty, shall be responsible for complying with all state and federal laws or rules governing the practice of pharmacy.

(E) A distributing pharmacist shall be responsible for and ensure that the drug is prepared for distribution safely, and accurately as prescribed unless the pharmacy's data processing system can record the identity of each pharmacist involved in a specific portion of the preparation of medication orders for distribution, in which case each pharmacist involved in the preparation of medication orders shall be responsible for and ensure that the portion of the process the pharmacist is performing results in the safe and accurate distribution and delivery of the drug as ordered. The preparation and distribution process for medication orders shall include, but not be limited to, drug regimen review, and verification of accurate medication order data entry, preparation, and distribution, and performance of the final check of the prepared medication.

(2) Duties. Duties of the pharmacist-in-charge and all other pharmacists shall include, but need not be limited to the following:

(A) providing those acts or services necessary to provide pharmaceutical care;

(B) receiving, interpreting, and evaluating prescription drug orders, and reducing verbal medication orders to writing either manually or electronically;

(C) participating in drug and/or device selection as authorized by law, drug and/or device supplier selection, drug administration, drug regimen review, or drug or drug-related research;

(D) performing a specific act of drug therapy management for a patient delegated to a pharmacist by a written protocol from a physician licensed in this state in compliance with the Medical Practice Act Subtitle B, Chapter 157, Occupations Code;

(E) accepting the responsibility for:

(i) distributing prescription drugs and devices with drug components pursuant to medication orders;

(ii) compounding and labeling of prescription drugs and devices with drug components;

(iii) proper and safe storage of prescription drugs and devices with drug components; and

(iv) maintaining proper records for prescription drugs and devices with drug components.

(3) Special requirements for compounding. All pharmacists engaged in compounding non-sterile preparations shall meet the training requirements specified in §291.131 of this title (relating to Pharmacies Compounding Non-sterile Preparations).

(e) Pharmacy technicians and pharmacy technician trainees.

(1) General.

(A) All pharmacy technicians and pharmacy technician trainees shall meet the training requirements specified in §297.6 of this title (relating to Pharmacy Technician and Pharmacy Technician Trainee Training).

(B) A pharmacy technician performing the duties specified in paragraph (2)(C) of this subsection shall complete training regarding:

(i) procedures for one pharmacy technician to verify the accuracy of actions performed by another pharmacy technician including required documentation; and

(ii) the duties that may be performed by one pharmacy technician and checked by another pharmacy technician.

(C) In addition to the training requirements specified in subparagraph (A) of this paragraph, pharmacy technicians working in a rural hospital and performing the duties specified in paragraph (2)(D)(ii) of this subsection shall complete the following. Training on the:

(i) procedures for verification of the accuracy of actions performed by pharmacy technicians including required documentation;

(ii) duties which may and may not be performed by pharmacy technicians in the absence of a pharmacist; and

(iii) pharmacy technician's role in preventing dispensing and distribution errors.

(2) Duties. Duties may include, but need not be limited to, the following functions under the supervision of and responsible to a pharmacist:

(A) Facilities with 101 beds or more. The following functions must be performed under the physically present supervision of a pharmacist:

(i) pre-packing and labeling unit and multiple dose packages, provided a pharmacist supervises and conducts a final check and affixes his or her name, initials or electronic signature to the appropriate quality control records prior to distribution;

(ii) preparing, packaging, compounding, or labeling prescription drugs pursuant to medication orders, provided a pharmacist supervises and checks the preparation prior to distribution;

(iii) bulk compounding or batch preparation provided a pharmacist supervises and conducts in-process and final checks and affixes his or her name, initials, or electronic signature to the appropriate quality control records prior to distribution;

(iv) distributing routine orders for stock supplies to patient care areas;

(v) entering medication order and drug distribution information into a data processing system, provided judgmental decisions are not required and a pharmacist checks the accuracy of the information entered into the system prior to releasing the order;

(vi) loading unlabeled drugs into an automated compounding or counting device provided a pharmacist supervises, verifies that the system was properly loaded prior to use, and affixes his or her name, initials or electronic signature to the appropriate quality control records;
(vii) accessing automated medication supply systems after proper training on the use of the automated medication supply system and demonstration of comprehensive knowledge of the written policies and procedures for its operation; and
(viii) compounding non-sterile preparations pursuant to medication orders provided the pharmacy technicians or pharmacy technician trainees have completed the training specified in §291.131 of this title.

(B) Facilities with 100 beds or less.

(i) Physically present supervision. The following functions must be performed under the physically present supervision of a pharmacist unless the pharmacy meets the requirements for a rural hospital and has been approved by the board to allow pharmacy technicians to perform the duties specified in §562.1011 of the Texas Pharmacy Act and subparagraph (D)(ii) of this paragraph:

(I) pre-packing and labeling unit and multiple dose packages, provided a pharmacist supervises and conducts a final check and affixes his or her name, initials or electronic signature to the appropriate quality control records prior to distribution;
(II) bulk compounding or batch preparation provided a pharmacist supervises and conducts in-process and final checks and affixes his or her name, initials, or electronic signature to the appropriate quality control records prior to distribution;
(III) loading unlabeled drugs into an automated compounding or counting device provided a pharmacist supervises, verifies that the system was properly loaded prior to use, and affixes his or her name, initials, or electronic signature to the appropriate quality control records; and
(IV) compounding medium-risk and high-risk sterile preparations pursuant to medication orders provided the pharmacy technicians or pharmacy technician trainees:

(-a-) have completed the training specified in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations); and
(-b-) are supervised by a pharmacist who has completed the training specified in §291.133 of this title and who conducts in-process and final checks, and affixes his or her name, initials, or electronic signature to the label or if batch prepared, to the appropriate quality control records. (The name, initials, or electronic signature are not required on the label if it is maintained in a permanent record of the pharmacy.)

(ii) Electronic supervision or physically present supervision. The following functions may be performed under the electronic supervision or physically present supervision of a pharmacist:

(I) preparing, packaging, or labeling prescription drugs pursuant to medication orders, provided a pharmacist checks the preparation prior to distribution;
(II) distributing routine orders for stock supplies to patient care areas;
(III) entering medication order and drug distribution information into a data processing system, provided judgmental decisions are not required and a pharmacist checks the accuracy of the information entered into the system prior to releasing the order;
(IV) accessing automated medication supply systems after proper training on the use of the automated medication supply system and demonstration of comprehensive knowledge of the written polices and procedures for its operation;

(V) compounding non-sterile preparations pursuant to medication orders provided the pharmacy technicians or pharmacy technician trainees have completed the training specified in §291.131 of this title; and

(VI) compounding low-risk sterile preparations pursuant to medication orders provided the pharmacy technicians or pharmacy technician trainees:

(-a-) have completed the training specified in §291.133 of this title; and

(-b-) are supervised by a pharmacist who has completed the training specified in §291.133 of this title, and who conducts in-process and final checks, and affixes his or her name, initials, or electronic signature to the label or if batch prepared, to the appropriate quality control records. (The name, initials, or electronic signature are not required on the label if it is maintained in a permanent record of the pharmacy.)

(C) Facilities with an ongoing clinical pharmacy program. A Class C pharmacy with an ongoing clinical pharmacy program may allow a pharmacy technician to verify the accuracy of the duties specified in clause (ii) of this subparagraph when performed by another pharmacy technician, under the following conditions:

(i) The pharmacy technician:

(I) is a registered pharmacy technician and not a pharmacy technician trainee; and

(II) meets the training requirements specified in §297.6 of this title and the training requirements specified in paragraph (1) of this subsection.

(ii) If the requirements of clause (i) of this subparagraph are met, a pharmacy technician may verify the accuracy of the following duties performed by another pharmacy technician:

(I) filling medication carts;

(II) distributing routine orders for stock supplies to patient care areas; and

(III) accessing and restocking automated medication supply systems after proper training on the use of the automated medication supply system and demonstration of comprehensive knowledge of the written policies and procedures for its operation; and

(iii) The patient's orders have previously been reviewed and approved by a pharmacist.

(iv) A pharmacist is on duty in the facility at all times that the pharmacy is open for pharmacy services.

(D) Rural Hospitals.

(i) A rural hospital may allow a pharmacy technician to perform the duties specified in clause (ii) of this subparagraph when a pharmacist is not on duty, if:

(I) the pharmacy technician:

(-a-) is a registered pharmacy technician and not a pharmacy technician trainee; and

(-b-) meets the training requirements specified in §297.6 of this title and those specified in paragraph (1) of this subsection;

(II) a pharmacist is accessible at all times to respond to any questions and needs of the pharmacy technician or other hospital employees, by telephone, answering or paging service, e-mail, or any other system that makes a pharmacist immediately accessible;

(III) the pharmacy is appropriately staffed to meet the needs of the pharmacy; and

(IV) a nurse or practitioner at the rural hospital or a pharmacist through electronic supervision as specified in paragraph (2)(B)(ii) of this subsection, verifies the accuracy of the actions of the pharmacy technician.

(ii) If the requirements of clause (i) of this subparagraph are met, the pharmacy technician may, during the hours that the institutional pharmacy in the hospital is open, perform the following duties in the pharmacy without the direct supervision of a pharmacist:

(I) enter medication order and drug distribution information into a data processing system;
(II) prepare, package, or label a prescription drug according to a medication order if a licensed nurse or practitioner verifies the accuracy of the order before administration of the drug to the patient;
(III) fill a medication cart used in the rural hospital;
(IV) distribute routine orders for stock supplies to patient care areas; and
(V) access and restock automated medication supply cabinets.

(3) Procedures.

(A) Pharmacy technicians and pharmacy technician trainees shall handle medication orders in accordance with standard, written procedures and guidelines.

(B) Pharmacy technicians and pharmacy technician trainees shall handle prescription drug orders in the same manner as those working in a Class A pharmacy.

(f) Owner. The owner of a Class C 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) establishing policies for procurement of prescription drugs and devices and other products dispensed from the Class C pharmacy;

(2) establishing and maintaining effective controls against the theft or diversion of prescription drugs;

(3) if the pharmacy uses an automated pharmacy dispensing system, reviewing and approving all policies and procedures for system operation, safety, security, accuracy and access, patient confidentiality, prevention of unauthorized access, and malfunction;

(4) providing the pharmacy with the necessary equipment and resources commensurate with its level and type of practice; and

(5) establishing policies and procedures regarding maintenance, storage, and retrieval of records in a data processing system such that the system is in compliance with state and federal requirements.

(g) Identification of pharmacy personnel. All pharmacy personnel shall be identified as follows.

(1) Pharmacy technicians. All pharmacy technicians shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacy technician.

(2) Pharmacy technician trainees. All pharmacy technician trainees shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacy technician trainee.

(3) Pharmacist interns. All pharmacist interns shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacist intern.

(4) Pharmacists. All pharmacists shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacist.

§291.74 Operational Standards

(a) Licensing requirements.

(1) A Class C pharmacy shall register annually or biennially with the board on a pharmacy license application provided by the board, following the procedures specified in §291.1 of this title (relating to Pharmacy License Application).

(2) A Class C pharmacy which changes ownership shall notify the board within 10 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).

(3) A Class C pharmacy which changes location and/or name shall notify the board of the change as specified in §291.3 of this title.

(4) A Class C pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within 10 days of the change following the procedures in §291.3 of this title.
(5) A Class C pharmacy shall notify the board in writing within 10 days of closing, following the procedures in §291.5 of this title (relating to Closing a Pharmacy).
(6) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for the issuance and renewal of a license and the issuance of an amended license.
(7) A separate license is required for each principal place of business and only one pharmacy license may be issued to a specific location.
(8) A Class C pharmacy, licensed under the Act, §560.051(a)(3), which also operates another type of pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(1) (Community Pharmacy (Class A)) or the Act, §560.051(a)(2) (Nuclear Pharmacy (Class B)), is not required to secure a license for the such other type of pharmacy; provided, however, such licensee is required to comply with the provisions of §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 Records), contained in Community Pharmacy (Class A), or §291.51 of this title (relating to Purpose), §291.52 of this title (relating to Definitions), §291.53 of this title (relating to Personnel), §291.54 of this title (relating to Operational Standards), and §291.55 of this title (relating to Records), contained in Nuclear Pharmacy (Class B), to the extent such sections are applicable to the operation of the pharmacy.
(9) A Class C pharmacy engaged in the compounding of non-sterile preparations shall comply with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-sterile Preparations).
(10) Class C pharmacy personnel shall not compound sterile preparations unless the pharmacy has applied for and obtained a Class C-S pharmacy.
(11) A Class C pharmacy engaged in the provision of remote pharmacy services, including storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of this title (relating to Remote Pharmacy Services).
(12) A Class C pharmacy engaged in centralized prescription dispensing and/or prescription drug or medication order processing shall comply with the provisions of §291.123 of this title (relating to Central Prescription Drug or Medication Order Processing) and/or §291.125 of this title (relating to Centralized Prescription Dispensing).
(13) A Class C pharmacy with an ongoing clinical pharmacy program that proposes to allow a pharmacy technician to verify the accuracy of work performed by another pharmacy technician relating to the filling of floor stock and unit dose distribution systems for a patient admitted to the hospital if the patient's orders have previously been reviewed and approved by a pharmacist shall make application to the board and submit any information specified on the application.
(14) A rural hospital that wishes to allow a pharmacy technician to perform the duties specified in §291.73(e)(2)(D) of this title (relating to Personnel), shall make application to the board and submit any information specified on the application.

(A) A rural hospital may not allow a pharmacy technician to perform the duties specified in §291.73(e)(2)(D) of this title until the board has reviewed and approved the application and issued an amended license to the pharmacy.

(B) Every two years, in conjunction with the application for renewal of the pharmacy license, the pharmacist-in-charge shall update the application for pharmacy technicians to perform the duties specified in §291.73(e)(2)(D) of this title and shall attest as required on the application.

(b) Environment.

(1) General requirements.

(A) The institutional pharmacy shall have adequate space necessary for the storage, compounding, labeling, dispensing, and sterile preparation of drugs prepared in the pharmacy, and additional space, depending on the size and scope of pharmaceutical services.

(B) The institutional pharmacy shall be arranged in an orderly fashion and shall be kept clean. All required equipment shall be clean and in good operating condition.

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

(D) The institutional pharmacy shall be properly lighted and ventilated.

(E) The temperature of the institutional pharmacy shall be maintained within a range compatible with the proper storage of drugs. The temperature of the refrigerator and/or freezer shall be maintained within a range compatible with the proper storage of drugs.

(F) If the institutional pharmacy has flammable materials, the pharmacy shall have a designated area for the storage of flammable materials. Such area shall meet the requirements set by local and state fire laws.

(G) The institutional pharmacy shall store antiseptics, other drugs for external use, and disinfectants separately from internal and injectable medications.

(2) Security requirements.

(A) The institutional pharmacy shall be enclosed and capable of being locked by key, combination or other mechanical or electronic means, so as to prohibit access by unauthorized individuals. Only individuals authorized by the pharmacist-in-charge shall enter the pharmacy.

(B) Each pharmacist on duty shall be responsible for the security of the institutional pharmacy, including provisions for adequate safeguards against theft or diversion of dangerous drugs, controlled substances, and records for such drugs.

(C) The institutional pharmacy shall have locked storage for Schedule II controlled substances and other drugs requiring additional security.

(c) Equipment and supplies. Institutional pharmacies distributing medication orders shall have the following equipment:

(1) data processing system including a printer or comparable equipment; and

(2) refrigerator and/or freezer and a system or device (e.g., thermometer) to monitor the temperature to ensure that proper storage requirements are met.

(d) Library. A reference library shall be maintained that includes the following in hard-copy or electronic format and that pharmacy personnel shall be capable of accessing at all times:

(1) current copies of the following:

(A) Texas Pharmacy Act and rules;

(B) Texas Dangerous Drug Act and rules;

(C) Texas Controlled Substances Act and regulations; and

(D) Federal Controlled Substances Act and regulations (or official publication describing the requirements of the Federal Controlled Substances Act and regulations);

(2) at least one current or updated reference from each of the following categories:

(A) drug interactions. 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;

(B) a general information reference text;

(3) a current or updated reference on injectable drug products;

(4) basic antidote information and the telephone number of the nearest regional poison control center;

(5) metric-apothecary weight and measure conversion charts.

(e) Absence of a pharmacist.

(1) Medication orders.

(A) In facilities with a full-time pharmacist, if a practitioner orders a drug for administration to a bona fide patient of the facility when the pharmacy is closed, the following is applicable:

(i) Prescription drugs and devices only in sufficient quantities for immediate therapeutic needs may be removed from the institutional pharmacy;
(ii) Only a designated licensed nurse or practitioner may remove such drugs and devices;
(iii) A record shall be made at the time of withdrawal by the authorized person removing the drugs and devices. The record shall contain the following information:
(I) name of patient;
(II) name of device or drug, strength, and dosage form;
(III) dose prescribed;
(IV) quantity taken;
(V) time and date; and
(VI) signature (first initial and last name or full signature) or electronic signature of person making withdrawal;
(iv) The original or direct copy of the medication order may substitute for such record, providing the medication order meets all the requirements of clause (iii) of this subparagraph; and
(v) The pharmacist shall verify the withdrawal of drugs from the pharmacy and perform a drug regimen review as specified in subsection (g)(1)(B) of this section as soon as practical, but in no event more than 72 hours from the time of such withdrawal.

(B) In facilities with a part-time or consultant pharmacist, if a practitioner orders a drug for administration to a bona fide patient of the facility when the pharmacist is not on duty, or when the pharmacy is closed, the following is applicable:
(i) Prescription drugs and devices only in sufficient quantities for therapeutic needs may be removed from the institutional pharmacy;
(ii) Only a designated licensed nurse or practitioner may remove such drugs and devices;
(iii) A record shall be made at the time of withdrawal by the authorized person removing the drugs and devices; the record shall meet the same requirements as specified in subparagraph (A)(iii) and (iv) of this paragraph;
(iv) The pharmacist shall verify the withdrawal of drugs from the pharmacy after a reasonable interval, but in no event may such interval exceed seven days; and
(v) The pharmacist shall perform a drug regimen review as specified in subsection (g)(1)(B) of this section as follows:
(I) If the facility has an average daily inpatient census of ten or less, the pharmacist shall perform the drug review after a reasonable interval, but in no event may such interval exceed seven (7) days; or
(II) If the facility has an average inpatient daily census above ten, the pharmacist shall perform the drug review after a reasonable interval, but in no event may such interval exceed 96 hours.
(vi) The average daily inpatient census shall be calculated by hospitals annually immediately following the submission of the hospital's Medicare Cost Report and the number used for purposes of subparagraph (B)(v)(I) and (II) of this paragraph shall be the average of the inpatient daily census in the report and the previous two reports for a three year period.

(2) Floor stock. In facilities using a floor stock method of drug distribution, the following is applicable:
(A) Prescription drugs and devices may be removed from the pharmacy only in the original manufacturer's container or prepackaged container.
(B) Only a designated licensed nurse or practitioner may remove such drugs and devices.
(C) A record shall be made at the time of withdrawal by the authorized person removing the drug or device; the record shall contain the following information:
(i) name of the drug, strength, and dosage form;
(ii) quantity removed;

(iii) location of floor stock;
(iv) date and time; and
(v) signature (first initial and last name or full signature) or electronic signature of person making the withdrawal.

(D) The pharmacist shall verify the withdrawal of drugs from the pharmacy after a reasonable interval, but in no event may such interval exceed seven days.

(3) Rural hospitals. In rural hospitals when a pharmacy technician performs the duties listed in §291.73(e)(2)(D) of this title, the following is applicable:

(A) the pharmacy technician shall make a record of all drugs distributed from the pharmacy. The record shall be maintained in the pharmacy for two years and contain the following information:
(i) name of patient or location where floor stock is distributed;
(ii) name of device or drug, strength, and dosage form;
(iii) dose prescribed or ordered;
(iv) quantity distributed;
(v) time and date of the distribution; and
(vi) signature (first initial and last name or full signature) or electronic signature of nurse or practitioner that verified the actions of the pharmacy technician.

(B) The original or direct copy of the medication order may substitute for the record specified in subparagraph (A) of this paragraph, provided the medication order meets all the requirements of subparagraph (A) of this paragraph.

(C) The pharmacist shall:
(i) verify and document the verification of all distributions made from the pharmacy in the absence of a pharmacist as soon as practical, but in no event more than seven (7) days from the time of such distribution;
(ii) perform a drug regimen review for all medication orders as specified in subsection (g)(1)(B) of this section and document such verification including any discrepancies noted by the pharmacist as follows:
(I) If the facility has an average daily inpatient census of ten or less, the pharmacist shall perform the drug review as soon as practical, but in no event more than seven (7) days from the time of such distribution; or
(II) If the facility has an average daily inpatient census above ten, the pharmacist shall perform the drug review after a reasonable interval, but in no event may such interval exceed 96 hours;
(iii) review any discrepancy noted by the pharmacist with the pharmacy technician(s) and make any change in procedures or processes necessary to prevent future problems; and
(iv) report any adverse events that have a potential for harm to a patient to the appropriate committee of the hospital that reviews adverse events.

(D) The average daily inpatient census shall be calculated by hospitals annually immediately following the submission of the hospital's Medicare Cost Report and the number used for purposes of subparagraph (C)(ii)(I) and (II) of this paragraph shall be the average of the inpatient daily census in the report and the previous two reports for a three year period.

(f) Drugs.

(1) Procurement, preparation and storage.

(A) The pharmacist-in-charge shall have the responsibility for the procurement and storage of drugs, but may receive input from other appropriate staff of the facility, relative to such responsibility.

(B) The pharmacist-in-charge shall have the responsibility for determining specifications of all drugs procured by the facility.

(C) Institutional pharmacies may not sell, purchase, trade or possess prescription drug samples, unless the pharmacy meets the requirements as specified in §291.16 of this title (relating to Samples).
(D) All drugs shall be stored at the proper temperatures, as defined in the USP/NF and in §291.15 of this title (relating to Storage of Drugs).
(E) Any drug bearing an expiration date may not be distributed beyond the expiration date of the drug.
(F) Outdated and other unusable drugs shall be removed from stock and shall be quarantined together until such drugs are disposed of properly.

(2) Formulary.

(A) A formulary shall be developed by the facility committee performing the pharmacy and therapeutics function for the facility. For the purpose of this section, a formulary is a compilation of pharmaceuticals that reflects the current clinical judgment of a facility's medical staff.
(B) The pharmacist-in-charge or pharmacist designated by the pharmacist-in-charge shall be a full voting member of the committee performing the pharmacy and therapeutics function for the facility, when such committee is performing the pharmacy and therapeutics function.
(C) A practitioner may grant approval for pharmacists at the facility to interchange, in accordance with the facility's formulary, for the prescribed drugs on the practitioner's medication orders provided:

(i) the pharmacy and therapeutics committee has developed a formulary;
(ii) the formulary has been approved by the medical staff committee of the facility;
(iii) there is a reasonable method for the practitioner to override any interchange; and
(iv) the practitioner authorizes pharmacists in the facility to interchange on his/her medication orders in accordance with the facility's formulary through his/her written agreement to abide by the policies and procedures of the medical staff and facility.

(3) Prepackaging of drugs.

(A) Distribution within a facility.

(i) Drugs may be prepackaged in quantities suitable for internal distribution by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist.
(ii) The label of a prepackaged unit shall indicate:

(I) brand name and strength of the drug; or if no brand name, then the generic name, strength, and name of the manufacturer or distributor;
(II) facility's unique lot number;
(III) expiration date based on currently available literature; and
(IV) quantity of the drug, if the quantity is greater than one.

(iii) Records of prepackaging shall be maintained to show:

(I) name of the drug, strength, and dosage form;
(II) facility's unique lot number;
(III) manufacturer or distributor;
(IV) manufacturer's lot number;
(V) expiration date;
(VI) quantity per prepackaged unit;
(VII) number of prepackaged units;
(VIII) date packaged;
(IX) name, initials, or electronic signature of the prepacker; and
(X) name, initials, or electronic signature of the responsible pharmacist.

(iv) Stock packages, prepackaged units, and control records shall be quarantined together until checked/released by the pharmacist.

(B) Distribution to other Class C (Institutional) pharmacies under common ownership.

(i) Drugs may be prepackaged in quantities suitable for distribution to other Class C (Institutional) pharmacies under common ownership by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist.

(ii) The label of a prepackaged unit shall indicate:

(I) brand name and strength of the drug; or if no brand name, then the generic name, strength, and name of the manufacturer or distributor;

(II) facility's unique lot number;

(III) expiration date based on currently available literature;

(IV) quantity of the drug, if the quantity is greater than one; and

(V) name of the facility responsible for prepackaging the drug.

(iii) Records of prepackaging shall be maintained to show:

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

(II) facility's unique lot number;

(III) manufacturer or distributor;

(IV) manufacturer's lot number;

(V) expiration date;

(VI) quantity per prepackaged unit;

(VII) number of prepackaged units;

(VIII) date packaged;

(IX) name, initials, or electronic signature of the prepacker;

(X) name, initials, or electronic signature of the responsible pharmacist; and

(XI) name of the facility receiving the prepackaged drug.

(iv) Stock packages, prepackaged units, and control records shall be quarantined together until checked/released by the pharmacist.

(v) The pharmacy shall have written procedure for the recall of any drug prepackaged for another Class C pharmacy under common ownership. The recall procedures shall require:

(I) notification to the pharmacy to which the prepackaged drug was distributed;

(II) quarantine of the product if there is a suspicion of harm to a patient;

(III) a mandatory recall if there is confirmed or probable harm to a patient; and

(IV) notification to the board if a mandatory recall is instituted.

(4) Sterile preparations prepared in a location other than the pharmacy. A distinctive supplementary label shall be affixed to the container of any admixture. The label shall bear at a minimum:

(A) patient's name and location, if not immediately administered;

(B) name and amount of drug(s) added;

(C) name of the basic solution;

(D) name or identifying code of person who prepared admixture; and

(E) expiration date of solution.

(5) Distribution.

(A) Medication orders.

(i) Drugs may be given to patients in facilities only on the order of a practitioner. No change in the order for drugs may be made without the approval of a practitioner except as authorized by the practitioner in compliance with paragraph (2)(C) of this subsection.

(ii) Drugs may be distributed only from the original or a direct copy of the practitioner's medication order.

(iii) Pharmacy technicians and pharmacy technician trainees may not receive oral medication orders.

(iv) Institutional pharmacies shall be exempt from the labeling provisions and patient notification requirements of §562.006 and §562.009 of the Act, as respects drugs distributed pursuant to medication orders.

(B) Procedures.

(i) Written policies and procedures for a drug distribution system (best suited for the particular institutional pharmacy) shall be developed and implemented by the pharmacist-in-charge, with the advice of the committee performing the pharmacy and therapeutics function for the facility.

(ii) The written policies and procedures for the drug distribution system shall include, but not be limited to, procedures regarding the following:

(I) pharmaceutical care services;
(II) handling, storage and disposal of cytotoxic drugs and waste;
(III) disposal of unusable drugs and supplies;
(IV) security;
(V) equipment;
(VI) sanitation;
(VII) reference materials;
(VIII) drug selection and procurement;
(IX) drug storage;
(X) controlled substances;
(XI) investigational drugs, including the obtaining of protocols from the principal investigator;
(XII) prepackaging and manufacturing;
(XIII) stop orders;
(XIV) reporting of medication errors, adverse drug reactions/events, and drug product defects;
(XV) physician orders;
(XVI) floor stocks;
(XVII) drugs brought into the facility;
(XVIII) furlough medications;
(XIX) self-administration;
(XX) emergency drug supply;
(XXI) formulary;
(XXII) monthly inspections of nursing stations and other areas where drugs are stored, distributed, administered or dispensed;
(XXIII) control of drug samples;
(XXIV) outdated and other unusable drugs;
(XXV) routine distribution of patient medication;
(XXVI) preparation and distribution of sterile preparations;
(XXVII) handling of medication orders when a pharmacist is not on duty;
(XXVIII) use of automated compounding or counting devices;
(XXIX) use of data processing and direct imaging systems;
(XXX) drug administration to include infusion devices and drug delivery systems;
(XXXI) drug labeling;
(XXXII) recordkeeping;
(XXXIII) quality assurance/quality control;
(XXXIV) duties and education and training of professional and nonprofessional staff;
(XXXV) procedures for a pharmacy technician to verify the accuracy of work performed by another pharmacy technician, if applicable;

(XXXVI) operation of the pharmacy when a pharmacist in not on-site; and
(XXXVII) emergency preparedness plan, to include continuity of patient therapy and public safety.

(6) Discharge Prescriptions. Discharge prescriptions must be dispensed and labeled in accordance with §291.33 of this title (relating to Operational Standards) except that certain medications packaged in unit-of-use containers, such as metered-dose inhalers, insulin pens, topical creams or ointments, or ophthalmic or otic preparation that are administered to the patient during the time the patient was a patient in the hospital, may be provided to the patient upon discharge provided the pharmacy receives a discharge order and the product bears a label containing the following information:

(A) name of the patient;
(B) name and strength of the medication;
(C) name of the prescribing or attending practitioner;
(D) directions for use;
(E) duration of therapy (if applicable); and
(F) name and telephone number of the pharmacy.

(7) Redistribution of Donated Prepackaged Prescription Drugs.

(A) A participating provider may dispense to a recipient donated prescription drugs that are prepackaged and labeled in accordance with §442.0515, Health and Safety Code, and this paragraph.
(B) Drugs may be prepackaged in quantities suitable for distribution to a recipient only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist.
(C) The label of a prepackaged prescription drug a participating provider dispenses to a recipient shall indicate:

(i) brand name and strength of the drug; or if no brand name, then the generic name, strength, and name of the manufacturer or distributor;
(ii) participating provider's lot number;
(iii) participating provider's beyond use date; and
(iv) quantity of the drug, if the quantity is greater than one.

(D) Records of prepackaged prescription drugs dispensed to a recipient shall be maintained to show:

(i) name of the drug, strength, and dosage form;
(ii) participating provider's lot number;
(iii) manufacturer or distributor;
(iv) manufacturer's lot number;
(v) manufacturer's expiration date;
(vi) quantity per prepackaged unit;
(vii) number of prepackaged units;
(viii) date packaged;
(ix) name, initials, or written or electronic signature of the prepacker; and
(x) written or electronic signature of the responsible pharmacist.

(E) Stock packages, repackaged units, and control records shall be quarantined together until checked/released by the pharmacist.

(g) Pharmaceutical care services.

(1) The pharmacist-in-charge shall assure that at least the following pharmaceutical care services are provided to patients of the facility:

(A) Drug utilization review. A systematic ongoing process of drug utilization review shall be developed in conjunction with the medical staff to increase the probability of desired patient outcomes and decrease the probability of undesired outcomes from drug therapy.
(B) Drug regimen review.

(i) For the purpose of promoting therapeutic appropriateness, a pharmacist shall evaluate medication orders and patient medication records for:

(I) known allergies;

(II) rational therapy--contraindications;

(III) reasonable dose and route of administration;

(IV) reasonable directions for use;

(V) duplication of therapy;

(VI) drug-drug interactions;

(VII) drug-food interactions;

(VIII) drug-disease interactions;

(IX) adverse drug reactions;

(X) proper utilization, including overutilization or underutilization; and

(XI) clinical laboratory or clinical monitoring methods to monitor and evaluate drug effectiveness, side effects, toxicity, or adverse effects, and appropriateness to continued use of the drug in its current regimen.

(ii) The drug regimen review shall be conducted on a prospective basis when a pharmacist is on duty, except for an emergency order, and on a retrospective basis as specified in subsection (e)(1) or (e)(3) of this section when a pharmacist is not on duty.

(iii) Any questions regarding the order must be resolved with the prescriber and a written notation of these discussions made and maintained.

(iv) The drug regimen review may be conducted by remotely accessing the pharmacy's electronic data base from outside the pharmacy by an individual Texas licensed pharmacist employee of the pharmacy, provided the pharmacy establishes controls to protect the privacy of the patient and the security of confidential records.

(C) Education. The pharmacist-in-charge in cooperation with appropriate multi-disciplinary staff of the facility shall develop policies that assure that:

(i) the patient and/or patient's caregiver receives information regarding drugs and their safe and appropriate use; and

(ii) health care providers are provided with patient specific drug information.

(D) Patient monitoring. The pharmacist-in-charge in cooperation with appropriate multi-disciplinary staff of the facility shall develop policies to ensure that the patient's response to drug therapy is monitored and conveyed to the appropriate health care provider.

(2) Other pharmaceutical care services which may be provided by pharmacists in the facility include, but are not limited to, the following:

(A) managing drug therapy as delegated by a practitioner as allowed under the provisions of the Medical Practice Act;

(B) administering immunizations and vaccinations under written protocol of a physician;

(C) managing patient compliance programs;

(D) providing preventative health care services; and

(E) providing case management of patients who are being treated with high-risk or high-cost drugs, or who are considered "high risk" due to their age, medical condition, family history, or related concern.

(h) Emergency rooms.

(1) During the times a pharmacist is on duty in the facility any prescription drugs supplied to an outpatient, including emergency department patients, may only be dispensed by a pharmacist.

(2) When a pharmacist is not on duty in the facility, the following is applicable for supplying prescription drugs to be taken home by the patient for self-administration from the emergency room. If the patient has been admitted to the emergency room and assessed by a practitioner at the hospital, the following procedures shall be observed in supplying prescription drugs from the emergency room.

(A) Dangerous drugs and/or controlled substances may only be supplied in accordance with the system of control and accountability for dangerous drugs and/or controlled substances administered or supplied from the emergency room; such system shall be developed and supervised by the pharmacist-in-charge or staff pharmacist designated by the pharmacist-in-charge.

(B) Only dangerous drugs and/or controlled substances listed on the emergency room drug list may be supplied; such list shall be developed by the pharmacist-in-charge and the facility's emergency department committee (or like group or person responsible for policy in that department) and shall consist of dangerous drugs and/or controlled substances of the nature and type to meet the immediate needs of emergency room patients.

(C) Dangerous drugs and/or controlled substances may only be supplied in prepackaged quantities not to exceed a 72-hour supply in suitable containers and appropriately prelabeled (including necessary auxiliary labels) by the institutional pharmacy.

(D) At the time of delivery of the dangerous drugs and/or controlled substances, the practitioner or licensed nurse under the supervision of a practitioner shall appropriately complete the label with at least the following information:

(i) name, address, and phone number of the facility;

(ii) date supplied;

(iii) name of practitioner;

(iv) name of patient;

(v) directions for use;

(vi) brand name and strength of the dangerous drug or controlled substance; or if no brand name, then the generic name, strength, and the name of the manufacturer or distributor of the dangerous drug or controlled substance;

(vii) quantity supplied; and

(viii) unique identification number.

(E) The practitioner, or a licensed nurse under the supervision of the practitioner, shall give the appropriately labeled, prepackaged drug to the patient and explain the correct use of the drug.

(F) A perpetual record of dangerous drugs and/or controlled substances supplied from the emergency room shall be maintained in the emergency room. Such record shall include the following:

(i) date supplied;

(ii) practitioner's name;

(iii) patient's name;

(iv) brand name and strength of the dangerous drug or controlled substance; or if no brand name, then the generic name, strength, and the name of the manufacturer or distributor of the dangerous drug or controlled substance;

(v) quantity supplied; and

(vi) unique identification number.

(G) The pharmacist-in-charge, or staff pharmacist designated by the pharmacist-in-charge, shall verify the correctness of this record at least once every seven days.

(i) Radiology departments.

(1) During the times a pharmacist is on duty, any prescription drugs dispensed to an outpatient, including radiology department patients, may only be dispensed by a pharmacist.

(2) When a pharmacist is not on duty, the following procedures shall be observed in supplying prescription drugs from the radiology department.

(A) Prescription drugs may only be supplied to patients who have been scheduled for an x-ray examination at the facility.

(B) Prescription drugs may only be supplied in accordance with the system of control and accountability for prescription drugs administered or supplied from the radiology department and supervised by the pharmacist-in-charge or staff pharmacist designated by the pharmacist-in-charge.
(C) Only prescription drugs listed on the radiology drug list may be supplied; such list shall be developed by the pharmacist-in-charge and the facility's radiology committee (or like group or persons responsible for policy in that department) and shall consist of drugs for the preparation of a patient for a radiological procedure.
(D) Prescription drugs may only be supplied in prepackaged quantities in suitable containers and prelabeled by the institutional pharmacy with the following information:
(i) name and address of the facility;
(ii) directions for use;
(iii) name and strength of the prescription drug--if generic name, the name of the manufacturer or distributor of the prescription drug;
(iv) quantity;
(v) facility's lot number and expiration date; and
(vi) appropriate ancillary label(s).
(E) At the time of delivery of the prescription drug, the practitioner or practitioner's agent shall complete the label with the following information:
(i) date supplied;
(ii) name of physician;
(iii) name of patient; and
(iv) unique identification number.
(F) The practitioner or practitioner's agent shall give the appropriately labeled, prepackaged prescription drug to the patient.
(G) A perpetual record of prescription drugs supplied from the radiology department shall be maintained in the radiology department. Such records shall include the following:
(i) date supplied;
(ii) practitioner's name;
(iii) patient's name;
(iv) brand name and strength of the prescription drug; or if no brand name, then the generic name, strength, dosage form, and the name of the manufacturer or distributor of the prescription drug;
(v) quantity supplied; and
(vi) unique identification number.
(H) The pharmacist-in-charge, or a pharmacist designated by the pharmacist-in-charge, shall verify the correctness of this record at least once every seven days.

(j) Automated devices and systems.

(1) Automated compounding or counting devices. If a pharmacy uses automated compounding or counting devices:
(A) the pharmacy shall have a method to calibrate and verify the accuracy of the automated compounding or counting device and document the calibration and verification on a routine basis;
(B) the devices may be loaded with unlabeled drugs only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist;
(C) the label of an automated compounding or counting device container shall indicate the brand name and strength of the drug; or if no brand name, then the generic name, strength, and name of the manufacturer or distributor;
(D) records of loading unlabeled drugs into an automated compounding or counting device shall be maintained to show:

(i) name of the drug, strength, and dosage form;
(ii) manufacturer or distributor;
(iii) manufacturer's lot number;
(iv) expiration date;
(v) date of loading;
(vi) name, initials, or electronic signature of the person loading the automated compounding or counting device; and
(vii) signature or electronic signature of the responsible pharmacist; and

(E) the automated compounding or counting device shall not be used until a pharmacist verifies that the system is properly loaded and affixes his or her signature to the record specified in subparagraph (D) of this paragraph.

(2) Automated medication supply systems.

(A) Authority to use automated medication supply systems. A pharmacy may use an automated medication supply system to fill medication orders provided that:

(i) the pharmacist-in-charge is responsible for the supervision of the operation of the system;
(ii) the automated medication supply system has been tested by the pharmacy and found to dispense accurately. The pharmacy shall make the results of such testing available to the Board upon request; and
(iii) the pharmacy will make the automated medication supply system available for inspection by the board for the purpose of validating the accuracy of the system.

(B) Quality assurance program. A pharmacy which uses an automated medication supply system to fill medication orders shall operate according to a written program for quality assurance of the automated medication supply system which:

(i) requires continuous monitoring of the automated medication supply system; and
(ii) establishes mechanisms and procedures to test the accuracy of the automated medication supply system at least every six months and whenever any upgrade or change is made to the system and documents each such activity.

(C) Policies and procedures of operation.

(i) When an automated medication supply system is used to store or distribute medications for administration pursuant to medication orders, it shall be operated according to written policies and procedures of operation. The policies and procedures of operation shall establish requirements for operation of the automated medication supply system and shall describe policies and procedures that:

(I) include a description of the policies and procedures of operation;
(II) provide for a pharmacist's review and approval of each original or new medication order prior to withdrawal from the automated medication supply system:

(-a-) before the order is filled when a pharmacist is on duty except for an emergency order;
(-b-) retrospectively within 72 hours in a facility with a full-time pharmacist when a pharmacist is not on duty at the time the order is made; or
(-c-) retrospectively within 7 days in a facility with a part-time or consultant pharmacist when a pharmacist is not on duty at the time the order is made;

(III) provide for access to the automated medication supply system for stocking and retrieval of medications which is limited to licensed healthcare professionals, pharmacy technicians, or pharmacy technician trainees acting under the supervision of a pharmacist;

(IV) provide that a pharmacist is responsible for the accuracy of the restocking of the system. The actual restocking may be performed by a pharmacy technician or pharmacy technician trainee;

(V) provide for an accountability record to be maintained which documents all transactions relative to stocking and removing medications from the automated medication supply system;

(VI) require a prospective or retrospective drug regimen review is conducted as specified in subsection (g) of this section; and

(VII) establish and make provisions for documentation of a preventative maintenance program for the automated medication supply system.

(ii) A pharmacy which uses an automated medication supply system to fill medication orders shall, at least annually, review its written policies and procedures, revise them if necessary, and document the review.

(D) Automated medication supply systems used for storage and recordkeeping of medications located outside of the pharmacy department (e.g., Pyxis). A pharmacy technician or pharmacy technician trainee may restock an automated medication supply system located outside of the pharmacy department with prescription drugs provided:

(i) prior to distribution of the prescription drugs a pharmacist verifies that the prescription drugs pulled to stock the automated supply system match the list of prescription drugs generated by the automated medication supply system except as specified in §291.73(e)(2)(C)(ii) of this title; or

(ii) all of the following occur:

(I) the prescription drugs to restock the system are labeled and verified with a machine readable product identifier, such as a barcode;

(II) either:

(-a-) the drugs are in tamper evident product packaging, packaged by an FDA registered repackager or manufacturer, that is shipped to the pharmacy; or

(-b-) if any manipulation of the product occurs in the pharmacy prior to restocking, such as repackaging or extemporaneous compounding, the product must be checked by a pharmacist; and

(III) quality assurance audits are conducted according to established policies and procedures to ensure accuracy of the process.

(E) Recovery Plan. A pharmacy which uses an automated medication supply system to store or distribute medications for administration pursuant to medication orders shall maintain a written plan for recovery from a disaster or any other situation which interrupts the ability of the automated medication supply system to provide services necessary for the operation of the pharmacy. The written plan for recovery shall include:

(i) planning and preparation for maintaining pharmacy services when an automated medication supply system is experiencing downtime;

(ii) procedures for response when an automated medication supply system is experiencing downtime;

(iii) procedures for the maintenance and testing of the written plan for recovery; and

(iv) procedures for notification of the Board and other appropriate agencies whenever an automated medication supply system experiences downtime for more than two days of operation or a period of time which significantly limits the pharmacy's ability to provide pharmacy services.

(3) Verification of medication orders prepared by the pharmacy department through the use of an automated medication supply system. A pharmacist must check drugs prepared pursuant to medication orders to ensure

that the drug is prepared for distribution accurately as prescribed. This paragraph does not apply to automated medication supply systems used for storage and recordkeeping of medications located outside of the pharmacy department.

(A) This check shall be considered accomplished if:

(i) a check of the final product is conducted by a pharmacist after the automated system has completed preparation of the medication order and prior to delivery to the patient; or

(ii) the following checks are conducted by a pharmacist:

(I) if the automated medication supply system contains unlabeled stock drugs, a pharmacist verifies that those drugs have been accurately stocked; and

(II) a pharmacist checks the accuracy of the data entry of each original or new medication order entered into the automated medication supply system before the order is filled.

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

(i) The medication order preparation process must be fully automated from the time the pharmacist releases the medication order to the automated system until a completed medication order, ready for delivery to the patient, is produced.

(ii) The pharmacy has conducted initial testing and has a continuous quality assurance program which documents that the automated medication supply system dispenses accurately as specified in paragraph (2)(A) and (B) of this subsection.

(iii) The automated medication supply system documents and maintains:

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

(II) the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist or pharmacy technician or pharmacy technician trainee who performs any other portion of the medication order preparation process.

(iv) The pharmacy establishes mechanisms and procedures to test the accuracy of the automated medication supply system at least every month rather than every six months as specified in paragraph (2)(B) of this subsection.

(4) Automated checking device.

(A) For the purpose of this subsection, an automated checking device is a fully automated device which confirms, after a drug is prepared for distribution but prior to delivery to the patient, that the correct drug and strength has been labeled with the correct label for the correct patient.

(B) The final check of a drug prepared pursuant to a medication order shall be considered accomplished using an automated checking device provided:

(i) a check of the final product is conducted by a pharmacist prior to delivery to the patient or the following checks are performed by a pharmacist:

(I) the prepackaged drug used to fill the order is checked by a pharmacist who verifies that the drug is labeled and packaged accurately; and

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

(ii) the medication order is prepared, labeled, and made ready for delivery to the patient in compliance with Class C (Institutional) 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 medication order has been prepared safely and accurately as prescribed.

(C) If the final check is accomplished as specified in subparagraph (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 (B)(i) of this paragraph; and

(II) the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist, pharmacy technician, or pharmacy technician trainee who performs any other portion of the medication order preparation process.

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

§291.75 Records

(a) Maintenance of records.

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

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

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

(2) Records of controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy.

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

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

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

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

(b) Outpatient records.

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

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

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

(c) Patient records.

(1) Original medication orders.

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

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

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

(iii) directions for use;

(iv) date; and

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

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

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

(A) Patient information:

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

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

(iii) weight and height;

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

(v) primary diagnoses and chronic conditions;

(vi) primary physician; and

(vii) other drugs the patient is receiving; and

(B) Medication order information:

(i) date of distribution;

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

(iii) directions for use.

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

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

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

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

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

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

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

(i) patient's name;

(ii) prescribing or attending practitioner;

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

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

(v) name, initials, or electronic signature of the individual administering the controlled substance;
(vi) returns to the pharmacy; and
(vii) waste (waste is required to be witnessed and cosigned, electronically or manually, by another individual).

(5) Floor stock records.

(A) Distribution records for Schedules II - V controlled substances floor stock shall include the following information:
(i) patient's name;
(ii) prescribing or attending practitioner;
(iii) name of controlled substance, dosage form, and strength;
(iv) time and date of administration to patient;
(v) quantity administered;
(vi) name, initials, or electronic signature of the individual administering drug;
(vii) returns to the pharmacy; and
(viii) waste (waste is required to be witnessed and cosigned, manually or electronically, by another individual).

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

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

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

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

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

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

(i) Records of distribution and return for all controlled substances. A pharmacy that changes or discontinues use of a data processing system must:
(I) transfer the records to the new data processing system; or
(II) purge the records to a printout which contains the same information as required on the audit trail printout as specified in paragraph (7)(B) of this subsection. The information on this printout shall be sorted and printed by drug name and list all distributions/returns chronologically.

(ii) Other records. A pharmacy that changes or discontinues use of a data processing system must:
(I) transfer the records to the new data processing system; or
(II) purge the records to a printout which contains all of the information required on the original document.

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

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

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

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

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

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

(ii) prescribing or attending practitioner's name;

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

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

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

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

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

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

(D) The pharmacy may elect not to produce the monthly audit trail printout if the data processing system has a workable (electronic) data retention system which can produce an audit trail of drug distribution and returns for the preceding two years. The audit trail required in this paragraph shall be supplied by the pharmacy within 72 hours, if requested by an authorized agent of the board, or other authorized local, state, or federal law enforcement or regulatory agencies.

(8) Failure to maintain records. Failure to provide records set out in this subsection, either on site or within 72 hours for whatever reason, constitutes prima facie evidence of failure to keep and maintain records.

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

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

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

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

(2) The total number of dosage units of controlled substances distributed by a pharmacy may not exceed 5.0% of all controlled substances dispensed or distributed by the pharmacy during the 12-month period in which the pharmacy is registered; if at any time it does exceed 5.0%, the pharmacy is required to obtain an additional registration to distribute controlled substances.

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

(A) the actual date of distribution;

(B) the name, strength, and quantity of controlled substances distributed;

(C) the name, address, and DEA registration number of the distributing pharmacy; and

(D) the name, address, and DEA registration number of the pharmacy, practitioner, or other registrant to whom the controlled substances are distributed.

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

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

(1) a log of the initials or identification codes which identifies pharmacy personnel by name. The initials or identification code shall be unique to ensure that each person can be identified, i.e., identical initials or identification codes cannot be used. Such log shall be maintained at the pharmacy for at least seven years from the date of the transaction;

(2) suppliers' invoices of dangerous drugs and controlled substances; a pharmacist shall verify that the controlled drugs listed on the invoices were actually received by clearly recording his/her initials and the actual date of receipt of the controlled substances;

(3) suppliers' credit memos for controlled substances and dangerous drugs;

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

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

(6) a hard copy Schedule V nonprescription register book;

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

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

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

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

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

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

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

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

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

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

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

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

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

§291.76 Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center

(a) Purpose. The purpose of this section is to provide standards in the conduct, practice activities, and operation of a pharmacy located in a freestanding ambulatory surgical center that is licensed by the Texas Department of State Health Services. Class C pharmacies located in a freestanding ambulatory surgical center shall comply with this section, in lieu of §§291.71 - 291.75 of this title (relating to Purpose; Definitions; Personnel; Operational Standards; and Records).

(b) Definitions. The following words and terms, when used in these sections, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Act--The Texas Pharmacy Act, Occupations Code, Subtitle J, as amended.

(2) Administer--The direct application of a prescription drug by injection, inhalation, ingestion, or any other means to the body of a patient by:

(A) a practitioner, an authorized agent under his supervision, or other person authorized by law; or

(B) the patient at the direction of a practitioner.

(3) Ambulatory surgical center (ASC)--A freestanding facility that is licensed by the Texas Department of State Health Services that primarily provides surgical services to patients who do not require overnight hospitalization or extensive recovery, convalescent time or observation. The planned total length of stay for an ASC patient shall not exceed 23 hours. Patient stays of greater than 23 hours shall be the result of an unanticipated medical condition and shall occur infrequently. The 23-hour period begins with the induction of anesthesia.

(4) Automated medication supply system--A mechanical system that performs operations or activities relative to the storage and distribution of medications for administration and which collects, controls, and maintains all transaction information.

(5) Board--The Texas State Board of Pharmacy.

(6) Consultant pharmacist--A pharmacist retained by a facility on a routine basis to consult with the ASC in areas that pertain to the practice of pharmacy.

(7) Controlled substance--A drug, immediate precursor, or other substance listed in Schedules I - V or Penalty Groups 1 - 4 of the Texas Controlled Substances Act, as amended, or a drug immediate precursor, or other substance included in Schedules I - V of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public Law 91-513).

(8) Dispense--Preparing, packaging, compounding, or labeling for delivery a prescription drug or device in the course of professional practice to an ultimate user or his agent by or pursuant to the lawful order of a practitioner.

(9) Distribute--The delivery of a prescription drug or device other than by administering or dispensing.

(10) Downtime--Period of time during which a data processing system is not operable.

(11) Electronic signature--A unique security code or other identifier which specifically identifies the person entering information into a data processing system. A facility which utilizes electronic signatures must:

(A) maintain a permanent list of the unique security codes assigned to persons authorized to use the data processing system; and

(B) have an ongoing security program which is capable of identifying misuse and/or unauthorized use of electronic signatures.

(12) Floor stock--Prescription drugs or devices not labeled for a specific patient and maintained at a nursing station or other ASC department (excluding the pharmacy) for the purpose of administration to a patient of the ASC.

(13) Formulary--List of drugs approved for use in the ASC by an appropriate committee of the ambulatory surgical center.

(14) Hard copy--A physical document that is readable without the use of a special device (i.e., data processing system, computer, etc.).

(15) Investigational new drug--New drug intended for investigational use by experts qualified to evaluate the safety and effectiveness of the drug as authorized by the federal Food and Drug Administration.

(16) Medication order--An order from a practitioner or his authorized agent for administration of a drug or device.
(17) Pharmacist-in-charge--Pharmacist designated on a pharmacy license as the pharmacist who has the authority or responsibility for a pharmacy's compliance with laws and rules pertaining to the practice of pharmacy.
(18) Pharmacy--Area or areas in a facility, separate from patient care areas, where drugs are stored, bulk compounded, delivered, compounded, dispensed, and/or distributed to other areas or departments of the ASC, or dispensed to an ultimate user or his or her agent.
(19) Prescription drug--
(A) A substance for which federal or state law requires a prescription before it may be legally dispensed to the public;
(B) A drug or device that under federal law is required, prior to being dispensed or delivered, to be labeled with either of the following statements:
(i) Caution: federal law prohibits dispensing without prescription or "Rx only" or another legend that complies with federal law; or
(ii) Caution: federal law restricts this drug to use by or on order of a licensed veterinarian; or
(C) A drug or device that is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by a practitioner only.
(20) Prescription drug order--
(A) An order from a practitioner or his authorized agent to a pharmacist for a drug or device to be dispensed; or
(B) An order pursuant to Subtitle B, Chapter 157, Occupations Code.
(21) Full-time pharmacist--A pharmacist who works in a pharmacy from 30 to 40 hours per week or if the pharmacy is open less than 60 hours per week, one-half of the time the pharmacy is open.
(22) Part-time pharmacist--A pharmacist who works less than full-time.
(23) Pharmacy technician--An individual who is registered with the board as a pharmacy technician and whose responsibility in a pharmacy is to provide technical services that do not require professional judgment regarding preparing and distributing drugs and who works under the direct supervision of and is responsible to a pharmacist.
(24) Pharmacy technician trainee--An individual who is registered with the board as a pharmacy technician trainee and is authorized to participate in a pharmacy's technician training program.
(25) Texas Controlled Substances Act--The Texas Controlled Substances Act, Health and Safety Code, Chapter 481, as amended.
(c) Personnel.
(1) Pharmacist-in-charge.
(A) General. Each ambulatory surgical center shall have one pharmacist-in-charge who is employed or under contract, at least on a consulting or part-time basis, but may be employed on a full-time basis.
(B) Responsibilities. The pharmacist-in-charge shall have the responsibility for, at a minimum, the following:
(i) establishing specifications for procurement and storage of all materials, including drugs, chemicals, and biologicals;
(ii) participating in the development of a formulary for the ASC, subject to approval of the appropriate committee of the ASC;
(iii) distributing drugs to be administered to patients pursuant to the practitioner's medication order;
(iv) filling and labeling all containers from which drugs are to be distributed or dispensed;
(v) maintaining and making available a sufficient inventory of antidotes and other emergency drugs, both in the pharmacy and patient care areas, as well as current antidote information,

telephone numbers of regional poison control center and other emergency assistance organizations, and such other materials and information as may be deemed necessary by the appropriate committee of the ASC;

(vi) maintaining records of all transactions of the ASC pharmacy as may be required by applicable state and federal law, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials;

(vii) participating in those aspects of the ASC's patient care evaluation program which relate to pharmaceutical material utilization and effectiveness;

(viii) participating in teaching and/or research programs in the ASC;

(ix) implementing the policies and decisions of the appropriate committee(s) relating to pharmaceutical services of the ASC;

(x) providing effective and efficient messenger and delivery service to connect the ASC pharmacy with appropriate areas of the ASC on a regular basis throughout the normal workday of the ASC;

(xi) labeling, storing, and distributing investigational new drugs, including maintaining information in the pharmacy and nursing station where such drugs are being administered, concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interactions, and symptoms of toxicity of investigational new drugs;

(xii) meeting all inspection and other requirements of the Texas Pharmacy Act and this subsection;

(xiii) maintaining records in a data processing system such that the data processing system is in compliance with the requirements for a Class C (institutional) pharmacy located in a freestanding ASC; and

(xiv) ensuring that a pharmacist visits the ASC at least once each calendar week that the facility is open.

(2) Consultant pharmacist.

(A) The consultant pharmacist may be the pharmacist-in-charge.

(B) A written contract shall exist between the ASC and any consultant pharmacist, and a copy of the written contract shall be made available to the board upon request.

(3) Pharmacists.

(A) General.

(i) The pharmacist-in-charge shall be assisted by a sufficient number of additional licensed pharmacists as may be required to operate the ASC pharmacy competently, safely, and adequately to meet the needs of the patients of the facility.

(ii) All pharmacists shall assist the pharmacist-in-charge in meeting the responsibilities as outlined in paragraph (1)(B) of this subsection and in ordering, administering, and accounting for pharmaceutical materials.

(iii) All pharmacists shall be responsible for any delegated act performed by pharmacy technicians or pharmacy technician trainees under his or her supervision.

(iv) All pharmacists while on duty shall be responsible for complying with all state and federal laws or rules governing the practice of pharmacy.

(B) Duties. Duties of the pharmacist-in-charge and all other pharmacists shall include, but need not be limited to, the following:

(i) receiving and interpreting prescription drug orders and oral medication orders and reducing these orders to writing either manually or electronically;

(ii) selecting prescription drugs and/or devices and/or suppliers; and

(iii) interpreting patient profiles.

(C) Special requirements for compounding non-sterile preparations. All pharmacists engaged in compounding non-sterile preparations shall meet the training requirements specified in §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

(4) Pharmacy technicians and pharmacy technician trainees.

(A) General. All pharmacy technicians and pharmacy technician trainees shall meet the training requirements specified in §297.6 of this title (relating to Pharmacy Technician and Pharmacy Technician Trainee Training).

(B) Duties. Pharmacy technicians and pharmacy technician trainees may not perform any of the duties listed in paragraph (3)(B) of this subsection. Duties may include, but need not be limited to, the following functions, under the direct supervision of a pharmacist:

(i) prepacking and labeling unit and multiple dose packages, provided a pharmacist supervises and conducts a final check and affixes his or her name, initials, or electronic signature to the appropriate quality control records prior to distribution;

(ii) preparing, packaging, compounding, or labeling prescription drugs pursuant to medication orders, provided a pharmacist supervises and checks the preparation;

(iii) compounding non-sterile preparations pursuant to medication orders provided the pharmacy technicians or pharmacy technician trainees have completed the training specified in §291.131 of this title;

(iv) bulk compounding, provided a pharmacist supervises and conducts in-process and final checks and affixes his or her name, initials, or electronic signature to the appropriate quality control records prior to distribution;

(v) distributing routine orders for stock supplies to patient care areas;

(vi) entering medication order and drug distribution information into a data processing system, provided judgmental decisions are not required and a pharmacist checks the accuracy of the information entered into the system prior to releasing the order or in compliance with the absence of pharmacist requirements contained in subsection (d)(6)(D) and (E) of this section;

(vii) maintaining inventories of drug supplies;

(viii) maintaining pharmacy records; and

(ix) loading drugs into an automated medication supply system. For the purpose of this clause, direct supervision may be accomplished by physically present supervision or electronic monitoring by a pharmacist.

(C) Procedures.

(i) Pharmacy technicians and pharmacy technician trainees shall handle medication orders in accordance with standard written procedures and guidelines.

(ii) Pharmacy technicians and pharmacy technician trainees shall handle prescription drug orders in the same manner as pharmacy technicians or pharmacy technician trainees working in a Class A pharmacy.

(D) Special requirements for compounding non-sterile preparations. All pharmacy technicians and pharmacy technician trainees engaged in compounding non-sterile preparations shall meet the training requirements specified in §291.131 of this title.

(5) Owner. The owner of an ASC 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:

(A) establishing policies for procurement of prescription drugs and devices and other products dispensed from the ASC pharmacy;

(B) establishing and maintaining effective controls against the theft or diversion of prescription drugs;

(C) if the pharmacy uses an automated medication supply system, reviewing and approving all policies and procedures for system operation, safety, security, accuracy and access, patient confidentiality, prevention of unauthorized access, and malfunction;

(D) providing the pharmacy with the necessary equipment and resources commensurate with its level and type of practice; and

(E) establishing policies and procedures regarding maintenance, storage, and retrieval of records in a data processing system such that the system is in compliance with state and federal requirements.

(6) Identification of pharmacy personnel. All pharmacy personnel shall be identified as follows:

(A) Pharmacy technicians. All pharmacy technicians shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacy technician.

(B) Pharmacy technician trainees. All pharmacy technician trainees shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacy technician trainee.

(C) Pharmacist interns. All pharmacist interns shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacist intern.

(D) Pharmacists. All pharmacists shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacist.

(d) Operational standards.

(1) Licensing requirements.

(A) An ASC pharmacy shall register annually or biennially with the board on a pharmacy license application provided by the board, following the procedures specified in §291.1 of this title (relating to Pharmacy License Application).

(B) An ASC pharmacy which changes ownership shall notify the board within 10 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).

(C) An ASC pharmacy which changes location and/or name shall notify the board of the change within 10 days and file for an amended license as specified in §291.3 of this title.

(D) An ASC pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within 10 days of the change, following the procedures in §291.3 of this title.

(E) An ASC pharmacy shall notify the board in writing within 10 days of closing, following the procedures in §291.5 of this title (relating to Closing a Pharmacy).

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

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

(H) An ASC pharmacy, licensed under the Act, §560.051(a)(3), concerning institutional pharmacy (Class C), which also operates another type of pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(1), concerning community pharmacy (Class A), or the Act, §560.051(a)(2), concerning nuclear pharmacy (Class B), is not required to secure a license for the other type of pharmacy; provided, however, such license is required to comply with the provisions of §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), or §291.51 of this title (relating to Purpose), §291.52 of this title (relating to Definitions), §291.53 of this title (relating to Personnel), §291.54 of this title (relating to Operational Standards), and §291.55 of this title (relating to Records), contained in Nuclear Pharmacy (Class B), to the extent such sections are applicable to the operation of the pharmacy.

(I) An ASC pharmacy engaged in the compounding of non-sterile preparations shall comply with the provisions of §291.131 of this title.

(J) ASC pharmacy personnel shall not compound sterile preparations unless the pharmacy has applied for and obtained a Class C-S pharmacy license.

(K) An ASC pharmacy engaged in the provision of remote pharmacy services, including storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of this title (relating to Remote Pharmacy Services).

(L) An ASC pharmacy engaged in centralized prescription dispensing and/or prescription drug or medication order processing shall comply with the provisions of §291.123 of this title (relating to Central Prescription Drug or Medication Order Processing) and/or §291.125 of this title (relating to Centralized Prescription Dispensing).

(2) Environment.

(A) General requirements.

(i) Each ambulatory surgical center shall have a designated work area separate from patient areas, and which shall have space adequate for the size and scope of pharmaceutical services and shall have adequate space and security for the storage of drugs.

(ii) The ASC pharmacy shall be arranged in an orderly fashion and shall be kept clean. All required equipment shall be clean and in good operating condition.

(B) Special requirements.

(i) The ASC pharmacy shall have locked storage for Schedule II controlled substances and other controlled drugs requiring additional security.

(ii) The ASC pharmacy shall have a designated area for the storage of poisons and externals separate from drug storage areas.

(C) Security.

(i) The pharmacy and storage areas for prescription drugs and/or devices shall be enclosed and capable of being locked by key, combination, or other mechanical or electronic means, so as to prohibit access by unauthorized individuals. Only individuals authorized by the pharmacist-in-charge may enter the pharmacy or have access to storage areas for prescription drugs and/or devices.

(ii) The pharmacist-in-charge shall consult with ASC personnel with respect to security of the drug storage areas, including provisions for adequate safeguards against theft or diversion of dangerous drugs and controlled substances, and to security of records for such drugs.

(iii) The pharmacy shall have locked storage for Schedule II controlled substances and other drugs requiring additional security.

(3) Equipment and supplies. Ambulatory surgical centers supplying drugs for postoperative use shall have the following equipment and supplies:

(A) data processing system including a printer or comparable equipment;

(B) adequate supply of child-resistant, moisture-proof, and light-proof containers; and

(C) adequate supply of prescription labels and other applicable identification labels.

(4) Library. A reference library shall be maintained that includes the following in hard copy or electronic format and that pharmacy personnel shall be capable of accessing at all times:

(A) current copies of the following:

(i) Texas Pharmacy Act and rules;

(ii) Texas Dangerous Drug Act and rules;

(iii) Texas Controlled Substances Act and rules;

(iv) Federal Controlled Substances Act and rules or official publication describing the requirements of the Federal Controlled Substances Act and rules;

(B) at least one current or updated general drug information reference which is required to contain drug interaction information including information needed to determine severity or significance of the interaction and appropriate recommendations or actions to be taken; and

(C) basic antidote information and the telephone number of the nearest regional poison control center.

(5) Drugs.

(A) Procurement, preparation, and storage.

(i) The pharmacist-in-charge shall have the responsibility for the procurement and storage of drugs, but may receive input from other appropriate staff of the facility, relative to such responsibility.

(ii) The pharmacist-in-charge shall have the responsibility for determining specifications of all drugs procured by the facility.

(iii) ASC pharmacies may not sell, purchase, trade, or possess prescription drug samples, unless the pharmacy meets the requirements as specified in §291.16 of this title (relating to Samples).

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

(v) Any drug bearing an expiration date may not be dispensed or distributed beyond the expiration date of the drug.

(vi) Outdated drugs shall be removed from dispensing stock and shall be quarantined together until such drugs are disposed of.

(B) Formulary.

(i) A formulary may be developed by an appropriate committee of the ASC.

(ii) The pharmacist-in-charge or consultant pharmacist shall be a full voting member of any committee which involves pharmaceutical services.

(iii) A practitioner may grant approval for pharmacists at the ASC to interchange, in accordance with the facility's formulary, for the drugs on the practitioner's medication orders provided:

(I) a formulary has been developed;

(II) the formulary has been approved by the medical staff of the ASC;

(III) there is a reasonable method for the practitioner to override any interchange; and

(IV) the practitioner authorizes a pharmacist in the ASC to interchange on his/her medication orders in accordance with the facility's formulary through his/her written agreement to abide by the policies and procedures of the medical staff and facility.

(C) Prepackaging and loading drugs into automated medication supply system.

(i) Prepackaging of drugs.

(I) Drugs may be prepackaged in quantities suitable for distribution to other Class C pharmacies under common ownership or for internal distribution only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist.

(II) The label of a prepackaged unit shall indicate:

(-a-) brand name and strength of the drug; or if no brand name, then the generic name, strength, and name of the manufacturer or distributor;

(-b-) facility's lot number;

(-c-) expiration date;

(-d-) quantity of the drug, if quantity is greater than one; and

(-e-) if the drug is distributed to another Class C pharmacy, name of the facility responsible for prepackaging the drug.

(III) Records of prepackaging shall be maintained to show:

(-a-) the name of the drug, strength, and dosage form;

(-b-) facility's lot number;

(-c-) manufacturer or distributor;

(-d-) manufacturer's lot number;

(-e-) expiration date;

(-f-) quantity per prepackaged unit;
(-g-) number of prepackaged units;
(-h-) date packaged;
(-i-) name, initials, or electronic signature of the prepacker;
(-j-) signature or electronic signature of the responsible pharmacist; and
(-k-) if the drug is distributed to another Class C pharmacy, name of the facility receiving the prepackaged drug.

(IV) Stock packages, repackaged units, and control records shall be quarantined together until checked/released by the pharmacist.

(ii) Loading bulk unit of use drugs into automated medication supply systems. Automated medication supply systems may be loaded with bulk unit of use drugs only by a pharmacist, by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist, or by a licensed nurse who is authorized by the pharmacist to perform the loading of the automated medication supply system. For the purpose of this clause, direct supervision may be accomplished by physically present supervision or electronic monitoring by a pharmacist. In order for the pharmacist to electronically monitor, the medication supply system must allow for bar code scanning to verify the loading of drugs, and a record of the loading must be maintained by the system and accessible for electronic review by the pharmacist.

(6) Medication orders.

(A) Drugs may be administered to patients in ASCs only on the order of a practitioner. No change in the order for drugs may be made without the approval of a practitioner except as authorized by the practitioner in compliance with paragraph (5)(B) of this subsection.

(B) Drugs may be distributed only pursuant to the practitioner's medication order.

(C) ASC pharmacies shall be exempt from the labeling provisions and patient notification requirements of §562.006 and §562.009 of the Act, as respects drugs distributed pursuant to medication orders.

(D) In ASCs with a full-time pharmacist, if a practitioner orders a drug for administration to a bona fide patient of the facility when the pharmacy is closed, the following is applicable:

(i) prescription drugs and devices only in sufficient quantities for immediate therapeutic needs of a patient may be removed from the ASC pharmacy;

(ii) only a designated licensed nurse or practitioner may remove such drugs and devices;

(iii) a record shall be made at the time of withdrawal by the authorized person removing the drugs and devices. The record shall contain the following information:

(I) name of the patient;
(II) name of device or drug, strength, and dosage form;
(III) dose prescribed;
(IV) quantity withdrawn;
(V) time and date; and
(VI) signature or electronic signature of the person making the withdrawal;

(iv) the medication order in the patient's chart may substitute for such record, provided the medication order meets all the requirements of clause (iii) of this subparagraph;

(v) the pharmacist shall verify the withdrawal as soon as practical, but in no event more than 72 hours from the time of such withdrawal; and

(vi) the pharmacist shall verify the withdrawal of a dangerous drug at a reasonable interval, but such verification must occur at least once in every calendar week.

(E) In ASCs with a part-time or consultant pharmacist, if a practitioner orders a drug for administration to a bona fide patient of the ASC when the pharmacist is not on duty, or when the pharmacy is closed, the following is applicable:

(i) prescription drugs and devices only in sufficient quantities for therapeutic needs may be removed from the ASC pharmacy;
(ii) only a designated licensed nurse or practitioner may remove such drugs and devices;
(iii) a record shall be made at the time of withdrawal by the authorized person removing the drug or device as described in subparagraph (D)(iii) and (iv) of this subsection; and
(iv) the pharmacist shall verify withdrawals at a reasonable interval, but such interval must occur at least once in every calendar week that the pharmacy is open.

(7) Floor stock. In facilities using a floor stock method of drug distribution, the pharmacy shall establish designated floor stock areas outside of the central pharmacy where drugs may be stored, in accordance with the pharmacy's policies and procedures. The following is applicable for removing drugs or devices in the absence of a pharmacist:

(A) prescription drugs and devices may be removed from the pharmacy only in the original manufacturer's container or prepackaged container;
(B) only a designated licensed nurse or practitioner may remove such drugs and devices;
(C) a record shall be made at the time of withdrawal by the authorized person removing the drug or device; and the record shall contain the following information:
(i) name of the drug, strength, and dosage form;
(ii) quantity removed;
(iii) location of floor stock;
(iv) date and time; and
(v) signature or electronic signature of person making the withdrawal;
(D) the medication order in the patient's chart may substitute for the record required in subparagraph (C) of this paragraph, provided the medication order meets all the requirements of subparagraph (C) of this paragraph; and
(E) if a stored drug or device is returned to the pharmacy from floor stock areas, a record shall be made by the authorized person returning the drug or device. The record shall contain the following information:
(i) drug name, strength, and dosage form, or device name;
(ii) quantity returned;
(iii) previous floor stock location for the drug or device;
(iv) date and time; and
(v) signature or electronic signature of person returning the drug or device.

(8) Policies and procedures. Written policies and procedures for a drug distribution system, appropriate for the ambulatory surgical center, shall be developed and implemented by the pharmacist-in-charge with the advice of the appropriate committee. The written policies and procedures for the drug distribution system shall include, but not be limited to, procedures regarding the following:

(A) controlled substances;
(B) investigational drugs;
(C) prepackaging and manufacturing;
(D) medication errors;
(E) orders of physician or other practitioner;
(F) floor stocks;
(G) adverse drug reactions;
(H) drugs brought into the facility by the patient;
(I) self-administration;
(J) emergency drug tray;
(K) formulary, if applicable;
(L) drug storage areas;

(M) drug samples;
(N) drug product defect reports;
(O) drug recalls;
(P) outdated drugs;
(Q) preparation and distribution of IV admixtures;
(R) procedures for supplying drugs for postoperative use, if applicable;
(S) use of automated medication supply systems;
(T) use of data processing systems; and
(U) drug regimen review.

(9) Drugs supplied for postoperative use. Drugs supplied to patients for postoperative use shall be supplied according to the following procedures.

(A) Drugs may only be supplied to patients who have been admitted to the ASC.

(B) Drugs may only be supplied in accordance with the system of control and accountability established for drugs supplied from the ambulatory surgical center; such system shall be developed and supervised by the pharmacist-in-charge or staff pharmacist designated by the pharmacist-in-charge.

(C) Only drugs listed on the approved postoperative drug list may be supplied; such list shall be developed by the pharmacist-in-charge and the medical staff and shall consist of drugs of the nature and type to meet the immediate postoperative needs of the ambulatory surgical center patient.

(D) Drugs may only be supplied in prepackaged quantities not to exceed a 72-hour supply in suitable containers and appropriately prelabeled (including name, address, and phone number of the facility, and necessary auxiliary labels) by the pharmacy provided, however, that topicals and ophthalmics in original manufacturer's containers may be supplied in a quantity exceeding a 72-hour supply.

(E) At the time of delivery of the drug, the practitioner shall complete the label, such that the prescription container bears a label with at least the following information:

(i) date supplied;
(ii) name of practitioner;
(iii) name of patient;
(iv) directions for use;
(v) brand name and strength of the drug; or if no brand name, then the generic name of the drug dispensed, strength, and the name of the manufacturer or distributor of the drug; and
(vi) unique identification number.

(F) After the drug has been labeled, the practitioner or a licensed nurse under the supervision of the practitioner shall give the appropriately labeled, prepackaged medication to the patient.

(G) A perpetual record of drugs which are supplied from the ASC shall be maintained which includes:

(i) name, address, and phone number of the facility;
(ii) date supplied;
(iii) name of practitioner;
(iv) name of patient;
(v) directions for use;
(vi) brand name and strength of the drug; or if no brand name, then the generic name of the drug dispensed, strength, and the name of the manufacturer or distributor of the drug; and
(vii) unique identification number.

(H) The pharmacist-in-charge, or a pharmacist designated by the pharmacist-in-charge, shall review the records at least once in every calendar week that the pharmacy is open.

(10) Drug regimen review.

(A) A pharmacist shall evaluate medication orders and patient medication records for:

(i) known allergies;
(ii) rational therapy--contraindications;

(iii) reasonable dose and route of administration;
(iv) reasonable directions for use;
(v) duplication of therapy;
(vi) drug-drug interactions;
(vii) drug-food interactions;
(viii) drug-disease interactions;
(ix) adverse drug reactions;
(x) proper utilization, including overutilization or underutilization; and
(xi) clinical laboratory or clinical monitoring methods to monitor and evaluate drug effectiveness, side effects, toxicity, or adverse effects, and appropriateness to continued use of the drug in its current regimen.

(B) A retrospective, random drug regimen review as specified in the pharmacy's policies and procedures shall be conducted on a periodic basis to verify proper usage of drugs not to exceed 31 days between such reviews.

(C) Any questions regarding the order must be resolved with the prescriber and a written notation of these discussions made and maintained.

(e) Records.

(1) Maintenance of records.

(A) Every inventory or other record required to be kept under the provisions of this section (relating to Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center) shall be:

(i) 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 other authorized local, state, or federal law enforcement agencies; and

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

(B) Records of controlled substances listed in Schedule II shall be maintained separately and readily retrievable from all other records of the pharmacy.

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

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

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

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

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

(F) An ASC pharmacy shall maintain a perpetual inventory of controlled substances listed in Schedules II - V which shall be verified by a pharmacist for completeness and reconciled at least once in every calendar week that the pharmacy is open.

(G) Distribution records for controlled substances, listed in Schedules II - V, shall include the following information:

(i) patient's name;

(ii) practitioner's name who ordered the drug;

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

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

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

(vi) returns to the pharmacy; and

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

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

(I) A pharmacist shall conduct an audit by randomly comparing the distribution records required by subparagraph (G) with the medication orders in the patient record on a periodic basis to verify proper administration of drugs not to exceed 30 days between such reviews.

(2) Patient records.

(A) Each medication order or set of orders issued together shall bear the following information:

(i) patient name;

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

(iii) directions for use;

(iv) date; and

(v) signature or electronic signature of the practitioner or that of his or her authorized agent, defined as an employee or consultant/full or part-time pharmacist of the ASC.

(B) Medication orders shall be maintained with the medication administration record in the medical records of the patient.

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

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

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

(C) A pharmacy that changes or discontinues use of a data processing system must:

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

(ii) purge the records to a printout which contains:

(I) all of the information required on the original document; or

(II) for records of distribution and return for all controlled substances, the same information as required on the audit trail printout as specified in subparagraph (F) of this paragraph. The information on the printout shall be sorted and printed by drug name and list all distributions and returns chronologically.

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

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

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

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

(ii) prescribing or attending practitioner's name;

(iii) name, strength, and dosage form of the drug product actually distributed;
(iv) total quantity distributed from and returned to the pharmacy;
(v) if not immediately retrievable via electronic image, the following shall also be included on the printout:
(I) prescribing or attending practitioner's address; and
(II) practitioner's DEA registration number, if the medication order is for a controlled substance.

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

(H) The pharmacy may elect not to produce the monthly audit trail printout if the data processing system has a workable (electronic) data retention system which can produce an audit trail of drug distribution and returns for the preceding two years. The audit trail required in this clause shall be supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy, or other authorized local, state, or federal law enforcement or regulatory agencies.

(I) In the event that an ASC pharmacy which uses a data processing system experiences system downtime, the pharmacy must have an auxiliary procedure which will ensure that all data is retained for online data entry as soon as the system is available for use again.

(4) 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.

(A) The registrant to whom the controlled substance is to be distributed is registered under the Controlled Substances Act to possess that controlled substance.

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

(C) If the distribution is for a Schedule III, IV, or V controlled substance, a record shall be maintained which indicates:
(i) the actual date of distribution;
(ii) the name, strength, and quantity of controlled substances distributed;
(iii) the name, address, and DEA registration number of the distributing pharmacy; and
(iv) the name, address, and DEA registration number of the pharmacy, practitioner, or other registrant to whom the controlled substances are distributed.

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

(5) Other records. Other records to be maintained by the pharmacy include:

(A) a log of the initials or identification codes which identifies each pharmacist by name. The initials or identification code shall be unique to ensure that each pharmacist can be identified, i.e., identical initials or identification codes cannot be used. Such log shall be maintained at the pharmacy for at least seven years from the date of the transaction;

(B) suppliers' invoices of dangerous drugs and controlled substances dated and initialed or signed by the person receiving the drugs;
(i) a pharmacist shall verify that the controlled substances listed on the invoices were added to the pharmacy's perpetual inventory by clearly recording his/her initials and the date of review of the perpetual inventory; and

(ii) for controlled substances, the documents retained must contain the name, strength, and quantity of controlled substances distributed, and the name, address, and DEA number of both the supplier and the receiving pharmacy;

(C) supplier's credit memos for controlled substances and dangerous drugs;

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

(E) reports of surrender or destruction of controlled substances and/or dangerous drugs to an appropriate state or federal agency or reverse distributor;

(F) records of distribution of controlled substances and/or dangerous drugs to other pharmacies, practitioners, or registrants; and

(G) a copy of any notification required by the Texas Pharmacy Act or these rules, including, but not limited to, the following:

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

(ii) notification of a change in pharmacist-in-charge of a pharmacy; and

(iii) reports of a fire or other disaster 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.

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

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

(i) Prior to the initiation of central recordkeeping, the pharmacy submits written notification by registered or certified mail to the divisional director of DEA as required by the Code of Federal Regulations, Title 21, §1304(a), and submits a copy of this written notification to the board. Unless the registrant is informed by the divisional director of DEA that permission to keep central records is denied, the pharmacy may maintain central records commencing 14 days after receipt of notification by the divisional director;

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

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

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

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

(D) 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.

§291.77 Pharmacies Compounding Sterile Preparations (Class C-S)

Licensing requirements. An institutional or ASC pharmacy engaged in the compounding of sterile preparations shall be designated as a Class C-S pharmacy.

(1) A Class C-S pharmacy shall register annually or biennially with the board on a pharmacy license application provided by the board, following the procedures specified in §291.1 of this title (relating to Pharmacy License Application). A Class C-S license may not be issued unless the pharmacy has been inspected by the board to ensure the pharmacy meets the requirements as specified in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).

(2) A Class C-S pharmacy may not renew a pharmacy license unless the pharmacy has been inspected by the board within the last renewal period.
(3) A Class C-S pharmacy which changes ownership shall notify the board within 10 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).
(4) A Class C-S pharmacy which changes location and/or name shall notify the board within 10 days of the change and file for an amended license as specified in §291.3 of this title.
(5) A Class C-S pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within 10 days of the change following the procedures in §291.3 of this title.
(6) A Class C-S pharmacy shall notify the board in writing within 10 days of closing, following the procedures in §291.5 of this title (relating to Closing a Pharmacy).
(7) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for the issuance and renewal of a license and the issuance of an amended license.
(8) A separate license is required for each principal place of business and only one pharmacy license may be issued to a specific location.
(9) A Class C-S pharmacy, licensed under the Act, §560.051(a)(3), which also operates another type of pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(1) (Community Pharmacy (Class A)) or the Act, §560.051(a)(2) (Nuclear Pharmacy (Class B)), is not required to secure a license for the such other type of pharmacy; provided, however, such licensee is required to comply with the provisions of §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), or §291.51 of this title (relating to Purpose), §291.52 of this title (relating to Definitions), §291.53 of this title (relating to Personnel), §291.54 of this title (relating to Operational Standards), and §291.55 of this title (relating to Records), contained in Nuclear Pharmacy (Class B), to the extent such sections are applicable to the operation of the pharmacy.
(10) A Class C-S pharmacy engaged in the compounding of non-sterile preparations shall comply with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).
(11) A Class C-S pharmacy engaged in the provision of remote pharmacy services, including storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of this title (relating to Remote Pharmacy Services).
(12) A Class C-S pharmacy engaged in centralized prescription dispensing and/or prescription drug or medication order processing shall comply with the provisions of §291.123 of this title (relating to Central Prescription Drug or Medication Order Processing) and/or §291.125 of this title (relating to Centralized Prescription Dispensing).
(13) A Class C-S pharmacy with an ongoing clinical pharmacy program that proposes to allow a pharmacy technician to verify the accuracy of work performed by another pharmacy technician relating to the filling of floor stock and unit dose distribution systems for a patient admitted to the hospital if the patient's orders have previously been reviewed and approved by a pharmacist shall make application to the board as follows.

(A) The pharmacist-in-charge must submit an application on a form provided by the board, containing the following information:

(i) name, address, and pharmacy license number;
(ii) name and license number of the pharmacist-in-charge;
(iii) name and registration numbers of the pharmacy technicians;
(iv) anticipated date the pharmacy plans to begin allowing a pharmacy technician to verify the accuracy of work performed by another pharmacy technician;
(v) documentation that the pharmacy has an ongoing clinical pharmacy program; and
(vi) any other information specified on the application.

(B) The pharmacy may not allow a pharmacy technician to check the work of another pharmacy technician until the board has reviewed and approved the application and issued an amended license to the pharmacy.

(C) Every two years, in connection with the application for renewal of the pharmacy license, the pharmacy shall provide updated documentation that the pharmacy continues to have an ongoing clinical pharmacy program as specified in subparagraph (A)(v) of this paragraph.

(14) A rural hospital that wishes to allow a pharmacy technician to perform the duties specified in §291.73(e)(2)(D) of this title (relating to Personnel) shall make application to the board as follows.

(A) Prior to allowing a pharmacy technician to perform the duties specified in §291.73(e)(2)(D) of this title, the pharmacist-in-charge must submit an application on a form provided by the board, containing the following information:

(i) name, address, and pharmacy license number;

(ii) name and license number of the pharmacist-in-charge;

(iii) name and registration number of the pharmacy technicians;

(iv) proposed date the pharmacy wishes to start allowing pharmacy technicians to perform the duties specified in §291.73(e)(2)(D) of this title;

(v) documentation that the hospital is a rural hospital with 75 or fewer beds and that the rural hospital is either:

(I) located in a county with a population of 50,000 or less as defined by the United States Census Bureau in the most recent U.S. census; or

(II) designated by the Centers for Medicare and Medicaid Services as a critical access hospital, rural referral center, or sole community hospital; and

(vi) any other information specified on the application.

(B) A rural hospital may not allow a pharmacy technician to perform the duties specified in §291.73(e)(2)(D) of this title until the board has reviewed and approved the application and issued an amended license to the pharmacy.

(C) Every two years in conjunction with the application for renewal of the pharmacy license, the pharmacist-in-charge shall update the application for pharmacy technicians to perform the duties specified in §291.73(e)(2)(D) of this title.

SUBCHAPTER E – CLINIC PHARMACY (CLASS D)

§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) Act--The Texas Pharmacy Act, Chapters 551 - 566, 568 - 569, Occupations Code as amended.

(2) Administer--The direct application of a prescription drug by injection, inhalation, ingestion, or any other means to the body of a patient by:

(A) a practitioner or an authorized agent under his supervision; or

(B) the patient at the direction of a practitioner.

(3) Board--The Texas State Board of Pharmacy.

(4) Clinic--A facility/location other than a physician's office, where limited types of dangerous drugs or devices restricted to those listed in and approved for the clinic's formulary are stored, administered, provided, or dispensed to outpatients.

(5) Consultant pharmacist--A pharmacist retained by a clinic on a routine basis to consult with the clinic in areas that pertain to the practice of pharmacy.

(6) Continuous supervision--Supervision provided by the pharmacist-in-charge, consultant pharmacist, and/or staff pharmacist, and consists of on-site and telephone supervision, routine inspection, and a policy and procedure manual.
(7) Controlled substance--A drug, immediate precursor, or other substance listed in Schedules I-V or Penalty Groups 1-4 of the Texas Controlled Substances Act, as amended, or a drug, immediate precursor, or other substance included in Schedule I, II, III, IV, or V of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public Law 91-513).
(8) Dangerous drug--Any drug or device that is not included in Penalty Groups 1-4 of the Controlled Substances Act and that is unsafe for self-medication or any drug or device that bears or is required to bear the legend:

(A) "Caution: federal law prohibits dispensing without prescription" or "Rx only";

(B) "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian."

(9) Dispense--Preparing, packaging, compounding, or labeling for delivery a prescription drug or device in the course of professional practice to an ultimate user or his agent by or pursuant to the lawful order of a practitioner.
(10) Indigent--Person who meets or falls below 185% of federal poverty income guidelines as established from time to time by the United States Department of Health and Human Services.
(11) Limited type of device--An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part or accessory, that is required under federal or state law to be ordered or prescribed by a practitioner, that is contained in the clinic formulary and is to be administered, dispensed, or provided according to the objectives of the clinic.
(12) Limited type of drug--A dangerous drug contained in the clinic formulary, and to be administered, dispensed, or provided according to the objectives of the clinic.
(13) Outpatient--An ambulatory patient who comes to a clinic to receive services related to the objectives of the clinic and departs the same day.
(14) Pharmacist--A person licensed by the board to practice pharmacy.
(15) Pharmacist-in-charge--The pharmacist designated on a pharmacy license as the pharmacist who is responsible for a pharmacy's compliance with laws and rules pertaining to the practice of pharmacy.
(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.

(17) Prepackaging--A method of packaging a drug product into a single container which contains more than one dosage unit and usually contains sufficient quantity of medication for one normal course of therapy.
(18) Provide--To supply one or more units of use of a nonprescription drug or dangerous drug to a patient.
(19) Standing delegation order--Written orders from a physician and designed for a patient population with specific diseases, disorders, health problems, or sets of symptoms, which provide authority for and a plan for use with patients presenting themselves prior to being examined or evaluated by a physician to assure that such acts are carried out correctly and are distinct from specific orders written for a particular patient.

(20) Standing medical order--Written orders from a physician or the medical staff of an institution for patients which have been examined or evaluated by a physician and which are used as a guide in preparation for and carrying out medical and/or surgical procedures.
(21) Supportive personnel--Individuals under the supervision of a pharmacist-in-charge, designated by the pharmacist-in-charge, and for whom the pharmacist-in-charge assumes legal responsibility, who function and perform under the instructions of the pharmacist-in-charge.
(22) Texas Controlled Substances Act--The Texas Controlled Substances Act, Health and Safety Code, Chapter 481, as amended.
(23) Unit of use--A sufficient quantity of a drug product for one normal course of therapy.

§291.92 Personnel

(a) Pharmacist-in-charge.

(1) General.

(A) Each Class D pharmacy shall have one pharmacist-in-charge who is employed or under written agreement, at least on a part-time basis, but may be employed on a full-time basis if desired, and who may be pharmacist-in-charge of more than one clinic pharmacy.

(B) A written agreement shall exist between the clinic and the pharmacist-in-charge, and a copy of the written agreement shall be made available to the board upon request.

(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) 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) 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 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) Consultant pharmacist.

(1) The consultant pharmacist may be the pharmacist-in-charge.

(2) The consultant pharmacist may be retained by more than one clinic.

(c) Staff pharmacists.

(1) The pharmacist-in-charge may be assisted by a sufficient number of additional pharmacists as may be required to operate the clinic pharmacy competently, safely, and adequately to meet the needs of the patients of the clinic.

(2) Staff pharmacists and/or the consultant pharmacist shall assist the pharmacist-in-charge in meeting the responsibilities as outlined in subsection (a)(2) of this section and in ordering, supervising, and accounting for drugs and/or devices.

(3) Staff pharmacists and/or the consultant pharmacist shall be responsible for any delegated act performed by supportive personnel under his or her supervision.

(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) 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) maintaining inventories of drugs and/or devices; and

(C) 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) establishment of policies for procurement of prescription drugs and devices and other products provided or dispensed from the Class D pharmacy;

(2) establishment and maintenance of effective controls against the theft or diversion of prescription drugs;

(3) providing the pharmacy with the necessary equipment and resources commensurate with its level and type of practice; and

(4) establishment of policies and procedures regarding maintenance, storage, and retrieval of records in a data processing system such that the system is in compliance with state and federal requirements.

§291.93 Operational Standards

(a) Registration.

(1) Licensing requirements.

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

(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 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) 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).

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

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

(G) 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) 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).

(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 pharmacy and provide dangerous drugs from these temporary locations provided:

(A) the Class D pharmacy complies with the registration requirements in paragraph (1) of this subsection;

(B) the Class D 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 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 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 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 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 pharmacy shall maintain the following equipment and supplies:

(1) if the Class D 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 pharmacy maintains dangerous drugs requiring refrigeration and/or freezing, a refrigerator and/or freezer;

(3) if the Class D 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.

(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 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 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 practitioner 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 practitioner 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 pharmacy.

(3) Drug samples.

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

(4) Prepackaging and labeling for provision.

(A) Drugs may be prepackaged and labeled for provision in the Class D 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, or licensed nurses 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 preparations may only be provided by the clinic pharmacy in accordance with §291.131 of this title (relating to Pharmacies Compounding Non-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 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.

§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) 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.

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

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

(2) name of the manufacturer;

(3) manufacturer's lot number;

(4) expiration date;

(5) facility's lot number;
(6) quantity per package and number of packages;
(7) date packaged;
(8) name(s), signatures, or electronic signatures of the supportive personnel who prepackages the drug under direct supervision of a pharmacist; and
(9) 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 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).

SUBCHAPTER F – NON-RESIDENT PHARMACY (CLASS E)

§291.101 Purpose

(a) The purpose of these rules is to provide standards for the operation of non-resident pharmacies (Class E) which:
(1) dispense a prescription drug or device under a prescription drug order and deliver the drug or device to a patient in this state, by the United States mail, a common carrier, or a delivery service;
(2) process a prescription drug order for a patient, including a patient in this state; or
(3) perform another pharmaceutical service defined by board rule.

(b) These rules are in accordance with §554.051(a) and (b) of the Act which permit the board to make rules concerning the operation of licensed pharmacies in this state applicable to pharmacies licensed by the board that are located in another state. The board has determined that these rules are necessary to protect the health and welfare of the citizens of this state.

(c) Unless compliance would violate the pharmacy or drug laws or rules in the state in which the pharmacy is located, Class E Pharmacies are required to comply with the provisions of §§291.101-291.105 of this chapter (relating to Purpose, Definitions, Personnel, Operational Standards, and Records).

§291.102 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.
(1) Act--The Texas Pharmacy Act, Chapters 551 - 569, Occupations Code, as amended.
(2) Accurately as prescribed--Dispensing, delivering, and/or distributing a prescription drug order:
(A) to the correct patient (or agent of the patient) for whom the drug or device was prescribed;

(B) with the correct drug in the correct strength, quantity, and dosage form ordered by the practitioner; and

(C) with correct labeling (including directions for use) as ordered by the practitioner. Provided, however, that nothing herein shall prohibit pharmacist substitution if substitution is conducted in strict accordance with applicable laws and rules, including Subchapter A of Chapter 562 of the Texas Pharmacy Act relating to Prescription and Substitution Requirements.

(3) Board--The Texas State Board of Pharmacy.

(4) Class E pharmacy license or non-resident pharmacy license--a license issued to a pharmacy located in another state whose primary business is to:

(A) dispense a prescription drug or device under a prescription drug order and to deliver the drug or device to a patient, including a patient in this state, by the United States mail, common carrier, or delivery service;

(B) process a prescription drug order for a patient, including a patient in this state; or

(C) perform another pharmaceutical service defined by board rule.

(5) Confidential Record--Any health related record, including a patient medication record, prescription drug order, or medication order that:

(A) contains information that identifies an individual; and

(B) is maintained by a pharmacy or pharmacist.

(6) Deliver or delivery--The actual, constructive, or attempted transfer of a prescription drug or device or controlled substance from one person to another, whether or not for a consideration.

(7) Dispense--Preparing, packaging, compounding, or labeling, in the course of professional practice, a prescription drug or device for delivery to an ultimate user or the user's agent under a practitioner's lawful order.

(8) Distribute--To deliver a prescription drug or device other than by administering or dispensing.

(9) Generically equivalent--A drug that is "pharmaceutically equivalent" and "therapeutically equivalent" to the drug prescribed.

(10) New prescription drug order--A prescription drug order that:

(A) has not been dispensed to the patient in the same strength and dosage form by this pharmacy within the last year;

(B) is transferred from another pharmacy; and/or

(C) is a discharge prescription drug order. (Note: furlough prescription drug orders are not considered new prescription drug orders.)

(11) Pharmaceutically equivalent--Drug products which have identical amounts of the same active chemical ingredients in the same dosage form and which meet the identical compendial or other applicable standards of strength, quality, and purity according to the United States Pharmacopoeia or other nationally recognized compendium.

(12) Pharmacist--For the purpose of this subchapter, a person licensed to practice pharmacy in the state where the Class E pharmacy is located.

(13) Pharmacist-in-charge--The pharmacist designated on a pharmacy license as the pharmacist who has the authority or responsibility for a pharmacy's compliance with statutes and rules pertaining to the practice of pharmacy.

(14) 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; or

(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.

(15) Prescription drug order--an order from a practitioner or a practitioner's designated agent to a pharmacist for a drug or device to be dispensed.

(16) Therapeutically equivalent--Pharmaceutically equivalent drug products which, when administered in the same amounts, will provide the same therapeutic effect, identical in duration and intensity.

§291.103 Personnel

As specified in §562.101(f) of the Act (relating to Supervision of Pharmacy), a Class E pharmacy shall be under the continuous on-site supervision of a pharmacist and shall designate one pharmacist licensed to practice pharmacy by the regulatory or licensing agency of the state in which the Class E pharmacy is located and effective September 1, 2016, is licensed as a pharmacist in Texas to serve as the pharmacist-in-charge of the Class E pharmacy license.

§291.104 Operational Standards

(a) Licensing requirements.

(1) A Class E pharmacy shall register with the board on a pharmacy license application provided by the board, following the procedures specified in §291.1 of this title (relating to Pharmacy License Application).

(2) On initial application, the pharmacy shall follow the procedures specified in §291.1 of this title (relating to Pharmacy License Application) and then provide the following additional information specified in §560.052(c) and (f) of the Act (relating to Qualifications):

(A) evidence that the applicant holds a pharmacy license, registration, or permit issued by the state in which the pharmacy is located;

(B) the name of the owner and pharmacist-in-charge of the pharmacy for service of process;

(C) evidence of the applicant's ability to provide to the board a record of a prescription drug order dispensed by the applicant to a resident of this state not later than 72 hours after the time the board requests the record;

(D) an affidavit by the pharmacist-in-charge which states that the pharmacist has read and understands the laws and rules relating to a Class E pharmacy;

(E) proof of creditworthiness; and

(F) an inspection report issued not more than two years before the date the license application is received and conducted by the pharmacy licensing board in the state of the pharmacy's physical location.

(i) A Class E pharmacy may submit an inspection report issued by an entity other than the pharmacy licensing board of the state in which the pharmacy is physically located if the state's licensing board does not conduct inspections as follows:

(I) an individual approved by the board who is not employed by the pharmacy but acting as a consultant to inspect the pharmacy;

(II) an agent of the National Association of Boards of Pharmacy;

(III) an agent of another State Board of Pharmacy; or

(IV) an agent of an accrediting body, such as the Joint Commission on Accreditation of Healthcare Organizations.

(ii) The inspection must be substantively equivalent to an inspection conducted by the board.

(3) On renewal of a license, the pharmacy shall complete the renewal application provided by the board and, as specified in §561.0031 of the Act, provide an inspection report issued not more than three years before the date the renewal application is received and conducted by the pharmacy licensing board in the state of the pharmacy's physical location.

(A) A Class E pharmacy may submit an inspection report issued by an entity other than the pharmacy licensing board of the state in which the pharmacy is physically located if the state's licensing board does not conduct inspections as follows:

(i) an individual approved by the board who is not employed by the pharmacy but acting as a consultant to inspect the pharmacy;

(ii) an agent of the National Association of Boards of Pharmacy;

(iii) an agent of another State Board of Pharmacy; or

(iv) an agent of an accrediting body, such as the Joint Commission on Accreditation of Healthcare Organizations.

(B) The inspection must be substantively equivalent to an inspection conducted by the board.

(4) A Class E 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).

(5) A Class E pharmacy which changes location and/or name shall notify the board of the change as specified in §291.3 of this title.

(6) A Class E pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within ten days of the change, following the procedures in §291.3 of this title.

(7) A Class E pharmacy shall notify the board in writing within ten days of closing.

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

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

(10) The board may grant an exemption from the licensing requirements of this Act on the application of a pharmacy located in a state of the United States other than this state that restricts its dispensing of prescription drugs or devices to residents of this state to isolated transactions.

(11) A Class E pharmacy engaged in the centralized dispensing of prescription drug or medication orders shall comply with the provisions of §291.125 of this title (relating to Centralized Prescription Dispensing).

(12) A Class E pharmacy engaged in central processing of prescription drug or medication orders or outsourcing of prescription drug order dispensing to a central fill pharmacy shall comply with the provisions of §291.123 of this title (relating to Central Prescription or Medication Order Processing).

(13) A Class E pharmacy engaged in the compounding of non-sterile preparations shall comply with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

(14) Class E pharmacy personnel shall not compound sterile preparations unless the pharmacy has applied for and obtained a Class E-S pharmacy license.

(15) A Class E pharmacy, which operates as a community type of pharmacy which would otherwise be required to be licensed under the Act §560.051(a)(1) (Community Pharmacy (Class A)), shall comply with the provisions of §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); or which operates as a nuclear type of pharmacy which would otherwise be required to be licensed under the Act §560.051(a)(2) (Nuclear Pharmacy (Class B)), shall comply with the provisions of §291.51 of this title (relating to Purpose), §291.52 of this title (relating to Definitions), §291.53 of this title (relating to Personnel), §291.54 of this title (relating to Operational Standards), and §291.55 of this title (relating to Records), contained in Nuclear Pharmacy (Class B), to the extent such sections are applicable to the operation of the pharmacy.

(b) Prescription dispensing and delivery.

(1) General.

(A) All prescription drugs and/or devices shall be dispensed and delivered safely and accurately as prescribed.

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

(C) The pharmacy shall utilize a delivery system which is designed to assure that the drugs are delivered to the appropriate patient.

(D) All pharmacists shall exercise sound professional judgment with respect to the accuracy and authenticity of any prescription drug order they dispense. If the pharmacist questions the accuracy or authenticity of a prescription drug order, he/she shall verify the order with the practitioner prior to dispensing.

(E) Prior to dispensing a prescription, pharmacists shall determine, in the exercise of sound professional judgment, that the prescription is a valid prescription. A pharmacist may not dispense a prescription drug if the pharmacist knows or should have known that the prescription was issued on the basis of an Internet-based or telephonic consultation without a valid patient-practitioner relationship.

(F) Subparagraph (E) of this paragraph does not prohibit a pharmacist from dispensing a prescription when a valid patient-practitioner relationship is not present in an emergency situation (e.g. a practitioner taking calls for the patient's regular practitioner).

(2) Drug regimen review.

(A) For the purpose of promoting therapeutic appropriateness, a pharmacist shall prior to or at the time of dispensing a prescription drug order, review the patient's medication record. Such review shall at a minimum identify clinically significant:

(i) inappropriate drug utilization;

(ii) therapeutic duplication;

(iii) drug-disease contraindications;

(iv) drug-drug interactions;

(v) incorrect drug dosage or duration of drug treatment;

(vi) drug-allergy interactions; and

(vii) clinical abuse/misuse.

(B) Upon identifying any clinically significant conditions, situations, or items listed in subparagraph (A) of this paragraph, the pharmacist shall take appropriate steps to avoid or resolve the problem including consultation with the prescribing practitioner. The pharmacist shall document such occurrences.

(3) Patient counseling and provision of drug information.

(A) To optimize drug therapy, a pharmacist shall communicate to the patient or the patient's agent, information about the prescription drug or device which in the exercise of the pharmacist's professional judgment the pharmacist deems significant, such as the following:

(i) the name and description of the drug or device;

(ii) dosage form, dosage, route of administration, and duration of drug therapy;

(iii) special directions and precautions for preparation, administration, and use by the patient;

(iv) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(v) techniques for self-monitoring of drug therapy;

(vi) proper storage;

(vii) refill information; and

(viii) action to be taken in the event of a missed dose.

(B) Such communication shall be:

(i) provided to new and existing patients of a pharmacy with each new prescription drug order. A new prescription drug order is one that has not been dispensed by the pharmacy to the patient in the same dosage and strength within the last year;
(ii) provided for any prescription drug order dispensed by the pharmacy on the request of the patient or patient's agent;
(iii) communicated orally in person unless the patient or patient's agent is not at the pharmacy or a specific communication barrier prohibits such oral communication; and
(iv) reinforced with written information. The following is applicable concerning this written information:

(I) Written information must be in plain language designed for the patient and printed in an easily readable font comparable to but no smaller than ten-point Times Roman. This information may be provided to the patient in an electronic format, such as by e-mail, unless the patient or patient's agent requests the information in a hard-copy format.
(II) When a compounded product is dispensed, information shall be provided for the major active ingredient(s), if available.
(III) For new drug entities, if no written information is initially available, the pharmacist is not required to provide information until such information is available, provided:

(-a-) the pharmacist informs the patient or the patient's agent that the product is a new drug entity and written information is not available;
(-b-) the pharmacist documents the fact that no written information was provided; and
(-c-) if the prescription is refilled after written information is available, such information is provided to the patient or patient's agent.

(IV) The written information accompanying the prescription or the prescription label shall contain the statement "Do not flush unused medications or pour down a sink or drain." A drug product on a list developed by the Federal Food and Drug Administration of medicines recommended for disposal by flushing is not required to bear this statement.

(C) Only a pharmacist may orally provide drug information to a patient or patient's agent and answer questions concerning prescription drugs. Non-pharmacist personnel may not ask questions of a patient or patient's agent which are intended to screen and/or limit interaction with the pharmacist.
(D) If prescriptions are routinely delivered outside the area covered by the pharmacy's local telephone service, the pharmacy shall provide a toll-free telephone line which is answered during normal business hours to enable communication between the patient and a pharmacist.
(E) The pharmacist shall place on the prescription container or on a separate sheet delivered with the prescription container in both English and Spanish the local and toll-free telephone number of the pharmacy and the statement: "Written information about this prescription has been provided for you. Please read this information before you take the medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions at (insert the pharmacy's local and toll-free telephone numbers)."
(F) The provisions of this paragraph do not apply to patients in facilities where drugs are administered to patients by a person required to do so by the laws of the state (i.e., nursing homes).
(G) Upon delivery of a refill prescription, a pharmacist shall ensure that the patient or patient's agent is offered information about the refilled prescription and that a pharmacist is available to discuss the patient's prescription and provide information.
(H) Nothing in this subparagraph shall be construed as requiring a pharmacist to provide consultation when a patient or patient's agent refuses such consultation. The pharmacist shall document such refusal for consultation.

(4) Labeling. At the time of delivery, the dispensing container shall bear a label that contains the following information:

(A) the name, physical address, and phone number of the pharmacy;

(B) if the drug is dispensed in a container other than the manufacturer's original container, the date after which the prescription should not be used or beyond-use-date. Unless otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date the drug is dispensed or the manufacturer's expiration date, whichever is earlier. The beyond-use-date may be placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is not required on the label of a prescription dispensed to a person at the time of release from prison or jail if the prescription is for not more than a 10-day supply of medication;

(C) either on the prescription label or the written information accompanying the prescription, the statement, "Do not flush unused medications or pour down a sink or drain." A drug product on a list developed by the Federal Food and Drug Administration of medicines recommended for disposal by flushing is not required to bear this statement; and

(D) any other information that is required by the pharmacy or drug laws or rules in the state in which the pharmacy is located.

(c) Substitution requirements.

(1) Unless compliance would violate the pharmacy or drug laws or rules in the state in which the pharmacy is located a pharmacist in a Class E pharmacy may dispense a generically equivalent drug or interchangeable biological product and shall comply with the provisions of §309.3 of this title (relating to Substitution Requirements) and §309.7 of this title (relating to Dispensing Responsibilities).

(2) The pharmacy must include on the prescription order form completed by the patient or the patient's agent information that clearly and conspicuously:

(A) states that if a less expensive generically equivalent drug or interchangeable biological product is available for the brand prescribed, the patient or the patient's agent may choose between the generically equivalent drug or interchangeable biological product and the brand prescribed; and

(B) allows the patient or the patient's agent to indicate the choice of the generically equivalent drug or interchangeable biological product or the brand prescribed.

(d) Therapeutic Drug Interchange. A switch to a drug providing a similar therapeutic response to the one prescribed shall not be made without prior approval of the prescribing practitioner. This subsection does not apply to generic substitution. For generic substitution, see the requirements of subsection (c) of this section.

(1) The patient shall be notified of the therapeutic drug interchange prior to, or upon delivery, of the dispensed prescription to the patient. Such notification shall include:

(A) a description of the change;

(B) the reason for the change;

(C) whom to notify with questions concerning the change; and

(D) instructions for return of the drug if not wanted by the patient.

(2) The pharmacy shall maintain documentation of patient notification of therapeutic drug interchange which shall include:

(A) the date of the notification;

(B) the method of notification;

(C) a description of the change; and

(D) the reason for the change.

(e) Transfer of Prescription Drug Order Information. Unless compliance would violate the pharmacy or drug laws or rules in the state in which the pharmacy is located, a pharmacist in a Class E pharmacy may not refuse to transfer prescriptions to another pharmacy that is making the transfer request on behalf of the patient. The transfer of original prescription information must be done within four business hours of the request.

(f) Prescriptions for Schedules II - V controlled substances. Unless compliance would violate the pharmacy or drug laws or rules in the state in which the pharmacy is located, a pharmacist in a Class E pharmacy who dispenses a prescription for a Schedules II - V controlled substance for a resident of Texas shall electronically send the prescription information to the Texas State Board of Pharmacy as specified in §315.6 of this title (relating to Pharmacy Responsibility - Electronic Reporting) not later than the next business day after the prescription is dispensed.

§291.105 Records

(a) Maintenance of records.

(1) Every record required to be kept under this section shall be:

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

(B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the 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.

(b) 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.

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

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

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

(4) 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.

(c) Civil litigation and complaint records. A Class E pharmacy shall keep a permanent record of:

(1) any civil litigation commenced against the pharmacy by a Texas resident; and

(2) complaints that arise out of a prescription for a Texas resident lost during delivery.

§291.106 Pharmacies Compounding Sterile Preparations (Class E-S)

Licensing requirements. A non-resident pharmacy engaged in the compounding of sterile preparations shall be licensed as a Class E-S pharmacy.

(1) A Class E-S pharmacy shall register with the board on a pharmacy license application provided by the board, following the procedures specified in §291.1 of this title (relating to Pharmacy License Application).

(2) A Class E-S license may not be issued unless the pharmacy has been inspected by the board or its designee to ensure the pharmacy meets the requirements as specified in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations). A Class E-S pharmacy shall reimburse the board for all expenses, including travel, related to the inspection of the Class E-S pharmacy.
(3) On initial application, the pharmacy shall follow the procedures specified in §291.1 of this title and then provide the following additional information specified in §560.052(c) and (f) of the Act (relating to Qualifications):

(A) evidence that the applicant holds a pharmacy license, registration, or permit issued by the state in which the pharmacy is located;
(B) the name of the owner and pharmacist-in-charge of the pharmacy for service of process;
(C) evidence of the applicant's ability to provide to the board a record of a prescription drug order dispensed by the applicant to a resident of this state not later than 72 hours after the time the board requests the record;
(D) an affidavit by the pharmacist-in-charge which states that the pharmacist has read and understands the laws and rules relating to a Class E pharmacy; and
(E) proof of creditworthiness.

(4) A Class E-S pharmacy may not renew a pharmacy license unless the pharmacy has been inspected by the board or its designee within the last renewal period.
(5) A Class E-S 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).
(6) A Class E-S pharmacy which changes location and/or name shall notify the board as specified in §291.3 of this title.
(7) A Class E-S pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within ten days of the change, as specified in §291.3 of this title.
(8) A Class E-S pharmacy shall notify the board in writing within ten days of closing.
(9) A separate license is required for each principal place of business and only one pharmacy license may be issued to a specific location.
(10) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for the issuance and renewal of a license and the issuance of an amended license.
(11) The board may grant an exemption from the licensing requirements of this Act on the application of a pharmacy located in a state of the United States other than this state that restricts its dispensing of prescription drugs or devices to residents of this state to isolated transactions.
(12) A Class E-S pharmacy engaged in the centralized dispensing of prescription drug or medication orders shall comply with the provisions of §291.125 of this title (relating to Centralized Prescription Dispensing).
(13) A Class E-S pharmacy engaged in central processing of prescription drug or medication orders shall comply with the provisions of §291.123 of this title (relating to Central Prescription or Medication Order Processing).
(14) A Class E-S pharmacy engaged in the compounding of non-sterile preparations shall comply with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).
(15) A Class E-S pharmacy engaged in the compounding of sterile preparations shall comply with the provisions of §291.133 of this title.
(16) A Class E-S pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(5) concerning Non-Resident Pharmacy (Class E) is required to comply with the provisions of §291.101 of this title (relating to Purpose), §291.102 of this title (relating to Definitions), §291.103 of this title (relating to Personnel), §291.104 of this title (relating to Operational Standards) and §291.105 of this title (relating to Records).

SUBCHAPTER G – SERVICES PROVIDED BY PHARMACIES

§291.120 General

(a) Purpose. This subchapter applies to all classes of pharmacies except as otherwise noted.

(b) Definitions.

(1) The Texas Pharmacy Act or Act--Subtitle J, other than Chapter 567, Occupations Code, as amended.

(2) Board--The Texas State Board of Pharmacy.

(3) Common ownership--Two or more pharmacies with an identical owner of record with the board or that have owners of record with the board that are a parent, subsidiary, or affiliate of one another under §1.002, Business Organizations Code.

(4) Owner of record--The direct owner of the pharmacy provided on the pharmacy's application for a pharmacy license or most recent approved change of ownership form.

§291.121 Remote Pharmacy Services

(a) Remote pharmacy services using automated pharmacy systems.

(1) Purpose. The purpose of this section is to provide standards for the provision of pharmacy services by a Class A or Class C pharmacy in a facility that is not at the same location as the Class A or Class C pharmacy through an automated pharmacy system as outlined in §562.109 of the Texas Pharmacy Act.

(2) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise. All other words and terms shall have the meanings defined in the Act.

(A) Automated pharmacy system--A mechanical system that dispenses prescription drugs and maintains related transaction information.

(B) Prepackaging--The act of repackaging and relabeling quantities of drug products from a manufacturer's original commercial container, or quantities of unit dosed drugs, into another cartridge or container for dispensing by a pharmacist using an automated pharmacy system.

(C) Provider pharmacy--The community pharmacy (Class A) or the institutional pharmacy (Class C) providing remote pharmacy services.

(D) Remote pharmacy service--The provision of pharmacy services, including the storage and dispensing of prescription drugs, in remote sites.

(E) Remote site--A facility not located at the same location as a Class A or Class C pharmacy, at which remote pharmacy services are provided using an automated pharmacy dispensing system.

(F) Unit dose--An amount of a drug packaged in a dosage form ready for administration to a particular patient, by the prescribed route at the prescribed time, and properly labeled with name, strength, and expiration date of the drug.

(3) General requirements.

(A) A provider pharmacy may provide remote pharmacy services using an automated pharmacy system to a jail or prison operated by or for the State of Texas, a jail or prison operated by local government or a healthcare facility regulated under Chapter 142, 241, 242, 247, 252, 464, 534 or 577, Health and Safety Code, provided drugs are administered by a licensed healthcare professional working in the jail, prison, or healthcare facility.

(B) A provider pharmacy may provide remote pharmacy services at more than one remote site.

(C) Before providing remote pharmacy services, the automated pharmacy system at the remote site must be tested by the provider pharmacy and found to dispense accurately. The provider pharmacy shall make the results of such testing available to the board upon request.

(D) A provider pharmacy which is licensed as an institutional (Class C) pharmacy is required to comply with the provisions of §§291.31 - 291.34 of this title (relating to Definitions, Personnel, Operational Standards, and Records, respectively) and this section.

(E) The pharmacist-in-charge of the provider pharmacy is responsible for all pharmacy operations involving the automated pharmacy system located at the remote site including supervision of the automated pharmacy system and compliance with this section.

(F) A pharmacist from the provider pharmacy shall be accessible at all times to respond to patients' or other health professionals' questions and needs pertaining to drugs dispensed through the use of the automated pharmacy system. Such access may be through a 24 hour pager service or telephone which is answered 24 hours a day.

(4) Operational standards.

(A) Application for permission to provide pharmacy services using an automated pharmacy system.

(i) A Class A or Class C Pharmacy shall file a completed application containing all information required by the board to provide remote pharmacy services using an automated pharmacy system and pay the application fee specified in §291.6(e)(1) of this title (relating to Pharmacy License Fees).

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

(iii) Upon approval of the application, the provider pharmacy will be issued a certificate which must be displayed at the remote site.

(B) Notification requirements.

(i) A provider pharmacy shall notify the board in writing within ten days of a discontinuance of service, or closure of:

(I) a remote site where an automated pharmacy system is operated by the pharmacy; or

(II) a remote pharmacy service at a remote site.

(ii) A provider pharmacy shall comply with appropriate federal and state controlled substance registrations for each remote site if controlled substances are maintained within an automated pharmacy system at the facility.

(iii) A provider pharmacy shall file a change of location and/or name of a remote site as specified in §291.3 of this title (relating to Notifications).

(C) Environment/Security.

(i) A provider pharmacy shall only store drugs at a remote site within an automated pharmacy system which is locked by key, combination or other mechanical or electronic means so as to prohibit access by unauthorized personnel.

(ii) An automated pharmacy system shall be under the continuous supervision of a provider pharmacy pharmacist. To qualify as continuous supervision, the pharmacist is not required to be physically present at the site of the automated pharmacy system if the system is supervised electronically by a pharmacist.

(iii) Automated pharmacy systems shall have adequate security and procedures to:

(I) comply with federal and state laws and regulations; and

(II) maintain patient confidentiality.

(iv) Access to the automated pharmacy system shall be limited to pharmacists or personnel who:

(I) are designated in writing by the pharmacist-in-charge; and

(II) have completed documented training concerning their duties associated with the automated pharmacy system.

(v) Drugs shall be stored in compliance with the provisions of §291.15 of this title (relating to Storage of Drugs) and §291.33(f)(2) of this title including the requirements for temperature and handling of outdated drugs.

(D) Prescription dispensing and delivery.

(i) Drugs shall only be dispensed at a remote site through an automated pharmacy system after receipt of an original prescription drug order by a pharmacist at the provider pharmacy in a manner authorized by §291.34(b) of this title.

(ii) A pharmacist at the provider pharmacy shall control all operations of the automated pharmacy system and approve the release of the initial dose of a prescription drug order. Subsequent doses from an approved prescription drug order may be removed from the automated medication system after this initial approval. Any change made in the prescription drug order shall require a new approval by a pharmacist to release the drug.

(iii) A pharmacist at the provider pharmacy shall conduct a drug regimen review as specified in §291.33(c) of this title prior to releasing a prescription drug order to the automated pharmacy system.

(iv) Drugs dispensed by the provider pharmacy through an automated pharmacy system shall comply with the labeling or labeling alternatives specified in §291.33(c) of this title.

(v) An automated pharmacy system used to meet the emergency medication needs for residents of a remote site must comply with the requirements for emergency medication kits in subsection (b) of this section.

(E) Drugs.

(i) Drugs for use in an automated pharmacy system shall be packaged in the original manufacturer's container or be prepackaged in the provider pharmacy and labeled in compliance with the board's prepackaging requirements for the class of pharmacy.

(ii) Drugs dispensed from the automated pharmacy system may be returned to the pharmacy for reuse provided the drugs are in sealed, tamper evident packaging which has not been opened.

(F) Stocking an automated pharmacy system.

(i) Stocking of drugs in an automated pharmacy system shall be completed by a pharmacist, pharmacy technician, or pharmacy technician trainee under the direct supervision of a pharmacist, except as provided in clause (ii) of this subparagraph.

(ii) If the automated pharmacy system uses removable cartridges or containers to hold drugs, the prepackaging of the cartridges or containers shall occur at the provider pharmacy unless provided by an FDA approved repackager. The prepackaged cartridges or containers may be sent to the remote site to be loaded into the machine by personnel designated by the pharmacist-in-charge provided:

(I) a pharmacist verifies the cartridge or container has been properly filled and labeled;

(II) the individual cartridges or containers are transported to the remote site in a secure, tamper-evident container; and

(III) the automated pharmacy system uses bar-coding, microchip, or other technologies to ensure that the containers are accurately loaded in the automated pharmacy system.

(iii) All drugs to be stocked in the automated pharmacy system shall be delivered to the remote site by the provider pharmacy.

(G) Quality assurance program. A pharmacy that provides pharmacy services through an automated pharmacy system at a remote site shall operate according to a written program for quality assurance of the automated pharmacy system which:

(i) requires continuous supervision of the automated pharmacy system; and

(ii) establishes mechanisms and procedures to routinely test the accuracy of the automated pharmacy system at a minimum of every six months and whenever any upgrade or change is made to the system and documents each such activity.

(H) Policies and procedures of operation.

(i) A pharmacy that provides pharmacy services through an automated pharmacy system at a remote site shall operate according to written policies and procedures. The policy and procedure manual shall include, but not be limited to, the following:

(I) a current list of the name and address of the pharmacist-in-charge and personnel designated by the pharmacist-in-charge to have access to the drugs stored in the automated pharmacy system;

(II) duties which may only be performed by a pharmacist;

(III) a copy of the portion of the written contract or agreement between the pharmacy and the facility which outlines the services to be provided and the responsibilities and accountabilities of each party relating to the operation of the automated pharmacy system in fulfilling the terms of the contract in compliance with federal and state laws and regulations;

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

(V) policies and procedures for:

(-a-) security;

(-b-) operation of the automated pharmacy system;

(-c-) preventative maintenance of the automated pharmacy system;

(-d-) sanitation;

(-e-) storage of drugs;

(-f-) dispensing;

(-g-) supervision;

(-h-) drug procurement;

(-i-) receiving of drugs;

(-j-) delivery of drugs; and

(-k-) recordkeeping.

(ii) A pharmacy that provides pharmacy services through an automated pharmacy system at a remote site shall, at least annually, review its written policies and procedures, revise them if necessary, and document the review.

(iii) A pharmacy providing remote pharmacy services using an automated pharmacy system shall maintain a written plan for recovery from an event which interrupts the ability of the automated pharmacy system to dispense prescription drugs. The written plan for recovery shall include:

(I) planning and preparation for maintaining pharmacy services when an automated pharmacy system is experiencing downtime;

(II) procedures for response when an automated pharmacy system is experiencing downtime; and

(III) procedures for the maintenance and testing of the written plan for recovery.

(5) Records.

(A) Maintenance of records.

(i) Every record required under this section must be:

(I) kept by the provider pharmacy and be available, for at least two years for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies; and

(II) supplied by the provider 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 an 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.

(ii) The provider pharmacy shall maintain original prescription drug orders for drugs dispensed from an automated pharmacy system in compliance with §291.34(b) of this title.

(iii) if prescription drug records are maintained in a data processing system, the system shall have a workable (electronic) data retention system which can produce a separate audit trail of drug usage by the provider pharmacy and each remote site for the preceding two years as specified in §291.34(e) of this title.

(B) Prescriptions. Prescription drug orders shall meet the requirements of §291.34(b) of this title.

(C) Records of dispensing. Dispensing records for a prescription drug order shall be maintained by the provider pharmacy in the manner required by §291.34(d) or (e) of this title.

(D) Transaction information.

(i) The automated pharmacy system shall electronically record all transactions involving drugs stored in, removed, or dispensed from the system.

(ii) Records of dispensing from an automated pharmacy system for a patient shall be maintained by the providing pharmacy and include the:

(I) identity of the system accessed;

(II) identification of the individual accessing the system;

(III) date of transaction;

(IV) name, strength, dosage form, and quantity of drug accessed; and

(V) name of the patient for whom the drug was accessed.

(iii) Records of stocking or removal from an automated pharmacy system shall be maintained by the pharmacy and include the:

(I) date;

(II) name, strength, dosage form, and quantity of drug stocked or removed;

(III) name, initials, or identification code of the person stocking or removing drugs from the system; and

(IV) name, initials, or identification code of the pharmacist who checks and verifies that the system has been accurately filled.

(E) Patient medication records. Patient medication records shall be created and maintained by the provider pharmacy in the manner required by §291.34(c) of this title.

(F) Inventory.

(i) A provider pharmacy shall:

(I) keep a record of all drugs sent to and returned from a remote site separate from the records of the provider pharmacy and from any other remote site's records; and

(II) keep a perpetual inventory of controlled substances and other drugs required to be inventoried under §291.17 of this title (relating to Inventory Requirements) that are received and dispensed or distributed from each remote site.

(ii) As specified in §291.17 of this title, a provider pharmacy shall conduct an inventory at each remote site. The following is applicable to this inventory.

(I) The inventory of each remote site and the provider pharmacy shall be taken on the same day.

(II) The inventory of each remote site shall be included with, but listed separately from, the drugs of other remote sites and separately from the drugs of the provider pharmacy.

(b) Remote pharmacy services using emergency medication kits.

(1) Purpose. The purpose of this section is to provide standards for the provision of pharmacy services by a Class A or Class C pharmacy in a facility that is not at the same location as the Class A or Class C pharmacy through an emergency medication kit as outlined in §562.108 of the Texas Pharmacy Act.

(2) Definitions. The following words and terms, when used in this subsection, shall have the following meanings, unless the context clearly indicates otherwise. All other words and terms shall have the meanings defined in the Act or §291.31 of this title.

(A) Automated pharmacy system--A mechanical system that dispenses prescription drugs and maintains related transaction information.

(B) Emergency medication kits--Controlled substances and dangerous drugs maintained by a provider pharmacy to meet the emergency medication needs of a resident:

(i) at an institution licensed under Chapter 242 or 252, Health and Safety Code; or

(ii) at an institution licensed under Chapter 242, Health and Safety Code and that is a veterans home as defined by the §164.002, Natural Resources Code, if the provider pharmacy is a United States Department of Veterans Affairs pharmacy or another federally operated pharmacy.

(C) Prepackaging--The act of repackaging and relabeling quantities of drug products from a manufacturer's original commercial container, or quantities of unit dosed drugs, into another cartridge or container for dispensing by a pharmacist using an emergency medication kit.

(D) Provider pharmacy--The community pharmacy (Class A), the institutional pharmacy (Class C), the non-resident pharmacy (Class E) located not more than 20 miles from an institution licensed under Chapter 242 or 252, Health and Safety Code, or the United States Department of Veterans Affairs pharmacy or another federally operated pharmacy providing remote pharmacy services.

(E) Remote pharmacy service--The provision of pharmacy services, including the storage and dispensing of prescription drugs, in remote sites.

(F) Remote site--A facility not located at the same location as a Class A, Class C, Class E pharmacy or a United States Department of Veterans Affairs pharmacy or another federally operated pharmacy, at which remote pharmacy services are provided using an emergency medication kit.

(3) General requirements.

(A) A provider pharmacy may provide remote pharmacy services using an emergency medication kit to an institution regulated under Chapter 242, or 252, Health and Safety Code.

(B) A provider pharmacy may provide remote pharmacy services at more than one remote site.

(C) A provider pharmacy shall not place an emergency medication kit in a remote site which already has a kit from another provider pharmacy except as provided by paragraph (4)(B)(iii) of this subsection.

(D) A provider pharmacy which is licensed as an institutional (Class C) or a non-resident (Class E) pharmacy is required to comply with the provisions of §§291.31 - 291.34 of this title and this section.

(E) The pharmacist-in-charge of the provider pharmacy is responsible for all pharmacy operations involving the emergency medication kit located at the remote site including supervision of the emergency medication kit and compliance with this section.

(4) Operational standards.

(A) Application for permission to provide pharmacy services using an emergency medication kit.

(i) A Class A, Class C, or Class E pharmacy shall file a completed application containing all information required by the board to provide remote pharmacy services using an emergency medication kit and pay the application fee specified in §291.6(e)(2) of this title.

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

(iii) Upon approval of the application, the provider pharmacy will be issued a certificate which must be displayed at the remote site.

(B) Notification requirements.

(i) A provider pharmacy shall notify the board in writing within ten days of a discontinuance of service, or closure of:

(I) a remote site where an emergency medication kit is operated by the pharmacy; or

(II) a remote pharmacy service at a remote site.

(ii) A provider pharmacy shall comply with appropriate federal and state controlled substance registrations for each remote site if controlled substances are maintained within an emergency medication kit at the facility.

(iii) If more than one provider pharmacy provides an emergency kit to a remote site, the provider pharmacies must enter into a written agreement as to the emergency medications supplied by each pharmacy. The written agreement shall include reasons why an additional pharmacy is required to meet the emergency medication needs of the residents of the institution.

(iv) A provider pharmacy shall file a change of location and/or name of a remote site as specified in §291.3 of this title.

(C) Environment/Security.

(i) Emergency medication kits shall have adequate security and procedures to:

(I) prohibit unauthorized access;

(II) comply with federal and state laws and regulations; and

(III) maintain patient confidentiality.

(ii) Access to the emergency medication kit shall be limited to pharmacists and licensed healthcare personnel employed by the facility.

(iii) Drugs shall be stored in compliance with the provisions of §291.15 and §291.33(f)(2) of this title including the requirements for temperature and handling outdated drugs.

(D) Prescription dispensing and delivery.

(i) Drugs in the emergency medication kit shall be accessed for administration to meet the emergency medication needs of a resident of the remote site pursuant to an order from a practitioner. The prescription drug order for the drugs used from the emergency medication kit shall be forwarded to the provider pharmacy in a manner authorized by §291.34(b) of this title.

(ii) The remote site shall notify the provider pharmacy of each entry into an emergency medication kit. Such notification shall meet the requirements of paragraph (5)(D)(ii) of this subsection.

(E) Drugs.

(i) The contents of an emergency medication kit:

(I) may consist of dangerous drugs and controlled substances; and

(II) shall be determined by the consultant pharmacist, pharmacist-in-charge of the provider pharmacy, medical director, and the director of nurses and limited to those drugs necessary to meet the resident's emergency medication needs. For the purpose of this subsection, this shall mean a situation in which a drug cannot be supplied by a pharmacy within a reasonable time period.

(ii) When deciding on the drugs to be placed in the emergency medication kit, the consultant pharmacist, pharmacist-in-charge of the provider pharmacy, medical director, and the director of nurses must determine, select, and record a prudent number of drugs for potential emergency incidents based on:

(I) clinical criteria applicable to each facility's demographics;

(II) the facility's census; and

(III) the facility's healthcare environment.

(iii) A current list of the drugs stored in each remote site's emergency medication kit shall be maintained by the provider pharmacy and a copy kept with the emergency medication kit.

(iv) An automated pharmacy system may be used as an emergency medication kit provided the system limits emergency access to only those drugs approved for the emergency medication kit.

(v) Drugs for use in an emergency medication kit shall be packaged in the original manufacturer's container or prepackaged in the provider pharmacy and labeled in compliance with the board's prepackaging requirements for the class of pharmacy.

(F) Stocking emergency medication kits.

(i) Stocking of drugs in an emergency medication kit shall be completed at the provider pharmacy or remote site by a pharmacist, pharmacy technician, or pharmacy technician trainee under the direct supervision of a pharmacist, except as provided in clause (ii) of this subparagraph.

(ii) If the emergency medication kit is an automated pharmacy system which uses bar-coding, microchip, or other technologies to ensure that the containers or unit dose drugs are accurately loaded, the prepackaging of the containers or unit dose drugs shall occur at the provider pharmacy unless provided by an FDA approved repackager. The prepackaged containers or unit dose drugs may be sent to the remote site to be loaded into the machine by personnel designated by the pharmacist-in-charge provided:

(I) a pharmacist verifies the container or unit dose drug has been properly filled and labeled;

(II) the individual containers or unit dose drugs are transported to the remote site in a secure, tamper-evident container; and

(III) the automated pharmacy system uses bar-coding, microchip, or other technologies to ensure that the containers or unit dose drugs are accurately loaded in the automated pharmacy system.

(iii) All drugs to be stocked in the emergency medication kit shall be delivered to the remote site by the provider pharmacy.

(G) Policies and procedures of operation.

(i) A provider pharmacy that provides pharmacy services through an emergency medication kit at a remote site shall operate according to written policies and procedures. The policy and procedure manual shall include, but not be limited to, the following:

(I) duties which may only be performed by a pharmacist;

(II) a copy of the written contract or agreement between the pharmacy and the facility which outlines the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract in compliance with federal and state laws and regulations;

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

(IV) policies and procedures for:

(-a-) security;

(-b-) operation of the emergency medication kit;

(-c-) preventative maintenance of the automated pharmacy system if the emergency medication kit is an automated pharmacy system;

(-d-) sanitation;

(-e-) storage of drugs;

(-f-) dispensing;

(-g-) supervision;

(-h-) drug procurement;

(-i-) receiving of drugs;

(-j-) delivery of drugs; and

(-k-) recordkeeping.

(ii) A pharmacy that provides pharmacy services through an emergency medication kit at a remote site shall, at least annually, review its written policies and procedures, revise them if necessary, and document the review.

(iii) A pharmacy providing remote pharmacy services using an emergency medication kit which is an automated pharmacy system shall maintain a written plan for recovery from an event which interrupts the ability of the automated pharmacy system to provide emergency medications. The written plan for recovery shall include:

(I) planning and preparation for maintaining pharmacy services when an automated pharmacy system is experiencing downtime;

(II) procedures for response when an automated pharmacy system is experiencing downtime; and

(III) procedures for the maintenance and testing of the written plan for recovery.

(5) Records.

(A) Maintenance of records.

(i) Every record required under this section must be:

(I) kept by the provider pharmacy and be available, for at least two years for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies; and

(II) supplied by the provider 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 an 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.

(ii) The provider pharmacy shall maintain original prescription drug orders for drugs dispensed from an emergency medication kit in compliance with §291.34(b) of this title.

(B) Prescriptions. Prescription drug orders shall meet the requirements of §291.34(b) of this title.

(C) Records of dispensing. Dispensing records for a prescription drug order shall be maintained by the provider pharmacy in the manner required by §291.34(d) or (e) of this title.

(D) Transaction information.

(i) A prescription drug order shall be maintained by the provider pharmacy as the record of removal of a drug from an emergency medication kit for administration to a patient.

(ii) The remote site shall notify the provider pharmacy electronically or in writing of each entry into an emergency medication kit. Such notification may be included on the prescription drug order or a separate document and shall include the name, strength, and quantity of the drug removed, the time of removal, and the name of the person removing the drug.

(iii) A separate record of stocking, removal, or dispensing for administration from an emergency medication kit shall be maintained by the pharmacy and include the:

(I) date;

(II) name, strength, dosage form, and quantity of drug stocked, removed, or dispensed for administration;

(III) name, initials, or identification code of the person stocking, removing, or dispensing for administration, drugs from the system;

(IV) name, initials, or identification code of the pharmacist who checks and verifies that the system has been accurately filled; and

(V) unique prescription number assigned to the prescription drug order when the drug is administered to the patient.

(E) Inventory.

(i) A provider pharmacy shall:

(I) keep a record of all drugs sent to and returned from a remote site separate from the records of the provider pharmacy and from any other remote site's records; and

(II) keep a perpetual inventory of controlled substances and other drugs required to be inventoried under §291.17 of this title, that are received and dispensed or distributed from each remote site.

(ii) As specified in §291.17 of this title, a provider pharmacy shall conduct an inventory at each remote site. The following is applicable to this inventory.

(I) The inventory of each remote site and the provider pharmacy shall be taken on the same day.

(II) The inventory of each remote site shall be included with, but listed separately from, the drugs of other remote sites and separately from the drugs of the provider pharmacy.

(c) Remote pharmacy services using telepharmacy systems.

(1) Purpose. The purpose of this section is to provide standards for the provision of pharmacy services by a Class A or Class C pharmacy in a healthcare facility that is not at the same location as a Class A or Class C pharmacy through a telepharmacy system as outlined in §562.110 of the Texas Pharmacy Act.

(2) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise. All other words and terms shall have the meanings defined in the Act or §291.31 of this title.

(A) Provider pharmacy--

(i) a Class A pharmacy that provides pharmacy services through a telepharmacy system at a remote dispensing site or at a healthcare facility that is regulated by this state or the United States; or

(ii) a Class C pharmacy that provides pharmacy services though a telepharmacy system at a healthcare facility that is regulated by this state or the United States.

(B) Remote dispensing site--a location licensed as a telepharmacy that is authorized by a provider pharmacy through a telepharmacy system to store and dispense prescription drugs and devices, including dangerous drugs and controlled substances.

(C) Remote healthcare site--a healthcare facility regulated by this state or the United States that is a:

(i) rural health clinic regulated under 42 U.S.C. Section 1395x(aa);

(ii) health center as defined by 42 U.S.C. Section 254b;

(iii) healthcare facility located in a medically underserved area as determined by the United States Department of Health and Human Services;

(iv) healthcare facility located in a health professional shortage area as determined by the United States Department of Health and Human Services; or

(v) a federally qualified health center as defined by 42 U.S.C. Section 1396d(I)(2)(B).

(D) Remote pharmacy service--The provision of pharmacy services, including the storage and dispensing of prescription drugs, drug regimen review, and patient counseling, at a remote site.

(E) Remote site--a remote healthcare site or a remote dispensing site.

(F) Still image capture--A specific image captured electronically from a video or other image capture device.

(G) Store and forward--A video or still image record which is saved electronically for future review.

(H) Telepharmacy system--A system that monitors the dispensing of prescription drugs and provides for related drug use review and patient counseling services by an electronic method which shall include the use of the following types of technology:

(i) audio and video;

(ii) still image capture; and

(iii) store and forward.

(3) General requirements.

(A) A provider pharmacy may provide remote pharmacy services using a telepharmacy system at a:

(i) remote healthcare site; or;

(ii) remote dispensing site.

(B) A provider pharmacy may not provide remote pharmacy services at a remote healthcare site if a Class A or Class C pharmacy that dispenses prescription drug orders to out-patients is located in the same community, unless the remote healthcare site is a federally qualified health center as defined by 42 U.S.C. Section 1396d(l)(2)(B). For the purposes of this subsection a community is defined as:

(i) the census tract in which the remote site is located, if the remote site is located in a Metropolitan Statistical Area (MSA) as defined by the United States Census Bureau in the most recent U.S. Census; or

(ii) within 10 miles of the remote site, if the remote site is not located in an MSA.

(C) A provider pharmacy may not provide remote pharmacy services at a remote dispensing site if a Class A pharmacy is located within 22 miles by road of the remote dispensing site.

(D) If a Class A or Class C pharmacy is established in a community in which a remote healthcare site has been located, the remote healthcare site may continue to operate.

(E) If a Class A pharmacy is established within 22 miles by road of a remote dispensing site that is currently operating, the remote dispensing site may continue to operate at that location.

(F) Before providing remote pharmacy services, the telepharmacy system at the remote site must be tested by the provider pharmacy and found to operate properly. The provider pharmacy shall make the results of such testing available to the board upon request.

(G) A provider pharmacy which is licensed as a Class C pharmacy is required to comply with the provisions of §§291.31 - 291.34 of this title and this section.

(H) A provider pharmacy can only provide pharmacy services at no more than two remote dispensing sites.

(4) Personnel.

(A) The pharmacist-in-charge of the provider pharmacy is responsible for all operations at the remote site including supervision of the telepharmacy system and compliance with this section.

(B) The provider pharmacy shall have sufficient pharmacists on duty such that each pharmacist may supervise no more than two remote sites that are simultaneously open to provide services.

(C) The following duties shall be performed only by a pharmacist at the provider pharmacy:

(i) receiving an oral prescription drug order for a controlled substance;

(ii) interpreting the prescription drug order;

(iii) verifying the accuracy of prescription data entry;

(iv) selecting the drug product to be stored and dispensed at the remote site;

(v) interpreting the patient's medication record and conducting a drug regimen review;

(vi) authorizing the telepharmacy system to print a prescription label at the remote site;

(vii) performing the final check of the dispensed prescription to ensure that the prescription drug order has been dispensed accurately as prescribed; and

(viii) counseling the patient.

(D) A pharmacy technician at the remote site may receive an oral prescription drug order for a dangerous drug.

(5) Operational standards.

(A) Application to provide remote pharmacy services using a telepharmacy system.

(i) A Class A or Class C pharmacy shall file a completed application containing all information required by the board to provide remote pharmacy services using a telepharmacy system and pay the application fee specified in §291.6(e)(3) of this title.

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

(iii) On approval of the application, the provider pharmacy will be issued a license for the remote site, which must be displayed at the remote site.

(iv) If the average number of prescriptions dispensed each day at a remote dispensing site is open for business is more than 125 prescriptions, as calculated each calendar year, the remote dispensing site shall apply for a Class A pharmacy license as specified in §291.1 of this title (relating to Pharmacy License Application).

(B) Notification requirements.

(i) A provider pharmacy shall notify the board in writing within ten days of a discontinuance of service, or closure of a remote site where a telepharmacy system is operated by the pharmacy.

(ii) A provider pharmacy shall comply with appropriate federal and state controlled substance registrations for each remote site, if controlled substances are maintained.

(iii) A provider pharmacy shall file a change of location and/or name of a remote site as specified in §291.3 of this title.

(C) Environment/Security.

(i) A remote site shall be under the continuous supervision of a provider pharmacy pharmacist at all times the site is open to provide pharmacy services. To qualify as continuous supervision, the pharmacist is not required to be physically present at the remote site and shall supervise electronically through the use of the following types of technology:

(I) audio and video;

(II) still image capture; and

(III) store and forward.

(ii) Drugs shall be stored in compliance with the provisions of §291.15 and §291.33(f)(2) of this title including the requirements for temperature and handling of outdated drugs.

(iii) Drugs for use in the telepharmacy system at a remote healthcare site shall be stored in an area that is:

(I) separate from any other drugs used by the healthcare facility; and

(II) locked by key, combination or other mechanical or electronic means, so as to prohibit access by unauthorized personnel.

(iv) Drugs for use in the telepharmacy system at a remote dispensing site shall be stored in an area that is locked by key, combination, or other mechanical or electronic means, so as to prohibit access by unauthorized personnel.

(v) Access to the area where drugs are stored at the remote site and operation of the telepharmacy system shall be limited to:

(I) pharmacists employed by the provider pharmacy;

(II) licensed healthcare providers, if the remote site is a remote healthcare site; and

(III) pharmacy technicians;

(vi) Individuals authorized to access the remote site and operate the telepharmacy system shall:

(I) be designated in writing by the pharmacist-in-charge; and

(II) have completed documented training concerning their duties associated with the telepharmacy pharmacy system.

(vii) Remote sites shall have adequate security and procedures to:

(I) comply with federal and state laws and regulations; and

(II) maintain patient confidentiality.

(D) Prescription dispensing and delivery.

(i) A pharmacist at the provider pharmacy shall conduct a drug regimen review as specified in §291.33(c) of this title prior to delivery of the dispensed prescription to the patient or patient's agent.

(ii) The dispensed prescription shall be labeled at the remote site with the information specified in §291.33(c) of this title.

(iii) A pharmacist at the provider pharmacy shall perform the final check of the dispensed prescription before delivery to the patient to ensure that the prescription has been dispensed accurately as prescribed. This final check shall be accomplished through a visual check using electronic methods.

(iv) A pharmacist at the provider pharmacy shall counsel the patient or patient's agent as specified in §291.33(c) of this title. This counseling may be performed using electronic methods. Non-pharmacist personnel may not ask questions of a patient or patient's agent which are intended to screen and/or limit interaction with the pharmacist.

(v) If the remote site has direct access to the provider pharmacy's data processing system, only a pharmacist or pharmacy technician may enter prescription information into the data processing system.

(vi) Drugs which require reconstitution through the addition of a specified amount of water may be dispensed by the remote site only if a pharmacy technician, pharmacy technician trainee, or licensed healthcare provider reconstitutes the product.

(vii) A telepharmacy system located at a remote dispensing site may not dispense a schedule II controlled substance.

(viii) Drugs dispensed at the remote site through a telepharmacy system shall only be delivered to the patient or patient's agent at the remote site.

(E) Quality assurance program. A pharmacy that provides remote pharmacy services through a telepharmacy system at a remote site shall operate according to a written program for quality assurance of the telepharmacy system which:

(i) requires continuous supervision of the telepharmacy system at all times the site is open to provide remote pharmacy services; and

(ii) establishes mechanisms and procedures to routinely test the operation of the telepharmacy system at a minimum of every six months and whenever any upgrade or change is made to the system and documents each such activity.

(F) Policies and procedures.

(i) A pharmacy that provides pharmacy services through a telepharmacy system at a remote site shall operate according to written policies and procedures. The policy and procedure manual shall include, but not be limited to, the following:

(I) a current list of the name and address of the pharmacist-in-charge and personnel designated by the pharmacist-in-charge to have:

(-a-) access to the area where drugs are stored at the remote site; and

(-b-) operate the telepharmacy system;

(II) duties which may only be performed by a pharmacist;

(III) if the remote site is located at a remote healthcare site, a copy of the written contact or agreement between the provider pharmacy and the healthcare facility which outlines the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract or agreement in compliance with federal and state laws and regulations;

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

(V) policies and procedures for:

(-a-) security;

(-b-) operation of the telepharmacy system;
(-c-) sanitation;
(-d-) storage of drugs;
(-e-) dispensing;
(-f-) supervision;
(-g-) drug and/or device procurement;
(-h-) receiving of drugs and/or devices;
(-i-) delivery of drugs and/or devices; and
(-j-) recordkeeping.

(ii) A pharmacy that provides remote pharmacy services through a telepharmacy system at a remote site shall, at least annually, review its written policies and procedures, revise them if necessary, and document the review.

(iii) A pharmacy providing remote pharmacy services through a telepharmacy system shall maintain a written plan for recovery from an event which interrupts the ability of a pharmacist to electronically supervise the telepharmacy system and the dispensing of prescription drugs at the remote site. The written plan for recovery shall include:

(I) a statement that prescription drugs shall not be dispensed at the remote site, if a pharmacist is not able to electronically supervise the telepharmacy system and the dispensing of prescription drugs;

(II) procedures for response when a telepharmacy system is experiencing downtime; and

(III) procedures for the maintenance and testing of the written plan for recovery.

(6) Additional operational standards for remote dispensing sites.

(A) A pharmacist employed by a provider pharmacy shall make at least monthly on-site visits to a remote site. The remote site shall maintain documentation of the visit.

(B) A pharmacist employed by a provider pharmacy shall be physically present at a remote dispensing site when the pharmacist is providing services requiring the physical presence of the pharmacist, including immunizations.

(C) A remote dispensing site shall be staffed by an on-site pharmacy technician who is under the continuous supervision of a pharmacist employed by the provider pharmacy.

(D) All pharmacy technicians at a remote dispensing site shall be counted for the purpose of establishing the pharmacist-pharmacy technician ratio of the provider pharmacy which, notwithstanding Section 568.006 of the Act, may not exceed three pharmacy technicians for each pharmacist providing supervision.

(E) A pharmacy technician working at a remote dispensing site must:

(i) have worked at least one year at a retail pharmacy during the three years preceding the date the pharmacy technician begins working at the remote dispensing site; and

(ii) have completed a training program on the proper use of a telepharmacy system.

(F) A pharmacy technician at a remote dispensing site may not perform sterile or nonsterile compounding. However, a pharmacy technician may prepare commercially available medications for dispensing, including the reconstitution of orally administered powder antibiotics.

(7) Records.

(A) Maintenance of records.

(i) Every record required under this section must be:

(I) accessible by the provider pharmacy and be available, for at least two years for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies; and

(II) supplied by the provider 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 an 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.

(ii) The remote site shall maintain original prescription drug orders for medications dispensed from a remote site using a telepharmacy system in the manner required by §291.34(b) of this title and the provider pharmacy shall have electronic access to all prescription records.

(iii) If prescription drug records are maintained in a data processing system, the system shall have a workable (electronic) data retention system which can produce a separate audit trail of drug usage by the provider pharmacy and by each remote site for the preceding two years as specified in §291.34(e) of this title.

(B) Prescriptions. Prescription drug orders shall meet the requirements of §291.34(b) of this title.

(C) Patient medication records. Patient medication records shall be created and maintained at the remote site or provider pharmacy in the manner required by §291.34(c) of this title. If such records are maintained at the remote site, the provider pharmacy shall have electronic access to those records.

(D) Inventory.

(i) A provider pharmacy shall:

(I) keep a record of all drugs ordered and dispensed by a remote site separate from the records of the provider pharmacy and from any other remote site's records;

(II) keep a perpetual inventory of all controlled substances that are received and dispensed or distributed from each remote site. The perpetual inventory shall be reconciled, by a pharmacist employed by the provider pharmacy, at least monthly.

(ii) As specified in §291.17 of this title, a provider pharmacy shall conduct an inventory at each remote site. The following is applicable to this inventory.

(I) The inventory of each remote site and the provider pharmacy shall be taken on the same day.

(II) The inventory of each remote site shall be included with, but listed separately from, the drugs of other remote sites and separately from the drugs at the provider pharmacy.

(III) A copy of the inventory of the remote site shall be maintained at the remote site.

(d) Remote pharmacy services using automated dispensing and delivery systems.

(1) Purpose. The purpose of this section is to provide standards for the provision of pharmacy services by a Class A or Class C pharmacy in a facility that is not at the same location as the Class A or Class C pharmacy through an automated dispensing and delivery system.

(2) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise. All other words and terms shall have the meanings defined in the Act.

(A) Automated dispensing and delivery system--A mechanical system that dispenses and delivers prescription drugs to patients at a remote delivery site and maintains related transaction information.

(B) Deliver or delivery--The actual, constructive, or attempted transfer of a prescription drug or device or controlled substance from one person to another, whether or not for a consideration.

(C) Dispense--Preparing, packaging, compounding, or labeling for delivery a prescription drug or device in the course of professional practice to an ultimate user or his agent by or pursuant to the lawful order of a practitioner.

(D) Provider pharmacy--The community pharmacy (Class A) or the institutional pharmacy (Class C) providing remote pharmacy services.

(E) Remote delivery site--A location at which remote pharmacy services are provided using an automated dispensing and delivery system.

(F) Remote pharmacy service--The provision of pharmacy services, including the dispensing and delivery of prescription drugs, in remote delivery sites.

(3) General requirements for a provider pharmacy to provide remote pharmacy services using an automated dispensing and delivery system to dispense and deliver a prescription that is verified by the provider pharmacy to a patient or patient's agent.

(A) The pharmacist-in-charge of the provider pharmacy is responsible for all pharmacy operations involving the automated dispensing and delivery system located at the remote delivery site including supervision of the automated dispensing and delivery system and compliance with this section.

(B) The patient or patient's agent shall receive counseling via a direct link to audio or video communication by a Texas licensed pharmacist who has access to the complete patient medication record (patient profile) maintained by the provider pharmacy prior to the release of any new prescription released from the system.

(C) A pharmacist shall be accessible at all times to respond to patients' or other health professionals' questions and needs pertaining to drugs delivered through the use of the automated dispensing and delivery system. Such access may be through a 24 hour pager service or telephone which is answered 24 hours a day.

(D) The patient or patient's agent shall be given the option whether to use the system.

(E) An electronic notice shall be provided to the patient or patient's agent at the remote delivery site with the following information:

(i) the name and address of the pharmacy that verified the previously dispensed prescription; and

(ii) a statement that a pharmacist is available 24 hours a day, 7 days a week through the use of telephonic communication.

(F) Drugs stored in the automated dispensing and distribution system shall be stored at proper temperatures, as defined in the USP/NF and §291.15 of this title.

(G) A provider pharmacy may only provide remote pharmacy services using an automated dispensing and delivery system to patients at a board-approved remote delivery site.

(H) A provider pharmacy may provide remote pharmacy services at more than one remote delivery site.

(I) Before providing remote pharmacy services, the automated dispensing and delivery system at the remote delivery site must be tested by the provider pharmacy and found to dispense and deliver accurately. The provider pharmacy shall make the results of such testing available to the board upon request.

(J) A provider pharmacy which is licensed as an institutional (Class C) pharmacy is required to comply with the provisions of §§291.31 - 291.34 of this title and this section.

(4) Operational standards.

(A) Application to provide remote pharmacy services using an automated dispensing and delivery system.

(i) A community (Class A) or institutional (Class C) pharmacy shall file a completed application containing all information required by the board to provide remote pharmacy services using an automated dispensing and delivery system and pay the application fee specified in §291.6(e)(4) of this title.

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

(iii) Upon approval of the application, the provider pharmacy will be issued a certificate which must be displayed at the provider pharmacy.

(B) Notification requirements.

(i) A provider pharmacy shall notify the board in writing within ten days of a discontinuance of service.

(ii) A provider pharmacy shall comply with appropriate controlled substance registrations for each remote delivery site if dispensed controlled substances are maintained within an automated dispensing and delivery system at the facility.

(iii) A provider pharmacy shall file an application for change of location and/or name of a remote delivery site as specified in §291.3 of this title.

(C) Environment/Security.

(i) A provider pharmacy shall only store prescription drugs at a remote delivery site within an automated dispensing and delivery system which is locked by key, combination or other mechanical or electronic means so as to prohibit access by unauthorized personnel.

(ii) Access to the automated dispensing and delivery system shall be limited to pharmacists, and pharmacy technicians or pharmacy technician trainees under the direct supervision of a pharmacist who:

(I) are designated in writing by the pharmacist-in-charge; and

(II) have completed documented training concerning their duties associated with the automated dispensing and delivery system.

(iii) Drugs shall be stored in compliance with the provisions of §291.15 of this title and §291.33(c)(8) of this title, including the requirements for temperature and the return of undelivered medication to stock.

(iv) the automated storage and delivery system must have an adequate security system, including security camera(s), to prevent unauthorized access and to maintain patient confidentiality.

(D) Stocking an automated dispensing and delivery system. Stocking of prescription drugs in an automated dispensing and delivery system shall be completed under the supervision of a pharmacist.

(E) Quality assurance program. A pharmacy that provides pharmacy services through an automated dispensing and delivery system at a remote delivery site shall operate according to a written program for quality assurance of the automated dispensing and delivery system which:

(i) requires continuous supervision of the automated dispensing the accuracy of the automated dispensing and delivery system; and

(ii) establishes mechanisms and procedures to routinely test the accuracy of the automated dispensing and delivery system at a minimum of every six months and whenever any upgrade or change is made to the system and documents each such activity.

(F) Policies and procedures of operation.

(i) A pharmacy that provides pharmacy services through an automated dispensing and delivery system at a remote delivery site shall operate according to written policies and procedures. The policy and procedure manual shall include, but not be limited to, the following:

(I) a current list of the names and addresses of the pharmacist-in-charge and all personnel designated by the pharmacist-in-charge to have access to the prescription drugs stored in the automated dispensing and delivery system;

(II) duties which may only be performed by a pharmacist;

(III) a copy of the portion of the written contract or lease agreement between the pharmacy and the remote delivery site location which outlines the services to be provided and the responsibilities and accountabilities of each party relating to the operation of the automated dispensing and delivery system in fulfilling the terms of the contract in compliance with federal and state laws and regulations;

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

(V) policies and procedures for:

(-a-) security;
(-b-) operation of the automated dispensing and delivery system;
(-c-) preventative maintenance of the automated dispensing and delivery system;
(-d-) sanitation;
(-e-) storage of prescription drugs;
(-f-) supervision;
(-g-) delivery of prescription drugs; and
(-h-) recordkeeping.

(ii) A pharmacy that provides pharmacy services through an automated dispensing and delivery system at a remote delivery site shall, at least annually, review its written policies and procedures, revise them if necessary, and document the review.

(iii) A pharmacy providing remote pharmacy services using an automated dispensing and delivery system shall maintain a written plan for recovery from an event which interrupts the ability of the automated dispensing and delivery system to dispense and deliver prescription drugs. The written plan for recovery shall include:

(I) planning and preparation for maintaining pharmacy services when an automated dispensing and delivery system is experiencing downtime;

(II) procedures for response when an automated dispensing and delivery system is experiencing downtime; and

(III) procedures for the maintenance and testing of the written plan for recovery.

(5) Records.

(A) Maintenance of records.

(i) Every record required under this section must be:

(I) kept by the provider pharmacy and be available, for at least two years for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies; and

(II) supplied by the provider 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 an 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.

(ii) The provider pharmacy shall have a workable (electronic) data retention system which can produce a separate audit trail of drug delivery and retrieval transactions at each remote delivery site for the preceding two years.

(B) Transaction information.

(i) The automated dispensing and delivery system shall electronically record all transactions involving drugs stored in, removed, or delivered from the system.

(ii) Records of delivery from an automated dispensing and delivery system for a patient shall be maintained by the provider pharmacy and include the:

(I) identity of the system accessed;

(II) identification of the individual accessing the system;

(III) date of transaction;

(IV) prescription number, drug name, strength, dosage form;

(V) number of prescriptions retrieved;

(VI) name of the patient for whom the prescription was retrieved;

(VII) name of prescribing practitioner; and

(VIII) name of pharmacist responsible for consultation with the patient, if required, and documentation that the consultation was performed.

(iii) Records of stocking or removal from an automated dispensing and delivery system shall be maintained by the pharmacy and include the:

(I) count of bulk prescription drugs stored or removed; (II) prescription number;

(II) number of dispensed prescription packages removed;

(III) name, initials, or identification code of the person stocking or removing prescription drugs from the system; and

(IV) name, initials, or identification code of the pharmacist who checks and verifies that the system has been accurately filled.

(C) The pharmacy shall make the automated dispensing and delivery system and any records of the system, including testing records, available for inspection by the board.

(D) The automated dispensing and delivery system records a digital image of the individual accessing the system to pick-up a prescription and such record is maintained by the pharmacy for two years.

§291.123 Central Prescription Drug or Medication Order Processing

(a) Purpose.

(1) The purpose of this section is to provide standards for centralized prescription drug or medication order processing by a Class A (Community), Class C (Institutional), or Class E (Non-Resident) pharmacy.

(2) Any facility established for the purpose of processing prescription drug or medication drug orders shall be licensed as a Class A, Class C, or Class E pharmacy under the Act. However, nothing in this subsection shall prohibit an individual pharmacist employee, individual pharmacy technician employee, or individual pharmacy technician trainee employee who is licensed in Texas from remotely accessing the pharmacy's electronic data base from outside the pharmacy in order to process prescription or medication drug orders, provided the pharmacy establishes controls to protect the privacy and security of confidential records.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section shall have the definition set out in the Act. Centralized prescription drug or medication order processing--the processing of a prescription drug or medication orders by a Class A, Class C, or Class E pharmacy on behalf of another pharmacy, a health care provider, or a payor. Centralized prescription drug or medication order processing does not include the dispensing of a prescription drug order but includes any of the following:

(1) receiving, interpreting, or clarifying prescription drug or medication drug orders;

(2) data entering and transferring of prescription drug or medication order information;

(3) performing drug regimen review;

(4) obtaining refill and substitution authorizations;

(5) interpreting clinical data for prior authorization for dispensing;

(6) performing therapeutic interventions; and

(7) providing drug information concerning a patient's prescription.

(c) Operational Standards.

(1) General requirements.

(A) A Class A, Class C, or Class E Pharmacy may outsource prescription drug or medication order processing to another Class A, Class C, or Class E pharmacy provided the pharmacies:

(i) have:

(I) the same owner; or

(II) entered into a written contract or agreement which outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations; and

(ii) share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to process a non-dispensing function.

(B) A pharmacy that performs centralized prescription drug or medication order processing shall comply with the provisions applicable to the class of pharmacy contained in either §§291.31 - 291.35 of this title (relating to Definitions, Personnel, Operational Standards, Records, and Official Prescription Requirements in Class A (Community) Pharmacies), or §§291.72 - 291.75 of this title (relating to Definitions, Personnel, Operational Standards, and Records in a Class C (Institutional) Pharmacy), or §§291.102 - 291.105 of this title (relating to Definitions, Personnel, Operational Standards, and Records in a Class E (Non-Resident) Pharmacy) to the extent applicable for the specific processing activity and this section including:

(i) duties which must be performed by a pharmacist; and

(ii) supervision requirements for pharmacy technicians and pharmacy technician trainees.

(2) Notifications to patients.

(A) A pharmacy that outsources prescription drug or medication order processing to another pharmacy shall prior to outsourcing their prescription:

(i) notify patients that prescription processing may be outsourced to another pharmacy; and

(ii) give the name of that pharmacy; or if the pharmacy is part of a network of pharmacies under common ownership and any of the network pharmacies may process the prescription, the patient shall be notified of this fact. Such notification may be provided through a one-time written notice to the patient or through use of a sign in the pharmacy.

(B) The provisions of this paragraph do not apply to patients in facilities where drugs are administered to patients by a person required to do so by the laws of the state (i.e., hospitals or nursing homes).

(3) Policy and Procedures. A policy and procedure manual as it relates to central processing shall be maintained at all pharmacies involved in central processing and be available for inspection. Each pharmacy is required to maintain only those portions of the policy and procedure manual that relate to that pharmacy's operations. The manual shall:

(A) outline the responsibilities of each of the pharmacies;

(B) include a list of the name, address, telephone numbers, and all license/registration numbers of the pharmacies involved in centralized prescription drug or medication order processing; and

(C) include policies and procedures for:

(i) protecting the confidentiality and integrity of patient information;

(ii) maintenance of appropriate records to identify the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist or pharmacy technician who performed any processing;

(iii) complying with federal and state laws and regulations;

(iv) operating a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems; and

(v) annually reviewing the written policies and procedures and documenting such review.

(d) Records. All pharmacies shall maintain appropriate records which identify, by prescription drug or medication order, the name(s), initials, or identification code(s) of each pharmacist, pharmacy technician, or pharmacy technician trainee who performs a processing function for a prescription drug or medication order. Such records may be maintained:

(1) separately by each pharmacy and pharmacist; or

(2) in a common electronic file as long as the records are maintained in such a manner that the data processing system can produce a printout which lists the functions performed by each pharmacy and pharmacist.

§291.125 Centralized Prescription Dispensing

(a) Purpose. The purpose of this section is to provide standards for centralized prescription dispensing by a Class A (Community), Class C (Institutional) pharmacy, or Class E (Non-Resident) Pharmacy.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section shall have the definition set out in the Act.

(1) Central fill pharmacy--a Class A, Class A-S, Class C, Class C-S, Class E, or Class E-S pharmacy that prepares prescription drug orders for dispensing pursuant to a valid prescription transmitted to the central fill pharmacy by an outsourcing pharmacy.

(2) Centralized prescription dispensing--the dispensing or refilling of a prescription drug order by a Class A, Class C, or Class E pharmacy at the request of another Class A, Class C, or Class E pharmacy and the return of the dispensed prescriptions to the outsourcing pharmacy for delivery to the patient or patient's agent, or at the request of the outsourcing pharmacy for direct delivery to the patient.

(3) Outsourcing pharmacy--a Class A, Class C, or Class E pharmacy that transmits a prescription drug order via facsimile or communicates prescription information electronically to a central fill pharmacy to be dispensed by the central fill pharmacy.

(c) Operational standards.

(1) General requirements.

(A) A Class A or Class C pharmacy may outsource prescription drug order dispensing to a central fill pharmacy provided the pharmacies:

(i) have:

(I) the same owner; or

(II) entered into a written contract or agreement which outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations; and

(ii) share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to dispense or process a prescription drug order.

(B) Unless compliance would violate the pharmacy or drug laws or rules in the state in which the pharmacy is located, a Class E pharmacy may outsource prescription drug order dispensing to a central fill pharmacy provided the pharmacies meet the requirements of subparagraph (A) of this paragraph.

(C) The pharmacist-in-charge of the central fill pharmacy shall ensure that:

(i) the pharmacy maintains and uses adequate storage or shipment containers and 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; and

(ii) the dispensed prescriptions are shipped in containers which are sealed in a manner as to show evidence of opening or tampering.

(D) A Class A or Class C central fill pharmacy shall comply with the provisions of §§291.31 - 291.35 of this title (relating to Definitions, Personnel, Operational Standards, Records, and Official Prescription Requirements) and this section.

(E) A Class E central fill pharmacy shall comply with §§291.101 - 291.105 of this title (relating to Purpose, Definitions, Personnel, Operational Standards, and Records) and this section.

(2) Notifications to patients.

(A) A pharmacy that outsources prescription dispensing to a central fill pharmacy shall:

(i) prior to outsourcing the prescription:

(I) notify patients that their prescription may be outsourced to a central fill pharmacy; and

(II) give the name of the central fill pharmacy or if the pharmacy is part of a network of pharmacies under common ownership and any of the network pharmacies may

dispense the prescription, the patient shall be notified of this fact. Such notification may be provided through a one-time written notice to the patient or through use of a sign in the pharmacy; and

(ii) if a prescription that is not for a controlled substance is delivered directly to the patient by the central fill pharmacy and not returned to the outsourcing pharmacy, place on the prescription container or on a separate sheet delivered with the prescription container, in both English and Spanish, the local, and if applicable, the toll-free telephone number of the pharmacy and the statement: "Written information about this prescription has been provided for you. Please read this information before you take the medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions at (insert the pharmacy's local and toll-free telephone numbers)." A prescription for a controlled substance may not be delivered directly to the patient by the central fill pharmacy.

(B) The provisions of this paragraph do not apply to patients in facilities where drugs are administered to patients by a person required to do so by the laws of the state (e.g., hospitals or nursing homes).

(3) Prescription Labeling. The central fill pharmacy shall place on the prescription label, the name and address of the outsourcing pharmacy and a unique identifier (i.e., the central fill pharmacy's DEA registration number or, if the pharmacy does not have a DEA registration number, the central fill pharmacy's Texas license number) indicating that the prescription was dispensed by the central fill pharmacy; and comply with all other labeling requirements in §291.33 of this title.

(4) Policies and Procedures. A policy and procedure manual as it relates to centralized dispensing shall be maintained at both pharmacies and be available for inspection. Each pharmacy is required to maintain only those portions of the policy and procedure manual that relate to that pharmacy's operations. The manual shall:

(A) outline the responsibilities of each of the pharmacies;

(B) include a list of the name, address, telephone numbers, and all license/registration numbers of the pharmacies involved in centralized prescription dispensing; and

(C) include policies and procedures for:

(i) notifying patients that their prescription may be outsourced to a central fill pharmacy for dispensing and providing the name of that pharmacy;

(ii) protecting the confidentiality and integrity of patient information;

(iii) dispensing prescription drug orders when the dispensed order is not received or the patient comes in before the order is received;

(iv) complying with federal and state laws and regulations;

(v) operating a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems; and

(vi) annually reviewing the written policies and procedures and documenting such review.

(d) Records.

(1) Records 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.

(2) Each pharmacy shall comply with all the laws and rules relating to the maintenance of records and be able to produce an audit trail showing all prescriptions dispensed by the pharmacy.

(3) The outsourcing pharmacy shall maintain records, in addition to the prescription drug order, which indicate the:

(A) date:

(i) the request for dispensing was transmitted to the central fill pharmacy; and

(ii) the dispensed prescription was received by the outsourcing pharmacy, including the method of delivery (e.g., private, common, or contract carrier) and the name of the person accepting delivery; and

(B) name, address, license number, and the unique identifier of the central fill pharmacy.

(4) The central fill pharmacy shall maintain records, in addition to the prescription drug order, which indicate the:

(A) date the prescription was shipped to the outsourcing pharmacy or the patient;

(B) name and address where the prescription was shipped;

(C) method of delivery (e.g., private, common, or contract carrier); and

(D) name, address, and license number of the outsourcing pharmacy.

(e) Nothing in this section shall be construed as requiring a nonresident pharmacy that outsources drug order dispensing to a central fill pharmacy to be licensed as a Class E pharmacy in accordance with §291.101 of this title, provided that the nonresident pharmacy does not physically ship, mail, or deliver prescription drugs or devices directly to a patient or patient's agent in this state.

§291.127 Emergency Remote Pharmacy License

(a) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise. All other words and terms shall have the meanings defined in the Act.

(1) Emergency remote pharmacy--A pharmacy not located at the same Texas location as a home pharmacy at which pharmacy services are provided during an emergency situation.

(2) Emergency situation--An emergency caused by a natural or manmade disaster or any other exceptional situation that causes an extraordinary demand for pharmacy services.

(3) Home pharmacy--A currently licensed Class A (Community), Class C (Institutional), or Class D (Clinic) pharmacy that is providing emergency pharmacy services through an emergency remote pharmacy.

(b) Emergency remote pharmacy license. In an emergency situation, the board may grant a holder of a Class A (Community), Class C (Institutional), or Class D (Clinic) pharmacy license, the authority to operate a pharmacy and provide pharmacy services at an alternate location. The following is applicable for the emergency remote pharmacy.

(1) The emergency remote pharmacy will not be issued a separate pharmacy license, but shall operate under the license of the home pharmacy. To qualify for an emergency remote pharmacy license, the applicant must submit an application including the following information:

(A) license number, name, address, and phone number of the home pharmacy;

(B) name, address, and phone number of the emergency remote pharmacy;

(C) name and Texas pharmacist license number of the pharmacist-in-charge of the home pharmacy and of the pharmacist-in-charge of the emergency remote pharmacy; and

(D) any other information required by the board.

(2) The board will notify the home pharmacy of the approval of an emergency remote pharmacy license.

(3) The emergency remote pharmacy license shall be valid for a period as determined by the board not to exceed six months. The executive director of the board, in his/her discretion, may renew the remote license for an additional six months, if the emergency situation still exists and the holder of the license shows good cause for emergency remote pharmacy to continue operation.

(4) The emergency remote pharmacy shall have a written contract or agreement with the home pharmacy which outlines the services to be provided and the responsibilities and accountabilities of the remote and home pharmacy in fulfilling the terms of the contract or agreement in compliance with federal and state laws and regulations.

(5) The home pharmacy shall designate a pharmacist to serve as the pharmacist-in-charge of the emergency remote pharmacy.

(6) The emergency remote pharmacy shall comply with the rules for the class of pharmacy under which the home pharmacy is licensed. A Class A pharmacy shall comply with the rules under Subchapter B of this chapter titled Community Pharmacy (Class A). A Class C pharmacy shall comply with the rules under Subchapter D of this chapter titled Institutional Pharmacy (Class C). A Class D pharmacy shall comply with the rules under Subchapter E of this chapter titled Clinic Pharmacy (Class D).

(7) The records of services provided at the emergency remote pharmacy shall be:

(A) kept by the home pharmacy and be available, for at least two years from the date of provision of the service, 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 an 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.

§291.129 Satellite Pharmacy

(a) Purpose. The purpose of this section is to create a new class of pharmacy for the provision of pharmacy services by a Class A or Class C pharmacy in a location that is not at the same location as the Class A or Class C pharmacy through a satellite pharmacy and to provide standards for the operation of this class of pharmacy established under §560.053 of the Texas Pharmacy Act.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise. All other words and terms shall have the meanings as defined in the Act or in §291.31 of this title.

(1) Provider pharmacy--The Class A or Class C pharmacy providing satellite pharmacy services.

(2) Satellite pharmacy--A facility not located at the same location as a Class A or Class C pharmacy at which satellite pharmacy services are provided.

(3) Satellite pharmacy services--The provision of pharmacy services, including the storage and delivery of prescription drugs, in an alternate location.

(c) General requirements.

(1) A Class A or Class C provider pharmacy may establish a satellite pharmacy in a location that is not at the same location as the Class A or Class C pharmacy.

(2) The pharmacist-in-charge of the provider pharmacy is responsible for all pharmacy operations involving the satellite pharmacy including supervision of satellite pharmacy personnel and compliance with this section.

(3) A satellite pharmacy may not store bulk drugs and may only store prescription medications that have been previously verified and dispensed by the provider pharmacy.

(4) A Class C pharmacy that is a provider pharmacy dispensing outpatient prescriptions for a satellite pharmacy shall comply with the provisions of §§291.31 - 291.34 of this title (relating to Definitions, Personnel, Operational Standards, and Records for Class A (Community) pharmacies) and this section.

(5) The provider pharmacy and the satellite pharmacy must have:

(A) the same owner; and

(B) share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to process a non-dispensing function.

(d) Personnel.

(1) All individuals working at the satellite pharmacy shall be employees of the provider pharmacy and must report their employment to the board as such.

(2) A satellite pharmacy shall have sufficient pharmacists on duty to operate the satellite pharmacy competently, safely, and adequately to meet the needs of the patients of the pharmacy.

(3) Pharmacists are solely responsible for the direct supervision of pharmacy technicians and pharmacy technician trainees and for designating and delegating duties, other than those listed in paragraph (7) of this subsection, to pharmacy technicians and pharmacy technician trainees. Each pharmacist:

(A) shall verify the accuracy of all acts, tasks, and functions performed by pharmacy technicians and pharmacy technician trainees; and

(B) shall be responsible for any delegated act performed by pharmacy technicians and pharmacy technician trainees under his or her supervision.

(4) A pharmacist shall be physically present to directly supervise a pharmacy technician or pharmacy technician trainee who is entering prescription data into the data processing system. Each prescription entered into the data processing system shall be verified at the time of data entry.

(5) All pharmacists while on duty, shall be responsible for complying with all state and federal laws or rules governing the practice of pharmacy.

(6) A pharmacist shall ensure that the drug is dispensed and delivered safely and accurately as prescribed. A pharmacist shall ensure the safety and accuracy of the portion of the process the pharmacist is performing.

(7) Duties in a satellite pharmacy that may only be performed by a pharmacist are as follows:

(A) receiving oral prescription drug orders for controlled substances and reducing these orders to writing, either manually or electronically;

(B) interpreting or clarifying prescription drug orders;

(C) communicating to the patient or patient's agent information about the prescription drug or device, which in the exercise of the pharmacist's professional judgment the pharmacist deems significant, as specified in §291.33(c) of this title;

(D) communicating to the patient or the patient's agent on his or her request for information concerning any prescription drugs dispensed to the patient by the pharmacy;

(E) assuring that a reasonable effort is made to obtain, record, and maintain patient medication records;

(F) interpreting patient medication records and performing drug regimen reviews; and

(G) performing a specific act of drug therapy management for a patient when delegated to a pharmacist by a written protocol from a physician licensed in this state in compliance with the Medical Practice Act.

(8) Pharmacy technicians and pharmacy technician trainees may not perform any of the duties listed in paragraph (7) of this subsection. However, a pharmacist may delegate to pharmacy technicians and pharmacy technician trainees any nonjudgmental technical duty associated with the preparation and distribution of prescription drugs provided:

(A) a pharmacist verifies the accuracy of all acts, tasks, and functions performed by pharmacy technicians and pharmacy technician trainees; and

(B) pharmacy technicians and pharmacy technician trainees are under the direct supervision of, and responsible to, a pharmacist.

(9) Pharmacy technicians and pharmacy technician trainees in a satellite pharmacy may perform only nonjudgmental technical duties associated with the preparation and distribution of prescription drugs as follows:

(A) initiating and receiving refill authorization requests;

(B) entering prescription data into a data processing system; and

(C) reconstituting medications.

(10) In addition to the duties listed above in paragraph (9) of this subsection, pharmacy technicians may perform the following nonjudgmental technical duties associated with the preparation and distribution of prescription drugs:

(A) receiving oral prescription drug orders for dangerous drugs and reducing these orders to writing, either manually or electronically; and

(B) transferring or receiving a transfer of original prescription information for a dangerous drug on behalf of a patient.

(11) All satellite pharmacy personnel shall wear identification tags or badges that bear the person's name and identifies him or her as a pharmacist, pharmacist intern, pharmacy technician, or pharmacy technician trainee.

(e) Operational requirements.

(1) Application for permission to provide satellite pharmacy services.

(A) A Class A or Class C pharmacy shall make an application to the board to provide satellite pharmacy services. The application shall include the following:

(i) the name, address, and license number of the provider pharmacy;

(ii) the name and address of the facility where the satellite pharmacy will be located;

(iii) the anticipated date of opening and hours of operation; and

(iv) a copy of the lease agreement or if the location of the satellite pharmacy is owned by the applicant, a notarized statement certifying such location ownership.

(B) A renewal application shall be resubmitted every two years in conjunction with the application for renewal of the provider pharmacy's license. The renewal application shall contain the documentation required in subparagraph (A) of this paragraph.

(C) Upon approval of the application, the provider pharmacy will be issued a certificate which must be displayed at the satellite pharmacy.

(2) Notification requirements.

(A) A provider pharmacy shall notify the board in writing within ten days of a change of location, discontinuance of service, or closure of a satellite pharmacy that is operated by the pharmacy.

(B) A provider pharmacy shall comply with appropriate federal and state controlled substance registrations for each satellite pharmacy if controlled substances are maintained at the satellite pharmacy.

(3) Environment.

(A) The satellite pharmacy shall be arranged in an orderly fashion and kept clean. All required equipment shall be clean and in good operating condition.

(B) A satellite pharmacy shall contain an area which is suitable for confidential patient counseling.

(i) Such counseling area shall:

(I) be easily accessible to both the patient and pharmacists and not allow patient access to prescription drugs;

(II) be designed to maintain the confidentiality and privacy of the pharmacist/patient communication.

(ii) In determining whether the area is suitable for confidential patient counseling and designed to maintain the confidentiality and privacy of the pharmacist/patient communication, the board may consider factors such as the following:

(I) the proximity of the counseling area to the check-out or cash register area;

(II) the volume of pedestrian traffic in and around the counseling area;

(III) the presence of walls or other barriers between the counseling area and other areas of the pharmacy; and

(IV) any evidence of confidential information being overheard by persons other than the patient or patient's agent or the pharmacist or agents of the pharmacist.

(C) The satellite pharmacy shall be properly lighted and ventilated.

(D) The temperature of the satellite pharmacy shall be maintained within a range compatible with the proper storage of drugs in compliance with the provisions of §291.15 of this title (relating to storage of drugs). The temperature of the refrigerator shall be maintained within a range compatible with the proper storage of drugs requiring refrigeration.

(E) Animals, including birds and reptiles, shall not be kept within the pharmacy and in immediately adjacent areas under the control of the pharmacy. This provision does not apply to fish in aquariums,

guide dogs accompanying disabled persons, or animals for sale to the general public in a separate area that is inspected by local health jurisdictions.

(4) Security.

(A) A satellite pharmacy shall be under the continuous, physically present supervision of a pharmacist at all times the satellite pharmacy is open to provide pharmacy services.

(B) The satellite pharmacy shall be enclosed by walls, partitions or other means of floor-to-ceiling enclosure. In addition to the security requirements outlined in §291.33(b)(2) of this title, satellite pharmacies shall have adequate security and procedures to:

(i) prohibit unauthorized access;

(ii) comply with federal and state regulations; and

(iii) maintain patient confidentiality.

(C) Access to the satellite pharmacy shall be limited to pharmacists, pharmacy technicians, and pharmacy technician trainees employed by the provider pharmacy and who are designated in writing by the pharmacist-in-charge.

(D) The provider pharmacy shall have procedures that specify that prescriptions may only be delivered to the satellite pharmacy by the provider pharmacy and shall:

(i) be delivered in a sealed container with a list of the prescriptions delivered;

(ii) be signed for on receipt by the pharmacist at the satellite pharmacy;

(iii) be checked by personnel designated by the pharmacist-in-charge to verify that the prescriptions sent by the provider pharmacy were actually received. The designated person who checks the order shall document the verification by signing and dating the list of prescriptions delivered.

(5) Prescription dispensing and delivery. A satellite pharmacy shall comply with the requirements outlined in §291.33(c) of this title with regard to prescription dispensing and delivery.

(6) Equipment and supplies. A satellite pharmacy shall have the following equipment and supplies:

(A) typewriter or comparable equipment;

(B) refrigerator, if storing drugs requiring refrigeration;

(C) metric-apothecary weight and measure conversion charts.

(7) Library. A reference library shall be maintained by the satellite pharmacy that includes the following in hard-copy or electronic format:

(A) current copies of the following:

(i) Texas Pharmacy Act and rules;

(ii) Texas Dangerous Drug Act and rules;

(iii) Texas Controlled Substances Act and rules; and

(iv) Federal Controlled Substances Act and rules (or official publication describing the requirements of the Federal Controlled Substances Act and rules);

(B) at least one current or updated reference from each of the following categories:

(i) patient information:

(I) United States Pharmacopeia Dispensing Information, Volume II (Advice to the Patient); or

(II) a reference text or information leaflets which provide patient information;

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

(iii) a general information reference text, such as:

(I) Facts and Comparisons with current supplements;

(II) United States Pharmacopeia Dispensing Information Volume I (Drug Information for the Healthcare Provider);
(III) Clinical Pharmacology;
(IV) American Hospital Formulary Service with current supplements; or
(V) Remington's Pharmaceutical Sciences; and

(C) basic antidote information and the telephone number of the nearest Regional Poison Control Center.

(f) Records.

(1) Maintenance of records.

(A) Every record required to be kept under §291.34 of this title and under this section shall be:

(i) kept by the provider 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

(ii) supplied by the provider pharmacy within 72 hours, if requested by an authorized agent of the board. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an 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.

(B) 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:

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

(ii) 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.

(C) Prescription drug orders shall be maintained by the provider pharmacy in the manner required by §291.34(d) or (e) of this title.

(2) Prescriptions.

(A) Prescription drug orders shall meet the requirements of §291.34(b) of this title.

(B) The provider pharmacy must maintain appropriate records to identify the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist, pharmacy technician, or pharmacy technician trainee who performed any processing at the satellite pharmacy.

(C) A provider pharmacy shall keep a record of all prescriptions sent and returned between the pharmacies separate from the records of the provider pharmacy and from any other satellite pharmacy's records.

(D) A satellite pharmacy shall keep a record of all prescriptions received and returned between the pharmacies.

§291.131 Pharmacies Compounding Non-Sterile Preparations

(a) Purpose. Pharmacies compounding non-sterile preparations, prepackaging pharmaceutical products and distributing those products shall comply with all requirements for their specific license classification and this section. The purpose of this section is to provide standards for the:

(1) compounding of non-sterile preparations pursuant to a prescription or medication order for a patient from a practitioner in Class A (Community), Class C (Institutional), and Class E (Non-resident) pharmacies;

(2) compounding, dispensing, and delivery of a reasonable quantity of a compounded non-sterile preparation in a Class A (Community), Class C (Institutional), and Class E (Non-resident) pharmacies to a practitioner's office for office use by the practitioner;

(3) compounding and distribution of compounded non-sterile preparations by a Class A (Community) pharmacy for a Class C (Institutional) pharmacy; and

(4) compounding of non-sterile preparations by a Class C (Institutional) pharmacy and the distribution of the compounded preparations to other Class C (Institutional) pharmacies under common ownership.

(b) Definitions. In addition to the definitions for specific license classifications, the following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Active pharmaceutical ingredient--Any substance intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals or affecting the structure and function of the body.

(2) Beyond-use date--The date or time after which the compounded non-sterile preparation shall not be stored or transported or begin to be administered to a patient. The beyond-use date is determined from the date or time when the preparation was compounded.

(3) Cleaning--The process of removing soil (e.g., organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products.

(4) Component--Any ingredient intended for use in the compounding of a drug preparation, including those that may not appear in such preparation.

(5) Compounding--The preparation, mixing, assembling, packaging, or labeling of a drug or device:

(A) as the result of a practitioner's prescription drug or medication order, based on the practitioner-patient-pharmacist relationship in the course of professional practice;

(B) for administration to a patient by a practitioner as the result of a practitioner's initiative based on the practitioner-patient-pharmacist relationship in the course of professional practice;

(C) in anticipation of prescription drug or medication orders based on routine, regularly observed prescribing patterns; or

(D) for or as an incident to research, teaching, or chemical analysis and not for sale or dispensing, except as allowed under §562.154 or Chapter 563 of the Occupations Code.

(6) Containment primary engineering control--A ventilated device designed and operated to minimize worker and environmental exposures to airborne contaminants through the full or partial enclosure of a potential contaminant source, the use of airflow capture velocities to trap and remove airborne contaminants near their point of generation, the use of air pressure relationships that define the direction of airflow into the cabinet, and the use of high-efficiency particulate air (HEPA) filtration on all potentially contaminated exhaust streams. Examples of containment primary engineering control include containment ventilated enclosures, biological safety cabinets, and compounding aseptic containment isolators.

(7) Controlled room temperature--The temperature maintained thermostatically that encompasses the usual and customary working environment of 20 - 25 degrees C (68 - 77 degrees F).

(8) Designated person(s)--One or more individuals assigned by the pharmacist-in-charge or the pharmacist-in-charge's designee to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of compounded non-sterile preparations.

(9) Hot water--The temperature of water from the pharmacy's sink maintained at a minimum of 41 degrees C (105 degrees F).

(10) Reasonable quantity--An amount of a compounded drug that:

(A) does not exceed the amount a practitioner anticipates may be used in the practitioner's office or facility before the beyond use date of the drug;

(B) is reasonable considering the intended use of the compounded drug and the nature of the practitioner's practice; and

(C) for any practitioner and all practitioners as a whole, is not greater than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality,

and purity of the compounded drug that are consistent with United States Pharmacopoeia guidelines and accreditation practices.

(11) Refrigerator--A cold place in which the temperature is controlled between 2 - 8 degrees C (36 - 46 degrees F).

(12)Sanitizing--A process for reducing on inanimate surfaces the number of all forms of microbial life including fungi, viruses, and bacteria using an appropriate agent.

(13) SOPs--Standard operating procedures.

(14) USP/NF--The current edition of the United States Pharmacopeia/National Formulary.

(15) Water activity--A measure of the fraction of total water that is unbound and freely available to participate in chemical, biochemical, or physiochemical reactions or provide an environment that can support microbial growth.

(c) Personnel. All personnel who compound or have direct oversight of compounding non-sterile preparations shall be initially trained and qualified by demonstrating knowledge and competency in the areas outlined in paragraph (5)(C) of this subsection.

(1) Pharmacist-in-charge. In addition to the responsibilities for the specific class of pharmacy, the pharmacist-in-charge shall have the responsibility for, at a minimum, the following concerning non-sterile compounding:

(A) determining that all personnel involved in non-sterile compounding possess the education, training, and proficiency necessary to properly and safely perform compounding duties undertaken or supervised;

(B) determining that all personnel involved in non-sterile compounding obtain continuing education appropriate for the type of compounding done by the personnel;

(C) assuring that the equipment used in compounding is properly maintained;

(D) maintaining an appropriate environment in areas where non-sterile compounding occurs; and

(E) assuring that effective quality control procedures are developed and followed.

(2) Designated person(s). The pharmacist-in-charge or the pharmacist-in-charge's designee shall designate one or more individuals to be responsible and accountable for the performance and operation of the facility and personnel for the preparation of compounded non-sterile preparations. The designated person(s) shall be identified in the facility's SOPs. If the compounding facility has only one person responsible for all compounding in the facility, then that person is the designated person.

(3) Pharmacists. Special requirements for non-sterile compounding.

(A) All pharmacists engaged in compounding shall:

(i) possess the education, training, and proficiency necessary to properly and safely perform compounding duties undertaken or supervised; and

(ii) obtain continuing education appropriate for the type of compounding undertaken or supervised by the pharmacist.

(B) A pharmacist shall inspect and approve all components, including consideration of all physical and chemical properties of the components, drug product containers, closures, labeling, and any other materials involved in the compounding process.

(C) A pharmacist shall review all compounding records for accuracy and conduct in-process and final checks to ensure that errors have not occurred in the compounding process.

(D) A pharmacist is responsible for the proper maintenance, cleanliness, and use of all equipment used in the compounding process.

(4) Pharmacy technicians and pharmacy technician trainees. All pharmacy technicians and pharmacy technician trainees engaged in non-sterile compounding shall:

(A) possess the education, training, and proficiency necessary to properly and safely perform compounding duties undertaken;

(B) obtain continuing education appropriate for the type of compounding done by the pharmacy technician or pharmacy technician trainee; and

(C) perform compounding duties under the direct supervision of and responsible to a pharmacist.

(5) Training.

(A) All training activities shall be documented and covered by appropriate SOPs as outlined in subsection (d)(8)(A) of this section.

(B) All personnel involved in non-sterile compounding shall be well trained and must participate in continuing relevant training programs.

(C) Training shall include instruction, experience, and demonstrated proficiency in the following areas:

(i) hand hygiene;

(ii) garbing;

(iii) cleaning and sanitizing;

(iv) handling and transporting components and compounded non-sterile preparations;

(v) measuring and mixing;

(vi) proper use of equipment and devices selected to compound non-sterile preparations; and

(vii) documentation of the compounding process (e.g., Master Formulation Records and Compounding Records).

(d) Operational Standards.

(1) General requirements.

(A) Non-sterile drug preparations may be compounded in licensed pharmacies:

(i) upon presentation of a practitioner's prescription drug or medication order based on a valid pharmacist/patient/prescriber relationship;

(ii) in anticipation of future prescription drug or medication orders based on routine, regularly observed prescribing patterns; or

(iii) in reasonable quantities for office use by a practitioner and for use by a veterinarian.

(B) Non-sterile compounding in anticipation of future prescription drug or medication orders must be based upon a history of receiving valid prescriptions issued within an established pharmacist/patient/prescriber relationship, provided that in the pharmacist's professional judgment the quantity prepared is stable for the anticipated shelf time.

(i) The pharmacist's professional judgment shall be based on the criteria used to determine a beyond-use date outlined in paragraph (5)(C) of this subsection.

(ii) Documentation of the criteria used to determine the stability for the anticipated shelf time must be maintained and be available for inspection.

(iii) Any preparation compounded in anticipation of future prescription drug or medication orders shall be labeled. Such label shall contain:

(I) name and strength of the compounded preparation or list of the active ingredients and strengths;

(II) facility's lot number;

(III) beyond-use date as determined by the pharmacist using appropriate documented criteria as outlined in paragraph (5)(C) of this subsection; and

(IV) quantity or amount in the container.

(C) Commercially available products may be compounded for dispensing to individual patients provided the following conditions are met:

(i) the commercial product is not reasonably available from normal distribution channels in a timely manner to meet patient's needs;

(ii) the pharmacy maintains documentation that the product is not reasonably available due to a drug shortage or unavailability from the manufacturer; and

(iii) the prescribing practitioner has requested that the drug be compounded as described in subparagraph (D) of this paragraph.

(D) A pharmacy may not compound preparations that are essentially copies of commercially available products (e.g., the preparation is dispensed in a strength that is only slightly different from a commercially available product) unless the prescribing practitioner specifically orders the strength or dosage form and specifies why the patient needs the particular strength or dosage form of the preparation. The prescribing practitioner shall provide documentation of a patient specific medical need and the preparation produces a clinically significant therapeutic response (e.g. the physician requests an alternate product due to hypersensitivity to excipients or preservative in the FDA-approved product, or the physician requests an effective alternate dosage form) or if the drug product is not commercially available. The unavailability of such drug product must be documented prior to compounding. The methodology for documenting unavailability includes maintaining a copy of the wholesaler's notification showing back-ordered, discontinued, or out-of-stock items. This documentation must be available in hard-copy or electronic format for inspection by the board.

(E) A pharmacy may enter into an agreement to compound and dispense prescription/medication orders for another pharmacy provided the pharmacy complies with the provisions of §291.125 of this title (relating to Centralized Prescription Dispensing).

(F) Compounding pharmacies/pharmacists may advertise and promote the fact that they provide non-sterile prescription compounding services, which may include specific drug products and classes of drugs.

(G) A pharmacy may not compound veterinary preparations for use in food producing animals except in accordance with federal guidelines.

(H) A pharmacist may add flavoring to a prescription at the request of a patient, the patient's agent, or the prescriber. The pharmacist shall label the flavored prescription with a beyond-use-date that shall be no longer than fourteen days if stored in a refrigerator unless otherwise documented. Documentation of beyond-use-dates longer than fourteen days shall be maintained by the pharmacy electronically or manually and made available to agents of the board on request. A pharmacist may not add flavoring to an over-the-counter product at the request of a patient or patient's agent unless the pharmacist obtains a prescription for the over-the-counter product from the patient's practitioner.

(2) Library. In addition to the library requirements of the pharmacy's specific license classification, a pharmacy shall maintain a current copy, in hard-copy or electronic format, of Chapter 795 of the USP/NF concerning Pharmacy Compounding Non-Sterile Preparations.

(3) Environment.

(A) Pharmacies engaging in compounding shall have a designated and adequate area for the safe and orderly compounding of non-sterile preparations, including the placement of equipment and materials.

(B) Only personnel authorized by the responsible pharmacist shall be in the immediate vicinity of a drug compounding operation.

(C) A sink with hot and cold running water, exclusive of rest room facilities, shall be accessible to the compounding areas and be maintained in a sanitary condition. Supplies necessary for adequate washing shall be accessible in the immediate area of the sink and include:

(i) soap or detergent; and

(ii) air-driers or single-use towels.

(D) Appropriate measures shall be used to prevent cross-contamination between compounding non-sterile preparations, including dedication of equipment for such operations or the meticulous cleaning of contaminated equipment prior to its use for the preparation of subsequent compounds.

(E) Cleaning and sanitizing of surfaces in the non-sterile compounding area(s) shall occur on a regular basis as defined in appropriate SOPs as outlined in paragraph (8)(A) of this subsection.

(4) Equipment and Supplies.

(A)If the pharmacy engages in compounding non-sterile preparations that require weighing a component of the preparation, the pharmacy shall have a Class A prescription balance, or analytical

balance and weights which shall be calibrated and have the accuracy of the balance verified by the pharmacy at least every 12 months as specified in the pharmacy's SOPs. The pharmacy shall document the calibration and verification.

(B) The pharmacy shall have equipment and utensils necessary for the proper compounding of prescription drug or medication orders. Such equipment and utensils used in the compounding process shall be:

(i) of appropriate design and capacity, and be operated within designed operational limits;

(ii) of suitable composition so that surfaces that contact components, in-process material, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the desired result;

(iii) cleaned and sanitized immediately prior and after to each use; and

(iv) routinely inspected, calibrated (if necessary), or checked to ensure proper performance.

(C) Weighing, measuring, or otherwise manipulating components that could generate airborne chemical particles (e.g., active pharmaceutical ingredients, added substances, and conventionally manufactured products) shall be evaluated to determine if these activities must be performed in a containment primary engineering control to reduce the potential exposure to personnel or contamination of the facility or compounded non-sterile preparations. The process evaluation shall be carried out in accordance with the facility's SOPs, and the assessment shall be documented.

(D) If a containment ventilated enclosure or biological safety cabinet is used, it shall be certified at least every 12 months or according to manufacturer specifications.

(5) Labeling. In addition to the labeling requirements of the pharmacy's specific license classification, the label dispensed or distributed pursuant to a prescription drug or medication order shall contain the following.

(A) The generic name(s) or the official name(s) of the principal active ingredient(s) of the compounded preparation.

(B) A statement that the preparation has been compounded by the pharmacy. (An auxiliary label may be used on the container to meet this requirement).

(C) A beyond-use date after which the compounded preparation should not be used. The beyond-use date shall be determined as outlined in Chapter 795 of the USP/NF concerning Pharmacy Compounding Non-Sterile Preparations including the following:

(i) The pharmacist shall consider:

(I) physical and chemical properties of active ingredients;

(II) use of preservatives and/or stabilizing agents;

(III) dosage form;

(IV) storage containers and conditions; and

(V) scientific, laboratory, or reference data from a peer reviewed source and retained in the pharmacy. The reference data should follow the same preparation instructions for combining components and packaged in a container with similar properties.

(ii) In the absence of stability information applicable for a specific drug or preparation, the following maximum beyond-use dates are to be used when the compounded preparation is packaged in tight, light-resistant containers.

(I) Aqueous dosage forms. An aqueous preparation is one that has a water activity equal to or greater than 0.6 (e.g., emulsions, gels, creams, solutions, sprays, or suspensions).

(-a-) Nonpreserved aqueous dosage forms: Not later than 14 days when stored in a refrigerator.

(-b-) Preserved aqueous dosage forms: Not later than 35 days when stored at controlled room temperature or in a refrigerator.

(II) Nonaqueous dosage forms. A nonaqueous dosage form is one that has a water activity less than 0.6.

(-a-) Nonaqueous oral liquids: Not later than 90 days when stored at controlled room temperature or in a refrigerator.

(-b-) Other nonaqueous dosage forms: Not later than 180 days when stored at controlled room temperature or refrigerator. Other nonaqueous dosage forms that have a water activity of less than 0.6 (e.g., capsules, tablets, granules, powders, nonaqueous topicals, suppositories, and troches or lozenges).

(iii) Compounded non-sterile preparations requiring shorter beyond-use dates. The beyond-use dates in subclauses (I) and (II) of clause (ii) are the beyond-use dates for compounded nonsterile preparations in the absence of specific stability information. However, the designated person(s) shall still perform due diligence to determine if there is existing stability data that would require a shorter beyond-use date.

(I) The beyond-use date of the compounded non-sterile preparation shall not exceed the shortest remaining expiration date of any of the commercially available starting components.

(II) For compounded non-sterile preparations prepared from one or more compounded components, the beyond-use date generally shall not exceed the shortest beyond-use date of any of the individual compounded components. However, there may be acceptable instances when the beyond-use date of the final compounded non-sterile preparation exceeds the beyond-use date assigned to compounded components (e.g., pH-altering solutions). If the assigned beyond-use date of the final compounded non-sterile preparation exceeds the beyond-use date of the compounded components, the physical, chemical, and microbiological quality of the final compounded non-sterile preparation shall not be negatively impacted.

(iv) Extending beyond-use dates for compounded non-sterile preparations. Beyond-use date limits may be exceeded when supported by valid scientific stability information for the specific compounded preparation.

(I) Compounded non-sterile preparations with a USP/NF monograph. When compounding from a USP/NF compounded preparation monograph for the compounded non-sterile preparation, the beyond-use date shall not exceed the beyond-use date specified in the monograph.

(II) Compounded non-sterile preparations with stability information. If there is a stability study using a stability-indicating analytical method for the active pharmaceutical ingredient(s), compounded non-sterile preparation formulation, and material of composition of the container closure that will be used, then the beyond-use date indicated by the study may be used in lieu of the beyond-use date specified in subclauses (I) and (II) of clause (ii) for aqueous and nonaqueous dosage forms, up to a maximum of 180 days.

(III) If the beyond-use date of the compounded non-sterile preparation is extended beyond the beyond-use date specified in subclauses (I) and (II) of clause (ii), an aqueous compounded non-sterile preparation must pass antimicrobial effectiveness testing.

(-a-) The designated person(s) may rely on antimicrobial effectiveness testing that is conducted, or contracted for, once for each formulation in the particular container closure system, including materials of composition or the container closure system, in which it will be packaged.

(-b-) Alternatively, the designated person(s) may rely on antimicrobial effectiveness testing results provided by an FDA-registered facility or published in peer-reviewed literature as long as the compounded non-sterile preparation formulation, including any preservative, and container closure materials of

composition are the same as those tested, unless a bracketing study is performed.

(-c-) When a bracketing study is performed, antimicrobial effectiveness testing may be performed on a low concentration and on a high concentration of the active ingredient in the formulation to establish preservative effectiveness across various strengths of the same formulation (e.g. bracketing). The concentration of all other ingredients, including preservatives, must fall within the bracketed range.

(6) Written drug information. Written information about the compounded preparation or its major active ingredient(s) shall be given to the patient at the time of dispensing. A statement which indicates that the preparation was compounded by the pharmacy must be included in this written information. If there is no written information available, the patient should be advised that the drug has been compounded and how to contact a pharmacist, and if appropriate the prescriber, concerning the drug.

(7) Drugs, components, and materials used in non-sterile compounding.

(A) Drugs used in non-sterile compounding shall be a USP/NF grade substances manufactured in an FDA-registered facility.

(B) If USP/NF grade substances are not available, or when food, cosmetics, or other substances are, or must be used, the substance shall be of a chemical grade in one of the following categories:

(i) Chemically Pure (CP);

(ii) Analytical Reagent (AR); or

(iii) American Chemical Society (ACS); or

(iv) Food Chemical Codex; or

(C) If a drug, component or material is not purchased from a FDA-registered facility, the pharmacist shall establish purity and stability by obtaining a Certificate of Analysis from the supplier and the pharmacist shall compare the monograph of drugs in a similar class to the Certificate of Analysis.

(D) A manufactured drug product may be a source of active ingredient. Only manufactured drugs from containers labeled with a batch control number and a future expiration date are acceptable as a potential source of active ingredients. When compounding with manufactured drug products, the pharmacist must consider all ingredients present in the drug product relative to the intended use of the compounded preparation.

(E) All components shall be stored in properly labeled containers in a clean, dry area, under proper temperatures.

(F) Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the compounded drug product beyond the desired result.

(G) Components, drug product containers, and closures shall be rotated so that the oldest stock is used first.

(H) Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded drug product.

(I) A pharmacy may not compound a preparation that contains ingredients appearing on a federal Food and Drug Administration list of drug products withdrawn or removed from the market for safety reasons.

(8) Compounding process.

(A) All significant procedures performed in the compounding area shall be covered by written SOPs designed to ensure accountability, accuracy, quality, safety, and uniformity in the compounding process. At a minimum, SOPs shall be developed for:

(i) the facility;

(ii) equipment;

(iii) personnel;

(iv) preparation evaluation;
(v) quality assurance;
(vi) preparation recall;
(vii) packaging;
(viii) storage of compounded preparations;
(ix) hand hygiene and garbing; and
(x) cleaning and sanitizing.

(B) Any compounded preparation with an official monograph in the USP/NF shall be compounded, labeled, and packaged in conformity with the USP/NF monograph for the drug.

(C) Any person with a communicable illness or open lesion that may adversely affect the safety or quality of a drug product being compounded shall report these conditions to the designated person(s). The designated person(s) shall determine whether the person must be excluded from compounding areas until the person's conditions have resolved.

(D) Personnel engaged in the compounding of drug preparations shall perform proper hand hygiene prior to engaging in compounding activities. Proper hand hygiene shall be defined in appropriate SOPs as outlined in subparagraph (A) of this paragraph and appropriate for prevention of preparation and facility contamination.

(E) Garbing requirements and the frequency of changing garb shall be determined by the pharmacy and documented in appropriate SOPs as outlined in subparagraph (A) of this paragraph. The garbing requirements under the pharmacy's SOPs must be appropriate for the type of compounding performed. Gloves shall be worn for the prevention of preparation and facility contamination.

(F) At each step of the compounding process, the pharmacist shall ensure that components used in compounding are accurately weighed, measured, or subdivided as appropriate to conform to the formula being prepared.

(9) Quality Assurance.

(A) Initial formula validation. Prior to routine compounding of a non-sterile preparation, a pharmacy shall conduct an evaluation that shows that the pharmacy is capable of compounding a product that contains the stated amount of active ingredient(s).

(B) Finished preparation checks. The prescription drug and medication orders, written compounding procedure, preparation records, and expended materials used to make compounded non-sterile preparations shall be inspected for accuracy of correct identities and amounts of ingredients, packaging, labeling, and expected physical appearance and properties before the non-sterile preparations are dispensed.

(10) Quality Control.

(A) The pharmacy shall follow established quality control procedures to monitor the quality of compounded drug preparations for uniformity and consistency such as capsule weight variations, adequacy of mixing, clarity, or pH of solutions. When developing these procedures, pharmacy personnel shall consider the provisions of Chapter 795, concerning Pharmacy Compounding Non-Sterile Preparations, Chapter 1075, concerning Good Compounding Practices, and Chapter 1160, concerning Pharmaceutical Calculations in Prescription Compounding contained in the current USP/NF. Such procedures shall be documented and be available for inspection.

(B) Compounding procedures that are routinely performed, including batch compounding, shall be completed and verified according to written procedures. The act of verification of a compounding procedure involves checking to ensure that calculations, weighing and measuring, order of mixing, and compounding techniques were appropriate and accurately performed.

(C) Unless otherwise indicated or appropriate, compounded preparations are to be prepared to ensure that each preparation shall contain not less than 90.0 percent and not more than 110.0 percent of the theoretically calculated and labeled quantity of active ingredient per unit weight or volume and not less

than 90.0 percent and not more than 110.0 percent of the theoretically calculated weight or volume per unit of the preparation.

(e) Records.

(1) Maintenance of records. Every record required by this section shall be:

(A) kept by the pharmacy and be available, for at least two years 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 an electronic format. 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.

(C) Documentation of the performance of quality control procedures is not required if the compounding process is done pursuant to a patient specific order and involves the mixing of two or more commercially available oral liquids or commercially available preparations when the final product is intended for external use.

(2) Master Formulation Record and Compounding Record.

(A) Master Formulation Record. A master formulation record shall be developed and approved by a pharmacist for all compounded preparations. Once approved, a duplicate of the master formulation record shall be used as the compound record each time the compound is prepared and on which all documentation for that compound occurs. The master formulation record shall contain at a minimum:

(i) the formula;

(ii) the components;

(iii) the compounding directions;

(iv) evaluation and testing requirements;

(v) specific equipment used during preparation;

(vi) storage requirements;

(vii) a reference to the location of the following documentation which may be maintained 561 with other records, such as quality control records:

(I) the criteria used to determine the beyond-use date; and

(II) documentation of performance of quality control procedures, including, but not limited to, expected physical appearance of the final product.

(B) Compounding Record. The record for each preparation shall document the following:

(i) identity of all components and their corresponding amounts, concentrations, or volumes;

(ii) lot number and expiration date of each component;

(iii) component manufacturer/distributor or suitable identifying number;

(iv) container specifications;

(v) unique lot or control number;

(vi) beyond use date;

(vii) date of preparation;

(viii) name, initials, or electronic signature of the person(s) involved in the preparation;

(ix) name, initials, or electronic signature of the responsible pharmacist;

(x) finished preparation evaluation and testing specifications, if applicable; and

(xi) comparison of actual yield to anticipated or theoretical yield, when appropriate.

(f) Office Use Compounding and Distribution of Compounded Preparations to Class C Pharmacies or Veterinarians in Accordance With §563.054 of the Act.

(1) General.

(A) A pharmacy may dispense and deliver a reasonable quantity of a compounded preparation to a practitioner for office use by the practitioner in accordance with this subsection.

(B) A Class A pharmacy is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute non-sterile compounded preparations to a Class C pharmacy.

(C) A Class C pharmacy is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute non-sterile compounded preparations that the Class C pharmacy has compounded for other Class C pharmacies under common ownership.

(D) To dispense and deliver a compounded preparation under this subsection, a pharmacy must:

(i) verify the source of the raw materials to be used in a compounded drug;

(ii) comply with applicable United States Pharmacopoeia guidelines, including the testing requirements, and the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191);

(iii) enter into a written agreement with a practitioner for the practitioner's office use of a compounded preparation;

(iv) comply with all applicable competency and accrediting standards as determined by the board; and

(v) comply with the provisions of this subsection.

(2) Written Agreement. A pharmacy that provides non-sterile compounded preparations to practitioners for office use or to another pharmacy shall enter into a written agreement with the practitioner or pharmacy. The written agreement shall:

(A) address acceptable standards of practice for a compounding pharmacy and a practitioner and receiving pharmacy that enter into the agreement including a statement that the compounded preparations may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity except as authorized by §563.054 of the Act;

(B) state that the practitioner or receiving pharmacy should include on a separate log or in a patient's chart, medication order, or medication administration record, the lot number and beyond-use date of a compounded preparation administered to a patient; and

(C) describe the scope of services to be performed by the pharmacy and practitioner or receiving pharmacy, including a statement of the process for:

(i) a patient to report an adverse reaction or submit a complaint; and

(ii) the pharmacy to recall batches of compounded preparations.

(3) Recordkeeping.

(A) Maintenance of Records.

(i) Records of orders and distribution of non-sterile compounded preparations to a practitioner for office use or to a Class C pharmacy for administration to a patient shall:

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

(II) maintained separately from the records of products dispensed pursuant to a prescription or medication order; and

(III) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy or its representative. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format. Failure to provide the records set out in this subsection, either on site or within 72 hours for whatever reason, constitutes prima facie evidence of failure to keep and maintain records.

(ii) Records may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided the data processing system is capable of producing a hard copy of the record upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.

(B) Orders. The pharmacy shall maintain a record of all non-sterile compounded preparations ordered by a practitioner for office use or by a Class C pharmacy for administration to a patient. The record shall include the following information:

(i) date of the order;

(ii) name, address, and phone number of the practitioner who ordered the preparation and if applicable, the name, address and phone number of the Class C pharmacy ordering the preparation; and

(iii) name, strength, and quantity of the preparation ordered.

(C) Distributions. The pharmacy shall maintain a record of all non-sterile compounded preparations distributed pursuant to an order to a practitioner for office use or by a Class C pharmacy for administration to a patient. The record shall include the following information:

(i) date the preparation was compounded;

(ii) date the preparation was distributed;

(iii) name, strength and quantity in each container of the preparation;

(iv) pharmacy's lot number;

(v) quantity of containers shipped; and

(vi) name, address, and phone number of the practitioner or Class C pharmacy to whom the preparation is distributed.

(D) Audit Trail.

(i) The pharmacy shall store the order and distribution records of preparations for all non-sterile compounded preparations ordered by and or distributed to a practitioner for office use or by a Class C pharmacy for administration to a patient in such a manner as to be able to provide a audit trail for all orders and distributions of any of the following during a specified time period.

(I) any strength and dosage form of a preparation (by either brand or generic name or both);

(II) any ingredient;

(III) any lot number;

(IV) any practitioner;

(V) any facility; and

(VI) any pharmacy, if applicable.

(ii) The audit trail shall contain the following information:

(I) date of order and date of the distribution;

(II) practitioner's name, address, and name of the Class C pharmacy, if applicable;

(III) name, strength and quantity of the preparation in each container of the preparation;

(IV) name and quantity of each active ingredient;

(V) quantity of containers distributed; and

(VI) pharmacy's lot number;

(4) Labeling. The pharmacy shall affix a label to the preparation containing the following information:

(A) name, address, and phone number of the compounding pharmacy;

(B) the statement: "For Institutional or Office Use Only--Not for Resale"; or if the preparation is distributed to a veterinarian the statement: "Compounded Preparation";

(C) name and strength of the preparation or list of the active ingredients and strengths;

(D) pharmacy's lot number;

(E) beyond-use date as determined by the pharmacist using appropriate documented criteria;

(F) quantity or amount in the container;

(G) appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and

(H) device-specific instructions, where appropriate.

(g) Recall Procedures.

(1) The pharmacy shall have written procedures for the recall of any compounded non-sterile preparations provided to a patient, to a practitioner for office use, or a pharmacy for administration. Written procedures shall include, but not be limited to the requirements as specified in paragraph (3) of this subsection.

(2) The pharmacy shall immediately initiate a recall of any non-sterile preparation compounded by the pharmacy upon identification of a potential or confirmed harm to a patient.

(3) In the event of a recall, the pharmacist-in-charge shall ensure that:

(A) each practitioner, facility, and/or pharmacy to which the preparation was distributed is notified, in writing, of the recall;

(B) each patient to whom the preparation was dispensed is notified, in writing, of the recall;

(C) if the preparation is prepared as a batch, the board is notified of the recall, in writing;

(D) if the preparation is distributed for office use, the Texas Department of State Health Services, Drugs and Medical Devices Group, is notified of the recall, in writing;

(E) the preparation is quarantined; and

(F) the pharmacy keeps a written record of the recall including all actions taken to notify all parties and steps taken to ensure corrective measures.

(4) If a pharmacy fails to initiate a recall, the board may require a pharmacy to initiate a recall if there is potential for or confirmed harm to a patient.

§291.133 Pharmacies Compounding Sterile Preparations

(a) Purpose. Pharmacies compounding sterile preparations, prepackaging pharmaceutical products, and distributing those products shall comply with all requirements for their specific license classification and this section. The purpose of this section is to provide standards for the:

(1) compounding of sterile preparations pursuant to a prescription or medication order for a patient from a practitioner in Class A-S, Class B, Class C-S, and Class E-S pharmacies;

(2) compounding, dispensing, and delivery of a reasonable quantity of a compounded sterile preparation in Class A-S, Class B, Class C-S, and Class E-S pharmacies to a practitioner's office for office use by the practitioner;

(3) compounding and distribution of compounded sterile preparations by a Class A-S pharmacy for a Class C-S pharmacy; and

(4) compounding of sterile preparations by a Class C-S pharmacy and the distribution of the compounded preparations to other Class C or Class C-S pharmacies under common ownership.

(b) Definitions. In addition to the definitions for specific license classifications, the following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) ACPE--Accreditation Council for Pharmacy Education.

(2) Airborne particulate cleanliness class--The level of cleanliness specified by the maximum allowable number of particles per cubic meter of air as specified in the International Organization of Standardization (ISO) Classification Air Cleanliness (ISO 14644-1). For example:

(A) ISO Class 5 (formerly Class 100) is an atmospheric environment that contains less than 3,520 particles 0.5 microns and larger in diameter per cubic meter of air (formerly stated as 100 particles 0.5 microns in diameter per cubic foot of air);

(B) ISO Class 7 (formerly Class 10,000) is an atmospheric environment that contains less than 352,000 particles 0.5 microns and larger in diameter per cubic meter of air (formerly stated as 10,000 particles 0.5 microns in diameter per cubic foot of air); and

(C) ISO Class 8 (formerly Class 100,000) is an atmospheric environment that contains less than 3,520,000 particles 0.5 microns and larger in diameter per cubic meter of air (formerly stated as 100,000 particles 0.5 microns in diameter per cubic foot of air).

(3) Ancillary supplies--Supplies necessary for the preparation and administration of compounded sterile preparations.
(4) Anteroom--An ISO Class 8 or cleaner room with fixed walls and doors where personnel hand hygiene, garbing procedures, and other activities that generate high particulate levels may be performed. The anteroom is the transition room between the unclassified area of the pharmacy and the buffer room.
(5) Aseptic processing--A mode of processing pharmaceutical and medical preparations that involves the separate sterilization of the preparation and of the package (containers-closures or packaging material for medical devices) and the transfer of the preparation into the container and its closure under at least ISO Class 5 conditions.
(6) Automated compounding device--An automated device that compounds, measures, and/or packages a specified quantity of individual components in a predetermined sequence for a designated sterile preparation.
(7) Batch--A specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced during a single preparation cycle.
(8) Batch preparation compounding--Compounding of multiple sterile preparation units, in a single discrete process, by the same individual(s), carried out during one limited time period. Batch preparation/compounding does not include the preparation of multiple sterile preparation units pursuant to patient specific medication orders.
(9) Beyond-use date-- The date, or hour and the date, after which a compounded sterile preparation shall not be used, stored, or transported. The date is determined from the date and time the preparation is compounded.
(10) Biological safety cabinet, Class II--A ventilated cabinet for personnel, product or preparation, and environmental protection having an open front with inward airflow for personnel protection, downward HEPA filtered laminar airflow for product protection, and HEPA filtered exhausted air for environmental protection.
(11) Buffer room--An ISO Class 7 or cleaner or, if a Class B pharmacy, an ISO Class 8 or cleaner, room with fixed walls and doors where primary engineering controls that generate and maintain an ISO Class 5 environment are physically located. The buffer room may only be accessed through the anteroom or another buffer room.
(12) Clean room--A room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear are not exceeded for a specified cleanliness class.
(13) Cleaning agent--An agent, usually containing a surfactant, used for the removal of substances (e.g., dirt, debris, microbes, residual drugs or chemicals) from surfaces.
(14) Cleanroom suite--A classified area that consists of both an anteroom and buffer room.
(15) Component--Any ingredient used in the compounding of a preparation, including any active ingredient, added substance, or conventionally manufactured product.
(16) Compounding--The preparation, mixing, assembling, packaging, or labeling of a drug or device:
(A) as the result of a practitioner's prescription drug or medication order based on the practitioner-patient-pharmacist relationship in the course of professional practice;
(B) for administration to a patient by a practitioner as the result of a practitioner's initiative based on the practitioner-patient-pharmacist relationship in the course of professional practice;
(C) in anticipation of prescription drug or medication orders based on routine, regularly observed prescribing patterns; or
(D) for or as an incident to research, teaching, or chemical analysis and not for sale or dispensing, except as allowed under §562.154 or Chapter 563 of the Occupations Code.
(17) Compounding aseptic isolator--A form of barrier isolator specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment shall not occur unless it has first passed through a microbial retentive filter (HEPA minimum).

(18) Compounding aseptic containment isolator--A compounding aseptic isolator designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where volatile hazardous drugs are prepared, the exhaust air from the isolator should be appropriately removed by properly designed building ventilation.
(19) Compounding personnel--A pharmacist, pharmacy technician, or pharmacy technician trainee who performs the actual compounding; a pharmacist who supervises pharmacy technicians or pharmacy technician trainees compounding sterile preparations, and a pharmacist who performs an intermediate or final verification of a compounded sterile preparation.
(20) Critical area--An ISO Class 5 environment.
(21) Critical sites--A location that includes any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampules, needle hubs) exposed and at risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination. Risk of microbial and particulate contamination of the critical site increases with the size of the openings and exposure time.
(22) Device--An instrument, apparatus, implement, machine, contrivance, implant, in-vitro reagent, or other similar or related article, including any component part or accessory, that is required under federal or state law to be ordered or prescribed by a practitioner.
(23) Direct compounding area--A critical area within the ISO Class 5 primary engineering control where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.
(24) Disinfectant--An agent that frees from infection, usually a chemical agent but sometimes a physical one, and that destroys disease-causing pathogens or other harmful microorganisms but may not kill bacterial and fungal spores. It refers to substances applied to inanimate objects.
(25) First air--The air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.
(26) Hazardous drugs--Drugs that, studies in animals or humans indicate exposure to the drugs, have a potential for causing cancer, development or reproductive toxicity, or harm to organs. For the purposes of this chapter, radiopharmaceuticals are not considered hazardous drugs.
(27) Hot water--The temperature of water from the pharmacy's sink maintained at a minimum of 105 degrees F (41 degrees C).
(28) HVAC--Heating, ventilation, and air conditioning.
(29) Immediate use--A sterile preparation that is not prepared according to USP 797 standards (i.e., outside the pharmacy and most likely not by pharmacy personnel) which shall be stored for no longer than four hours following the start of preparing the preparation.
(30) IPA--Isopropyl alcohol (2-propanol).
(31) Labeling--All labels and other written, printed, or graphic matter on an immediate container of an article or preparation or on, or in, any package or wrapper in which it is enclosed, except any outer shipping container. The term "label" designates that part of the labeling on the immediate container.
(32) Master formulation record--A detailed record of procedures that describes how the compounded sterile preparation is to be prepared.
(33) Media-fill test--A test used to qualify aseptic technique of compounding personnel or processes and to ensure that the processes used are able to produce sterile preparation without microbial contamination. During this test, a microbiological growth medium such as Soybean-Casein Digest Medium is substituted for the actual drug preparation to simulate admixture compounding. The issues to consider in the development of a media-fill test are the following: media-fill procedures, media selection, fill volume, incubation, time and temperature, inspection of filled units, documentation, interpretation of results, and possible corrective actions required.

(34) Multiple-dose container--A multiple-unit container for articles or preparations intended for parenteral administration only and usually contains antimicrobial preservatives. The beyond-use date for an opened or entered (e.g., needle-punctured) multiple-dose container with antimicrobial preservatives is 28 days, unless otherwise specified by the manufacturer.
(35) Negative pressure room--A room that is at a lower pressure compared to adjacent spaces and, therefore, the net flow of air is into the room.
(36) Office use--The administration of a compounded drug to a patient by a practitioner in the practitioner's office or by the practitioner in a health care facility or treatment setting, including a hospital, ambulatory surgical center, or pharmacy in accordance with Chapter 562 of the Act, or for administration or provision by a veterinarian in accordance with §563.054 of the Act.
(37) Pharmacy bulk package--A container of a sterile preparation for potential use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes. The closure shall be penetrated only one time after constitution with a suitable sterile transfer device or dispensing set, which allows measured dispensing of the contents. The pharmacy bulk package is to be used only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area).
(38) Prepackaging--The act of repackaging and relabeling quantities of drug products from a manufacturer's original container into unit dose packaging or a multiple-dose container for distribution within a pharmacy licensed as a Class C pharmacy or to other pharmacies under common ownership for distribution within those pharmacies. The term as defined does not prohibit the prepackaging of drug products for use within other pharmacy classes.
(39) Preparation or compounded sterile preparation--A sterile admixture compounded in a licensed pharmacy or other healthcare-related facility pursuant to the order of a licensed prescriber. The components of the preparation may or may not be sterile products.
(40) Primary engineering control--A device or room that provides an ISO Class 5 environment for the exposure of critical sites when compounding sterile preparations. Such devices include, but may not be limited to, laminar airflow workbenches, biological safety cabinets, compounding aseptic isolators, and compounding aseptic containment isolators.
(41) Product--A commercially manufactured sterile drug or nutrient that has been evaluated for safety and efficacy by the U.S. Food and Drug Administration (FDA). Products are accompanied by full prescribing information, which is commonly known as the FDA-approved manufacturer's labeling or product package insert.
(42) Positive control--A quality assurance sample prepared to test positive for microbial growth.
(43) Quality assurance--The set of activities used to ensure that the process used in the preparation of sterile drug preparations lead to preparations that meet predetermined standards of quality.
(44) Quality control--The set of testing activities used to determine that the ingredients, components (e.g., containers), and final compounded sterile preparations prepared meet predetermined requirements with respect to identity, purity, non-pyrogenicity, and sterility.
(45) Reasonable quantity--An amount of a compounded drug that:

(A) does not exceed the amount a practitioner anticipates may be used in the practitioner's office or facility before the beyond-use date of the drug;

(B) is reasonable considering the intended use of the compounded drug and the nature of the practitioner's practice; and

(C) for any practitioner and all practitioners as a whole, is not greater than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality, and purity of the compounded drug that are consistent with United States Pharmacopeia guidelines and accreditation practices.

(46) Restricted-access barrier system--An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air that allows for the ingress and/or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations.
(47) Segregated compounding area--A designated space, area, or room that is not required to be classified and is defined with a visible perimeter. The segregated compounding area shall contain a PEC and is suitable for preparation of Category 1 compounded sterile preparations only.
(48) Single-dose container--A single-unit container for articles or preparations intended for parenteral administration only. It is intended for a single use. A single-dose container is labeled as such. Examples of single-dose containers include pre-filled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when so labeled.
(49) SOPs--Standard operating procedures.
(50) Sterilizing grade membranes--Membranes that are documented to retain 100% of a culture of 10^7 microorganisms of a strain of Brevundimonas (Pseudomonas) diminuta per square centimeter of membrane surface under a pressure of not less than 30 psi (2.0 bar). Such filter membranes are nominally at 0.22-micron or 0.2 micron nominal pore size, depending on the manufacturer's practice.
(51) Sterilization by filtration--Passage of a fluid or solution through a sterilizing grade membrane to produce a sterile filtrate.
(52) Terminal sterilization--The application of a lethal process, e.g., steam under pressure or autoclaving, to sealed final preparation containers for the purpose of achieving a predetermined sterility assurance level of usually less than 10^-6 or a probability of less than one in one million of a non-sterile unit.
(53) Unidirectional airflow--An airflow moving in a single direction in a robust and uniform manner and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area.
(54) USP/NF--The current edition of the United States Pharmacopeia/National Formulary.

(c) Personnel.

(1) Pharmacist-in-charge.

(A) General. The pharmacy shall have a pharmacist-in-charge in compliance with the specific license classification of the pharmacy.

(B) Responsibilities. In addition to the responsibilities for the specific class of pharmacy, the pharmacist-in-charge shall have the responsibility for, at a minimum, the following concerning the compounding of sterile preparations:

(i) developing a system to ensure that all pharmacy personnel responsible for compounding and/or supervising the compounding of sterile preparations within the pharmacy receive appropriate education and training and competency evaluation;
(ii) determining that all personnel involved in compounding sterile preparations obtain continuing education appropriate for the type of compounding done by the personnel;
(iii) supervising a system to ensure appropriate procurement of drugs and devices and storage of all pharmaceutical materials including pharmaceuticals, components used in the compounding of sterile preparations, and drug delivery devices;
(iv) ensuring that the equipment used in compounding is properly maintained;
(v) developing a system for the disposal and distribution of drugs from the pharmacy;
(vi) developing a system for bulk compounding or batch preparation of drugs;
(vii) developing a system for the compounding, sterility assurance, quality assurance, and quality control of sterile preparations; and
(viii) if applicable, ensuring that the pharmacy has a system to dispose of hazardous waste in a manner so as not to endanger the public health.

(2) Pharmacists.

(A) General.

(i) A pharmacist is responsible for ensuring that compounded sterile preparations are accurately identified, measured, diluted, and mixed and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed.
(ii) A pharmacist shall inspect and approve all components, drug preparation containers, closures, labeling, and any other materials involved in the compounding process.
(iii) A pharmacist shall review all compounding records for accuracy and conduct periodic in-process checks as defined in the pharmacy's policy and procedures.
(iv) A pharmacist shall review all compounding records for accuracy and conduct a final check.
(v) A pharmacist is responsible for ensuring the proper maintenance, cleanliness, and use of all equipment used in the compounding process.
(vi) A pharmacist shall be accessible at all times, 24 hours a day, to respond to patients' and other health professionals' questions and needs.

(B) Initial training and continuing education.

(i) All pharmacists who compound sterile preparations or supervise pharmacy technicians and pharmacy technician trainees compounding sterile preparations shall comply with the following:

(I) complete through a single course, a minimum of 20 hours of instruction and experience in the areas listed in paragraph (4)(D) of this subsection. Such training shall be obtained through completion of a recognized course in an accredited college of pharmacy or a course sponsored by an ACPE accredited provider;
(II) complete a structured on-the-job didactic and experiential training program at this pharmacy which provides sufficient hours of instruction and experience in the pharmacy's sterile compounding processes and procedures. Such training may not be transferred to another pharmacy unless the pharmacies are under common ownership and control and use a common training program; and
(III) possess knowledge about:

(-a-) aseptic processing;
(-b-) quality control and quality assurance as related to environmental, component, and finished preparation release checks and tests;
(-c-) chemical, pharmaceutical, and clinical properties of drugs;
(-d-) container, equipment, and closure system selection; and
(-e-) sterilization techniques.

(ii) The required experiential portion of the training programs specified in this subparagraph shall be supervised by an individual who is actively engaged in performing sterile compounding and is qualified and has completed training as specified in this paragraph or paragraph (3) of this subsection.
(iii) In order to renew a license to practice pharmacy, during the previous licensure period, a pharmacist engaged in sterile compounding shall complete a minimum of:

(I) two hours of ACPE-accredited continuing education relating to one or more of the areas listed in paragraph (4)(D) of this subsection if the pharmacist is engaged in compounding Category 1 or Category 2 compounded sterile preparations; or
(II) four hours of ACPE-accredited continuing education relating to one or more of the areas listed in paragraph (4)(D) of this subsection if the pharmacist is engaged in compounding Category 2 prepared from any non-sterile starting component or Category 3 compounded sterile preparations.

(3) Pharmacy technicians and pharmacy technician trainees.

(A) General. All pharmacy technicians and pharmacy technician trainees shall meet the training requirements specified in §297.6 of this title (relating to Pharmacy Technician and Pharmacy Technician Trainee Training).

(B) Initial training and continuing education.

(i) Pharmacy technicians and pharmacy technician trainees may compound sterile preparations provided the pharmacy technicians and/or pharmacy technician trainees are supervised by a pharmacist as specified in paragraph (2) of this subsection.

(ii) All pharmacy technicians and pharmacy technician trainees who compound sterile preparations for administration to patients shall:

(I) have initial training obtained either through completion of:

(-a-) a single course, a minimum of 40 hours of instruction and experience in the areas listed in paragraph (4)(D) of this subsection. Such training shall be obtained through completion of a course sponsored by an ACPE accredited provider which provides 40 hours of instruction and experience; or

(-b-) a training program which is accredited by the American Society of Health-System Pharmacists.

(II) and

(-a-) complete a structured on-the-job didactic and experiential training program at this pharmacy which provides sufficient hours of instruction and experience in the pharmacy's sterile compounding processes and procedures. Such training may not be transferred to another pharmacy unless the pharmacies are under common ownership and control and use a common training program; and

(-b-) possess knowledge about:

(-1-) aseptic processing;

(-2-) quality control and quality assurance as related to environmental, component, and finished preparation release checks and tests;

(-3-) chemical, pharmaceutical, and clinical properties of drugs;

(-4-) container, equipment, and closure system selection; and

(-5-) sterilization techniques.

(iii) Individuals enrolled in training programs accredited by the American Society of Health-System Pharmacists may compound sterile preparations in a licensed pharmacy provided the:

(I) compounding occurs only during times the individual is assigned to a pharmacy as a part of the experiential component of the American Society of Health-System Pharmacists training program;

(II) individual is under the direct supervision of and responsible to a pharmacist who has completed training as specified in paragraph (2) of this subsection;

(III) supervising pharmacist conducts periodic in-process checks as defined in the pharmacy's policy and procedures; and

(IV) supervising pharmacist conducts a final check.

(iv) The required experiential portion of the training programs specified in this subparagraph shall be supervised by an individual who is actively engaged in performing sterile compounding, is qualified and has completed training as specified in paragraph (2) of this subsection or this paragraph.

(v) In order to renew a registration as a pharmacy technician, during the previous registration period, a pharmacy technician engaged in sterile compounding shall complete a minimum of:

(I) two hours of ACPE accredited continuing education relating to one or more of the areas listed in paragraph (4)(D) of this subsection if the pharmacy technician is engaged in compounding Category 1 or Category 2 compounded sterile preparations; or

(II) four hours of ACPE accredited continuing education relating to one or more of the areas listed in paragraph (4)(D) of this subsection if the pharmacy technician is engaged

in compounding Category 2 prepared from any non-sterile starting component or Category 3 compounded sterile preparations.

(4) Evaluation and testing requirements.

(A) All persons who perform or oversee compounding or support activities shall be trained in the pharmacy's SOPs. All pharmacy personnel preparing sterile preparations shall be trained conscientiously and skillfully by expert personnel through multimedia instructional sources and professional publications in the theoretical principles and practical skills of aseptic manipulations, garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 environmental conditions, and cleaning and disinfection procedures before beginning to prepare compounded sterile preparations.

(B) All pharmacy personnel preparing sterile preparations shall perform didactic review and pass written testing of aseptic manipulative skills initially and every 12 months.

(C) Pharmacy personnel who fail written tests or whose media-fill tests result in gross microbial colonization shall:

(i) be immediately re-instructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies; and

(ii) not be allowed to compound sterile preparations for patient use until passing results are achieved.

(D) The didactic and experiential training shall include instruction, experience, and demonstrated proficiency in the following areas:

(i) aseptic technique;

(ii) critical area contamination factors;

(iii) environmental monitoring;

(iv) structure and engineering controls related to facilities;

(v) equipment and supplies;

(vi) sterile preparation calculations and terminology;

(vii) sterile preparation compounding documentation;

(viii) quality assurance procedures;

(ix) aseptic preparation procedures including proper gowning and gloving technique;

(x) handling of hazardous drugs, if applicable;

(xi) cleaning procedures; and

(xii) general conduct in the clean room.

(E) The aseptic technique of all compounding personnel and personnel who have direct oversight of compounding personnel but do not compound shall be observed and evaluated by expert personnel as satisfactory through written and practical tests, and media-fill testing, and such evaluation documented. Compounding personnel shall not evaluate their own aseptic technique or results of their own media-fill testing. The pharmacy's SOPs shall define the aseptic technique evaluation for personnel who do not compound nor have direct oversight of compounding personnel such as personnel who restock or clean and disinfect the sterile compounding area, personnel who perform in-process checks or final verification of compounded sterile preparations, and others (e.g., maintenance personnel, certifiers, contractors, inspectors, surveyors).

(F) Media-fill tests shall be conducted at each pharmacy where an individual compounds sterile preparations under the most challenging or stressful conditions. If pharmacies are under common ownership and control, the media-fill testing may be conducted at only one of the pharmacies provided each of the pharmacies are operated under equivalent policies and procedures and the testing is conducted under the most challenging or stressful conditions. In addition, each pharmacy shall maintain documentation of the media-fill test. No preparation intended for patient use shall be compounded by an individual until the on-site media-fill tests indicate that the individual can competently perform aseptic procedures, except that a pharmacist may temporarily compound sterile preparations and

supervise pharmacy technicians compounding sterile preparations without media-fill tests provided the pharmacist completes the on-site media-fill tests within seven days of commencing work at the pharmacy.

(G) For media-fill testing of compounds using only sterile starting components, the components shall be manipulated in a manner that simulates sterile-to-sterile compounding activities. The sterile soybean-casein digest media shall be transferred into the same types of container closure systems commonly used at the pharmacy.

(H) For media-fill testing of compounds using any non-sterile starting components, a commercially available non-sterile soybean-casein digest powder shall be dissolved in non-bacteriostatic water to make a 3.0% non-sterile solution. The components shall be manipulated in a manner that simulates non-sterile-to-sterile compounding activities. At least one container shall be prepared as the positive control to demonstrate growth promotion, as indicated by visible turbidity upon incubation.

(I) Final containers shall be incubated in an incubator at 20 to 25 degrees Celsius and 30 to 35 degrees Celsius for a minimum of 7 days at each temperature band to detect a broad spectrum of microorganisms. The order of the incubation temperatures shall be described in the pharmacy's SOPs. Failure is indicated by visible turbidity or other visual manifestations of growth in the media in one or more container closure unit(s) on or before the end of the incubation period.

(J) The pharmacist-in-charge shall ensure continuing competency of pharmacy personnel through in-service education, training, and media-fill tests to supplement initial training. Personnel competency shall be evaluated:

(i) during orientation and training prior to the regular performance of those tasks;

(ii) whenever the quality assurance program yields an unacceptable result;

(iii) whenever unacceptable techniques are observed; and

(iv) at least every 12 months, with the exception of media-fill testing which shall be completed every six months for compounding personnel.

(K) The pharmacist-in-charge shall ensure that proper hand hygiene and garbing practices of all compounding personnel and personnel who have direct oversight of compounding personnel but do not compound are evaluated prior to compounding, supervising, or verifying sterile preparations intended for patient use and whenever an aseptic media-fill is performed.

(i) Gloved fingertip sampling shall be performed for all compounding personnel and personnel who have direct oversight of compounding personnel but do not compound. If pharmacies are under common ownership and control, the gloved fingertip and thumb sampling may be conducted at only one of the pharmacies provided each of the pharmacies are operated under equivalent policies and procedures and the testing is conducted under the most challenging or stressful conditions. In addition, each pharmacy shall maintain documentation of the gloved fingertip and thumb sampling.

(ii) All compounding personnel and personnel who have direct oversight of compounding personnel but do not compound shall demonstrate competency in proper hand hygiene and garbing procedures and in aseptic work practices (e.g., disinfection of component surfaces, routine disinfection of gloved hands).

(iii) Sterile sampling media devices shall be used to sample the gloved fingertips of compounding personnel and personnel who have direct oversight of compounding personnel but do not compound after garbing in order to assess garbing competency and after completing the media-fill preparation (without applying sterile 70% IPA).

(iv) The visual observation shall be documented and maintained to provide a permanent record and long-term assessment of personnel competency.

(v) All compounding personnel and personnel who have direct oversight of compounding personnel but do not compound shall successfully complete an initial competency evaluation

and gloved fingertip and thumb sampling procedure no less than three times before initially being allowed to compound sterile preparations for patient use. Immediately after the personnel completes the hand hygiene and garbing procedure (i.e., after donning of sterile gloves and before any disinfecting with sterile 70% IPA), the evaluator will collect a gloved fingertip and thumb sample from both hands of the compounding personnel onto contact plates or swabs by having the individual lightly touching each fingertip onto the testing medium. Samples shall be incubated in an incubator. The media device shall be incubated at 30 to 35 degrees Celsius for no less than 48 hours and then at 20 to 25 degrees Celsius for no less than five additional days. Alternatively, to shorten the overall incubation period, two sampling media devices may be incubated concurrently in separate incubators with one media device incubated at 30 to 35 degrees Celsius for no less than 48 hours and the other media device incubated at 20 to 25 degrees Celsius for no less than five days. Media devices shall be handled and stored so as to avoid contamination and prevent condensate from dropping onto the agar during incubation and affecting the accuracy of the cfu reading (e.g., invert containers). Action levels for gloved fingertip and thumb sampling are based on the total cfu count from both hands. Results of the initial gloved fingertip and thumb sampling evaluations after garbing shall indicate not greater than zero colony-forming units (0 cfu) growth on the contact plates or swabs, or the test shall be considered a failure. Results of the initial gloved fingertip evaluations after media-fill testing shall indicate not greater than three colony-forming units (3 cfus) growth on the contact plates or swabs, or the test shall be considered a failure. In the event of a failed gloved fingertip and thumb test, the evaluation shall be repeated until the individual can successfully don sterile gloves and pass the gloved fingertip and thumb sampling evaluation, defined as zero cfus growth. Surface sampling of the direct compounding area shall be performed. No preparation intended for patient use shall be compounded by an individual until the results of the initial gloved fingertip and thumb and surface sampling evaluations indicate that the individual can competently perform aseptic procedures except that a pharmacist may temporarily physically supervise pharmacy technicians compounding sterile preparations before the results of the evaluation have been received for no more than three days from the date of the test.

(vi) Re-evaluation of all compounding personnel shall occur at least every six months. Re-evaluation of personnel who have direct oversight of compounding personnel but do not compound shall occur at least every 12 months. Results of gloved fingertip and thumb tests conducted immediately after compounding personnel complete a compounding procedure shall indicate no more than 3 cfus growth, or the test shall be considered a failure, in which case, the evaluation shall be repeated until an acceptable test can be achieved (i.e., the results indicated no more than 3 cfus growth).

(vii) Personnel who have direct oversight of compounding personnel but do not compound shall complete a garbing competency evaluation every 12 months. The pharmacy's SOPs shall define the garbing competency evaluation for personnel who do not compound nor have direct oversight of compounding personnel such as personnel who restock or clean and disinfect the sterile compounding area, personnel who perform in-process checks or final verification of compounded sterile preparations, and others (e.g., maintenance personnel, certifiers, contractors, inspectors, surveyors).

(L) The pharmacist-in-charge shall ensure surface sampling shall be conducted in all ISO classified areas on a periodic basis. Sampling shall be accomplished using contact plates or swabs at the conclusion of compounding. The sample area shall be gently touched with the agar surface by rolling the plate across the surface to be sampled.

(i) Each classified area, including each room and the interior of each ISO Class 5 primary engineering control (PEC) and pass-through chambers connecting to classified areas (e.g.,

equipment contained within the PEC, staging or work area(s) near the PEC, frequently touched areas), shall be sampled for microbial contamination using a risk-based approach.

(ii) For pharmacies compounding Category 1 or Category 2 compounded sterile preparations, surface sampling of all classified areas and pass-through chambers connecting to classified areas shall be conducted at least monthly. For pharmacies compounding any Category 3 compounded sterile preparations, surface sampling of all classified areas and pass-through chambers connecting to classified areas shall be completed prior to assigning a beyond-use-date longer than the limits established for Category 2 compounded sterile preparations and at least weekly on a regularly scheduled basis regardless of the frequency of compounding Category 3 compounded sterile preparations.

(iii) The following action levels for surface sampling apply:

(I) for ISO Class 5, greater than 3 cfus per media device;

(II) for ISO Class 7, greater than 5 cfus per media device; and

(III) for ISO Class 8, greater than 50 cfus per media device.

(iv) If levels measured during surface sampling exceed the levels in clause (iii) of this subparagraph for the ISO classification levels of the area sampled, the cause shall be investigated and corrective action shall be taken. Data collected in response to corrective actions shall be reviewed to confirm that the actions taken have been effective. The corrective action plan shall be dependent on the cfu count and the microorganism recovered. The corrective action plan shall be documented. If levels measured during surface sampling exceed the levels in clause (iii) of this subparagraph, an attempt shall be made to identify any microorganism recovered to the genus level with the assistance of a competent microbiologist.

(M) Personnel who only perform restocking or cleaning and disinfecting duties outside of the primary engineering control shall complete ongoing training as required by the pharmacy's SOPs.

(5) Documentation of training. The pharmacy shall maintain a record of the training and continuing education on each person who compounds sterile preparations. The record shall contain, at a minimum, a written record of initial and in-service training, education, and the results of written and practical testing and media-fill testing of pharmacy personnel. The record shall be maintained and available for inspection by the board and contain the following information:

(A) name of the person receiving the training or completing the testing or media-fill tests;

(B) date(s) of the training, testing, or media-fill testing;

(C) general description of the topics covered in the training or testing or of the process validated;

(D) name of the person supervising the training, testing, or media-fill testing; and

(E) signature or initials of the person receiving the training or completing the testing or media-fill testing and the pharmacist-in-charge or other pharmacist employed by the pharmacy and designated by the pharmacist-in-charge as responsible for training, testing, or media-fill testing of personnel.

(d) Operational standards.

(1) General requirements.

(A) Sterile preparations may be compounded:

(i) upon presentation of a practitioner's prescription drug or medication order based on a valid pharmacist/patient/prescriber relationship;

(ii) in anticipation of future prescription drug or medication orders based on routine, regularly observed prescribing patterns; or

(iii) in reasonable quantities for office use by a practitioner and for use by a veterinarian.

(B) Sterile compounding in anticipation of future prescription drug or medication orders shall be based upon a history of receiving valid prescriptions issued within an established pharmacist/patient/prescriber relationship, provided that in the pharmacist's professional judgment the quantity prepared is stable for the anticipated shelf time. The maximum batch size for all preparations

requiring sterility testing shall be limited to 250 final yield units, except the maximum batch size shall be limited to 1,000 final yield units for preparations fully packaged using an automated compounding device (e.g., repeater pump).

(i) The pharmacist's professional judgment shall be based on the criteria used to determine a beyond-use date outlined in paragraph (8)(J) of this subsection.

(ii) Documentation of the criteria used to determine the stability for the anticipated shelf time shall be maintained and be available for inspection.

(iii) Any preparation compounded in anticipation of future prescription drug or medication orders shall be labeled. Such label shall contain:

(I) name and strength of the compounded preparation or list of the active ingredients and strengths;

(II) facility's lot number;

(III) beyond-use date as determined by the pharmacist using appropriate documented criteria as outlined in paragraph (8)(J) of this subsection;

(IV) quantity or amount in the container;

(V) appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and

(VI) device-specific instructions, where appropriate.

(C) Commercially available products may be compounded for dispensing to individual patients or for office use provided the following conditions are met:

(i) the commercial product is not reasonably available from normal distribution channels in a timely manner to meet individual patient's needs;

(ii) the pharmacy maintains documentation that the product is not reasonably available due to a drug shortage or unavailability from the manufacturer; and

(iii) the prescribing practitioner has requested that the drug be compounded as described in subparagraph (D) of this paragraph.

(D) A pharmacy may not compound preparations that are essentially copies of commercially available products (e.g., the preparation is dispensed in a strength that is only slightly different from a commercially available product) unless the prescribing practitioner specifically orders the strength or dosage form and specifies why the individual patient needs the particular strength or dosage form of the preparation or why the preparation for office use is needed in the particular strength or dosage form of the preparation. The prescribing practitioner shall provide documentation of a patient specific medical need and the preparation produces a clinically significant therapeutic response (e.g., the physician requests an alternate preparation due to hypersensitivity to excipients or preservative in the FDA-approved product, or the physician requests an effective alternate dosage form) or if the drug product is not commercially available. The unavailability of such drug product shall be documented prior to compounding. The methodology for documenting unavailability includes maintaining a copy of the wholesaler's notification showing back-ordered, discontinued, or out-of-stock items. This documentation shall be available in hard-copy or electronic format for inspection by the board.

(E) A pharmacy may enter into an agreement to compound and dispense prescription drug or medication orders for another pharmacy provided the pharmacy complies with the provisions of §291.125 of this title (relating to Centralized Prescription Dispensing).

(F) Compounding pharmacies/pharmacists may advertise and promote the fact that they provide sterile prescription compounding services, which may include specific drug preparations and classes of drugs.

(G) A pharmacy may not compound veterinary preparations for use in food producing animals except in accordance with federal guidelines.

(H) Compounded sterile preparations, including hazardous drugs and radiopharmaceuticals, shall be prepared only under conditions that protect the pharmacy personnel in the preparation and storage areas.

(2) Compounded sterile preparation categories. Category 1, Category 2, and Category 3 are primarily based on the state of environmental control under which they are compounded, the probability for microbial growth during the time they will be stored, and the time period within which they must be used.

(A) A Category 1 compounded sterile preparation is a compounded sterile preparation that is assigned a beyond-use date in accordance with paragraph (8)(J)(ii)(I) of this subsection and all applicable requirements of this section for Category 1 compounded sterile preparations.

(B) A Category 2 compounded sterile preparation is a compounded sterile preparation that is assigned a beyond-use date in accordance with paragraph (8)(J)(ii)(II) of this subsection and all applicable requirements of this section for Category 2 compounded sterile preparations.

(C) A Category 3 compounded sterile preparation is a compounded sterile preparation that is assigned a beyond-use date in accordance with paragraph (8)(J)(ii)(III) of this subsection and all applicable requirements of this section for Category 3 compounded sterile preparations.

(3) Depyrogenation. Dry heat depyrogenation shall be used to render glassware, metal, and other thermostable containers and components pyrogen free. The duration of the exposure period shall include sufficient time for the items to reach the depyrogenation temperature. The items shall remain at the depyrogenation temperature for the duration of the depyrogenation period. The effectiveness of the dry heat depyrogenation cycle shall be established initially and verified annually using endotoxin challenge vials to demonstrate that the cycle is capable of achieving a greater than or equal to 3-log reduction in endotoxins. The effectiveness of the depyrogenation cycle shall be re-established if there are changes to the depyrogenation cycle described in the pharmacy's SOPs (e.g., changes in load conditions, duration, or temperature). This verification shall be documented.

(4) Immediate use compounded sterile preparations. When all of the following conditions are met, compounding of compounded sterile preparations for direct and immediate administration is not subject to the requirements for Category 1, Category 2, or Category 3 compounded sterile preparations:

(A) Only simple aseptic measuring and transfer manipulations are performed with not more than three different sterile drug products, including an infusion or diluent solution, from the manufacturers' original containers and not more than two entries into any one container or package of sterile infusion solution or administration container/device;

(B) Unless required for the preparation, the compounding procedure occurs continuously without delays or interruptions and does not exceed 1 hour;

(C) During preparation, aseptic technique is followed and, if not immediately administered, the finished compounded sterile preparation is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter of biological fluids, mix-ups with other compounded sterile preparations, and direct contact with outside surfaces;

(D) Administration begins not later than four hours following the start of preparing the compounded sterile preparation;

(E) When the compounded sterile preparation is not administered by the person who prepared it, or its administration is not witnessed by the person who prepared it, the compounded sterile preparation shall bear a label listing patient identification information such as name and identification number(s), the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact 4-hours beyond-use time and date;

(F) If administration has not begun within four hours following the completion of preparing the compounded sterile preparation, the compounded sterile preparation is promptly and safely discarded. Immediate use compounded sterile preparations shall not be stored for later use;

(G) Hazardous drugs shall not be prepared as immediate use compounded sterile preparations; and

(H) Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the pharmacy's SOPs.

(5) Single-dose and multiple-dose containers.

(A) Opened or needle punctured single-dose containers, such as bags bottles, syringes, and vials of sterile products shall be used within one hour if opened in worse than ISO Class 5 air quality. Any remaining contents shall be discarded.

(B) If a single-dose vial is entered or punctured only in ISO Class 5 or cleaner air, it may be used up to 12 hours after initial entry or puncture as long as the labeled storage requirements during that 12 hour period are maintained.

(C) Open single-dose ampules shall not be stored for any time period.

(D) Once initially entering or puncturing a multiple-dose container, the multiple-dose container shall not be used for more than 28 days unless otherwise specified by the manufacturer on the labeling.

(E) Conventionally manufactured pharmacy bulk packages shall be restricted to the sterile preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile containers. The pharmacy bulk package shall be used according to the manufacturer's labeling and entered or punctured only in an ISO Class 5 primary engineering control.

(F) Multiple-dose compounded sterile preparations shall meet the criteria for antimicrobial effectiveness testing and the requirements of subparagraph (G) of this paragraph. Multiple-dose compounded sterile preparations shall be stored under conditions upon which the beyond-use date is based (e.g., refrigerator or controlled room temperature). After a multiple-dose compounded sterile preparation is initially entered or punctured, the multiple-dose compounded sterile preparation shall not be used for longer than the assigned beyond-use date or 28 days, whichever is shorter.

(G) A multiple-dose compounded sterile preparation shall be prepared as a Category 2 or Category 3 compounded sterile preparation. An aqueous multiple-dose compounded sterile preparation shall additionally pass antimicrobial effectiveness testing. In the absence of supporting documentation or data in a USP/NF monograph, manufacturer's data, or previously conducted or contracted for testing, compounding personnel may rely on antimicrobial effectiveness testing conducted or contracted for in the particular container closure system in which it will be packaged.

(H) In the absence of container closure data, the container closure system used to package the multiple-dose compounded sterile preparation shall be evaluated for and conform to container closure integrity. The container closure integrity test shall be conducted only once in the particular container closure system in which the multiple-dose compounded sterile preparation shall be packaged.

(I) Multiple-dose, nonpreserved, aqueous topical, and topical ophthalmic compounded sterile preparations. Antimicrobial effectiveness testing under subparagraph (G) of this paragraph is not required if the preparation is prepared as a Category 2 or Category 3 compounded sterile preparation, for use by a single patient, and labeled to indicate that once opened, it shall be discarded after 24 hours when stored at controlled room temperature, 72 hours when stored under refrigeration, or 90 days when frozen if based on documented published stability and effectiveness data.

(J) When a single-dose compounded sterile preparation or compounded sterile preparation stock solution is used as a component to compound additional compounded sterile preparations, the original single-dose compounded sterile preparation or compounded sterile preparation stock solution shall be entered or punctured in ISO Class 5 or cleaner air and stored under the conditions upon which its beyond-use date is based (e.g., refrigerator or controlled room temperature). The component compounded sterile preparation may be used for sterile compounding for up to 12 hours once accessed or its assigned beyond-use date, whichever is shorter, and any remainder shall be discarded.

(6) Proprietary bag and vial systems. Docking and activation of proprietary bag and vial systems in accordance with the manufacturer's labeling for immediate administration to an individual patient is not considered compounding and may be performed outside of an ISO Class 5 environment. Docking of the proprietary bag and

vial system for future activation and administration is considered compounding and shall be performed in an ISO Class 5 environment. Beyond-use dates for proprietary bag and vial systems shall not be longer than those specified in the manufacturer's labeling.

(7) Library. In addition to the library requirements of the pharmacy's specific license classification, a pharmacy shall maintain current or updated copies in hard-copy or electronic format of each of the following:

(A) a reference text on injectable drug preparations, such as Handbook on Injectable Drug Products;

(B) a specialty reference text appropriate for the scope of pharmacy services provided by the pharmacy, e.g., if the pharmacy prepares hazardous drugs, a reference text on the preparation of hazardous drugs;

(C) the United States Pharmacopeia/National Formulary containing USP Chapter 71, Sterility Tests, USP Chapter 85, Bacterial Endotoxins Test, Pharmaceutical Compounding--Nonsterile Preparations, USP Chapter 795, USP Chapter 797, Pharmaceutical Compounding--Sterile Preparations, and USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding; and

(D) any additional USP/NF chapters applicable to the practice of the pharmacy (e.g., USP Chapter 800, Hazardous Drugs--Handling in Healthcare Settings, USP Chapter 823, Positron Emission Tomography Drugs for Compounding, Investigational, and Research Uses).

(8) Environment. Compounding facilities shall be physically designed and environmentally controlled to minimize airborne contamination from contacting critical sites.

(A) Air exchange requirements. For cleanroom suites, adequate HEPA-filtered airflow to the buffer room(s) and anteroom(s) is required to maintain appropriate ISO classification during compounding activities. Airflow is measured in terms of the number of air changes per hour (ACPH).

(i) Unclassified sterile compounding area. No requirement for ACPH.

(ii) ISO Class 7 room(s). A minimum of 30 total HEPA-filtered ACPH shall be supplied to ISO Class 7 rooms. At least 15 ACPH of the total air change rate in a room shall come from the HVAC through HEPA filters located in the ceiling. The ACPH from HVAC, ACPH contributed from the PEC, and the total ACPH shall be documented on the certification report.

(iii) ISO Class 8 room(s). A minimum of 20 total HEPA-filtered ACPH shall be supplied to ISO Class 8 rooms. At least 15 ACPH of the total air change rate in a room shall come from the HVAC through HEPA filters located in the ceiling. The total ACPH shall be documented on the certification report.

(B) Cleanroom suite. Seals and sweeps should not be installed at doors between buffer rooms and anterooms. Access doors should be hands-free. Tacky mats shall not be placed within ISO-classified areas.

(C) Category 1 and Category 2 Preparations. A pharmacy that prepares Category 1 compounded sterile preparations outside of a segregated compounding area or Category 2 compounded sterile preparations shall have a clean room for the compounding of sterile preparations that is constructed to minimize the opportunities for particulate and microbial contamination. The clean room shall:

(i) be clean, well lit, and of sufficient size to support sterile compounding activities;

(ii) be maintained at a temperature of 20 degrees Celsius or cooler, except that a clean room for the compounding of sterile radiopharmaceuticals shall be maintained at a temperature of 25 degrees Celsius or cooler, and at a humidity of 60% or below, with excursions in temperature or humidity of no more than 10% and lasting no longer than 30 minutes;

(iii) be used only for the compounding of sterile preparations;

(iv) be designed such that hand sanitizing and gowning occurs outside the buffer area but allows hands-free access by compounding personnel to the buffer area;

(v) have non-porous and washable floors or floor covering to enable regular disinfection;

(vi) be ventilated in a manner to avoid disruption from the HVAC system and room cross-drafts;

(vii) have walls, ceilings, floors, fixtures, shelving, counters, and cabinets that are smooth, impervious, free from cracks and crevices (e.g., coved), non-shedding and resistant to damage by disinfectant agents;
(viii) have junctures of ceilings to walls coved or caulked to avoid cracks and crevices;
(ix) have drugs and supplies stored on shelving areas above the floor to permit adequate floor cleaning;
(x) contain only the appropriate compounding supplies and not be used for bulk storage for supplies and materials. Objects that shed particles shall not be brought into the clean room. A Class B pharmacy may use low-linting absorbent materials in the primary engineering control device;
(xi) contain an anteroom that contains a sink with hot and cold running water that enables hands-free use with a closed system of soap dispensing to minimize the risk of extrinsic contamination. A Class B pharmacy may have a sink with hot and cold running water that enables hands-free use with a closed system of soap dispensing immediately outside the anteroom if antiseptic hand cleansing is performed using a waterless alcohol-based surgical hand scrub with persistent activity following manufacturers' recommendations once inside the anteroom; and
(xii) contain a buffer room. The buffer room shall not contain sources of water (i.e., sinks) or floor drains other than distilled or sterile water introduced for facilitating the use of heat block wells for radiopharmaceuticals.

(D) Category 2 prepared from any non-sterile starting component and Category 3 preparations.
(i) In addition to the requirements in subparagraph (C) of this paragraph, when Category 2 prepared from any non-sterile starting component or Category 3 compounded sterile preparations are compounded, the primary engineering control shall be located in a buffer room that provides a physical separation, through the use of walls, doors and pass-throughs and has a minimum differential positive pressure of 0.02 inches water column.
(ii) Presterilization procedures for Category 2 prepared from any non-sterile starting component or Category 3 compounded sterile preparations, such as weighing and mixing, shall be completed in no worse than an ISO Class 8 environment using depyrogenated equipment.

(E) Automated compounding device.
(i) General. If automated compounding devices are used, the pharmacy shall have a method to calibrate and verify the accuracy of automated compounding devices used in aseptic processing and document the calibration and verification on a daily basis, based on the manufacturer's recommendations, and review the results at least weekly.
(ii) Loading bulk drugs into automated compounding devices.
(I) Automated compounding devices may be loaded with bulk drugs only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist.
(II) The label of an automated compounding device container shall indicate the brand name and strength of the drug; or if no brand name, then the generic name, strength, and name of the manufacturer or distributor.
(III) Records of loading bulk drugs into an automated compounding device shall be maintained to show:
(-a-) name of the drug, strength, and dosage form;
(-b-) manufacturer or distributor;
(-c-) manufacturer's lot number;
(-d-) manufacturer's expiration date;
(-e-) quantity added to the automated compounding device;

(-f-) date of loading;
(-g-) name, initials, or electronic signature of the person loading the automated compounding device; and
(-h-) name, initials, or electronic signature of the responsible pharmacist.

(IV) The automated compounding device shall not be used until a pharmacist verifies that the system is properly loaded and affixes his or her signature or electronic signature to the record specified in subclause (III) of this clause.

(F) Hazardous drugs. If the preparation is hazardous, the following is also applicable:

(i) Hazardous drugs shall be prepared only under conditions that protect personnel during preparation and storage;

(ii) Hazardous drugs shall be stored separately from other inventory in a manner to prevent contamination and personnel exposure;

(iii) All personnel involved in the compounding of hazardous drugs shall wear appropriate protective apparel, such as gowns, face masks, eye protection, hair covers, shoe covers or dedicated shoes, and appropriate gloving at all times when handling hazardous drugs, including receiving, distribution, stocking, inventorying, preparation, for administration and disposal;

(iv) Appropriate safety and containment techniques for compounding hazardous drugs shall be used in conjunction with aseptic techniques required for preparing sterile preparations;

(v) Disposal of hazardous waste shall comply with all applicable local, state, and federal requirements;

(vi) Prepared doses of hazardous drugs shall be dispensed, labeled with proper precautions inside and outside, and distributed in a manner to minimize patient contact with hazardous agents.

(G) Blood-labeling procedures. When compounding activities require the manipulation of a patient's blood-derived material (e.g., radiolabeling a patient's or donor's white blood cells), the manipulations shall be performed in an ISO Class 5 biological safety cabinet located in a buffer room and shall be clearly separated from routine material-handling procedures and equipment used in preparation activities to avoid any cross-contamination. The preparations shall not require sterilization.

(H) Cleaning and disinfecting the sterile compounding areas. The following cleaning and disinfecting practices and frequencies apply to direct and contiguous compounding areas, which include ISO Class 5 compounding areas for exposure of critical sites as well as buffer rooms, anterooms, and segregated compounding areas.

(i) The pharmacist-in-charge is responsible for developing written standard operating procedures (SOPs) for cleaning and disinfecting the direct and contiguous compounding areas and assuring the procedures are followed.

(ii) In a PEC, sterile 70% IPA shall be applied after cleaning and disinfecting, or after the application of a one-step disinfectant cleaner or sporicidal disinfectant, to remove any residue. Sterile 70% IPA shall also be applied immediately before initiating compounding. During the compounding process sterile 70% IPA shall be applied to the horizontal work surface, including any removable work trays, of the PEC at least every 30 minutes if the compounding process takes 30 minutes or less. If the compounding process takes more than 30 minutes, compounding shall not be disrupted and the work surface of the PEC shall be disinfected immediately after compounding.

(iii) Surfaces shall be cleaned prior to being disinfected unless a one-step disinfectant cleaner is used to accomplish both the cleaning and disinfection in one step. The manufacturer's directions or published data for the minimum contact time shall be followed for each of the cleaning, disinfecting, and sporicidal disinfectants used. When sterile 70% IPA is used, it shall be allowed to dry. In a Class B pharmacy, objects used in preparing sterile radiopharmaceuticals (e.g., dose

calibrator) which cannot be reasonably removed from the compounding area shall be sterilized with an application of a residue-free disinfection agent.

(iv) Surfaces in classified areas used to prepare Category 1, Category 2, and Category 3 compounded sterile preparations shall be cleaned, disinfected, and sporicidal disinfectants applied in accordance with the following:

(I) PEC(s) and equipment inside PEC(s).

(-a-) Equipment and all interior surfaces of the PEC shall be cleaned daily on days when compounding occurs and when surface contamination is known or suspected. Equipment and all interior surfaces of the PEC shall be disinfected on days when compounding occurs and when surface contamination is known or suspected. Sporicidal disinfectants shall be applied monthly for pharmacies compounding Category 1 or Category 2 compounded sterile preparations and weekly for pharmacies compounding Category 3 compounded sterile preparations.

(-b-) Cleaning and disinfecting agents, with the exception of sporicidal disinfectants, used within the PEC shall be sterile. When diluting concentrated cleaning and disinfecting agents for use in the PEC, sterile water shall be used.

(II) Removable work tray of the PEC, when applicable. Work surfaces of the tray shall be cleaned daily on days when compounding occurs and all surfaces and the area underneath the work tray shall be cleaned monthly. Work surfaces of the tray shall be disinfected on days when compounding occurs and all surfaces and the area underneath the work tray shall be disinfected monthly. Sporicidal disinfectants shall be applied monthly on work surfaces of the tray, all surfaces, and the area underneath the work tray monthly.

(III) Pass-through chambers. Pass-through chambers shall be cleaned daily on days when compounding occurs and disinfected daily on days when compounding occurs. Sporicidal disinfectants shall be applied monthly for pharmacies compounding Category 1 or Category 2 compounded sterile preparations and weekly for pharmacies compounding Category 3 compounded sterile preparations.

(IV) Work surface(s) outside the PEC. Work surfaces outside the PEC shall be cleaned daily on days when compounding occurs and disinfected daily on days when compounding occurs. Sporicidal disinfectants shall be applied monthly for pharmacies compounding Category 1 or Category 2 compounded sterile preparations and weekly for pharmacies compounding Category 3 compounded sterile preparations.

(V) Floor(s). Floors shall be cleaned daily on days when compounding occurs and disinfected daily on days when compounding occurs. Sporicidal disinfectants shall be applied monthly for pharmacies compounding Category 1 or Category 2 compounded sterile preparations and weekly for pharmacies compounding Category 3 compounded sterile preparations.

(VI) Wall(s), door(s), door frame(s), storage shelving and bin(s), and equipment outside of the PEC(s). Walls, doors, door frames, storage shelving and bins, and equipment outside of the PECs shall be cleaned, disinfected, and sporicidal disinfectants applied on a monthly basis.

(VII) Ceiling(s). Ceilings of the classified areas shall be cleaned, disinfected, and sporicidal disinfectant applied on a monthly basis. Ceilings of the segregated compounding area shall be cleaned, disinfected, and sporicidal disinfectants applied when visibly soiled and when surface contamination is known or suspected.

(v) All cleaning materials, such as wipers, sponges, and mops, shall be non-shedding, and dedicated to use in the buffer room, anteroom, and segregated compounding areas and shall not be removed from these areas except for disposal. Floor mops may be used in both the buffer room and anteroom, but only in that order. If cleaning materials are reused, procedures shall be developed that ensure that the effectiveness of the cleaning device is maintained and that repeated use does not add to the bio-burden of the area being cleaned.

(vi) Supplies and equipment removed from shipping cartons shall be wiped with a disinfecting agent, such as sterile IPA. After the disinfectant is sprayed or wiped on a surface to be disinfected, the disinfectant shall be allowed to dry, during which time the item shall not be used for compounding purposes. However, if sterile supplies are received in sealed pouches, the pouches may be removed as the supplies are introduced into the ISO Class 5 area without the need to disinfect the individual sterile supply items. No shipping or other external cartons may be taken into the buffer room or segregated compounding area.

(vii) Before any item is introduced into the clean side of the anteroom(s), placed into pass-through chamber(s), or brought into the segregated compounding area, providing that packaging integrity will not be compromised, the item shall be wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA using low-lint wipers by personnel wearing gloves. If an EPA-registered disinfectant or sporicidal disinfectant is used, the agent shall be allowed to dwell the minimum contact time specified by the manufacturer. If sterile 70% IPA is used, it shall be allowed to dry. The wiping procedure should not compromise the packaging integrity or render the product label unreadable.

(viii) Immediately before any item is introduced into the PEC, it shall be wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use. When sterile items are received in sealed containers designed to keep them sterile until opening, the sterile items may be removed from the covering as the supplies are introduced into the ISO Class 5 PEC without the need to wipe the individual sterile supply items with sterile 70% IPA. The wiping procedure shall not render the product label unreadable.

(ix) Critical sites (e.g., vial stoppers, ampule necks, and intravenous bag septums) shall be wiped with sterile 70% IPA in the PEC to provide both chemical and mechanical actions to remove contaminants. The sterile 70% IPA shall be allowed to dry before personnel enter or puncture stoppers and septums or break the necks of ampules.

(x) Cleaning shall be done by personnel trained in appropriate cleaning techniques.

(xi) Proper documentation and frequency of cleaning shall be maintained and shall contain the following:

(I) date of cleaning;

(II) type of cleaning performed; and

(III) name of individual who performed the cleaning.

(I) Security requirements. The pharmacist-in-charge may authorize personnel to gain access to that area of the pharmacy containing dispensed sterile preparations, in the absence of the pharmacist, for the purpose of retrieving dispensed prescriptions to deliver to patients. If the pharmacy allows such after-hours access, the area containing the dispensed sterile preparations shall be an enclosed and lockable area separate from the area containing undispensed prescription drugs. A list of the authorized personnel having such access shall be in the pharmacy's policy and procedure manual.

(J) Storage requirements and beyond-use dating.

(i) Storage requirements. All drugs shall be stored at the proper temperature and conditions, as defined in the USP/NF and in §291.15 of this title (relating to Storage of Drugs).

(ii) Beyond-use dating. When assigning a beyond-use date, compounding personnel shall consult and apply drug-specific and general stability documentation and literature where available, and

they should consider the nature of the drug and its degradation mechanism, the container in which it is packaged, the expected storage conditions, and the intended duration of therapy. A shorter beyond-use date shall be assigned when the physical and chemical stability of the preparation is less than the beyond-use date limits provided in subclauses (I) - (III) of this clause.

(I) Beyond-use date limits for Category 1 compounded sterile preparations. Category 1 compounded sterile preparations shall be prepared in a segregated compounding area or cleanroom suite and have a beyond-use date of not more than 12 hours when stored at controlled room temperature or 24 hours when stored in a refrigerator.

(II) Beyond-use date limits for Category 2 compounded sterile preparations. Category 2 compounded sterile preparations shall be prepared in a cleanroom suite.

(-a-) Aseptically processed compounded sterile preparations without sterility testing performed and passed.

(-1-) If prepared from one or more non-sterile starting component(s), the preparation shall have a beyond-use date of not more than one day when stored at controlled room temperature, four days when stored in a refrigerator, or 45 days when stored in a freezer.

(-2-) If prepared from only sterile starting component(s), the preparation shall have a beyond-use date of not more than four days when stored at controlled room temperature, 10 days when stored in a refrigerator, or 45 days when stored in a freezer.

(-b-) Terminally sterilized compounded sterile preparations without sterility testing performed and passed shall have a beyond-use date of not more than 14 days when stored at controlled room temperature, 28 days when stored in a refrigerator, or 45 days when stored in a freezer.

(-c-) If sterility testing is performed and passed, aseptically processed or terminally sterilized compounded sterile preparations shall have a beyond-use date of not more than 45 days when stored at controlled room temperature, 60 days when stored in a refrigerator, or 90 days when stored in a freezer.

(-d-) A Category 2 compounded sterile preparation in a nonaqueous dosage form (i.e., water activity less than 0.6) may have a beyond-use date of not more than 90 days if based on documented current literature supporting stability and sterility.

(III) Beyond-use date limits for Category 3 compounded sterile preparations. Category 3 compounded sterile preparations shall be prepared in a cleanroom suite.

(-a-) Aseptically processed compounded sterile preparations that are sterility tested and passed all applicable tests for Category 3 compounded sterile preparations shall have a beyond-use date of not more than 60 days when stored at controlled room temperature, 90 days when stored in a refrigerator, or 120 days when stored in a freezer.

(-b-) Terminally sterilized compounded sterile preparations that are sterility tested and passed all applicable tests for Category 3 compounded sterile preparations shall have a beyond-use date of not more than 90 days when stored at controlled room temperature, 120 days when stored in a refrigerator, or 180 days when stored in a freezer.

(-c-) In the presence of documented published data supporting stability, aseptically processed or terminally sterilized aqueous compounded sterile preparations in batch sizes less than 24 final yield units without sterility and endotoxin testing shall have a beyond-use date of not more than 60 days when

stored at controlled room temperature, 90 days when stored in a refrigerator, or 120 days when stored in a freezer. A pharmacy may only compound one batch of less than 24 final yield units of an aseptically processed or terminally sterilized aqueous compounded sterile preparation per day without sterility and endotoxin testing, with the exception of sterile compounding for a patient specific prescription.

(-d-) A Category 3 compounded sterile preparation in a nonaqueous dosage form (i.e., water activity level less than 0.6) may have a beyond-use date of not more than 180 days if based on documented current literature supporting stability and sterility.

(-e-) Additional requirements to assign Category 3 beyond-use dates to compounded sterile preparations.

(-1-) Increased personnel competency requirements as specified in subsection (c)(4)(K) of this section apply to personnel who participate in or oversee the compounding of Category 3 compounded sterile preparations.

(-2-) Category 3 garbing requirements as specified in paragraph (15)(C)(iv)(II) of this subsection apply to all personnel entering the buffer room where Category 3 compounded sterile preparations are compounded and apply at all times regardless of whether Category 3 compounded sterile preparations are being compounded on a given day.

(-3-) Increased environmental monitoring requirements as specified in subsection (c)(4)(L) of this section and paragraph (16)(C)(vi) of this subsection apply to all classified areas where Category 3 compounded sterile preparations are compounded and apply at all times regardless of whether Category 3 compound sterile preparations are being compounded on a given day.

(-4-) The frequency of application of sporicidal disinfectants as specified in paragraph (8)(H)(iv) of this subsection applies to all classified areas where Category 3 compounded sterile preparations are compounded and applies at all times regardless of whether Category 3 compounded sterile preparations are being compounded on a given day.

(9) Primary engineering control device. The pharmacy shall prepare sterile preparations in a primary engineering control device (PEC), such as a laminar air flow hood, biological safety cabinet, compounding aseptic isolator (CAI), or compounding aseptic containment isolator (CACI) which is capable of maintaining at least ISO Class 5 conditions for 0.5 micron and larger particles while compounding sterile preparations.

(A) Laminar air flow hood. If the pharmacy is using a laminar air flow hood as its PEC, the laminar air flow hood shall:

(i) be located in the buffer room and placed in the buffer room in a manner as to avoid conditions that could adversely affect its operation such as strong air currents from opened doors, personnel traffic, or air streams from the heating, ventilating and air condition system;

(ii) be certified for operational efficiency using certification procedures, such as those outlined in the Certification Guide for Sterile Compounding Facilities (CAG-003-2022), which shall be performed by a qualified independent individual initially and no less than every six months and whenever the device or room is relocated or altered or major service to the pharmacy is performed;

(iii) have pre-filters inspected periodically and replaced as needed, in accordance with written policies and procedures and the manufacturer's specification, and the inspection and/or replacement date documented; and

(iv) be located in a buffer room that has a minimum differential positive pressure of 0.02 inches water column.

(B) Biological safety cabinet.

(i) If the pharmacy is using a biological safety cabinet (BSC) as its PEC for the preparation of hazardous sterile compounded preparations, the biological safety cabinet shall be a Class II or III vertical flow biological safety cabinet located in an ISO Class 7 area that is physically separated from other preparation areas. The area for preparation of sterile chemotherapeutic preparations shall:

(I) have not less than 0.01 inches water column negative pressure to the adjacent positive pressure ISO Class 7 or better anteroom; and

(II) have a pressure indicator that can be readily monitored for correct room pressurization.

(ii) Pharmacies that prepare a low volume of hazardous drugs, are not required to comply with the provisions of clause (i) of this subparagraph if the pharmacy uses a device that provides two tiers of containment (e.g., closed-system vial transfer device within a BSC).

(iii) If the pharmacy is using a biological safety cabinet as its PEC for the preparation of non-hazardous sterile compounded preparations, the biological safety cabinet shall:

(I) be located in the buffer room and placed in the buffer room in a manner as to avoid conditions that could adversely affect its operation such as strong air currents from opened doors, personnel traffic, or air streams from the heating, ventilating and air condition system;

(II) be certified for operational efficiency using certification procedures, such as those outlined in the Certification Guide for Sterile Compounding Facilities (CAG-003-2022), which shall be performed by a qualified independent individual initially and no less than every six months and whenever the device or room is relocated or altered or major service to the pharmacy is performed;

(III) have pre-filters inspected periodically and replaced as needed, in accordance with written policies and procedures and the manufacturer's specification, and the inspection and/or replacement date documented; and

(IV) be located in a buffer room that has a minimum differential positive pressure of 0.02 inches water column.

(C) Compounding aseptic isolator.

(i) If the pharmacy is using a compounding aseptic isolator (CAI) as its PEC, the CAI shall provide unidirectional airflow within the main processing and antechambers, and be placed in an ISO Class 7 buffer room unless the isolator meets all of the following conditions:

(I) The isolator shall provide isolation from the room and maintain ISO Class 5 during dynamic operating conditions including transferring ingredients, components, and devices into and out of the isolator and during preparation of compounded sterile preparations;

(II) Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations;

(III) The CAI shall be certified for operational efficiency using certification procedures, such as those outlined in the Certification Guide for Sterile Compounding Facilities (CAG-003-2022), which shall be performed by a qualified independent individual initially and

no less than every six months and whenever the device or room is relocated or altered or major service to the pharmacy is performed; and

(IV) The pharmacy shall maintain documentation from the manufacturer that the isolator meets this standard when located in worse than ISO Class 7 environments.

(ii) If the isolator meets the requirements in clause (i) of this subparagraph, the CAI may be placed in a non-ISO classified area of the pharmacy; however, the area shall be segregated from other areas of the pharmacy and shall:

(I) be clean, well lit, and of sufficient size;

(II) be used only for the compounding of Category 1 or Category 2 non-hazardous sterile preparations;

(III) be located in an area of the pharmacy with non-porous and washable floors or floor covering to enable regular disinfection; and

(IV) be an area in which the CAI is placed in a manner as to avoid conditions that could adversely affect its operation.

(iii) In addition to the requirements specified in clauses (i) and (ii) of this subparagraph, if the CAI is used in the compounding of Category 2 prepared from any non-sterile starting component or Category 3 non-hazardous preparations, the CAI shall be placed in an area or room with at least ISO Class 7 quality air so that high-risk powders weighed in at least ISO Class 7 air quality conditions, compounding utensils for measuring and other compounding equipment are not exposed to lesser air quality prior to the completion of compounding and packaging of the Category 2 prepared from any non-sterile starting component or Category 3 preparation.

(D) Compounding aseptic containment isolator.

(i) If the pharmacy is using a compounding aseptic containment isolator (CACI) as its PEC for the preparation of Category 1 or Category 2 hazardous drugs, the CACI shall be located in a separate room away from other areas of the pharmacy and shall:

(I) provide at least 0.01 inches water column negative pressure compared to the other areas of the pharmacy;

(II) provide unidirectional airflow within the main processing and antechambers, and be placed in an ISO Class 7 room, unless the CACI meets all of the following conditions;

(-a-) The isolator shall provide isolation from the room and maintain ISO Class 5 during dynamic operating conditions including transferring ingredients, components, and devices into and out of the isolator and during preparation of compounded sterile preparations;

(-b-) Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations;

(-c-) The CACI shall be certified for operational efficiency using certification procedures, such as those outlined in the Certification Guide for Sterile Compounding Facilities (CAG-003-2022), which shall be performed by a qualified independent individual initially and no less than every six months and whenever the device or room is relocated or altered or major service to the pharmacy is performed; and

(-d-) The pharmacy shall maintain documentation from the manufacturer that the isolator meets this standard when located in worse than ISO Class 7 environments.

(ii) If the CACI meets all conditions specified in clause (i) of this subparagraph, the CACI shall not be located in the same room as a CAI, but shall be located in a separate room in the pharmacy, that is not required to maintain ISO classified air. The room in which the CACI is located shall

provide a minimum of 0.01 inches water column negative pressure compared with the other areas of the pharmacy and shall meet the following requirements:

(I) be clean, well lit, and of sufficient size;

(II) be maintained at a temperature of 20 degrees Celsius or cooler, except that a clean room for the compounding of sterile radiopharmaceuticals shall be maintained at a temperature of 25 degrees Celsius or cooler, and at a humidity of 60% or below, with excursions in temperature or humidity of no more than 10% and lasting no longer than 30 minutes;

(III) be used only for the compounding of Category 1 or Category 2 hazardous sterile preparations;

(IV) be located in an area of the pharmacy with walls, ceilings, floors, fixtures, shelving, counters, and cabinets that are smooth, impervious, free from cracks and crevices, non-shedding and resistant to damage by disinfectant agents; and

(V) have non-porous and washable floors or floor covering to enable regular disinfection.

(iii) If the CACI is used in the compounding of Category 2 prepared from any non-sterile starting component or Category 3 hazardous preparations, the CACI shall be placed in an area or room with at least ISO Class 7 quality air so that high-risk powders, weighed in at least ISO Class 7 air quality conditions, are not exposed to lesser air quality prior to the completion of compounding and packaging of the Category 2 prepared from any non-sterile starting component or Category 3 preparation.

(iv) Pharmacies that prepare a low volume of hazardous drugs, are not required to comply with the provisions of clauses (i) and (iii) of this subparagraph if the pharmacy uses a device that provides two tiers of containment (e.g., CACI that is located in a non-negative pressure room).

(10) Additional Equipment and Supplies. Pharmacies compounding sterile preparations shall have the following equipment and supplies:

(A) a calibrated system or device (i.e., thermometer) to monitor the temperature to ensure that proper storage requirements are met, if sterile preparations are stored in the refrigerator;

(B) a calibrated system or device to monitor the temperature where bulk chemicals are stored;

(C) a temperature-sensing mechanism suitably placed in the controlled temperature storage space to reflect accurately the true temperature;

(D) if applicable, a Class A prescription balance, or analytical balance and weights. Such balance shall be properly maintained and subject to periodic inspection by the Texas State Board of Pharmacy;

(E) equipment and utensils necessary for the proper compounding of sterile preparations. Such equipment and utensils used in the compounding process shall be:

(i) of appropriate design, appropriate capacity, and be operated within designed operational limits;

(ii) of suitable composition so that surfaces that contact components, in-process material, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug preparation beyond the desired result;

(iii) cleaned and sanitized immediately prior to and after each use; and

(iv) routinely inspected, calibrated (if necessary), or checked to ensure proper performance;

(F) appropriate disposal containers for used needles, syringes, etc., and if applicable, hazardous waste from the preparation of hazardous drugs and/or biohazardous waste;

(G) appropriate packaging or delivery containers to maintain proper storage conditions for sterile preparations;

(H) infusion devices, if applicable; and

(I) all necessary supplies, including:

(i) disposable needles, syringes, and other supplies for aseptic mixing;
(ii) disinfectant cleaning solutions;
(iii) sterile 70% isopropyl alcohol;
(iv) sterile gloves, both for hazardous and non-hazardous drug compounding;
(v) sterile alcohol-based or water-less alcohol based surgical scrub;
(vi) hand washing agents with bactericidal action;
(vii) disposable, lint free towels or wipes;
(viii) appropriate filters and filtration equipment;
(ix) hazardous spill kits, if applicable; and
(x) masks, caps, coveralls or gowns with tight cuffs, shoe covers, and gloves, as applicable.

(11) Labeling.

(A) Prescription drug or medication orders. In addition to the labeling requirements for the pharmacy's specific license classification, the label dispensed or distributed pursuant to a prescription drug or medication order shall contain the following:

(i) the generic name(s) or the official name(s) of the principal active ingredient(s) of the compounded sterile preparation;
(ii) for outpatient prescription orders other than sterile radiopharmaceuticals, a statement that the compounded sterile preparation has been compounded by the pharmacy. (An auxiliary label may be used on the container to meet this requirement); and
(iii) a beyond-use date. The beyond-use date shall be determined as outlined in Chapter 797, Pharmacy Compounding--Sterile Preparations of the USP/NF, and paragraph (8)(J) of this subsection;

(B) Batch. If the sterile preparation is compounded in a batch, the following shall also be included on the batch label:

(i) unique lot number assigned to the batch;
(ii) quantity;
(iii) appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and
(iv) device-specific instructions, where appropriate.

(C) Pharmacy bulk package. The label of a pharmacy bulk package shall:

(i) state prominently "Pharmacy Bulk Package--Not for Direct Infusion;"
(ii) contain or refer to information on proper techniques to help ensure safe use of the preparation; and
(iii) bear a statement limiting the time frame in which the container may be used once it has been entered, provided it is held under the labeled storage conditions.

(12) Written drug information for prescription drug orders only. Written information about the compounded preparation or its major active ingredient(s) shall be given to the patient at the time of dispensing a prescription drug order. A statement which indicates that the preparation was compounded by the pharmacy shall be included in this written information. If there is no written information available, the patient shall be advised that the drug has been compounded and how to contact a pharmacist, and if appropriate, the prescriber, concerning the drug. This paragraph does not apply to the preparation of radiopharmaceuticals.

(13) Pharmaceutical care services. In addition to the pharmaceutical care requirements for the pharmacy's specific license classification, the following requirements for sterile preparations compounded pursuant to prescription drug orders shall be met. This paragraph does not apply to the preparation of radiopharmaceuticals.

(A) Primary provider. There shall be a designated physician primarily responsible for the patient's medical care. There shall be a clear understanding between the physician, the patient, and the

pharmacy of the responsibilities of each in the areas of the delivery of care, and the monitoring of the patient. This shall be documented in the patient medication record (PMR).

(B) Patient training. The pharmacist-in-charge shall develop policies to ensure that the patient and/or patient's caregiver receives information regarding drugs and their safe and appropriate use, including instruction when applicable, regarding:

(i) appropriate disposition of hazardous solutions and ancillary supplies;

(ii) proper disposition of controlled substances in the home;

(iii) self-administration of drugs, where appropriate;

(iv) emergency procedures, including how to contact an appropriate individual in the event of problems or emergencies related to drug therapy; and

(v) if the patient or patient's caregiver prepares sterile preparations in the home, the following additional information shall be provided:

(I) safeguards against microbial contamination, including aseptic techniques for compounding intravenous admixtures and aseptic techniques for injecting additives to premixed intravenous solutions;

(II) appropriate storage methods, including storage durations for sterile pharmaceuticals and expirations of self-mixed solutions;

(III) handling and disposition of premixed and self-mixed intravenous admixtures; and

(IV) proper disposition of intravenous admixture compounding supplies such as syringes, vials, ampules, and intravenous solution containers.

(C) Pharmacist-patient relationship. It is imperative that a pharmacist-patient relationship be established and maintained throughout the patient's course of therapy. This shall be documented in the patient's medication record (PMR).

(D) Patient monitoring. The pharmacist-in-charge shall develop policies to ensure that:

(i) the patient's response to drug therapy is monitored and conveyed to the appropriate health care provider;

(ii) the first dose of any new drug therapy is administered in the presence of an individual qualified to monitor for and respond to adverse drug reactions; and

(iii) reports of adverse events with a compounded sterile preparation are reviewed promptly and thoroughly to correct and prevent future occurrences.

(14) Drugs, components, and materials used in sterile compounding.

(A) Drugs used in sterile compounding shall be USP/NF grade substances manufactured in an FDA-registered facility.

(B) If USP/NF grade substances are not available, substances used in sterile compounding shall be of a chemical grade in one of the following categories:

(i) Chemically Pure (CP);

(ii) Analytical Reagent (AR);

(iii) American Chemical Society (ACS); or

(iv) Food Chemical Codex.

(C) If a drug, component or material is not purchased from a FDA-registered facility, the pharmacist shall establish purity and stability by obtaining a Certificate of Analysis from the supplier and the pharmacist shall compare the monograph of drugs in a similar class to the Certificate of Analysis.

(D) All components shall:

(i) be manufactured in an FDA-registered facility; or

(ii) in the professional judgment of the pharmacist, be of high quality and obtained from acceptable and reliable alternative sources; and

(iii) be stored in properly labeled containers in a clean, dry place, under proper temperatures.

(E) Drug preparation containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the compounded drug preparation beyond the desired result.

(F) Components, drug preparation containers, and closures shall be rotated so that the oldest stock is used first.

(G) Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded drug preparation.

(H) A pharmacy may not compound a preparation that contains ingredients appearing on a federal Food and Drug Administration list of drug products withdrawn or removed from the market for safety reasons.

(15) Compounding process.

(A) Standard operating procedures (SOPs). All significant procedures performed in the compounding area shall be covered by written SOPs designed to ensure accountability, accuracy, quality, safety, and uniformity in the compounding process. At a minimum, SOPs shall be developed and implemented for:

(i) the pharmacy;

(ii) equipment;

(iii) personnel;

(iv) preparation evaluation;

(v) quality assurance;

(vi) preparation recall;

(vii) packaging; and

(viii) storage of compounded sterile preparations.

(B) USP/NF. Any compounded formulation with an official monograph in the USP/NF shall be compounded, labeled, and packaged in conformity with the USP/NF monograph for the drug.

(C) Personnel cleansing and garbing.

(i) Any person with an apparent illness or open lesion, including rashes, sunburn, weeping sores, conjunctivitis, and active respiratory infection, that may adversely affect the safety or quality of a drug preparation being compounded shall be excluded from working in ISO Class 5, ISO Class 7, and ISO Class 8 compounding areas until the condition is remedied.

(ii) Before entering the buffer room, compounding personnel shall:

(I) remove personal outer garments (e.g., bandanas, coats, hats, jackets, scarves, sweaters, vests);

(II) remove all cosmetics;

(III) remove all hand, wrist, and other body jewelry or piercings (e.g., earrings, lip or eyebrow piercings) that can interfere with the effectiveness of personal protective equipment (e.g., fit of gloves and cuffs of sleeves); and

(IV) wipe eyeglasses, if worn.

(iii) The wearing of artificial nails or extenders is prohibited while working in the sterile compounding environment. Natural nails shall be kept neat and trimmed.

(iv) Personnel shall perform hand hygiene and garbing in an order determined by the pharmacy depending on the placement of the sink. The order of garbing shall be documented in the pharmacy's SOPs. Garb shall be donned and doffed in an order that reduces the risk of contamination. Donning and doffing garb shall not occur in the same area at the same time.

(I) The minimum garbing requirements for preparing Category 1 or Category 2 compounded sterile preparations include the following:

(-a-) low-lint garment with sleeves that fit snugly around the wrists and an enclosed neck (e.g., gown or coverall);

(-b-) low-lint covers for shoes;

(-c-) low-lint cover for head that covers the hair and ears, and if appliable, cover for facial hair;
(-d-) low-lint face mask;
(-e-) sterile powder-free gloves; and
(-f-) if using a restricted-access barrier system (i.e., a compounding aseptic isolator or compounding aseptic containment isolator), disposable gloves should be worn inside the gloves attached to the restricted-access barrier system sleeves. Sterile gloves shall be worn over the gloves attached to the restricted-access barrier system sleeve.

(II) The following additional garbing requirements shall be followed in the buffer room where Category 3 compounded sterile preparations are prepared for all personnel regardless of whether Category 3 compounded sterile preparations are compounded on a given day:

(-a-) skin may not be exposed in the buffer room (i.e., face and neck shall be covered);
(-b-) all low-lint outer garb shall be sterile, including the use of sterile sleeves over gauntlet sleeves when a restricted-access barrier system is used;
(-c-) disposable garbing items shall not be reused and any laundered garb shall not be reused without being laundered and resterilized with a validated cycle; and
(-d-) the pharmacy's SOPs shall describe disinfection procedures for reusing goggles, respirators, and other reusable equipment. If compounding a hazardous drug, appropriate personal protective equipment shall be worn.

(III) After donning dedicated shoes or shoe covers, head and facial hair covers, and face masks, personnel shall perform a hand hygiene procedure by removing debris from underneath fingernails using a nail cleaner under running warm water followed by vigorous hand washing. Personnel shall begin washing arms at the hands and continue washing to elbows for at least 30 seconds with either a plain (non-antimicrobial) soap, or antimicrobial soap, and water while in the anteroom. Disposable soap containers shall not be refilled or topped off. Brushes shall not be used for hand hygiene. Hands and forearms to the elbows shall be completely dried using lint-free disposable towels, an electronic hands-free hand dryer, or a HEPA filtered hand dryer.

(IV) After completion of hand washing, personnel shall don clean non-shedding gowns with sleeves that fit snugly around the wrists and enclosed at the neck.

(V) Once inside the buffer room or segregated compounding area, and prior to donning sterile powder-free gloves, antiseptic hand cleansing shall be performed using an alcohol-based hand rub. Hands shall be allowed to dry thoroughly before donning sterile gloves.

(VI) Sterile gloves that form a continuous barrier with the gown shall be the last item donned before compounding begins. Sterile gloves shall be donned in a classified area or segregated compounding area using proper technique to ensure the sterility of the glove is not compromised while donning. The cuff of the sterile glove shall cover the cuff of the gown at the wrist. When preparing hazardous preparations, the compounder shall double glove or shall use single gloves ensuring that the gloves are sterile powder-free chemotherapy-rated gloves. Routine application of sterile 70% IPA shall occur throughout the compounding day and whenever non-sterile surfaces are touched.

(v) Garb shall be replaced immediately if it becomes visibly soiled or if its integrity is compromised. Gowns and other garb shall be stored in a manner that minimizes contamination

(e.g., away from sinks to avoid splashing). If compounding Category 1 or Category 2 compounded sterile preparations, gowns may be reused within the same shift by the same person if the gown is maintained in a classified area or adjacent to, or within, the segregated compounding area in a manner that prevents contamination. When personnel exit the compounding area, garb, except for gowns, may not be reused and shall be discarded or laundered before use. The pharmacy's SOPs shall describe disinfection procedures for reusing goggle, respirators, and other reusable equipment.

(vi) During compounding activities that precede terminal sterilization, such as weighing and mixing of non-sterile ingredients, compounding personnel shall be garbed and gloved the same as when performing compounding in an ISO Class 5 environment. Properly garbed and gloved compounding personnel who are exposed to air quality that is either known or suspected to be worse than ISO Class 7 shall re-garb personal protective equipment along with washing their hands properly, performing antiseptic hand cleansing with a sterile 70% IPA-based or another suitable sterile alcohol-based surgical hand scrub, and donning sterile gloves upon re-entering the ISO Class 7 buffer room.

(vii) When compounding aseptic isolators or compounding aseptic containment isolators are the source of the ISO Class 5 environment, at the start of each new compounding procedure, a new pair of sterile gloves shall be donned within the CAI or CACI. In addition, the compounding personnel should follow the requirements as specified in this subparagraph, unless the isolator manufacturer can provide written documentation based on validated environmental testing that any components of personal protective equipment or cleansing are not required.

(16) Quality assurance.

(A) Initial formula validation. Prior to routine compounding of a sterile preparation, a pharmacy shall conduct an evaluation that shows that the pharmacy is capable of compounding a preparation that is sterile and that contains the stated amount of active ingredient(s).

(i) Quality assurance practices include, but are not limited to the following:

(I) Routine disinfection and air quality testing of the direct compounding environment to minimize microbial surface contamination and maintain ISO Class 5 air quality;

(II) Visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments and goggles;

(III) Confirmation that media-fill tests indicate that compounding personnel and personnel who have direct oversight of compounding personnel but do not compound can competently perform aseptic procedures;

(IV) Review of all orders and packages of ingredients to ensure that the correct identity and amounts of ingredients were compounded; and

(V) Visual inspection of compounded sterile preparations, except for sterile radiopharmaceuticals, to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling.

(ii) Filter integrity testing. Filters shall undergo testing to evaluate the integrity of filters used to sterilize Category 2 prepared from any non-sterile starting component or Category 3 compounded sterile preparations, such as bubble point testing or comparable filter integrity testing. Such testing is not a replacement for sterility testing and shall not be interpreted as such. Such test shall be performed after a sterilization procedure on all filters used to sterilize each Category 2 prepared from any non-sterile starting component or Category 3 compounded sterile preparation or batch preparation and the results documented. The results should be compared with the filter manufacturer's specification for the specific filter used. If a filter fails the integrity test, the preparation or batch shall be sterilized again using new unused filters.

(B) Finished preparation release checks and tests.

(i) Each time a Category 3 compounded sterile preparation is prepared, it shall be tested for sterility and meet the requirements of Chapter 71, Sterility Tests of the USP/NF, or a validated alternative method that is noninferior to Chapter 71 testing. Each time a Category 2 injectable compounded sterile preparation compounded from one or more non-sterile components and assigned a beyond-use date that requires sterility testing is prepared, the preparation shall be tested to ensure that it does not contain excessive bacterial endotoxins. Each time a Category 3 injectable compounded sterile preparation compounded from one or more non-sterile components is prepared, the preparation shall be tested to ensure that it does not contain excessive bacterial endotoxins.

(ii) All compounded sterile preparations, except for sterile radiopharmaceuticals, that are intended to be solutions shall be visually examined for the presence of particulate matter and not administered or dispensed when such matter is observed.

(iii) The prescription drug and medication orders, written compounding procedure, preparation records, and expended materials used to make compounded sterile preparations shall be inspected for accuracy of correct identities and amounts of ingredients, aseptic mixing and sterilization, packaging, labeling, and expected physical appearance before they are dispensed or administered.

(iv) Written procedures for checking compounding accuracy shall be followed for every compounded sterile preparation during preparation, in accordance with pharmacy's policies and procedures, and immediately prior to release, including label accuracy and the accuracy of the addition of all drug products or ingredients used to prepare the finished preparation and their volumes or quantities. A pharmacist shall ensure that components used in compounding are accurately weighed, measured, or subdivided as appropriate to conform to the formula being prepared.

(C) Environmental testing.

(i) Viable and nonviable environmental sampling testing. Environmental sampling shall occur, at a minimum, every six months as part of a comprehensive quality management program and under any of the following conditions:

(I) as part of the commissioning and certification of new facilities and equipment;

(II) following any servicing of facilities and equipment;

(III) as part of the re-certification of facilities and equipment;

(IV) in response to identified problems with end products or staff technique; or

(V) in response to issues with compounded sterile preparations, observed compounding personnel work practices, or patient-related infections (where the compounded sterile preparation is being considered as a potential source of the infection).

(ii) Total particle counts. Certification that each ISO classified area (e.g., ISO Class 5, 7, and 8), is within established guidelines shall be performed no less than every six months and whenever the equipment is relocated or the physical structure of the buffer room or anteroom has been altered. All certification records shall be maintained and reviewed to ensure that the controlled environments comply with the proper air cleanliness, room pressures, and air changes per hour. These certification records shall include acceptance criteria and be made available upon inspection by the Board. Testing shall be performed by qualified operators using current, state-of-the-art equipment, with results of the following:

(I) ISO Class 5 - not more than 3,520 particles 0.5 microns and larger in diameter per cubic meter of air;

(II) ISO Class 7 - not more than 352,000 particles of 0.5 microns and larger in diameter per cubic meter of air for any buffer room; and

(III) ISO Class 8 - not more than 3,520,000 particles of 0.5 microns and larger in diameter per cubic meter of air for any anteroom.

(iii) Pressure differential monitoring. A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the buffer room and the anteroom and between the anteroom and the general environment outside the compounding area. The results shall be reviewed and documented on a log at least every work shift (minimum frequency shall be at least daily) or by a continuous recording device. The pressure between the ISO Class 7 or ISO Class 8 and the general pharmacy area shall not be less than 0.02 inch water column.

(iv) Sampling plan. An appropriate environmental sampling plan shall be developed for airborne viable particles based on a risk assessment of compounding activities performed. Selected sampling sites shall include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas and in the segregated compounding areas at greatest risk of contamination. The plan shall include sample location, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels.

(v) Viable air sampling. Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments shall be performed by properly trained individuals for all compounded sterile preparations. Volumetric active air sampling of all active classified areas using an impaction air sampler shall be conducted in each classified area (e.g., ISO Class 5 PEC and ISO Class 7 and 8 room(s)) during dynamic operating conditions. For entities compounding Category 1 or Category 2 compounded sterile preparations, this shall be completed at least every six months. For entities compounding any Category 3 compounded sterile preparations, this shall be completed within 30 days prior to the commencement of any Category 3 compounding and at least every three months thereafter regardless of the frequency of compounding Category 3 compounded sterile preparations. Air sampling sites shall be selected in all classified areas.

(vi) Air sampling process.

(I) A sufficient volume of air shall be sampled. Follow the manufacturer's instructions for operation of the impaction air sampler, including placement of media device(s). Using the impaction air sampler, test at least 1 cubic meter or 1,000 liters of air from each location sampled. At the end of each sampling period, retrieve the media device and cover it. Handle and store media devices to avoid contamination and prevent condensate from dropping onto the agar during incubation and affecting the accuracy of the cfu reading (e.g., invert plates). At the end of the designated sampling or exposure period for air sampling activities, the microbial growth media plates are recovered and their covers secured and they are inverted and incubated pursuant to the procedures in subclause (II) of this clause. Sampling data shall be collected and reviewed on a periodic basis as a means of evaluating the overall control of the compounding environment.

(II) Incubation procedures.

(-a-) Incubate the media device at 30 to 35 degrees Celsius for no less than 48 hours. Examine for growth. Record the total number of discrete colonies of microorganisms on each media device as cfu per cubic meter of air on an environmental sampling form based on sample type (i.e., viable air), sample location, and sample date.

(-b-) Then incubate the media at 20 to 25 degrees Celsius for no less than five additional days. Examine for growth. Record the total number of discrete colonies of microorganisms on each media device as cfu per cubic meter of air on an environmental sampling form based on sample type (i.e., viable air), sample location, and sample date.

(-c-) Alternatively, to shorten the overall incubation period, two sampling media devices may be collected for each sample location and incubated concurrently.

(-1-) The media devices shall either both be trypticase soy agar or shall be one trypticase soy agar and the other fungal media (e.g., malt extract agar or Sabouraud dextrose agar).

(-2-) Incubate each media device in a separate incubator. Incubate one media device at 30 to 35 degrees Celsius for no less than 48 hours, and incubate the other media device at 20 to 25 degrees Celsius for no less than five days. If fungal media are used as one of the samples, incubate the fungal media sample at 20 to 25 degrees Celsius for no less than five days.

(-3-) Count the total number of discrete colonies of microorganisms on each media device, and record these results as cfu per cubic meter of air.

(-4-) Record the results of the sampling on an environmental sampling form based on sample type (i.e., viable air), and include the sample location and sample date.

(III) The following action levels for viable air sampling apply: a colony forming unit (cfu) count greater than 1 cfu per cubic meter of air for ISO Class 5, greater than 10 cfus per cubic meter of air for ISO Class 7, and greater than 100 cfus per cubic meter of air for ISO Class 8. If levels measured during viable air sampling exceed the action levels in this subclause for the ISO classification levels of the area sampled, the cause shall be investigated and corrective action shall be taken. Data collected in response to corrective actions shall be reviewed to confirm that the actions taken have been effective. The corrective action plan shall be dependent on the cfu count and the microorganism recovered. The corrective action plan shall be documented. If levels measured during viable air sampling exceed the action levels in this subclause, an attempt shall be made to identify any microorganism recovered to the genus level with the assistance of a competent microbiologist.

(vii) Compounding accuracy checks. Written procedures for checking compounding accuracy shall be followed for every compounded sterile preparation during preparation and immediately prior to release, including label accuracy and the accuracy of the addition of all drug products or ingredients used to prepare the finished preparation and their volumes or quantities. At each step of the compounding process, the pharmacist shall ensure that components used in compounding are accurately weighed, measured, or subdivided as appropriate to conform to the formula being prepared.

(17) Quality control.

(A) Quality control procedures. The pharmacy shall follow established quality control procedures to monitor the compounding environment and quality of compounded drug preparations for conformity with the quality indicators established for the preparation. When developing these procedures, pharmacy personnel shall consider the provisions of USP Chapter 71, Sterility Tests, USP Chapter 85, Bacterial Endotoxins Test, Pharmaceutical Compounding-Non-sterile Preparations, USP Chapter 795, USP Chapter 797, Pharmaceutical Compounding--Sterile Preparations, USP Chapter 800, Hazardous Drugs--Handling in Healthcare Settings, USP Chapter 823, Positron Emission Tomography Drugs for Compounding, Investigational, and Research Uses, USP Chapter 1160, Pharmaceutical Calculations in Prescription Compounding, and USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding of the current USP/NF. Such procedures shall be documented and be available for inspection.

(B) Verification of compounding accuracy and sterility.

(i) The accuracy of identities, concentrations, amounts, and purities of ingredients in compounded sterile preparations shall be confirmed by reviewing labels on packages, observing and documenting correct measurements with approved and correctly standardized devices, and reviewing information in labeling and certificates of analysis provided by suppliers.

(ii) If the correct identity, purity, strength, and sterility of ingredients and components of compounded sterile preparations cannot be confirmed such ingredients and components shall be discarded immediately. Any compounded sterile preparation that fails sterility testing following sterilization by one method (e.g., filtration) is to be discarded and not subjected to a second method of sterilization.

(iii) If individual ingredients, such as bulk drug substances, are not labeled with expiration dates, when the drug substances are stable indefinitely in their commercial packages under labeled storage conditions, such ingredients may gain or lose moisture during storage and use and shall require testing to determine the correct amount to weigh for accurate content of active chemical moieties in compounded sterile preparations.

(C) Sterility testing. Sterility testing shall be performed on a number of units equal to 5% of the number of compounded sterile preparations prepared, rounded up to the next whole number. Sterility tests resulting in failure shall prompt an investigation into the possible causes of the failure and shall include identification of the microorganism and an evaluation of the sterility testing procedure, compounding facility, process, and personnel that may have contributed to the failure. The sources of the contamination, if identified, shall be corrected and the pharmacy shall determine whether the conditions causing the sterility failure affect other compounded sterile preparations. The investigation and resulting corrective actions shall be documented.

(e) Records. Any testing, cleaning, procedures, or other activities required in this subsection shall be documented and such documentation shall be maintained by the pharmacy.

(1) Maintenance of records. Every record required under this section shall be:

(A) kept by the pharmacy and be available, for at least two years 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 shall be provided in an electronic format. 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) Compounding records.

(A) Compounding pursuant to patient specific prescription drug orders or medication orders not prepared from non-sterile ingredient(s). Compounding records for all compounded preparations shall be maintained by the pharmacy and shall include a complete formula, including methodology and necessary equipment which includes the brand name(s) of the raw materials, or if no brand name, the generic name(s) or official name and name(s) of the manufacturer(s) or distributor of the raw materials and the quantities of each; however, if the sterile preparation is compounded according to the manufacturer's labeling instructions, then documentation of the formula is not required.

(B) Compounding records for compounded sterile preparations prepared from non-sterile ingredient(s) or prepared for more than one patient.

(i) A master formulation record shall be created for compounded sterile preparations prepared from non-sterile ingredient(s) or prepared for more than one patient. Any changes or alterations to the master formulation record shall be approved and documented according to the pharmacy's SOPs. The master formulation record shall include at least the following information:

(I) name, strength or activity, and dosage form of the compounded sterile preparation;

(II) identities and amounts of all ingredients and, if applicable, relevant characteristics or components (e.g., particle size, salt form, purity grade, solubility, assay, loss on drying, water content);
(III) type and size of container closure system(s);
(IV) complete instructions for preparing the compounded sterile preparation, including equipment, supplies, a description of the compounding steps, and any special precautions;
(V) physical description of the final compounded sterile preparation, including desired pH of aqueous preparations for buffered eye drops and non-sterile to sterile compounding;
(VI) beyond-use date and storage requirements;
(VII) reference source to support the stability of the compounded sterile preparation;
(VIII) quality control procedures (e.g., pH testing, filter integrity testing); and
(IX) other information as needed to describe the compounding process and ensure repeatability (e.g., adjusting pH and tonicity; sterilization method, such as steam, dry heat, irradiation, or filter).

(ii) A compounding record that documents the compounding process shall be created for all compounded sterile preparations. The compounding record shall include at least the following information:

(I) name, strength or activity, and dosage form of the compounded sterile preparation;
(II) date and time of preparation of the compounded sterile preparation;
(III) assigned internal identification number (e.g., prescription, order, or lot number);
(IV) written or electronic signature or initials of the pharmacist or pharmacy technician or pharmacy technician trainee performing the compounding;
(V) written or electronic signature or initials of the pharmacist responsible for supervising pharmacy technicians or pharmacy technician trainees and conducting final checks of compounded preparations if pharmacy technicians or pharmacy technician trainees perform the compounding function;
(VI) name of each component;
(VII) vendor, lot number, and expiration date for each component for compounded sterile preparations prepared for more than one patient or prepared from non-sterile ingredient(s);
(VIII) weight or volume of each component;
(IX) strength or activity of each component;
(X) total quantity compounded;
(XI) final yield (e.g., quantity, containers, number of units);
(XII) assigned beyond-use date and storage requirements;
(XIII) results of quality control procedures (e.g., visual inspection, filter integrity testing, pH testing);
(XIV) if applicable, master formulation record for the compounded sterile preparation; and
(XV) if applicable, calculations made to determine and verify quantities or concentrations of components.

(f) Office use compounding and distribution of sterile compounded preparations.

(1) General.

(A) A pharmacy may compound, dispense, deliver, and distribute a compounded sterile preparation as specified in Subchapter D, Texas Pharmacy Act Chapter 562.

(B) A Class A-S pharmacy is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute sterile compounded preparations to a Class C or Class C-S pharmacy.

(C) A Class C-S pharmacy is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute sterile compounded preparations that the Class C-S pharmacy has compounded for other Class C or Class C-S pharmacies under common ownership.

(D) To compound and deliver a compounded preparation under this subsection, a pharmacy shall:

(i) verify the source of the raw materials to be used in a compounded drug;

(ii) comply with applicable United States Pharmacopeia guidelines, including the testing requirements, and the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191);

(iii) enter into a written agreement with a practitioner for the practitioner's office use of a compounded preparation;

(iv) comply with all applicable competency and accrediting standards as determined by the board; and

(v) comply with the provisions of this subsection.

(E) This subsection does not apply to Class B pharmacies compounding sterile radiopharmaceuticals that are furnished for departmental or physicians' use if such authorized users maintain a Texas radioactive materials license.

(2) Written Agreement. A pharmacy that provides sterile compounded preparations to practitioners for office use or to another pharmacy shall enter into a written agreement with the practitioner or pharmacy. The written agreement shall:

(A) address acceptable standards of practice for a compounding pharmacy and a practitioner and receiving pharmacy that enter into the agreement including a statement that the compounded drugs may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity except to a veterinarian as authorized by §563.054 of the Act;

(B) require the practitioner or receiving pharmacy to include on a patient's chart, medication order or medication administration record the lot number and beyond-use date of a compounded preparation administered to a patient; and

(C) describe the scope of services to be performed by the pharmacy and practitioner or receiving pharmacy, including a statement of the process for:

(i) a patient to report an adverse reaction or submit a complaint; and

(ii) the pharmacy to recall batches of compounded preparations.

(3) Recordkeeping.

(A) Maintenance of Records.

(i) Records of orders and distribution of sterile compounded preparations to a practitioner for office use or to an institutional pharmacy for administration to a patient shall:

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

(II) be maintained separately from the records of preparations dispensed pursuant to a prescription or medication order; and

(III) be supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy or its representative. If the pharmacy maintains the records in an electronic format, the requested records shall be provided in an electronic format. Failure to provide the records set out in this subsection, either on site or within 72 hours for whatever reason, constitutes prima facie evidence of failure to keep and maintain records.

(ii) Records may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided the data processing system is capable of producing a hard copy of the record upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.

(B) Orders. The pharmacy shall maintain a record of all sterile compounded preparations ordered by a practitioner for office use or by an institutional pharmacy for administration to a patient. The record shall include the following information:

(i) date of the order;

(ii) name, address, and phone number of the practitioner who ordered the preparation and if applicable, the name, address and phone number of the institutional pharmacy ordering the preparation; and

(iii) name, strength, and quantity of the preparation ordered.

(C) Distributions. The pharmacy shall maintain a record of all sterile compounded preparations distributed pursuant to an order to a practitioner for office use or by an institutional pharmacy for administration to a patient. The record shall include the following information:

(i) date the preparation was compounded;

(ii) date the preparation was distributed;

(iii) name, strength and quantity in each container of the preparation;

(iv) pharmacy's lot number;

(v) quantity of containers shipped; and

(vi) name, address, and phone number of the practitioner or institutional pharmacy to whom the preparation is distributed.

(D) Audit trail.

(i) The pharmacy shall store the order and distribution records of preparations for all sterile compounded preparations ordered by and or distributed to a practitioner for office use or by a pharmacy licensed to compound sterile preparations for administration to a patient in such a manner as to be able to provide an audit trail for all orders and distributions of any of the following during a specified time period:

(I) any strength and dosage form of a preparation (by either brand or generic name or both);

(II) any ingredient;

(III) any lot number;

(IV) any practitioner;

(V) any facility; and

(VI) any pharmacy, if applicable.

(ii) The audit trail shall contain the following information:

(I) date of order and date of the distribution;

(II) practitioner's name, address, and name of the institutional pharmacy, if applicable;

(III) name, strength and quantity of the preparation in each container of the preparation;

(IV) name and quantity of each active ingredient;

(V) quantity of containers distributed; and

(VI) pharmacy's lot number.

(4) Labeling. The pharmacy shall affix a label to the preparation containing the following information:

(A) name, address, and phone number of the compounding pharmacy;

(B) the statement: "For Institutional or Office Use Only--Not for Resale"; or if the preparation is distributed to a veterinarian the statement: "Compounded Preparation";

(C) name and strength of the preparation or list of the active ingredients and strengths;

(D) pharmacy's lot number;
(E) beyond-use date as determined by the pharmacist using appropriate documented criteria;
(F) quantity or amount in the container;
(G) appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and
(H) device-specific instructions, where appropriate.

(g) Recall procedures.

(1) The pharmacy shall have SOPs for the recall of any compounded sterile preparation provided to a patient, to a practitioner for office use, or a pharmacy for administration. The SOPs shall include, but not be limited to the requirements as specified in paragraph (3) of this subsection.

(2) The pharmacy shall immediately initiate a recall of any sterile preparation compounded by the pharmacy upon identification of a potential or confirmed harm to a patient.

(3) In the event of a recall, the pharmacist-in-charge shall ensure that:

(A) the distribution of any affected compounded sterile preparation is determined, including the date and quantity of distribution;
(B) each practitioner, facility, and/or pharmacy to which the preparation was distributed is notified, in writing, of the recall;
(C) each patient to whom the preparation was dispensed is notified, in writing, of the recall;
(D) the board is notified of the recall, in writing, not later than 24 hours after the recall is issued;
(E) if the preparation is distributed for office use, the Texas Department of State Health Services, Drugs and Medical Devices Group, is notified of the recall, in writing;
(F) any unused dispensed compounded sterile preparations are recalled and any stock remaining in the pharmacy is quarantined; and
(G) the pharmacy keeps a written record of the recall including all actions taken to notify all parties and steps taken to ensure corrective measures.

(4) Recall of out-of-specification dispensed compounded sterile preparations.

(A) If a compounded sterile preparation is dispensed or administered before the results of testing are known, the pharmacy shall have SOPs in place to:

(i) immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (e.g., sterility, strength, purity, bacterial endotoxin, or other quality attributes); and
(ii) investigate if other lots are affected and recall if necessary.

(B) SOPs for recall of out-of-specification dispensed compounded sterile preparations shall contain procedures to:

(i) determine the severity of the problem and the urgency for implementation and completion of the recall;
(ii) determine the disposal and documentation of the recalled compounded sterile preparation; and
(iii) investigate and document the reason for failure.

(5) If a pharmacy fails to initiate a recall, the board may require a pharmacy to initiate a recall if there is potential for or confirmed harm to a patient.

(6) A pharmacy that compounds sterile preparations shall notify the board immediately of any adverse effects reported to the pharmacy or that are known by the pharmacy to be potentially attributable to a sterile preparation compounded by the pharmacy.

SUBCHAPTER H – OTHER CLASSES OF PHARMACY

§291.151 Pharmacies Located in a Freestanding Emergency Medical Care Facility (Class F)

(a) Purpose. The purpose of this section is to provide standards in the conduct, practice activities, and operation of a pharmacy located in a freestanding emergency medical care facility that is licensed by the Texas Department of State Health Services or in a freestanding emergency medical care facility operated by a hospital that is exempt from registration as provided by §254.052, Health and Safety Code. Class F pharmacies located in a freestanding emergency medical care facility shall comply with this section.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Act--The Texas Pharmacy Act, Occupations Code, Subtitle J, as amended.

(2) Administer--The direct application of a prescription drug by injection, inhalation, ingestion, or any other means to the body of a patient by:

(A) a practitioner, an authorized agent under his supervision, or other person authorized by law; or

(B) the patient at the direction of a practitioner.

(3) Automated medication supply system--A mechanical system that performs operations or activities relative to the storage and distribution of medications for administration and which collects, controls, and maintains all transaction information.

(4) Board--The Texas State Board of Pharmacy.

(5) Consultant pharmacist--A pharmacist retained by a facility on a routine basis to consult with the FEMCF in areas that pertain to the practice of pharmacy.

(6) Controlled substance--A drug, immediate precursor, or other substance listed in Schedules I - V or Penalty Groups 1 - 4 of the Texas Controlled Substances Act, as amended, or a drug immediate precursor, or other substance included in Schedules I - V of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public Law 91-513).

(7) Dispense--Preparing, packaging, compounding, or labeling for delivery a prescription drug or device in the course of professional practice to an ultimate user or his agent by or pursuant to the lawful order of a practitioner.

(8) Distribute--The delivery of a prescription drug or device other than by administering or dispensing.

(9) Downtime--Period of time during which a data processing system is not operable.

(10) Electronic signature--A unique security code or other identifier which specifically identifies the person entering information into a data processing system. A facility which utilizes electronic signatures must:

(A) maintain a permanent list of the unique security codes assigned to persons authorized to use the data processing system; and

(B) have an ongoing security program which is capable of identifying misuse and/or unauthorized use of electronic signatures.

(11) Floor stock--Prescription drugs or devices not labeled for a specific patient and maintained at a nursing station or other FEMCF department (excluding the pharmacy) for the purpose of administration to a patient of the FEMCF.

(12) Formulary--List of drugs approved for use in the FEMCF by an appropriate committee of the FEMCF.

(13) Freestanding emergency medical care facility (FEMCF)--A freestanding facility that is licensed by the Texas Department of State Health Services pursuant to Chapter 254, Health and Safety Code, to provide emergency care to patients.

(14) Hard copy--A physical document that is readable without the use of a special device (i.e., data processing system, computer, etc.).

(15) Investigational new drug--New drug intended for investigational use by experts qualified to evaluate the safety and effectiveness of the drug as authorized by the federal Food and Drug Administration.

(16) Medication order--An order from a practitioner or his authorized agent for administration of a drug or device.

(17) Pharmacist-in-charge--Pharmacist designated on a pharmacy license as the pharmacist who has the authority or responsibility for a pharmacy's compliance with laws and rules pertaining to the practice of pharmacy.

(18) Pharmacy--Area or areas in a facility, separate from patient care areas, where drugs are stored, bulk compounded, delivered, compounded, dispensed, and/or distributed to other areas or departments of the FEMCF, or dispensed to an ultimate user or his or her agent.

(19) Prescription drug--

(A) A substance for which federal or state law requires a prescription before it may be legally dispensed to the public;

(B) A drug or device that under federal law is required, prior to being dispensed or delivered, to be labeled with either of the following statements:

(i) Caution: federal law prohibits dispensing without prescription or "Rx only" or another legend that complies with federal law; or

(ii) Caution: federal law restricts this drug to use by or on order of a licensed veterinarian; or

(C) A drug or device that is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by a practitioner only.

(20) Prescription drug order--

(A) An order from a practitioner or his authorized agent to a pharmacist for a drug or device to be dispensed; or

(B) An order pursuant to Subtitle B, Chapter 157, Occupations Code.

(21) Full-time pharmacist--A pharmacist who works in a pharmacy from 30 to 40 hours per week or if the pharmacy is open less than 60 hours per week, one-half of the time the pharmacy is open.

(22) Part-time pharmacist--A pharmacist who works less than full-time.

(23) Pharmacy technician--An individual who is registered with the board as a pharmacy technician and whose responsibility in a pharmacy is to provide technical services that do not require professional judgment regarding preparing and distributing drugs and who works under the direct supervision of and is responsible to a pharmacist.

(24) Pharmacy technician trainee--An individual who is registered with the board as a pharmacy technician trainee and is authorized to participate in a pharmacy's technician training program.

(25) Texas Controlled Substances Act--The Texas Controlled Substances Act, Health and Safety Code, Chapter 481, as amended.

(c) Personnel.

(1) Pharmacist-in-charge.

(A) General. Each FEMCF shall have one pharmacist-in-charge who is employed or under contract, at least on a consulting or part-time basis, but may be employed on a full-time basis.

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

(i) establishing specifications for procurement and storage of all materials, including drugs, chemicals, and biologicals;

(ii) participating in the development of a formulary for the FEMCF, subject to approval of the appropriate committee of the FEMCF;

(iii) distributing drugs to be administered to patients pursuant to the practitioner's medication order;

(iv) filling and labeling all containers from which drugs are to be distributed or dispensed;

(v) maintaining and making available a sufficient inventory of antidotes and other emergency drugs, both in the pharmacy and patient care areas, as well as current antidote information, telephone numbers of regional poison control center and other emergency assistance

organizations, and such other materials and information as may be deemed necessary by the appropriate committee of the FEMCF;

(vi) maintaining records of all transactions of the FEMCF pharmacy as may be required by applicable state and federal law, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials;

(vii) participating in those aspects of the FEMCF's patient care evaluation program which relate to pharmaceutical material utilization and effectiveness;

(viii) participating in teaching and/or research programs in the FEMCF;

(ix) implementing the policies and decisions of the appropriate committee(s) relating to pharmaceutical services of the FEMCF;

(x) providing effective and efficient messenger and delivery service to connect the FEMCF pharmacy with appropriate areas of the FEMCF on a regular basis throughout the normal workday of the FEMCF;

(xi) labeling, storing, and distributing investigational new drugs, including maintaining information in the pharmacy and nursing station where such drugs are being administered, concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interactions, and symptoms of toxicity of investigational new drugs;

(xii) meeting all inspection and other requirements of the Texas Pharmacy Act and this section; and

(xiii) maintaining records in a data processing system such that the data processing system is in compliance with the requirements for an FEMCF; and

(xiv) ensuring that a pharmacist visits the FEMCF at least once each calendar week that the facility is open.

(2) Consultant pharmacist.

(A) The consultant pharmacist may be the pharmacist-in-charge.

(B) A written contract shall exist between the FEMCF and any consultant pharmacist, and a copy of the written contract shall be made available to the board upon request.

(3) Pharmacists.

(A) General.

(i) The pharmacist-in-charge shall be assisted by a sufficient number of additional licensed pharmacists as may be required to operate the FEMCF pharmacy competently, safely, and adequately to meet the needs of the patients of the facility.

(ii) All pharmacists shall assist the pharmacist-in-charge in meeting the responsibilities as outlined in paragraph (1)(B) of this subsection and in ordering, administering, and accounting for pharmaceutical materials.

(iii) All pharmacists shall be responsible for any delegated act performed by pharmacy technicians or pharmacy technician trainees under his or her supervision.

(iv) All pharmacists while on duty shall be responsible for complying with all state and federal laws or rules governing the practice of pharmacy.

(B) Duties. Duties of the pharmacist-in-charge and all other pharmacists shall include, but need not be limited to, the following:

(i) receiving and interpreting prescription drug orders and oral medication orders and reducing these orders to writing either manually or electronically;

(ii) selecting prescription drugs and/or devices and/or suppliers; and

(iii) interpreting patient profiles.

(C) Special requirements for compounding non-sterile preparations. All pharmacists engaged in compounding non-sterile preparations shall meet the training requirements specified in §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

(4) Pharmacy technicians and pharmacy technician trainees.

(A) General. All pharmacy technicians and pharmacy technician trainees shall meet the training requirements specified in §297.6 of this title (relating to Pharmacy Technician and Pharmacy Technician Trainee Training).

(B) Duties. Pharmacy technicians and pharmacy technician trainees may not perform any of the duties listed in paragraph (3)(B) of this subsection. Duties may include, but need not be limited to, the following functions, under the direct supervision of a pharmacist:

(i) prepacking and labeling unit and multiple dose packages, provided a pharmacist supervises and conducts a final check and affixes his or her name, initials, or electronic signature to the appropriate quality control records prior to distribution;

(ii) preparing, packaging, compounding, or labeling prescription drugs pursuant to medication orders, provided a pharmacist supervises and checks the preparation;

(iii) compounding non-sterile preparations pursuant to medication orders provided the pharmacy technicians or pharmacy technician trainees have completed the training specified in §291.131 of this title;

(iv) bulk compounding, provided a pharmacist supervises and conducts in-process and final checks and affixes his or her name, initials, or electronic signature to the appropriate quality control records prior to distribution;

(v) distributing routine orders for stock supplies to patient care areas;

(vi) entering medication order and drug distribution information into a data processing system, provided judgmental decisions are not required and a pharmacist checks the accuracy of the information entered into the system prior to releasing the order or in compliance with the absence of pharmacist requirements contained in subsection (d)(6)(D) and (E) of this section;

(vii) maintaining inventories of drug supplies;

(viii) maintaining pharmacy records; and

(ix) loading drugs into an automated medication supply system. For the purpose of this clause, direct supervision may be accomplished by physically present supervision or electronic monitoring by a pharmacist.

(C) Procedures.

(i) Pharmacy technicians and pharmacy technician trainees shall handle medication orders in accordance with standard written procedures and guidelines.

(ii) Pharmacy technicians and pharmacy technician trainees shall handle prescription drug orders in the same manner as pharmacy technicians or pharmacy technician trainees working in a Class A pharmacy.

(D) Special requirements for compounding non-sterile preparations. All pharmacy technicians and pharmacy technician trainees engaged in compounding non-sterile preparations shall meet the training requirements specified in §291.131 of this title.

(5) Owner. The owner of an FEMCF 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:

(A) establishing policies for procurement of prescription drugs and devices and other products dispensed from the FEMCF pharmacy;

(B) establishing and maintaining effective controls against the theft or diversion of prescription drugs;

(C) if the pharmacy uses an automated medication supply system, reviewing and approving all policies and procedures for system operation, safety, security, accuracy and access, patient confidentiality, prevention of unauthorized access, and malfunction;

(D) providing the pharmacy with the necessary equipment and resources commensurate with its level and type of practice; and

(E) establishing policies and procedures regarding maintenance, storage, and retrieval of records in a data processing system such that the system is in compliance with state and federal requirements.

(6) Identification of pharmacy personnel. All pharmacy personnel shall be identified as follows:

(A) Pharmacy technicians. All pharmacy technicians shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacy technician.

(B) Pharmacy technician trainees. All pharmacy technician trainees shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacy technician trainee.

(C) Pharmacist interns. All pharmacist interns shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacist intern.

(D) Pharmacists. All pharmacists shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacist.

(d) Operational standards.

(1) Licensing requirements.

(A) An FEMCF pharmacy shall register annually or biennially with the board on a pharmacy license application provided by the board, following the procedures specified in §291.1 of this title (relating to Pharmacy License Application).

(B) An FEMCF pharmacy which changes ownership shall notify the board within 10 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).

(C) An FEMCF pharmacy which changes location and/or name shall notify the board of the change within 10 days and file for an amended license as specified in §291.3 of this title.

(D) A pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within 10 days of the change, following the procedures in §291.3 of this title.

(E) An FEMCF pharmacy shall notify the board in writing within 10 days of closing, following the procedures in §291.5 of this title (relating to Closing a Pharmacy).

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

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

(H) An FEMCF pharmacy, which also operates another type of pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(1), concerning community pharmacy (Class A), is not required to secure a license for the other type of pharmacy; provided, however, such license is required to comply with the provisions of §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), to the extent such sections are applicable to the operation of the pharmacy.

(I) An FEMCF pharmacy engaged in the compounding of non-sterile preparations shall comply with the provisions of §291.131 of this title.

(2) Environment.

(A) General requirements.

(i) Each FEMCF shall have a designated work area separate from patient areas, and which shall have space adequate for the size and scope of pharmaceutical services and shall have adequate space and security for the storage of drugs.

(ii) The FEMCF pharmacy shall be arranged in an orderly fashion and shall be kept clean. All required equipment shall be clean and in good operating condition.

(B) Special requirements.

(i) The FEMCF pharmacy shall have locked storage for Schedule II controlled substances and other controlled drugs requiring additional security.

(ii) The FEMCF pharmacy shall have a designated area for the storage of poisons and externals separate from drug storage areas.

(C) Security.

(i) The pharmacy and storage areas for prescription drugs and/or devices shall be enclosed and capable of being locked by key, combination, or other mechanical or electronic means, so as to prohibit access by unauthorized individuals. Only individuals authorized by the pharmacist-in-charge may enter the pharmacy or have access to storage areas for prescription drugs and/or devices.

(ii) The pharmacist-in-charge shall consult with FEMCF personnel with respect to security of the drug storage areas, including provisions for adequate safeguards against theft or diversion of dangerous drugs, controlled substances, and records for such drugs.

(iii) The pharmacy shall have locked storage for Schedule II controlled substances and other drugs requiring additional security.

(3) Equipment and supplies. FEMCFs supplying drugs for outpatient use shall have the following equipment and supplies:

(A) data processing system including a printer or comparable equipment;

(B) adequate supply of child-resistant, moisture-proof, and light-proof containers; and

(C) adequate supply of prescription labels and other applicable identification labels.

(4) Library. A reference library shall be maintained that includes the following in hard copy or electronic format and that pharmacy personnel shall be capable of accessing at all times:

(A) current copies of the following:

(i) Texas Pharmacy Act and rules;

(ii) Texas Dangerous Drug Act and rules;

(iii) Texas Controlled Substances Act and rules; and

(iv) Federal Controlled Substances Act and rules or official publication describing the requirements of the Federal Controlled Substances Act and rules;

(B) at least one current or updated general drug information reference which is required to contain drug interaction information including information needed to determine severity or significance of the interaction and appropriate recommendations or actions to be taken; and

(C) basic antidote information and the telephone number of the nearest regional poison control center.

(5) Drugs.

(A) Procurement, preparation, and storage.

(i) The pharmacist-in-charge shall have the responsibility for the procurement and storage of drugs, but may receive input from other appropriate staff of the facility, relative to such responsibility.

(ii) The pharmacist-in-charge shall have the responsibility for determining specifications of all drugs procured by the facility.

(iii) FEMCF pharmacies may not sell, purchase, trade, or possess prescription drug samples, unless the pharmacy meets the requirements as specified in §291.16 of this title (relating to Samples).

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

(v) Any drug bearing an expiration date may not be dispensed or distributed beyond the expiration date of the drug.

(vi) Outdated drugs shall be removed from dispensing stock and shall be quarantined together until such drugs are disposed of.

(B) Formulary.

(i) A formulary may be developed by an appropriate committee of the FEMCF.

(ii) The pharmacist-in-charge, consultant pharmacist, or designee shall be a full voting member of any committee which involves pharmaceutical services.

(iii) A practitioner may grant approval for pharmacists at the FEMCF to interchange, in accordance with the facility's formulary, for the drugs on the practitioner's medication orders provided:

(I) a formulary has been developed;

(II) the formulary has been approved by the medical staff of the FEMCF;

(III) there is a reasonable method for the practitioner to override any interchange; and

(IV) the practitioner authorizes a pharmacist in the FEMCF to interchange on his/her medication orders in accordance with the facility's formulary through his/her written agreement to abide by the policies and procedures of the medical staff and facility.

(C) Prepackaging and loading drugs into automated medication supply system.

(i) Prepackaging of drugs.

(I) Drugs may be prepackaged in quantities suitable for internal distribution only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist.

(II) The label of a prepackaged unit shall indicate:

(-a-) brand name and strength of the drug; or if no brand name, then the generic name, strength, and name of the manufacturer or distributor;

(-b-) facility's lot number;

(-c-) expiration date; and

(-d-) quantity of the drug, if quantity is greater than one.

(III) Records of prepackaging shall be maintained to show:

(-a-) the name of the drug, strength, and dosage form;

(-b-) facility's lot number;

(-c-) manufacturer or distributor;

(-d-) manufacturer's lot number;

(-e-) expiration date;

(-f-) quantity per prepackaged unit;

(-g-) number of prepackaged units;

(-h-) date packaged;

(-i-) name, initials, or electronic signature of the prepacker; and

(-j-) signature or electronic signature of the responsible pharmacist.

(IV) Stock packages, repackaged units, and control records shall be quarantined together until checked/released by the pharmacist.

(ii) Loading bulk unit of use drugs into automated medication supply systems. Automated medication supply systems may be loaded with bulk unit of use drugs only by a pharmacist, by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist, or by a licensed nurse who is authorized by the pharmacist to perform the loading of the automated medication supply system. For the purpose of this clause, direct supervision may be accomplished by physically present supervision or electronic monitoring by a pharmacist. In order for the pharmacist to electronically monitor, the medication supply system must allow for bar code scanning to verify the loading of drugs, and a

record of the loading must be maintained by the system and accessible for electronic review by the pharmacist.

(6) Medication orders.

(A) Drugs may be administered to patients in FEMCFs only on the order of a practitioner. No change in the order for drugs may be made without the approval of a practitioner except as authorized by the practitioner in compliance with paragraph (5)(B) of this subsection.

(B) Drugs may be distributed only pursuant to the copy of the practitioner's medication order.

(C) FEMCF pharmacies shall be exempt from the labeling provisions and patient notification requirements of §562.006 and §562.009 of the Act, as respects drugs distributed pursuant to medication orders.

(D) In FEMCFs with a full-time pharmacist, if a practitioner orders a drug for administration to a bona fide patient of the facility when the pharmacy is closed, the following is applicable:

(i) prescription drugs and devices only in sufficient quantities for immediate therapeutic needs of a patient may be removed from the FEMCF pharmacy;

(ii) only a designated licensed nurse or practitioner may remove such drugs and devices;

(iii) a record shall be made at the time of withdrawal by the authorized person removing the drugs and devices. The record shall contain the following information:

(I) name of the patient;

(II) name of device or drug, strength, and dosage form;

(III) dose prescribed;

(IV) quantity withdrawn;

(V) time and date; and

(VI) signature or electronic signature of the person making the withdrawal;.

(iv) the medication order in the patient's chart may substitute for such record, provided the medication order meets all the requirements of clause (iii) of this subparagraph;

(v) the pharmacist shall verify the withdrawal of a controlled substance as soon as practical, but in no event more than 72 hours from the time of such withdrawal; and

(vi) the pharmacist shall verify the withdrawal of a dangerous drug at a reasonable interval, but such verification must occur at least once in every calendar week.

(E) In FEMCFs with a part-time or consultant pharmacist, if a practitioner orders a drug for administration to a bona fide patient of the FEMCF when the pharmacist is not on duty, or when the pharmacy is closed, the following is applicable:

(i) prescription drugs and devices only in sufficient quantities for therapeutic needs may be removed from the FEMCF pharmacy;

(ii) only a designated licensed nurse or practitioner may remove such drugs and devices;

(iii) a record shall be made at the time of withdrawal by the authorized person removing the drug or device as described in clauses (6)(D)(iii) and (iv) of this subsection; and

(iv) the pharmacist shall verify withdrawals at a reasonable interval, but such verification must occur at least once in every calendar week that the pharmacy is open.

(7) Floor stock. In facilities using a floor stock method of drug distribution, the pharmacy shall establish designated floor stock areas outside of the central pharmacy where drugs may be stored, in accordance with the pharmacy's policies and procedures. The following is applicable for removing drugs or devices in the absence of a pharmacist:

(A) prescription drugs and devices may be removed from the pharmacy only in the original manufacturer's container or prepackaged container;

(B) only a designated licensed nurse or practitioner may remove such drugs and devices;

(C) a record shall be made at the time of withdrawal by the authorized person removing the drug or device and the record shall contain the following information:

(i) name of the drug, strength, and dosage form;
(ii) quantity removed;
(iii) location of floor stock;
(iv) date and time; and
(v) signature or electronic signature of person making the withdrawal;

(D) the medication order in the patient's chart may substitute for the record required in subparagraph (C) of this paragraph, provided the medication order meets all the requirements of subparagraph (C) of this paragraph; and

(E) if a stored drug or device is returned to the pharmacy from floor stock areas, a record shall be made by the authorized person returning the drug or device. The record shall contain the following information:

(i) drug name, strength, and dosage form, or device name;
(ii) quantity returned;
(iii) previous floor stock location for the drug or device;
(iv) date and time; and
(v) signature or electronic signature of person returning the drug or device.

(8) Policies and procedures. Written policies and procedures for a drug distribution system, appropriate for the freestanding emergency medical facility, shall be developed and implemented by the pharmacist-in-charge with the advice of the appropriate committee. The written policies and procedures for the drug distribution system shall include, but not be limited to, procedures regarding the following:

(A) controlled substances;
(B) investigational drugs;
(C) prepackaging and manufacturing;
(D) medication errors;
(E) orders of physician or other practitioner;
(F) floor stocks;
(G) adverse drug reactions;
(H) drugs brought into the facility by the patient;
(I) self-administration;
(J) emergency drug tray;
(K) formulary, if applicable;
(L) drug storage areas;
(M) drug samples;
(N) drug product defect reports;
(O) drug recalls;
(P) outdated drugs;
(Q) preparation and distribution of IV admixtures;
(R) procedures for supplying drugs for postoperative use, if applicable;
(S) use of automated medication supply systems;
(T) use of data processing systems; and
(U) drug regimen review.

(9) Drugs supplied for outpatient use. Drugs provided to patients for take home use shall be supplied according to the following procedures.

(A) Drugs may only be supplied to patients who have been admitted to the FEMCF.

(B) Drugs may only be supplied in accordance with the system of control and accountability established for drugs supplied from the FEMCF; such system shall be developed and supervised by the pharmacist-in-charge or staff pharmacist designated by the pharmacist-in-charge.

(C) Only drugs listed on the approved outpatient drug list may be supplied; such list shall be developed by the pharmacist-in-charge and the medical staff and shall consist of drugs of the nature and type to meet the immediate postoperative needs of the FEMCF patient.

(D) Drugs may only be supplied in prepackaged quantities not to exceed a 72-hour supply in suitable containers and appropriately prelabeled (including name, address, and phone number of the facility and necessary auxiliary labels) by the pharmacy, provided, however that topicals and ophthalmics in original manufacturer's containers may be supplied in a quantity exceeding a 72-hour supply.

(E) At the time of delivery of the drug, the practitioner shall complete the label, such that the prescription container bears a label with at least the following information:

(i) date supplied;

(ii) name of practitioner;

(iii) name of patient;

(iv) directions for use;

(v) brand name and strength of the drug; or if no brand name, then the generic name of the drug dispensed, strength, and the name of the manufacturer or distributor of the drug; and

(vi) unique identification number.

(F) After the drug has been labeled, the practitioner or a licensed nurse under the supervision of the practitioner shall give the appropriately labeled, prepackaged medication to the patient.

(G) A perpetual record of drugs which are supplied from the FEMCF shall be maintained which includes:

(i) name, address, and phone number of the facility;

(ii) date supplied;

(iii) name of practitioner;

(iv) name of patient;

(v) directions for use;

(vi) brand name and strength of the drug; or if no brand name, then the generic name of the drug dispensed, strength, and the name of the manufacturer or distributor of the drug; and

(vii) unique identification number.

(H) The pharmacist-in-charge, or a pharmacist designated by the pharmacist-in-charge, shall review the records at least once in every calendar week that the pharmacy is open.

(10) Drug regimen review.

(A) A pharmacist shall evaluate medication orders and patient medication records for:

(i) known allergies;

(ii) rational therapy--contraindications;

(iii) reasonable dose and route of administration;

(iv) reasonable directions for use;

(v) duplication of therapy;

(vi) drug-drug interactions;

(vii) drug-food interactions;

(viii) drug-disease interactions;

(ix) adverse drug reactions;

(x) proper utilization, including overutilization or underutilization; and

(xi) clinical laboratory or clinical monitoring methods to monitor and evaluate drug effectiveness, side effects, toxicity, or adverse effects, and appropriateness to continued use of the drug in its current regimen.

(B) A retrospective, random drug regimen review as specified in the pharmacy's policies and procedures shall be conducted on a periodic basis to verify proper usage of drugs not to exceed 31 days between such reviews.

(C) Any questions regarding the order must be resolved with the prescriber and a written notation of these discussions made and maintained.

(e) Records.

(1) Maintenance of records.

(A) Every inventory or other record required to be kept under the provisions of this section (relating to Pharmacies Located in a Freestanding Emergency Medical Care Facility (Class F) shall be:

(i) 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 other authorized local, state, or federal law enforcement agencies; and

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

(B) Records of controlled substances listed in Schedule II shall be maintained separately and readily retrievable from all other records of the pharmacy.

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

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

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

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

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

(F) An FEMCF pharmacy shall maintain a perpetual inventory of controlled substances listed in Schedules II - V which shall be verified by a pharmacist for completeness and reconciled at least once in every calendar week that the pharmacy is open.

(G) Distribution records for controlled substances, listed in Schedules II - V shall include the following information:

(i) patient's name;

(ii) practitioner's name who ordered the drug;

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

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

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

(vi) returns to the pharmacy; and

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

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

(I) A pharmacist shall conduct an audit by randomly comparing the distribution records required by subparagraph (G) with the medication orders in the patient record on a periodic basis to verify proper administration of drugs not to exceed 30 days between such reviews.

(2) Patient records.

(A) Each medication order or set of orders issued together shall bear the following information:

(i) patient name;

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

(iii) directions for use;

(iv) date; and

(v) signature or electronic signature of the practitioner or that of his or her authorized agent, defined as a licensed nurse employee or consultant/full or part-time pharmacist of the FEMCF.

(B) Medication orders shall be maintained with the medication administration record in the medical records of the patient.

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

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

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

(C) A pharmacy that changes or discontinues use of a data processing system must:

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

(ii) purge the records to a printout which contains:

(I) all of the information required on the original document; or

(II) for records of distribution and return for all controlled substances, the same information as required on the audit trail printout as specified in subparagraph (F) of this paragraph. The information on the printout shall be sorted and printed by drug name and list all distributions and returns chronologically.

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

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

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

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

(ii) prescribing or attending practitioner's name;

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

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

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

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

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

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

(H) The pharmacy may elect not to produce the monthly audit trail printout if the data processing system has a workable (electronic) data retention system which can produce an audit trail of drug distribution and returns for the preceding two years. The audit trail required in this clause shall be supplied by the pharmacy within 72 hours, if requested by an authorized agent of the board, or other authorized local, state, or federal law enforcement or regulatory agencies.

(I) In the event that an FEMCF pharmacy which uses a data processing system experiences system downtime, the pharmacy must have an auxiliary procedure which will ensure that all data is retained for online data entry as soon as the system is available for use again.

(4) 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.

(A) The registrant to whom the controlled substance is to be distributed is registered under the Controlled Substances Act to possess that controlled substance.

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

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

(i) the actual date of distribution;

(ii) the name, strength, and quantity of controlled substances distributed;

(iii) the name, address, and DEA registration number of the distributing pharmacy; and

(iv) the name, address, and DEA registration number of the pharmacy, practitioner, or other registrant to whom the controlled substances are distributed.

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

(5) Other records. Other records to be maintained by the pharmacy include:

(A) a permanent log of the initials or identification codes which identifies each pharmacist by name. The initials or identification code shall be unique to ensure that each pharmacist can be identified, i.e., identical initials or identification codes cannot be used;

(B) suppliers' invoices of dangerous drugs and controlled substances dated and initialed or signed by the person receiving the drugs;

(i) a pharmacist shall verify that the controlled substances listed on the invoices were added to the pharmacy's perpetual inventory by clearly recording his/her initials and the date of review of the perpetual inventory; and

(ii) for controlled substances, the documents retained must contain the name, strength and quantity of controlled substances distributed, and the name, address and DEA number of both registrants; the supplier and the receiving pharmacy;

(C) supplier's credit memos for controlled substances and dangerous drugs;

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

(E) reports of surrender or destruction of controlled substances and/or dangerous drugs to an appropriate state or federal agency or reverse distributor;

(F) records of distribution of controlled substances and/or dangerous drugs to other pharmacies, practitioners, or registrants; and

(G) a copy of any notification required by the Texas Pharmacy Act or these rules, including, but not limited to, the following:

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

(ii) notification of a change in pharmacist-in-charge of a pharmacy; and

(iii) reports of a fire or other disaster 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.

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

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

(i) Prior to the initiation of central recordkeeping, the pharmacy submits written notification by registered or certified mail to the divisional director of DEA as required by the Code of Federal Regulations, Title 21, §1304(a), and submits a copy of this written notification to the board. Unless the registrant is informed by the divisional director of DEA that permission to keep central records is denied, the pharmacy may maintain central records commencing 14 days after receipt of notification by the divisional director;

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

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

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

(C) 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.

(D) 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.

§291.153 Central Prescription Drug or Medication Order Processing Pharmacy (Class G)

(a) Purpose.

(1) The purpose of this section is to provide standards for a centralized prescription drug or medication order processing pharmacy.

(2) Any facility established for the primary purpose of processing prescription drug or medication drug orders shall be licensed as a Class G pharmacy under the Act. A Class G pharmacy shall not store bulk drugs or dispense a prescription drug order. Nothing in this subsection shall prohibit an individual pharmacist employee, individual pharmacy technician employee, or individual pharmacy technician trainee employee who is licensed in Texas from remotely accessing the pharmacy's electronic database from a location other than a licensed pharmacy in order to process prescription or medication drug orders, provided the pharmacy establishes controls to protect the privacy and security of confidential records, and the Texas-licensed pharmacist, pharmacy technician, or pharmacy technician trainee does not engage in the receiving of written prescription or medication orders or the maintenance of prescription or medication drug orders at the non-licensed remote location.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section shall have the definition set out in the Act.

(1) Centralized prescription drug or medication order processing--The processing of prescription drug or medication orders by a Class G pharmacy on behalf of another pharmacy, a health care provider, or a payor. Centralized prescription drug or medication order processing does not include the dispensing of a prescription drug but includes any of the following:

(A) receiving, interpreting, or clarifying prescription drug or medication orders;
(B) data entering and transferring of prescription drug or medication order information;
(C) performing drug regimen review;
(D) obtaining refill and substitution authorizations;
(E) verifying accurate prescription data entry;
(F) interpreting clinical data for prior authorization for dispensing;
(G) performing therapeutic interventions; and
(H) providing drug information concerning a patient's prescription.

(2) Full-time pharmacist--A pharmacist who works in a pharmacy from 30 to 40 hours per week or, if the pharmacy is open less than 60 hours per week, one-half of the time the pharmacy is open.

(c) Personnel.

(1) Pharmacist-in-charge.

(A) General. Each Class G pharmacy shall have one pharmacist-in-charge who is employed on a full-time basis, who may be the pharmacist-in-charge for only one such pharmacy.

(B) Responsibilities. The pharmacist-in-charge shall have responsibility for the practice of pharmacy at the pharmacy for which he or she is the pharmacist-in-charge. The pharmacist-in-charge may advise the owner on administrative or operational concerns. The pharmacist-in-charge shall have responsibility for, at a minimum, the following:

(i) educating and training pharmacy technicians and pharmacy technician trainees;
(ii) maintaining records of all transactions of the Class G pharmacy required by applicable state and federal laws and regulations;
(iii) adhering to policies and procedures regarding the maintenance of records in a data processing system such that the data processing system is in compliance with Class G pharmacy requirements; and
(iv) legally operating the pharmacy, including meeting all inspection and other requirements of all state and federal laws or regulations governing the practice of pharmacy.

(2) Owner. The owner of a Class G 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:

(A) providing the pharmacy with the necessary equipment and resources commensurate with its level and type of practice; and
(B) establishing policies and procedures regarding maintenance, storage, and retrieval of records in a data processing system such that the system is in compliance with state and federal requirements.

(3) Pharmacists.

(A) General.

(i) The pharmacist-in-charge shall be assisted by a sufficient number of additional licensed pharmacists as may be required to operate the Class G pharmacy competently, safely, and adequately to meet the needs of the patients of the pharmacy.
(ii) All pharmacists shall assist the pharmacist-in-charge in meeting his or her responsibilities.
(iii) Pharmacists are solely responsible for the direct supervision of pharmacy technicians and pharmacy technician trainees and for designating and delegating duties, other than those listed in subparagraph (B) of this paragraph, to pharmacy technicians and pharmacy technician trainees. Each pharmacist shall be responsible for any delegated act performed by pharmacy technicians and pharmacy technician trainees under his or her supervision.

(iv) Pharmacists shall directly supervise pharmacy technicians and pharmacy technician trainees who are entering prescription data into the pharmacy's data processing system by one of the following methods.

(I) Physically present supervision. A pharmacist shall be physically present to directly supervise a pharmacy technician or pharmacy technician trainee who is entering prescription order or medication order data into the data processing system. Each prescription or medication order entered into the data processing system shall be verified at the time of data entry.

(II) Electronic supervision. A pharmacist may electronically supervise a pharmacy technician or pharmacy technician trainee who is entering prescription order or medication order data into the data processing system provided the pharmacist:

(-a-) has the ability to immediately communicate directly with the technician/trainee;

(-b-) has immediate access to any original document containing prescription or medication order information or other information related to the dispensing of the prescription or medication order. Such access may be through imaging technology provided the pharmacist has the ability to review the original, hardcopy documents if needed for clarification; and

(-c-) verifies the accuracy of the data entered information prior to the release of the information to the system for storage.

(III) Electronic verification of data entry by pharmacy technicians or pharmacy technician trainees. A pharmacist may electronically verify the data entry of prescription information into a data processing system provided:

(-a-) the pharmacist has the ability to immediately communicate directly with the technician/trainee;

(-b-) the pharmacist electronically conducting the verification is either a:

(-1-) Texas licensed pharmacist; or

(-2-) pharmacist employed by a Class E pharmacy that has the same owner as the Class G pharmacy where the pharmacy technicians/trainees are located or that has entered into a written contract or agreement with the Class G pharmacy which outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations;

(-c-) the pharmacy establishes controls to protect the privacy and security of confidential records; and

(-d-) the pharmacy keeps permanent records of prescriptions electronically verified for a period of two years.

(v) All pharmacists while on duty, shall be responsible for complying with all state and federal laws or rules governing the practice of pharmacy.

(B) Duties. Duties which may only be performed by a pharmacist are as follows:

(i) receiving oral prescription drug or medication orders for controlled substances and reducing these orders to writing, either manually or electronically;

(ii) interpreting prescription drug or medication orders;

(iii) selecting drug products;

(iv) verifying the data entry of the prescription drug or medication order information at the time of data entry prior to the release of the information to a Class A, Class C, or Class E pharmacy for dispensing;

(v) communicating to the patient or patient's agent information about the prescription drug or device which in the exercise of the pharmacist's professional judgment, the pharmacist deems significant, as specified in §291.33(c) of this title (relating to Operational Standards);
(vi) communicating to the patient or the patient's agent on his or her request information concerning any prescription drugs dispensed to the patient by the pharmacy;
(vii) assuring that a reasonable effort is made to obtain, record, and maintain patient medication records; and
(viii) interpreting patient medication records and performing drug regimen reviews.

(4) Pharmacy Technicians and Pharmacy Technician Trainees.

(A) General. All pharmacy technicians and pharmacy technician trainees shall meet the training requirements specified in §297.6 of this title (relating to Pharmacy Technician and Pharmacy Technician Trainee Training).

(B) Duties.

(i) Pharmacy technicians and pharmacy technician trainees may not perform any of the duties listed in paragraph (3)(B) of this subsection.

(ii) A pharmacist may delegate to pharmacy technicians and pharmacy technician trainees any nonjudgmental technical duty associated with the preparation and distribution of prescription drugs provided:

(I) a pharmacist verifies the accuracy of all acts, tasks, and functions performed by pharmacy technicians and pharmacy technician trainees; and
(II) pharmacy technicians and pharmacy technician trainees are under the direct supervision of and responsible to a pharmacist.

(iii) Pharmacy technicians and pharmacy technician trainees may perform only nonjudgmental technical duties associated with the preparation of prescription drugs, as follows:

(I) initiating and receiving refill authorization requests; and
(II) entering prescription or medication order data into a data processing system.

(iv) In addition to the duties listed above in clause (iii) of this subparagraph, pharmacy technicians may perform the following nonjudgmental technical duties associated with the preparation and distribution of prescription drugs:

(I) receiving oral prescription drug or medication orders for dangerous drugs and reducing these orders to writing, either manually or electronically; and
(II) transferring or receiving a transfer of original prescription drug or medication order information for a dangerous drug on behalf of a patient.

(5) Identification of pharmacy personnel. All pharmacy personnel shall be identified as follows.

(A) Pharmacy technicians. All pharmacy technicians shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacy technician, or a certified pharmacy technician, if the technician maintains current certification with the Pharmacy Technician Certification Board or any other entity providing an examination approved by the board.

(B) Pharmacy technician trainees. All pharmacy technician trainees shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacy technician trainee.

(C) Pharmacist interns. All pharmacist interns shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacist intern.

(D) Pharmacists. All pharmacists shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacist.

(d) Operational Standards.

(1) General requirements.

(A) A Class A, Class C, or Class E Pharmacy may outsource prescription drug or medication order processing to a Class G pharmacy provided the pharmacies:

(i) have:

(I) the same owner; or

(II) entered into a written contract or agreement which outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations; and

(ii) share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to perform a non-dispensing function.

(B) A Class G pharmacy shall comply with the provisions applicable to the class of pharmacy contained in either §§291.31 - 291.35 of this title (relating to Definitions, Personnel, Operational Standards, Records, and Official Prescription Requirements in a Class A (Community) Pharmacy, §§291.72 - 291.75 of this title (relating to Definitions, Personnel, Operational Standards, and Records in a Class C (Institutional) Pharmacy), or §§291.102 - 291.105 of this title (relating to Definitions, Personnel, Operational Standards, and Records in a Class E (Non-Resident) Pharmacy) to the extent applicable for the specific processing activity and this section including:

(i) duties which must be performed by a pharmacist; and

(ii) supervision requirements for pharmacy technicians and pharmacy technician trainees.

(2) Licensing requirements.

(A) A Class G pharmacy shall register with the board on a pharmacy license application provided by the board, following the procedures specified in §291.1 of this title (relating to Pharmacy License Application).

(B) A Class G pharmacy which changes ownership shall notify the board within 10 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).

(C) A Class G pharmacy which changes location and/or name shall notify the board of the change within 10 days and file for an amended license as specified in §291.3 of this title.

(D) A Class G pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within 10 days of the change, following the procedures in §291.3 of this title.

(E) A Class G pharmacy shall notify the board in writing within 10 days of closing, following the procedures in §291.5 of this title (relating to Closing a Pharmacy).

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

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

(3) Environment.

(A) General requirements.

(i) The pharmacy shall be arranged in an orderly fashion and kept clean. All required equipment shall be in good operating condition.

(ii) The pharmacy shall be properly lighted and ventilated.

(B) Security.

(i) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of prescription drug records.

(ii) Pharmacies shall employ appropriate measures to ensure that security of prescription drug records is maintained at all times to prohibit unauthorized access.

(iii) The pharmacy is not required to have a sink exclusive of restroom facilities.

(4) Policy and Procedures. A policy and procedure manual shall be maintained by the Class G pharmacy and be available for inspection. The manual shall:

(A) outline the responsibilities of each of the pharmacies;
(B) include a list of the name, address, telephone numbers, and all license/registration numbers of the pharmacies involved in centralized prescription drug or medication order processing; and
(C) include policies and procedures for:
(i) protecting the confidentiality and integrity of patient information;
(ii) maintaining appropriate records to identify the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist or pharmacy technician who performed any processing;
(iii) complying with federal and state laws and regulations;
(iv) operating a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems; and
(v) annually reviewing the written policies and procedures and documenting such review.

(e) Records.

(1) every record required to be kept under the provisions of this section 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 board. If the pharmacy maintains the records in an electronic format, the requested records must be provided in a mutually agreeable electronic format if specifically requested by the board or its representative. Failure to provide the records set out in this 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) The pharmacy shall maintain appropriate records which identify, by prescription drug or medication order, the name(s), initials, or identification code(s) of each pharmacist, pharmacy technician, or pharmacy technician trainee who performs a processing function for a prescription drug or medication order. Such records may be maintained:
(A) separately by each pharmacy and pharmacist; or
(B) in a common electronic file as long as the records are maintained in such a manner that the data processing system can produce a printout which lists the functions performed by each pharmacy and pharmacist.

(3) In addition, the pharmacy shall comply with the record keeping requirements applicable to the class of pharmacy to the extent applicable for the specific processing activity and this section.

CHAPTER 295 – PHARMACISTS

§295.1 Change of Address and/or Name

(a) Change of address. A pharmacist shall notify the board in writing within 10 days of a change of address, giving the old and new address and license number.

(b) Change of name.

(1) A pharmacist shall notify the board in writing within 10 days of a change of name by sending a copy of the official document reflecting the name change (e.g., marriage certificate, divorce decree, etc.).

(2) Pharmacists who change their name may retain the original license to practice pharmacy (wall certificate). However, if the pharmacist wants an amended license (wall certificate) issued which reflects the pharmacist's name change, the pharmacist must:

(A) return the original license (wall certificate); and

(B) pay a fee of $35.

(3) An amended electronic renewal certificate reflecting the new name of the pharmacist will be issued by the board without a fee.

§295.2 Change of Employment

(a) A pharmacist shall report in writing to the board within 10 days of a change of employment and be responsible for seeing that his or her name is removed from the pharmacy license of last employment and added to the pharmacy license of new employment.

(b) For the purposes of this section, the term "employment" means the pharmacy at which the pharmacist engages in work on a regular and routine basis, whether remunerative or not, including the practice of pharmacy, administrative or managerial duties, supervisory tasks, or direct or indirect contractual services for pay. The term does not include an isolated case of practicing pharmacy on a temporary basis in order to relieve another pharmacist, unless such isolated cases become regular and routine.

§295.3 Responsibility of Pharmacist

(a) The pharmacist-in-charge shall insure that a pharmacy is in compliance with all state and federal laws and rules governing the practice of pharmacy.

(b) All pharmacists while on duty, shall be responsible for complying with all state and federal laws and rules governing the practice of pharmacy.

§295.4 Sharing Money Received for Prescription

No pharmacist may share or offer to share the money received from a customer for filling a prescription with the practitioner.

§295.5 Pharmacist License or Renewal Fees

(a) Biennial Registration. The Texas State Board of Pharmacy shall require biennial renewal of all pharmacist licenses provided under the Pharmacy Act, §559.002.

(b) Initial License Fee.

(1) The fee for the initial license shall be $399 for a two year registration.

(2) New pharmacist licenses shall be assigned an expiration date and initial fee shall be prorated based on the assigned expiration date.

(c) Renewal Fee. The fee for biennial renewal of a pharmacist license shall be $396 for a two year registration.

(d) Exemption from fee. The license of a pharmacist who has been licensed by the Texas State Board of Pharmacy for at least 50 years or who is at least 72 years old shall be renewed without payment of a fee provided such pharmacist is not actively practicing pharmacy. The renewal certificate of such pharmacist issued by the board shall reflect an inactive

status. A person whose license is renewed pursuant to this subsection may not engage in the active practice of pharmacy without first paying the renewal fee as set out in subsection (c) of this section.

§295.6 Emergency Temporary Pharmacist License

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

(1) Emergency situation--an emergency caused by a natural or manmade disaster or any other exceptional situation that causes an extraordinary demand for pharmacist services.

(2) State--One of the 50 United States of America, the District of Columbia, and Puerto Rico.

(b) Emergency Temporary Pharmacist license. In an emergency situation, the board may grant a pharmacist who holds a license to practice pharmacy in another state an emergency temporary pharmacist license to practice in Texas. The following is applicable for the emergency temporary pharmacist license.

(1) An applicant for an emergency temporary pharmacist license under this section must hold a current pharmacist license in another state and that license and other licenses held by the applicant in any other state may not be suspended, revoked, canceled, surrendered, or otherwise restricted for any reason.

(2) To qualify for an emergency temporary pharmacist license, the applicant must submit an application including the following information:

(A) name, address, and phone number of the applicant; and

(B) any other information the required by the board.

(3) An emergency temporary pharmacist license shall be valid for a period as determined by the board not to exceed six months. The executive director of the board, in his/her discretion, may renew the license for an additional six months, if the emergency situation still exists.

(c) Exception. This section is not applicable to pharmacists enrolled in a volunteer health registry maintained by the Texas Department of State Health Services.

§295.7 Pharmacist License Renewal

For the purposes of the Act, Chapter 559, Subchapter A.

(1) A license to practice pharmacy expires on the last day of the assigned expiration month.

(2) Before the expiration date of the license means the receipt in the board's office of a completed application and renewal fee on or before the last day of the assigned expiration month.

(3) As specified in §559.003, if the completed application and renewal fee is not received on or before the last day of the assigned expiration month, the person's license to practice pharmacy shall expire. A person shall not practice pharmacy with an expired license. An expired license may be renewed according to the following schedule.

(A) If license has been expired for 90 days or less, the person may become licensed by making application and paying to the board a renewal fee that is equal to one and one-half times the renewal fee for the license as specified in §295.5 of this title (relating to Pharmacist License or Renewal Fees).

(B) If license has been expired for more than 90 days but less than one year, the person may become licensed by making application and paying to the board a renewal fee that is equal to two times the renewal fee for the license as specified in §295.5 of this title.

(C) If license has been expired for one year or more, the person shall apply for a new license as specified in §283.10 of this title (relating to Requirements for Application for a Pharmacist License Which Has Expired).

§295.8 Continuing Education Requirements

(a) Authority and purpose.

(1) Authority. In accordance with §559.053 of the Texas Pharmacy Act, (Chapters 551 - 569, Occupations Code), all pharmacists shall complete and report 30 contact hours (3.0 CEUs) of approved continuing education and any courses required under subsection (d)(1) of this section obtained during the previous license period in order to renew their license to practice pharmacy.

(2) Purpose. The board recognizes that the fundamental purpose of continuing education is to maintain and enhance the professional competency of pharmacists licensed to practice in Texas, for the protection of the health and welfare of the citizens of Texas.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) ACPE--Accreditation Council for Pharmacy Education.

(2) Act--The Texas Pharmacy Act, Chapters 551 - 569, Occupations Code.

(3) Approved programs--Live programs, home study, and other mediated instruction delivered by an approved provider or a program specified by the board and listed as an approved program in subsection (e) of this section.

(4) Approved provider--An individual, institution, organization, association, corporation, or agency that is approved by the board.

(5) Board--The Texas State Board of Pharmacy.

(6) Certificate of completion--A certificate or other official document presented to a participant upon the successful completion of an approved continuing education program.

(7) Contact hour--A unit of measure of educational credit which is equivalent to approximately 60 minutes of participation in an organized learning experience.

(8) Continuing education unit (CEU)--A unit of measure of education credit which is equivalent to 10 contact hours (i.e., one CEU = 10 contact hours).

(9) CPE Monitor--A collaborative service from the National Association of Boards of Pharmacy and ACPE that provides an electronic system for pharmacists to track their completed CPE credits.

(10) Credit hour--A unit of measurement for continuing education equal to 15 contact hours.

(11) Enduring Materials (Home Study)--Activities that are printed, recorded or computer assisted instructional materials that do not provide for direct interaction between faculty and participants.

(12) Initial license period--The time period between the date of issuance of a pharmacist's license and the next expiration date following the initial 30 day expiration date. This time period ranges from eighteen to thirty months depending upon the birth month of the licensee.

(13) License period--The time period between consecutive expiration dates of a license.

(14) Live programs--Activities that provide for direct interaction between faculty and participants and may include lectures, symposia, live teleconferences, workshops, etc.

(15) Standardized pharmacy examination--The North American Pharmacist Licensure Examination (NAPLEX).

(c) Methods for obtaining continuing education contact hours. A pharmacist may satisfy the continuing education contact hour requirements by either:

(1) successfully completing the number of continuing education hours necessary to renew a license as specified in subsection (a)(1) of this section;

(2) successfully completing during the preceding license period, one credit hour for each year of their license period, which is a part of the professional degree program in a college of pharmacy the professional degree program of which has been accredited by ACPE; or

(3) taking and passing the standardized pharmacy examination (NAPLEX) during the preceding license period as a Texas licensed pharmacist, which shall be equivalent to the number of continuing education hours necessary to renew a license as specified in subsection (a)(1) of this section. This paragraph does not apply to the standardized pharmacy examination (NAPLEX) that an individual uses to obtain initial licensure as a pharmacist.

(d) Reporting requirements.

(1) Renewal of a pharmacist license. To renew a license to practice pharmacy, a pharmacist shall report on the renewal application completion of at least thirty contact hours (3.0 CEUs) of continuing education, any specialty requirements applicable to the pharmacist (e.g., preceptor, sterile compounding, immunization, drug therapy management), and any courses required under this paragraph. The following is applicable to the reporting of continuing education:

(A) at least one contact hour (0.1 CEU) specified in paragraph (1) of this subsection shall be related to Texas pharmacy laws or rules;

(B) not later than the first anniversary of becoming licensed to practice pharmacy, a pharmacist shall have completed at least two contact hours (0.2 CEU) specified in paragraph (1) of this subsection related to approved procedures of prescribing and monitoring controlled substances as specified in §481.07635 of the Texas Health and Safety Code;

(C) any continuing education requirements which are imposed upon a pharmacist as a part of a board order or agreed board order shall be in addition to the requirements of this section; and

(D) a pharmacist shall have completed the human trafficking prevention course required in §116.002 of the Texas Occupations Code.

(2) Failure to report completion of required continuing education. The following is applicable if a pharmacist fails to report completion of the required continuing education:

(A) the license of a pharmacist who fails to report completion of the required number of continuing education contact hours or any courses required under this paragraph shall not be renewed and the pharmacist shall not be issued a renewal certificate for the license period until such time as the pharmacist successfully completes the required continuing education and reports the completion to the board; and

(B) a pharmacist who practices pharmacy without a current renewal certificate is subject to all penalties of practicing pharmacy without a license including the delinquent fees specified in the Act, §559.003.

(3) Extension of time for reporting. A pharmacist who has had a physical disability, illness, or other extenuating circumstances which prohibits the pharmacist from obtaining continuing education credit during the preceding license period may be granted an extension of time to complete the continuing education requirement. The following is applicable for this extension:

(A) the pharmacist shall submit a petition to the board with his/her license renewal application which contains:

(i) the name, address, and license number of the pharmacist;

(ii) a statement of the reason for the request for extension;

(iii) if the reason for the request for extension is health related, a statement from the attending physician(s) treating the pharmacist which includes the nature of the physical disability or illness and the dates the pharmacist was incapacitated; and

(iv) if the reason for the request for the extension is for other extenuating circumstances, a detailed explanation of the extenuating circumstances and if because of military deployment, documentation of the dates of the deployment;

(B) after review and approval of the petition, a pharmacist may be granted an extension of time to comply with the continuing education requirement which shall not exceed one license renewal period;

(C) an extension of time to complete continuing education credit does not relieve a pharmacist from the continuing education requirement during the current license period; and

(D) if a petition for extension to the reporting period for continuing education is denied, the pharmacist shall:

(i) have 60 days to complete and report completion of the required continuing education requirements; and

(ii) be subject to the requirements of paragraph (2) of this subsection relating to failure to report completion of the required continuing education if the required continuing education is not completed and reported within the required 60-day time period.

(4) Exemptions from reporting requirements.

(A) All pharmacists licensed in Texas shall be exempt from the continuing education requirements in paragraph (1) of this subsection during their initial license period, with the exception of the

requirements in paragraph (1)(B) and (D) of this subsection which shall be completed during the time periods specified in the subparagraphs.

(B) Pharmacists who are not actively practicing pharmacy shall be granted an exemption to the reporting requirements for continuing education provided the pharmacists submit a completed renewal application for each license period which states that they are not practicing pharmacy. Upon submission of the completed renewal application, the pharmacist shall be issued a renewal certificate which states that pharmacist is inactive. Pharmacists who wish to return to the practice of pharmacy after being exempted from the continuing education requirements as specified in this subparagraph shall:

(i) notify the board of their intent to actively practice pharmacy;

(ii) pay the fee as specified in §295.9 of this title (relating to Inactive License); and

(iii) provide copies of completion certificates from approved continuing education programs as specified in subsection (e) of this section for 30 contact hours (3.0 CEUs). Approved continuing education earned within two years prior to the licensee applying for the return to active status may be applied toward the continuing education requirement for reactivation of the license but may not be counted toward subsequent renewal of the license.

(e) Approved programs.

(1) Any program presented by an ACPE approved provider subject to the following conditions:

(A) pharmacists may receive credit for the completion of the same ACPE course only once during a license period;

(B) pharmacists who present approved ACPE continuing education programs may receive credit for the time expended during the actual presentation of the program. Pharmacists may receive credit for the same presentation only once during a license period; and

(C) proof of completion of an ACPE course shall contain the following information:

(i) name of the participant;

(ii) title and completion date of the program;

(iii) name of the approved provider sponsoring or cosponsoring the program;

(iv) number of contact hours and/or CEUs awarded;

(v) the assigned ACPE universal program number and a "P" designation indicating that the CE is targeted to pharmacists; and

(vi) either:

(I) a dated certifying signature of the approved provider and the official ACPE logo; or

(II) the CPE Monitor logo.

(2) Courses which are part of a professional degree program or an advanced pharmacy degree program offered by a college of pharmacy which has a professional degree program accredited by ACPE.

(A) Pharmacists may receive credit for the completion of the same course only once during a license period. A course is equivalent to one credit hour for each year of the renewal period.

(B) Pharmacists who teach these courses may receive credit towards their continuing education, but such credit may be received only once for teaching the same course during a license period. Documentation of the course instruction shall be a signed letter from the academic administrator (e.g., department head, program director) of the professional degree program or advanced pharmacy degree program that contains the course title and completion date, the name of the pharmacist who taught the course, and the proportion of the course taught by the pharmacist, if the course was co-taught. A pharmacist who co-teaches a course shall receive continuing education credit in proportion to the percentage of the course taught by the pharmacist, rounded to the nearest contact hour.

(3) Basic cardiopulmonary resuscitation (CPR) courses which lead to CPR certification by the American Red Cross or the American Heart Association or its equivalent shall be recognized as approved programs. Pharmacists may receive credit for one contact hour (0.1 CEU) towards their continuing education requirement for completion of

a CPR course only once during a license period. Proof of completion of a CPR course shall be the certificate issued by the American Red Cross or the American Heart Association or its equivalent.

(4) Advanced cardiovascular life support courses (ACLS) or pediatric advanced life support (PALS) courses which lead to initial ACLS or PALS certification by the American Heart Association or its equivalent shall be recognized as approved programs. Pharmacists may receive credit for twelve contact hours (1.2 CEUs) towards their continuing education requirement for completion of an ACLS or PALS course only once during a license period. Proof of completion of an ACLS or PALS course shall be the certificate issued by the American Heart Association or its equivalent.

(5) Advanced cardiovascular life support courses (ACLS) or pediatric advanced life support (PALS) courses which lead to ACLS or PALS recertification by the American Heart Association or its equivalent shall be recognized as approved programs. Pharmacists may receive credit for four contact hours (0.4 CEUs) towards their continuing education requirement for completion of an ACLS or PALS recertification course only once during a license period. Proof of completion of an ACLS or PALS recertification course shall be the certificate issued by the American Heart Association or its equivalent.

(6) Attendance at programs presented by the Texas State Board of Pharmacy or courses offered by the Texas State Board of Pharmacy as follows:

(A) pharmacists shall receive credit for the number of hours for the program or course as stated by the Texas State Board of Pharmacy; and

(B) proof of attendance at a program presented by the Texas State Board of Pharmacy or completion of a course offered by the Texas State Board of Pharmacy shall be a certificate issued by the Texas State Board of Pharmacy.

(7) Pharmacists shall receive credit for three contact hours (0.3 CEUs) toward their continuing education requirements for taking and successfully passing an initial Board of Pharmacy Specialties certification examination administered by the Board of Pharmacy Specialties. Proof of successfully passing the examination shall be a certificate issued by the Board of Pharmacy Specialties.

(8) Programs approved by the American Medical Association (AMA) as Category 1 Continuing Medical Education (CME) and accredited by the Accreditation Council for Continuing Medical Education (ACCME) subject to the following conditions:

(A) pharmacists may receive credit for the completion of the same CME course only once during a license period;

(B) pharmacists who present approved CME programs may receive credit for the time expended during the actual presentation of the program. Pharmacists may receive credit for the same presentation only once during a license period; and

(C) proof of completion of a CME course shall contain the following information:

(i) name of the participant;

(ii) title and completion date of the program;

(iii) name of the approved provider sponsoring or cosponsoring the program;

(iv) number of contact hours and/or CEUs awarded; and

(v) a dated certifying signature of the approved provider.

(f) Retention of continuing education records and audit of records by the board.

(1) Retention of records. Pharmacists are required to maintain certificates of completion of approved continuing education for three years from the date of reporting the contact hours or course completion on a license renewal application. Such records may be maintained in hard copy or electronic format.

(2) Audit of records by the board. The board shall use the continuing education tracking system described in subsection (g) of this section to audit the records of pharmacists for verification of reported continuing education contact hours or course completion. The following is applicable for such audits:

(A) upon written request, a pharmacist shall provide to the board documentation of proof for all continuing education contact hours and course completions reported during a specified license

period(s). Failure to provide all requested records during the specified time period constitutes prima facie evidence of failure to keep and maintain records and shall subject the pharmacist to disciplinary action by the board;

(B) credit for continuing education contact hours or course completion shall only be allowed for approved programs or required courses for which the pharmacist submits documentation of proof reflecting that the hours or courses were completed during the specified license period(s). Any other reported hours or course completion shall be disallowed. A pharmacist who has received credit for continuing education contact hours or course completion disallowed during an audit shall be subject to disciplinary action; and

(C) a pharmacist who submits false or fraudulent records to the board shall be subject to disciplinary action by the board.

(g) Continuing education tracking system. As specified in §112.103 of the Texas Occupations Code, proof of completion of all continuing education requirements shall be reported to the board through the board's continuing education tracking system. A pharmacist shall not be issued a renewal certificate for the license period unless the pharmacist has reported the completion of all required contact hours and any courses required under subsection (d)(1) of this section through the continuing education tracking system.

§295.9 Inactive License

(a) Placing a license on inactive status. A person who is licensed by the board to practice pharmacy but who is not eligible to renew the license for failure to comply with the continuing education requirements of the Act, Chapter 559, Subchapter A, and who is not engaged in the practice of pharmacy in this state, may place the license on inactive status at the time of license renewal or during a license period as follows:

(1) To place a license on inactive status at the time of renewal, the licensee shall:

(A) complete and submit before the expiration date a pharmacist license renewal application provided by the board;

(B) state on the renewal application that the license is to be placed on inactive status and that the licensee shall not practice pharmacy in Texas while the license is inactive; and

(C) pay the fee for renewal of the license as specified in §295.5 of this title (relating to Pharmacist License or Renewal Fees).

(2) To place a license on inactive status at a time other than the time of license renewal, the licensee shall:

(A) return the current renewal certificate to the board;

(B) submit a signed statement stating that the licensee shall not practice pharmacy in Texas while the license is inactive, and the date the license is to be placed on inactive status; and

(C) pay the fee for issuance of an amended license as specified in §295.5(e) of this title (relating to Pharmacist License or Renewal Fees).

(b) Prohibition against practicing pharmacy in Texas with an inactive license. A holder of a license that is on inactive status shall not practice pharmacy in this state. The practice of pharmacy by a holder of a license that is on inactive status constitutes the practice of pharmacy without a license.

(c) Reactivation of an inactive license.

(1) A holder of a license that is on inactive status may return the license to active status by:

(A) applying for active status on a form prescribed by the board;

(B) providing copies of completion certificates from approved continuing education programs as specified in §295.8(e) of this title (relating to Continuing Education Requirements) for 30 hours including at least one contact hour (0.1 CEU) related to Texas pharmacy laws or rules. Approved continuing education earned within two years prior to the licensee applying for the return to active status may be applied toward the continuing education requirement for reactivation of the license but may not be counted toward subsequent renewal of the license; and

(C) paying the fee specified in paragraph (2) of this subsection.

(2) If the application for reactivation of the license is made at the time of license renewal, the applicant shall pay the license renewal fee specified in §295.5 of this title (relating to Pharmacist License or Renewal Fees). If the application for reactivation of the license is made at a time other than the time of license renewal, the applicant shall pay the fee for issuance of an amended license to practice pharmacy as specified in §295.5(e) of this title (relating to Pharmacist License or Renewal Fees).

(3) In an emergency caused by a natural or manmade disaster or any other exceptional situation that causes an extraordinary demand for pharmacist services, the executive director of the board, in his/her discretion, may allow a pharmacist whose license has been inactive for no more than two years to reactivate their license prior to obtaining the required continuing education specified in paragraph (1)(B) of this subsection, provided the pharmacist completes the continuing education requirement within six months of reactivation of the license. If the required continuing education is not provided within six months, the license shall return to an inactive status.

§295.11 Notification to Consumers

(a) Pharmacist. Every pharmacist who practices pharmacy other than in a licensed pharmacy shall provide notification to consumers of the name, mailing address, internet site address and telephone number of the board for the purpose of directing complaints concerning the practice of pharmacy to the board. Such notification shall be provided as follows.

(1) If the pharmacist maintains an office and provides pharmacy services to patients who come to the office, the pharmacist shall either:

(A) post in a prominent place that is in clear public view where pharmacy services are provided:

(i) a sign which notifies the consumer that complaints concerning the practice of pharmacy may be filed with the board and list the board's mailing address, internet site address, telephone number, and a toll-free telephone number for filing complaints; or

(ii) an electronic messaging system in a type size no smaller than ten-point Times Roman which notifies the consumer that complaints concerning the practice of pharmacy may be filed with the board and list the board's name, mailing address, internet site address, and a toll-free number for filing complaints; or

(B) provide to the patient each time pharmacy services are provided a written notification in type size no smaller than ten-point Times Roman which states the following: "Complaints concerning the practice of pharmacy may be filed with the Texas State Board of Pharmacy at: (list the mailing address, internet site address, telephone number of the board, and a toll-free telephone number for filing complaints)."

(2) If the pharmacist provides pharmacy services to patients not at the pharmacist's office, the pharmacist shall provide to the patient each time pharmacy services are provided, a written notification in type size no smaller than ten-point Times Roman which states the following: "Complaints concerning the practice of pharmacy may be filed with the Texas State Board of Pharmacy at: (list the mailing address, telephone number of the board, internet site address, and a toll-free telephone number for filing complaints)." Such notification shall be included:

(A) in each written contract for pharmacist services; or

(B) on each bill for service provided by the pharmacist.

(3) The provisions of this section do not apply to prescriptions for patients in facilities where drugs are administered to patients by a person required to do so by the laws of the state (i.e., nursing homes).

(b) Texas State Board of Pharmacy. On or before January 1, 2005, the board shall establish a pharmacist profile system as specified in §2054.2606, Government Code.

(1) The board shall make the pharmacist profiles available to the public on the agency's internet site.

(2) A pharmacist profile shall contain at least the following information:

(A) pharmacist's name;

(B) pharmacist's license number, licensure status, and expiration date of the license;

(C) name, address, telephone number, and license number of all Texas pharmacies where the pharmacist works;
(D) the number of years the person has practiced in Texas;
(E) professional pharmacy degree held by the licensee, the year it was received, and the name of the institution that awarded the degree;
(F) whether the pharmacist is preceptor;
(G) any speciality certification held by the pharmacist; and
(H) whether the pharmacist has had prior disciplinary action by the board.

(3) The board shall gather this information on initial licensing and update the information in conjunction with the license renewal for the pharmacist.

§295.12 Pharmacist Certification Programs

(a) Purpose. The purpose of this section is to provide standards for the recognition and approval of pharmacist certification programs as authorized by §554.0021, Occupations Code.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) ACPE--The Accreditation Council for Pharmacy Education.

(2) Approved Provider of Pharmacist Certificate Programs--An individual, institution, organization, association, corporation, or agency that is approved by the board and recognized by ACPE in accordance with its policy and procedures, as having:

(A) met criteria indicative of the ability to provide quality continuing education programs; and
(B) met the procedures outlines in the ACPE "Guidance Document for Practice Based Activities."

(3) Board--The Texas State Board of Pharmacy.

(c) Recognized Certification Programs.

(1) The board shall recognize as certified, any pharmacist that successfully completes:

(A) any program offered by an approved provider of pharmacist certificate programs;
(B) any program that meets the requirements of §295.15 of this title (relating to Administration of Immunizations or Vaccinations by a Pharmacist under Written Protocol of a Physician);
(C) any certification offered by the:
(i) Board of Pharmaceutical Specialties;
(ii) American Society of Consultant Pharmacists;
(iii) American Board of Clinical Pharmacology;
(iv) American Board of Applied Toxicology; and
(v) American Academy of Pain Management; or
(D) any additional certifications as published on the board's website.

(2) Texas pharmacists may not identify themselves as certified unless they have completed one of the programs specified in paragraph (1) of this subsection.

§295.13 Drug Therapy Management by a Pharmacist under Written Protocol of a Physician

(a) Purpose. The purpose of this section is to provide standards for the maintenance of records of a pharmacist engaged in the provision of drug therapy management as authorized in Chapter 157 of the Medical Practice Act and §554.005 of the Act.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Act--The Texas Pharmacy Act, Chapter 551 - 566 and 568 - 569, Occupations Code, as amended.

(2) Board--The Texas State Board of Pharmacy.

(3) Confidential record--Any health-related record maintained by a pharmacy or pharmacist, such as a patient medication record, prescription drug order, or medication order.

(4) Drug therapy management--The performance of specific acts by pharmacists as authorized by a physician through written protocol. Drug therapy management does not include the selection of drug products not prescribed by the physician, unless the drug product is named in the physician initiated protocol or the physician initiated record of deviation from a standing protocol. Drug therapy management may include the following:

(A) collecting and reviewing patient drug use histories;

(B) ordering or performing routine drug therapy related patient assessment procedures including temperature, pulse, and respiration;

(C) ordering drug therapy related laboratory tests;

(D) implementing or modifying drug therapy following diagnosis, initial patient assessment, and ordering of drug therapy by a physician as detailed in the protocol; or

(E) any other drug therapy related act delegated by a physician.

(5) Medical Practice Act--The Texas Medical Practice Act, Subtitle B, Occupations Code, as amended.

(6) Written protocol--A physician's order, standing medical order, standing delegation order, or other order or protocol as defined by rule of the Texas Medical Board under the Medical Practice Act.

(A) A written protocol must contain at a minimum the following:

(i) a statement identifying the individual physician authorized to prescribe drugs and responsible for the delegation of drug therapy management;

(ii) a statement identifying the individual pharmacist authorized to dispense drugs and to engage in drug therapy management as delegated by the physician;

(iii) a statement identifying the types of drug therapy management decisions that the pharmacist is authorized to make which shall include:

(I) a statement of the ailments or diseases involved, drugs, and types of drug therapy management authorized; and

(II) a specific statement of the procedures, decision criteria, or plan the pharmacist shall follow when exercising drug therapy management authority;

(iv) a statement of the activities the pharmacist shall follow in the course of exercising drug therapy management authority, including the method for documenting decisions made and a plan for communication or feedback to the authorizing physician concerning specific decisions made. Documentation shall be recorded within a reasonable time of each intervention and may be performed on the patient medication record, patient medical chart, or in a separate log book; and

(v) a statement that describes appropriate mechanisms and time schedule for the pharmacist to report to the physician monitoring the pharmacist's exercise of delegated drug therapy management and the results of the drug therapy management.

(B) A standard protocol may be used or the attending physician may develop a drug therapy management protocol for the individual patient. If a standard protocol is used, the physician shall record what deviations, if any, from the standard protocol are ordered for that patient.

(c) Physician delegation to a pharmacist.

(1) As specified in Chapter 157 of the Texas Medical Practices Act, a physician may delegate to a properly qualified and trained pharmacist acting under adequate physician supervision the performance of specific acts of drug therapy management authorized by the physician through the physician's order, standing medical order, standing delegation order, or other order or protocol.

(2) A delegation under paragraph (1) of this subsection may include:

(A) the implementation or modification of a patient's drug therapy under a protocol, if:

(i) the delegation follows a diagnosis, initial patient assessment, and drug therapy order by the physician; and

(ii) the pharmacist maintains a copy of the protocol for inspection until at least the seventh anniversary of the expiration date of the protocol; or

(B) the authority to sign a prescription drug order for dangerous drugs, if:

(i) the delegation follows a diagnosis, initial patient assessment, and drug therapy order by the physician;

(ii) the pharmacist practices in a federally qualified health center, hospital, hospital-based clinic, or an academic health care institution; and

(iii) the federally qualified health center, hospital, hospital-based clinic, or academic health care institution in which the pharmacist practices has bylaws and a medical staff policy that permit a physician to delegate to a pharmacist the management of a patient's drug therapy.

(3) A pharmacist who signs a prescription for a dangerous drug under authority granted under paragraph (2) of this subsection shall:

(A) notify the board that a physician has delegated the authority to sign a prescription for dangerous drugs on an application provided by the board and prior to signing any prescription for a dangerous drug;

(B) submit a copy of the written protocol to the board at the time of initial notification;

(C) submit an updated copy of the written protocol to the board if the protocol has changed within 10 days of the change; and

(D) include the pharmacist's name, address, and telephone number as well as the name, address, and telephone number of the delegating physician on each prescription for a dangerous drug signed by the pharmacist.

(4) The board shall post the following information on its website:

(A) the name and license number of each pharmacist who has notified the board that a physician has delegated authority to sign a prescription for a dangerous drug; and

(B) the name and address of the physician who delegated the authority to the pharmacist.

(d) Pharmacist Training Requirements.

(1) Initial requirements. A pharmacist shall maintain and provide to the Board within 24 hours of request a statement attesting to the fact that the pharmacist has within the last year:

(A) completed at least six hours of continuing education related to drug therapy offered by a provider approved by the Accreditation Council for Pharmacy Education (ACPE); or

(B) engaged in drug therapy management as allowed under previous laws or rules. A statement from the physician supervising the acts shall be sufficient documentation.

(2) Continuing requirements. A pharmacist engaged in drug therapy management shall annually complete six hours of continuing education related to drug therapy offered by a provider approved by the Accreditation Council for Pharmacy Education (ACPE). (These hours may be applied towards the hours required for renewal of a license to practice pharmacy.)

(e) Supervision. Physician supervision shall be as specified in the Medical Practice Act, Chapter 157 and shall be considered adequate if the delegating physician:

(1) is responsible for the formulation or approval of the written protocol and any patient-specific deviations from the protocol and review of the written protocol and any patient-specific deviations from the protocol at least annually and the services provided to a patient under the protocol on a schedule defined in the written protocol;

(2) has established and maintains a physician-patient relationship with each patient provided drug therapy management by a delegated pharmacist and informs the patient that drug therapy will be managed by a pharmacist under written protocol;

(3) is geographically located so as to be able to be physically present daily to provide medical care and supervision;

(4) receives, on a schedule defined in the written protocol, a periodic status report on the patient, including any problem or complication encountered;

(5) is available through direct telecommunication for consultation, assistance, and direction; and

(6) determines that the pharmacist to whom the physician is delegating drug therapy management establishes and maintains a pharmacist-patient relationship with the patient.

(f) Records.

(1) Maintenance of records.

(A) Every record required to be kept under this section shall be kept by the pharmacist and be available, for at least two years from the date of such record, for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement or regulatory agencies.

(B) Records may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided:

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

(ii) 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.

(2) Written protocol.

(A) A copy of the written protocol and any patient-specific deviations from the protocol shall be maintained by the pharmacist.

(B) A pharmacist shall document all interventions undertaken under the written protocol within a reasonable time of each intervention. Documentation may be maintained in the patient medication record, patient medical chart, or in a separate log.

(C) A standard protocol may be used or the attending physician may develop a drug therapy management protocol for the individual patient. If a standard protocol is used, the physician shall record what deviations, if any, from the standard protocol are ordered for that patient. A pharmacist shall maintain a copy of any deviations from the standard protocol ordered by the physician.

(D) Written protocols, including standard protocols, any patient-specific deviations from a standard protocol, and any individual patient protocol, shall be reviewed by the physician and pharmacist at least annually and revised if necessary. Such review shall be documented in the pharmacist's records. Documentation of all services provided to the patient by the pharmacist shall be reviewed by the physician on the schedule established in the protocol.

(g) Confidentiality.

(1) In addition to the confidentiality requirements specified in §291.27 of this title (relating to Confidentiality) a pharmacist shall comply with:

(A) the privacy provisions of the federal Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191) and any rules adopted pursuant to this act;

(B) the requirements of Medical Records Privacy contained in Chapter 181, Health and Safety Code;

(C) the Privacy of Health Information requirements contained in Chapter 28B of the Insurance Code; and

(D) any other confidentiality provisions of federal or state laws.

(2) This section shall not affect or alter the provisions relating to the confidentiality of the physician-patient communication as specified in the Medical Practice Act, Chapter 159.

(h) Construction and Interpretation.

(1) As specified in the Medical Practice Act, Chapter 157, this section does not restrict the use of a pre-established health care program or restrict a physician from authorizing the provision of patient care by use of a pre-established health care program if the patient is institutionalized and the care is to be delivered in a licensed hospital with an organized medical staff that has authorized standing delegation orders, standing medical orders, or protocols.

(2) As specified in the Medical Practice Act, Chapter 157, this section may not be construed to limit, expand, or change any provision of law concerning or relating to therapeutic drug substitution or administration of medication, including the Act, §554.004.

§295.14 Dispensing of Opioid Antagonist by Pharmacist

(a) Purpose. The purpose of this section is to provide standards for pharmacists engaged in the dispensing of opioid antagonists as authorized in Chapter 483 of the Health and Safety Code.

(b) Definitions.

(1) Opioid antagonist--Any drug that binds to opioid receptors and blocks or otherwise inhibits the effects of opioids acting on those receptors.

(2) Opioid-related drug overdose--A condition, evidenced by symptoms such as extreme physical illness, decreased level of consciousness, constriction of the pupils, respiratory depression, or coma, that a layperson would reasonably believe to be the result of the consumption or use of an opioid.

(3) Prescriber--A person authorized by law to prescribe an opioid antagonist.

(c) Dispensing.

(1) A pharmacist may dispense an opioid antagonist under a valid prescription, including a prescription issued by a standing order, to:

(A) a person at risk of experiencing an opioid-related drug overdose; or

(B) a family member, friend, or other person in a position to assist a person described by subparagraph (A) of this paragraph.

(2) A prescription dispensed under this section is considered as dispensed for a legitimate medical purpose in the usual course of professional practice.

(3) A pharmacist who, acting in good faith and with reasonable care, dispenses or does not dispense an opioid antagonist under a valid prescription is not subject to any criminal or civil liability or any professional disciplinary action for:

(A) dispensing or failing to dispense the opioid antagonist; or

(B) if the pharmacist chooses to dispense an opioid antagonist, any outcome resulting from the eventual administration of the opioid antagonist.

§295.15 Administration of Immunizations or Vaccinations by a Pharmacist under Written Protocol of Physician

(a) Purpose. The purpose of this section is to provide standards for pharmacists engaged in the administration of immunizations or vaccinations as authorized in Chapter 554 of the Act.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) ACPE--The Accreditation Council for Pharmacy Education.

(2) Act--The Texas Pharmacy Act, Chapter 551 - 566 and 568 - 569, Occupations Code, as amended.

(3) Administer--The direct application of a prescription drug by injection, inhalation, ingestion, or any other means to the body of a patient by:

(A) a practitioner, an authorized agent under his supervision, or other person authorized by law; or

(B) the patient at the direction of a practitioner.

(4) Antibody--A protein in the blood that is produced in response to stimulation by a specific antigen. Antibodies help destroy the antigen that produced them. Antibodies against an antigen usually equate to immunity to that antigen.

(5) Antigen--A substance "recognized" by the body as being foreign; it results in the production of specific antibodies directed against it.

(6) Board--The Texas State Board of Pharmacy.

(7) Confidential record--Any health-related record that contains information that identifies an individual and that is maintained by a pharmacy or pharmacist such as a patient medication record, prescription drug order, or medication order.

(8) Data communication device--An electronic device that receives electronic information from one source and transmits or routes it to another (e.g., bridge, router, switch, or gateway).

(9) Immunization--The act of inducing antibody formation, thus leading to immunity.
(10) Medical Practice Act--The Texas Medical Practice Act, Subtitle B, Occupations Code, as amended.
(11) Vaccination--Administration of any antigen in order to induce immunity; is not synonymous with immunization since vaccination does not imply success.
(12) Vaccine--A specially prepared antigen, which upon administration to a person will result in immunity.
(13) Written Protocol--A physician's order, standing medical order, standing delegation order, or other order or protocol as defined by rule of the Texas Medical Board under the Medical Practice Act.

(A) A written protocol must contain, at a minimum, the following:

(i) a statement identifying the individual physician authorized to prescribe drugs and responsible for the delegation of administration of immunizations or vaccinations;

(ii) a statement identifying the individual pharmacist authorized to administer immunizations or vaccinations as delegated by the physician;

(iii) a statement identifying the location(s) (i.e., address) at which the pharmacist may administer immunizations or vaccinations;

(iv) a statement identifying the immunizations or vaccinations that may be administered by the pharmacist;

(v) a statement identifying the activities the pharmacist shall follow in the course of administering immunizations or vaccinations, including procedures to follow in the case of reactions following administration; and

(vi) a statement that describes the content of, and the appropriate mechanisms for the pharmacist to report the administration of immunizations or vaccinations to the physician issuing the written protocol within the time frames specified in this section.

(B) A standard protocol may be used or the physician may develop an immunization or vaccination protocol for the individual patient. If a standard protocol is used, the physician shall record what deviations, if any, from the standard protocol are ordered for the patient.

(c) Pharmacist certification requirements. Pharmacist who enter into a written protocol with a physician to administer immunizations or vaccinations shall:

(1) complete a course provided by an ACPE approved provider which:

(A) requires documentation by the pharmacist of current certification in the American Heart Association's Basic Cardiac Life Support for Health-Care Providers or its equivalent;

(B) is an evidence-based course which:

(i) includes study material;

(ii) includes hands-on training in techniques for administering immunizations or vaccines; and

(iii) requires testing with a passing score; and

(C) meets current Center for Disease Control training guidelines and provides a minimum of 20 hours of instruction and experiential training in the following content areas:

(i) standards for pediatric, adolescent, and adult immunization practices;

(ii) basic immunology and vaccine protection;

(iii) vaccine-preventable diseases;

(iv) recommended immunization schedules (pediatric/adolescent/adult);

(v) vaccine storage and management;

(vi) informed consent;

(vii) physiology and techniques for vaccine administration;

(viii) pre and post-vaccine assessment and counseling;

(ix) immunization record management; and

(x) adverse events:

(I) identification and appropriate response; and

(II) documentation and reporting; and

(2) maintain documentation of:

(A) completion of the initial course specified in paragraph (1) of this subsection;

(B) 3 hours of continuing education every 2 years which are designed to maintain competency in the disease states, drugs, and administration of immunizations or vaccinations; and

(C) current certification in the American Heart Association's Basic Cardiac Life Support for Health-Care Providers or its equivalent.

(d) Supervision. Pharmacists involved in the administration of immunizations or vaccinations shall be under the supervision of a physician. Physician supervision shall be considered adequate if the delegating physician:

(1) is responsible for the formulation or approval of the physician's order, standing medical order, standing delegation order, or other order or protocol and periodically reviews the order or protocol and the services provided to a patient under the order or protocol;

(2) has established a physician-patient relationship with each patient under 14 years of age and referred the patient to the pharmacist; except a pharmacist may administer an influenza vaccination to a patient over seven years of age without an established physician-patient relationship;

(3) is geographically located so as to be easily accessible to the pharmacist administering the immunization or vaccination;

(4) receives, as appropriate, a periodic status report on the patient, including any problem or complication encountered; and

(5) is available through direct telecommunication for consultation, assistance, and direction.

(e) Special Provisions. Pharmacists involved in the administration of immunizations or vaccinations under their license to practice pharmacy shall meet the following restrictions and requirements.

(1) Pharmacists may only administer immunizations or vaccinations pursuant to a written protocol from a physician authorizing the administration.

(2) Pharmacists may administer immunizations or vaccinations to a patient under 14 years of age only upon a referral from a physician who has an established physician-patient relationship with each patient. However, a pharmacist may administer an influenza vaccination to a patient over seven years of age without an established physician-patient relationship.

(3) Pharmacists may administer immunizations or vaccinations under written protocol of a physician within a pharmacy or at any other location specifically identified in the written protocol. Such other location may not include where the patient resides, except for a licensed nursing home or hospital.

(4) The authority of a pharmacist to administer immunizations or vaccinations may not be delegated.

(5) Pharmacists may administer immunizations and vaccinations only when a licensed health-care provider authorized to administer the medication is not reasonably available to administer the medication. For the purpose of this section, "reasonably available" means those times when the licensed health-care provider is immediately available to administer the immunization or vaccine and is specifically tasked to do so.

(6) Under the provisions of the National Vaccine Injury Compensation Program (NVICP), the health-care provider under whose authority a covered vaccine is administered (i.e., the physician issuing the written protocol) must maintain certain information in the patient's permanent record. In order for the physician to comply with the provisions of the NVICP, the pharmacist shall provide the physician with the information specified in subsection (g) of this section.

(7) Before preparing an immunization or vaccine and between each patient contact, the pharmacist shall cleanse his or her hands with an alcohol-based waterless antiseptic hand rub or shall wash his or her hands with soap and water. If gloves are worn, the pharmacist shall change gloves between patients.

(8) The pharmacist shall comply with all other state and federal requirements regarding immunizations or vaccinations.

(f) Drugs.

(1) Drugs administered by a pharmacist under the provisions of this section shall be in the legal possession of:

(A) a pharmacy, which shall be the pharmacy responsible for drug accountability, including the maintenance of records of administration of the immunization or vaccination; or

(B) a physician who shall be responsible for drug accountability, including the maintenance of records of administration of the immunization or vaccination.

(2) Drugs shall be transported and stored at the proper temperatures indicated for each drug.

(3) Pharmacists while actively engaged in the administration of immunizations or vaccinations under written protocol, may have in their custody and control the drugs for immunization or vaccination that are identified in the written protocol and any other dangerous drugs listed in the written protocol to treat adverse reactions.

(4) After administering immunizations or vaccinations at a location other than a pharmacy, the pharmacist shall return all unused prescription medications to the pharmacy or physician responsible for the drugs.

(g) Notifications.

(1) A pharmacist engaged in the administration of immunizations or vaccinations shall provide notification of the administration to:

(A) the physician who issued the written protocol within 24 hours of administering the immunization or vaccination; and

(B) the primary care physician of the patient, as provided by the patient or patient's agent, within 14 days of administering the immunization or vaccination.

(2) The notifications required in paragraph (1) of this subsection shall include the:

(A) name and address of the patient;

(B) age of the patient if under 14 years of age;

(C) name of the patient's primary care physician as provided by the patient or patient's agent;

(D) name, manufacturer, and lot number of the vaccine administered;

(E) amount administered;

(F) date the vaccine was administered;

(G) site of the immunization or vaccination (e.g., right arm, left leg, right upper arm);

(H) route of administration of the immunization or vaccination (e.g., intramuscular, subcutaneous, by mouth); and

(I) name, address, and title of the person administering the immunization or vaccination.

(h) Records.

(1) Maintenance of records.

(A) Every record, including notifications, required to be made under this section shall be kept by the pharmacist administering the immunization or vaccination and by the pharmacy when in legal possession of the drugs administered. Such records shall be available for at least two years from the date of such record, for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement or regulatory agencies.

(B) Records, including notifications, may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided:

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

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

(2) Records of administration under written protocol.

(A) Records of administration shall be maintained by the pharmacist administering immunizations or vaccinations. Such records shall include:

(i) all of the administration record requirements of subparagraph (B) of this paragraph; and

(ii) include the name and address of the pharmacy or physician in legal possession of the immunization or vaccination administered.

(B) A pharmacy, when responsible for drug accountability, shall maintain a record of administration of immunizations or vaccinations by a pharmacist. The records shall be kept and maintained by patient name. This record shall include:

(i) a copy of the written protocol under which the immunization or vaccination was administered and any patient-specific deviations from the protocol;
(ii) name and address of the patient;
(iii) age of the patient if under 14 years of age;
(iv) name of the patient's primary care physician as provided by the patient or patient's agent;
(v) name, manufacturer, and lot number of the vaccine administered;
(vi) amount administered;
(vii) date the vaccine was administered;
(viii) site of the immunization or vaccination (e.g., right arm, left leg, right upper arm);
(ix) route of administration of the immunization or vaccination (e.g., intramuscular, subcutaneous, by mouth); and
(x) name, address, and title of the person administering the immunization or vaccination.

(3) Written protocol.

(A) A copy of the written protocol and any patient-specific deviations from the protocol shall be maintained in accordance with paragraph (2) of this subsection.
(B) A standard protocol may be used or the attending physician may develop an immunization/vaccination protocol for the individual patient. If a standard protocol is used, the physician shall record what deviations, if any, from the standard protocol are ordered for the patient. The pharmacy that is in possession of the vaccines administered shall maintain a copy of any deviations from the standard protocol ordered by the physician.
(C) Written protocols, including standard protocols, any patient-specific deviations from a standard protocol, and any individual patient protocol, shall be reviewed by the physician and pharmacist at least annually and revised if necessary. Such review shall be documented in the records of the pharmacy that is in possession of the vaccines administered.

(i) Confidentiality.

(1) In addition to the confidentiality requirements specified in §291.27 of this title (relating to Confidentiality) a pharmacist shall comply with:

(A) the privacy provisions of the federal Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191) and any rules adopted pursuant to this act;
(B) the requirements of Medical Records Privacy contained in Chapter 181, Health and Safety Code;
(C) the Privacy of Health Information requirements contained in Chapter 28B of the Insurance Code; and
(D) any other confidentiality provisions of federal or state laws.

(2) This section shall not affect or alter the provisions relating to the confidentiality of the physician-patient communication as specified in the Medical Practice Act, Chapter 159.

§295.16 Administration of Epinephrine by a Pharmacist

(a) Purpose. The purpose of this section is to allow pharmacists to administer epinephrine through an auto-injector device to a patient in an emergency situation as authorized in Chapter 562 of the Act.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Act--The Texas Pharmacy Act, Chapter 551 - 569, Occupations Code, as amended.

(2) Administer--The direct application of a prescription drug to the body of an individual by any means, including injection, by a pharmacist.

(3) Anaphylaxis--A sudden, severe, and potentially life-threatening allergic reaction that occurs when a person is exposed to an allergen. Symptoms may include shortness of breath, wheezing, difficulty breathing, difficulty

talking or swallowing, hives, itching, swelling, shock, or asthma. Causes may include, but are not limited to, an insect sting, food allergy, drug reaction, and exercise.

(4) Epinephrine auto-injector--A disposable drug delivery system that contains a premeasured single dose of epinephrine that is used to treat anaphylaxis in an emergency situation.

(c) Administration requirements.

(1) Pharmacists may administer epinephrine through an auto-injector to a patient in an emergency situation.

(2) The authority of a pharmacist to administer epinephrine through an auto-injector may not be delegated.

(3) Epinephrine administered by a pharmacist under the provisions of this section shall be in the legal possession of a pharmacist or the legal possession of a pharmacy which shall be the pharmacy responsible for drug accountability, including the maintenance of records of administration of the epinephrine.

(d) Limitation on liability.

(1) A pharmacist who in good faith administers epinephrine through an auto-injector in accordance with this section and Chapter 562 of the Act is not liable for civil damages for an act performed in the administration unless the act is willfully or wantonly negligent.

(2) A pharmacist may not receive remuneration for the administration of epinephrine through an auto-injector but may seek reimbursement for the cost of the epinephrine auto-injector.

(3) The administration of epinephrine through an auto-injector to a patient in accordance with the requirements of this section and Chapter 562 of the Act does not constitute the unlawful practice of any health care profession.

(e) Notifications.

(1) A pharmacist who administers epinephrine through an auto-injector to a patient shall report the use to the patient's primary care physician, as identified by the patient, as soon as practical, but in no event more than 72 hours from the time of administering the epinephrine.

(2) Immediately, after administering the epinephrine auto-injector, the pharmacist shall ensure that 911 is called and the patient is evaluated by emergency personnel for possible transfer to the nearest emergency department for additional evaluation, monitoring, and treatment.

(3) The notifications required in paragraph (1) of this subsection shall include the:

(A) name of the patient;

(B) age of the patient if under 8 years of age;

(C) name and manufacturer of the epinephrine auto-injector;

(D) date the epinephrine was administered;

(E) name and title of the person administering the epinephrine; and

(F) name, address, and telephone number of the pharmacy.

(f) Records.

(1) The notification required to be made under this section shall be kept by the pharmacy and such records shall be available for at least two years from the date of such record, for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement or regulatory agencies.

(2) The notification 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 request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.

CHAPTER 297 – PHARMACY TECHNICIANS AND PHARMACY TECHNICIAN TRAINEES

§297.1 Purpose

The purpose of this chapter is to provide a comprehensive, coherent regulatory scheme for the registration and training of pharmacy technicians and pharmacy technician trainees in this state. The provisions of this chapter, in conjunction with the Texas Pharmacy Act (Chapters 551 - 566 and 568 - 569, Texas Occupations Code, as amended), govern the method for the issuance of a registration to a pharmacy technician and a pharmacy technician trainee in Texas.

§297.2 Definitions

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

(1) Act--The Texas Pharmacy Act, Chapters 551 - 566 and 568 - 569, Texas Occupations Code, as amended.

(2) Board--The Texas State Board of Pharmacy.

(3) Common ownership--Two or more pharmacies with an identical owner of record with the board or that have owners of record with the board that are a parent, subsidiary, or affiliate of one another under §1.002, Business Organizations Code.

(4) Owner of record--The direct owner of the pharmacy provided on the pharmacy's application for a pharmacy license or most recent approved change of ownership form.

(5) Pharmacy technician--An individual who is registered with the Board as a pharmacy technician and whose responsibility in a pharmacy is to provide technical services that do not require professional judgment regarding preparing and distributing drugs and who works under the direct supervision of and is responsible to a pharmacist.

(6) Pharmacy technician trainee--An individual who is registered with the board as a pharmacy technician trainee and is authorized to participate in a pharmacy's technician training program.

§297.3 Registration Requirements

(a) General.

(1) Individuals who are not registered with the Board may not be employed as or perform the duties of a pharmacy technician or pharmacy technician trainee.

(2) Individuals who have previously applied and registered as a pharmacy technician, regardless of the pharmacy technician's current registration status, may not register as a pharmacy technician trainee.

(3) Individuals who apply and are qualified for both a pharmacy technician trainee registration and a pharmacy technician registration concurrently will not be considered for a pharmacy technician trainee registration.

(b) Registration for pharmacy technician trainees. An individual may register as a pharmacy technician trainee only once and the registration may not be renewed.

(1) Each applicant for pharmacy technician trainee registration shall:

(A) have a high school or equivalent diploma (e.g., GED), or be working to achieve a high school or equivalent diploma. For the purposes of this subparagraph, an applicant for registration may be working to achieve a high school or equivalent diploma for no more than two years;

(B) complete the Texas application for registration that includes the following information:

(i) name;

(ii) addresses, phone numbers, date of birth, and social security number; and

(iii) any other information requested on the application.

(C) meet all requirements necessary in order for the Board to access the criminal history record information, including submitting fingerprint information and paying the required fees.

(2) Once an applicant has successfully completed all requirements of registration, and the board has determined there are no grounds to refuse registration, the applicant will be notified of registration as a pharmacy technician trainee and of his or her pharmacy technician trainee registration number.

(3) Pharmacy technician trainee registrations expire two years from the date of registration or upon issuance of registration as a registered pharmacy technician, whichever is earlier.

(c) Initial registration for pharmacy technicians.

(1) Each applicant for pharmacy technician registration shall:

(A) have a high school or equivalent diploma (e.g., GED), or be working to achieve a high school or equivalent diploma. For the purpose of this clause, an applicant for registration may be working to achieve a high school or equivalent diploma for no more than two years; and

(B) either have:

(i) taken and passed a pharmacy technician certification examination approved by the board and have a current certification certificate; or

(ii) been granted an exemption from certification by the board as specified in §297.7 of this title (relating to Exemption from Pharmacy Technician Certification Requirements); and

(C) complete the Texas application for registration that includes the following information:

(i) name;

(ii) addresses, phone numbers, date of birth, and social security number; and

(iii) any other information requested on the application.

(D) meet all requirements necessary in order for the Board to access the criminal history record information, including submitting fingerprint information and paying the required fees; and

(E) pay the registration fee specified in §297.4 of this title (relating to Fees).

(2) Once an applicant has successfully completed all requirements of registration, and the board has determined there are no grounds to refuse registration, the applicant will be notified of registration as a registered pharmacy technician and of his or her pharmacy technician registration number. If the pharmacy technician applicant was registered as a pharmacy technician trainee at the time the pharmacy technician registration is issued, the pharmacy technician trainee registration expires.

(d) Renewal.

(1) All applicants for renewal of a pharmacy technician registration shall:

(A) complete the Texas application for registration that includes the following information:

(i) name;

(ii) addresses, phone numbers, date of birth, and social security number;

(iii) meet all requirements necessary in order for the Board to access the criminal history record information, including submitting fingerprint information and being responsible for all associated costs; and

(iv) any other information requested on the application.

(B) pay the renewal fee specified in §297.4 of this title; and

(C) complete 20 contact hours of continuing education per renewal period as specified in §297.8 of this title (relating to Continuing Education).

(2) A pharmacy technician registration expires on the last day of the assigned expiration month.

(3) As specified in §568.004 of the Act, if the completed application and renewal fee are not received in the board's office on or before the last day of the assigned expiration month, the person's pharmacy technician registration shall expire. An expired registration shall be renewed according to the following schedule.

(A) If a pharmacy technician registration has expired for 90 days or less, the person may become registered by making application and paying to the board a renewal fee that is equal to one and one-half times the renewal fee for the registration as specified in §297.4 of this title (relating to Fees).

(B) If a pharmacy technician registration has been expired for more than 90 days but less than one year, the person may become registered by making application and paying to the board a renewal fee that is equal to two times the renewal fee for the registration as specified in §297.4 of this title.

(C) If a pharmacy technician registration has expired for more than one year, the pharmacy technician may not renew the registration and must complete the requirements for initial registration as specified in subsection (c) of this section.

(4) After review, the board may determine that paragraph (3)(C) of this subsection does not apply if the registrant is the subject of a pending investigation or disciplinary action.

(e) An individual may use the title "Registered Pharmacy Technician" or "Ph.T.R." if the individual is registered as a pharmacy technician in this state.

§297.4 Fees

(a) Pharmacy technician trainee. The fee for registration shall be $55 for a two-year registration.

(b) Pharmacy technician.

(1) Biennial Registration. The board shall require biennial renewal of all pharmacy technician registrations provided under Chapter 568 of the Act.

(2) Initial Registration Fee. The fee for initial registration shall be $88 for a two-year registration.

(3) Renewal Fee. The fee for biennial renewal shall be $85 for a two-year registration.

§297.5 Pharmacy Technician Trainees

(a) A person designated as a pharmacy technician trainee shall be registered with the board prior to beginning training in a Texas licensed pharmacy.

(b) A person may be designated as a pharmacy technician trainee for no more than two years and the requirements for registration as a pharmacy technician must be completed within the two year period.

§297.6 Pharmacy Technician and Pharmacy Technician Trainee Training

(a) Pharmacy technicians and pharmacy technician trainees shall complete initial training as outlined by the pharmacist-in-charge in a training manual. Such training:

(1) shall meet the requirements of subsections (d) or (e) of this section; and

(2) may not be transferred to another pharmacy unless:

(A) the pharmacies are under common ownership and control and have a common training program; and

(B) the pharmacist-in-charge of each pharmacy in which the pharmacy technician or pharmacy technician trainee works certifies that the pharmacy technician or pharmacy technician trainee is competent to perform the duties assigned in that pharmacy.

(b) The pharmacist-in-charge shall assure the continuing competency of pharmacy technicians and pharmacy technician trainees through in-service education and training to supplement initial training.

(c) The pharmacist-in-charge shall document the completion of the training program and certify the competency of pharmacy technicians and pharmacy technician trainees completing the training. A written record of initial and in-service training of pharmacy technicians and pharmacy technician trainees shall be maintained and contain the following information:

(1) name of the person receiving the training;

(2) date(s) of the training;

(3) general description of the topics covered;

(4) a statement that certifies that the pharmacy technician or pharmacy technician trainee is competent to perform the duties assigned;

(5) name of the person supervising the training; and

(6) signature of the pharmacy technician or pharmacy technician trainee and the pharmacist-in-charge or other pharmacist employed by the pharmacy and designated by the pharmacist-in-charge as responsible for training of pharmacy technicians and pharmacy technician trainees.

(d) A person who has previously completed the training program outlined in subsection (e) of this section, a licensed nurse, or physician assistant is not required to complete the entire training program outlined in subsection (e) of this section if the person is able to show competency through a documented assessment of competency. Such competency assessment may be conducted by personnel designated by the pharmacist-in-charge, but the final acceptance of competency must be approved by the pharmacist-in-charge.

(e) Pharmacy technician and pharmacy technician trainee training shall be outlined in a training manual. Such training manual shall, at a minimum, contain the following:

(1) written procedures and guidelines for the use and supervision of pharmacy technicians and pharmacy technician trainees. Such procedures and guidelines shall:

(A) specify the manner in which the pharmacist responsible for the supervision of pharmacy technicians and pharmacy technician trainees will supervise such personnel and verify the accuracy and completeness of all acts, tasks, and functions performed by such personnel; and

(B) specify duties which may and may not be performed by pharmacy technicians and pharmacy technician trainees; and

(2) instruction in the following areas and any additional areas appropriate to the duties of pharmacy technicians and pharmacy technician trainees in the pharmacy:

(A) Orientation;

(B) Job descriptions;

(C) Communication techniques;

(D) Laws and rules;

(E) Security and safety;

(F) Prescription drugs:

(i) Basic pharmaceutical nomenclature;

(ii) Dosage forms;

(G) Drug orders:

(i) Prescribers;

(ii) Directions for use;

(iii) Commonly-used abbreviations and symbols;

(iv) Number of dosage units;

(v) Strengths and systems of measurement;

(vi) Routes of administration;

(vii) Frequency of administration; and

(viii) Interpreting directions for use;

(H) Drug order preparation:

(i) Creating or updating patient medication records;

(ii) Entering drug order information into the computer or typing the label in a manual system;

(iii) Selecting the correct stock bottle;

(iv) Accurately counting or pouring the appropriate quantity of drug product;

(v) Selecting the proper container;

(vi) Affixing the prescription label;

(vii) Affixing auxiliary labels, if indicated; and

(viii) Preparing the finished product for inspection and final check by pharmacists;

(I) Other functions;

(J) Drug product prepackaging;

(K) Written policy and guidelines for use of and supervision of pharmacy technicians and pharmacy technician trainees; and

(L) Confidential patient medication records.

(f) Pharmacy technicians and pharmacy technician trainees compounding non-sterile pharmaceuticals shall meet the training and education requirements specified in the rules for the class of pharmacy in which the pharmacy technician or pharmacy technician trainee is working.

(g) Pharmacy technicians and pharmacy technician trainees compounding sterile pharmaceuticals shall meet the training and education requirements specified in the rules for class of pharmacy in which the pharmacy technician or pharmacy technician trainee is working.

§297.7 Exemption from Pharmacy Technician Certification Requirements

(a) Purpose. This section outlines procedures to petition the board for an exemption to the certification requirements established by §568.002 of the Act (relating to Pharmacy Technician Registration Required). The board will consider petitions for exemption on a case by case basis.

(b) Long-term exempt pharmacy technicians. Long-term exempt pharmacy technicians are pharmacy technicians who, on September 1, 2001, had been continuously employed as a pharmacy technician in this state for at least 10 years and who received an exemption from the board.

(c) Rural county exempt pharmacy technicians. Rural county exempt pharmacy technicians are pharmacy technicians working in counties with a population of 50,000 or less and meet the following requirements.

(1) Eligibility. An individual may petition the board for an exemption from the certification requirements established by §568.002 of the Act (relating to Pharmacy Technician Registration Required) if the individual works in a county with a population of 50,000 or less.

(2) Petition process.

(A) An individual shall petition the board for the exemption. The petition shall contain the following:

(i) name of the individual;

(ii) name, address, and license number of the pharmacy where the individual is employed;

(iii) name of the county in which the pharmacy is located and the most recent official population estimate for the county from the Texas State Data Center;

(iv) a notarized statement signed by the individual stating:

(I) the reason(s) the individual is asking for the exemption, including reason(s) the individual has not taken and passed a pharmacy technician certification examination approved by the board; and

(II) that the information provided in the petition is true and correct; and

(v) a notarized statement signed by the pharmacist-in-charge of the pharmacy the individual is currently working, stating that the:

(I) pharmacist-in-charge supports the individual's petition for exemption;

(II) individual has completed the pharmacy technician training program at the pharmacy; and

(III) pharmacist-in-charge has personally worked with and observed that the individual is competent to perform the duties of a pharmacy technician.

(B) Each petition shall be considered on an individual basis. In determining whether to grant the exemption, the board shall consider the information contained in the petition and additional information including the following:

(i) the accuracy and completeness of the petition;

(ii) reason(s) the individual is asking for the exemption;

(iii) the population of the county;

(iv) the number of pharmacies located in the county and adjacent counties and the number of pharmacy technicians working in these pharmacies;

(v) unemployment rate in the county and adjacent counties; and

(vi) the following information concerning the pharmacy where the individual is currently working:

(I) the degree of compliance on previous compliance inspections; and

(II) history of disciplinary action by the board or other regulatory agencies against the licenses held by the pharmacy or pharmacists working at the pharmacy.

(C) After review of the petition, the individual and the pharmacist-in-charge of the pharmacy where the individual is working shall be notified in writing of approval or denial of the petition.

(D) If the petition is approved, the individual shall register with the board as a pharmacy technician.

(3) Limitations.

(A) The exemption granted under this subsection may only be used at the pharmacy noted in the petition and may not be transferred to another pharmacy. If the pharmacy technician ceases employment at the pharmacy or changes employment, the exemption is canceled.

(B) If the population of the county exceeds 50,000, the board shall cancel the exemption. The pharmacy technician and the pharmacist-in-charge of the pharmacy shall be notified when an exemption is canceled.

(C) If the exemption granted under subparagraphs (A) or (B) of this paragraph is cancelled, the pharmacy technician's registration is void and the registration certificate must be surrendered to the Board.

§297.8 Continuing Education Requirements

(a) Pharmacy technician trainees. Pharmacy technician trainees are not required to complete continuing education.

(b) Pharmacy technicians.

(1) All pharmacy technicians shall be exempt from the continuing education requirements during their initial registration period.

(2) All pharmacy technicians shall complete and report 20 contact hours of approved continuing education and any courses required under paragraph (4) of this subsection obtained during the previous renewal period in order to renew their registration as a pharmacy technician. No more than 5 of the 20 contact hours may be earned at the pharmacy technician's workplace through in-service education and training under the direct supervision of the pharmacist(s).

(3) A pharmacy technician may satisfy the continuing education requirements by:

(A) successfully completing the number of continuing education hours necessary to renew a registration as specified in paragraph (2) of this subsection;

(B) successfully completing during the preceding license period, one credit hour for each year of the renewal period, in pharmacy related college course(s); or

(C) taking and passing a pharmacy technician certification examination approved by the board during the preceding renewal period, which shall be equivalent to the number of continuing education hours necessary to renew a registration as specified in paragraph (2) of this subsection.

(4) To renew a registration, a pharmacy technician shall report on the renewal application completion of at least twenty contact hours of continuing education and any courses required under this paragraph. The following is applicable to the reporting of continuing education:

(A) at least one contact hour of the 20 contact hours specified in paragraph (2) of this subsection shall be related to Texas pharmacy laws or rules;

(B) any continuing education requirements which are imposed upon a pharmacy technician as a part of a board order or agreed board order shall be in addition to the requirements of this section; and

(C) a pharmacy technician shall have completed the human trafficking prevention course required in §116.002 of the Texas Occupations Code.

(5) Pharmacy technicians are required to maintain records of completion of approved continuing education for three years from the date of reporting the contact hours or course completion on a renewal application. The records shall contain at least the following information:

(A) name of participant;

(B) title and date of program;

(C) program sponsor or provider (the organization);

(D) number of hours awarded; and

(E) dated signature of sponsor representative.

(6) The board shall use the continuing education tracking system described in subsection (c) of this section to audit the records of pharmacy technicians for verification of reported continuing education contact hours or course completion. The following is applicable for such audits.

(A) Upon written request, a pharmacy technician shall provide to the board copies of the record required to be maintained in paragraph (5) of this subsection or certificates of completion for all continuing education contact hours and course completions reported during a specified registration period. Failure to provide all requested records by the specified deadline constitutes prima facie evidence of a violation of this rule.

(B) Credit for continuing education contact hours or course completions shall only be allowed for approved programs or required courses for which the pharmacy technician submits copies of records reflecting that the hours or courses were completed during the specified registration period(s). Any other reported hours or course completion shall be disallowed.

(C) A pharmacy technician who submits false or fraudulent records to the board shall be subject to disciplinary action by the board.

(7) The following is applicable if a pharmacy technician fails to report completion of the required continuing education.

(A) The registration of a pharmacy technician who fails to report completion of the required number of continuing education contact hours or any courses required under paragraph (4) of this subsection shall not be renewed and the pharmacy technician shall not be issued a renewal certificate for the license period until such time as the pharmacy technician successfully completes the required continuing education and reports the completion to the board.

(B) A person shall not practice as a pharmacy technician without a current renewal certificate.

(8) A pharmacy technician who has had a physical disability, illness, or other extenuating circumstances which prohibits the pharmacy technician from obtaining continuing education credit during the preceding license period may be granted an extension of time to complete the continued education requirement. The following is applicable for this extension:

(A) The pharmacy technician shall submit a petition to the board with his/her registration renewal application which contains:

(i) the name, address, and registration number of the pharmacy technician;

(ii) a statement of the reason for the request for extension;

(iii) if the reason for the request for extension is health related, a statement from the attending physician(s) treating the pharmacy technician which includes the nature of the physical disability or illness and the dates the pharmacy technician was incapacitated; and

(iv) if the reason for the request for the extension is for other extenuating circumstances, a detailed explanation of the extenuating circumstances and if because of military deployment, documentation of the dates of the deployment.

(B) After review and approval of the petition, a pharmacy technician may be granted an extension of time to comply with the continuing education requirement which shall not exceed one license renewal period.

(C) An extension of time to complete continuing education credit does not relieve a pharmacy technician from the continuing education requirement during the current license period.

(D) If a petition for extension to the reporting period for continuing education is denied, the pharmacy technician shall:

(i) have 60 days to complete and report completion of the required continuing education requirements; and

(ii) be subject to the requirements of paragraph (6) of this subsection relating to failure to report completion of the required continuing education if the required continuing education is not completed and reported within the required 60-day time period.

(9) The following are considered approved programs for pharmacy technicians.

(A) Any program presented by an Accreditation Council for Pharmacy Education (ACPE) approved provider subject to the following conditions.

(i) Pharmacy technicians may receive credit for the completion of the same ACPE course only once during a renewal period.

(ii) Pharmacy technicians who present approved ACPE continuing education programs may receive credit for the time expended during the actual presentation of the program. Pharmacy technicians may receive credit for the same presentation only once during a license period.

(iii) Proof of completion of an ACPE course shall contain the following information:

(I) name of the participant;

(II) title and completion date of the program;

(III) name of the approved provider sponsoring or cosponsoring the program;

(IV) number of contact hours awarded;

(V) the assigned ACPE universal program number and a "T" designation indicating that the CE is targeted to pharmacy technicians; and

(VI) either:

(-a-) a dated certifying signature of the approved provider and the official ACPE logo; or

(-b-) the Continuing Pharmacy Education Monitor logo.

(B) Pharmacy related college courses which are part of a pharmacy technician training program or part of a professional degree program offered by a college of pharmacy.

(i) Pharmacy technicians may receive credit for the completion of the same course only once during a license period. A course is equivalent to one credit hour for each year of the renewal period. One credit hour is equal to 15 contact hours.

(ii) Pharmacy technicians who teach these courses may receive credit towards their continuing education, but such credit may be received only once for teaching the same course during a license period. Documentation of the course instruction shall be a signed letter from the academic administrator (e.g., department head, program director) of the training program or professional degree program that contains the course title and completion date, the name of the pharmacy technician who taught the course, and the proportion of the course taught by the pharmacy technician, if the course was co-taught. A pharmacy technician who co-teaches a course shall receive continuing education credit in proportion to the percentage of the course taught by the pharmacy technician, rounded to the nearest contact hour.

(C) Basic cardiopulmonary resuscitation (CPR) courses which lead to CPR certification by the American Red Cross or the American Heart Association or its equivalent shall be recognized as approved programs. Pharmacy technicians may receive credit for one contact hour towards their continuing education requirement for completion of a CPR course only once during a renewal period. Proof of completion of a CPR course shall be the certificate issued by the American Red Cross or the American Heart Association or its equivalent.

(D) Advanced cardiovascular life support courses (ACLS) or pediatric advanced life support (PALS) courses which lead to initial ACLS or PALS certification by the American Heart Association or its equivalent shall be recognized as approved programs. Pharmacy technicians may receive credit for twelve contact hours towards their continuing education requirement for completion of an ACLS or PALS course only once during a renewal period. Proof of completion of an ACLS or PALS course shall be the certificate issued by the American Heart Association or its equivalent.

(E) Advanced cardiovascular life support courses (ACLS) or pediatric advanced life support (PALS) courses which lead to ACLS or PALS recertification by the American Heart Association or its equivalent shall be recognized as approved programs. Pharmacy technicians may receive credit for four contact hours towards their continuing education requirement for completion of an ACLS or PALS recertification course only once during a renewal period. Proof of completion of an ACLS or PALS recertification course shall be the certificate issued by the American Heart Association or its equivalent.

(F) Attendance at programs presented by the Texas State Board of Pharmacy or courses offered by the Texas State Board of Pharmacy as follows:

(i) Pharmacy technicians shall receive credit for the number of hours for the program or course as stated by the Texas State Board of Pharmacy.

(ii) Proof of attendance at a program presented by the Texas State Board of Pharmacy or completion of a course offered by the Texas State Board of Pharmacy shall be a certificate issued by the Texas State Board of Pharmacy.

(G) Programs approved by the American Medical Association (AMA) as Category 1 Continuing Medical Education (CME) and accredited by the Accreditation Council for Continuing Medical Education (ACCME) subject to the following conditions.

(i) Pharmacy technicians may receive credit for the completion of the same CME course only once during a license period.

(ii) Pharmacy technicians who present approved CME programs may receive credit for the time expended during the actual presentation of the program. Pharmacy technicians may receive credit for the same presentation only once during a license period.

(iii) Proof of completion of a CME course shall contain the following information:

(I) name of the participant;

(II) title and completion date of the program;

(III) name of the approved provider sponsoring or cosponsoring the program;

(IV) number of contact hours awarded; and

(V) a dated certifying signature of the approved provider.

(H) In-service education provided under the direct supervision of a pharmacist shall be recognized as continuing education as follows:

(i) Pharmacy technicians shall receive credit for the number of hours provided by pharmacist(s) at the pharmacy technician's place of employment.

(ii) Proof of completion of in-service education shall contain the following information:

(I) name of the participant;

(II) title or description of the program;

(III) completion date of the program;

(IV) name of the pharmacist supervising the in-service education;

(V) number of hours; and

(VI) a dated signature of the pharmacist providing the in-service education.

(c) Continuing education tracking system. As specified in §112.103 of the Texas Occupations Code, proof of completion of all continuing education requirements shall be reported to the board through the board's continuing education tracking system. A pharmacy technician shall not be issued a renewal certificate for the license period unless the

pharmacy technician has reported the completion of all required contact hours and any courses required under subsection (b)(4) of this section through the continuing education tracking system.

§297.9 Notifications

(a) Change of Address and/or Name.

(1) Change of address. A pharmacy technician or pharmacy technician trainee shall notify the board electronically or in writing within 10 days of a change of address, giving the old and new address and registration number.

(2) Change of name.

(A) A pharmacy technician or pharmacy technician trainee shall notify the board in writing within 10 days of a change of name by sending a copy of the official document reflecting the name change (e.g., marriage certificate, divorce decree, etc.).

(B) An amended registration and/or certificate reflecting the new name of the pharmacy technician or pharmacy technician trainee will be issued by the board.

(b) Change of Employment. A pharmacy technician or pharmacy technician trainee shall report electronically or in writing to the board within 10 days of a change of employment giving the name and license number of the old and new pharmacy and registration number.

§297.10 Registration for Military Service Members, Military Veterans, and Military Spouses

(a) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Active duty--Current full-time military service in the armed forces of the United States or active duty military service as a member of the Texas military forces, or similar military service of another state.

(2) Armed forces of the United States--The army, navy, air force, space force, coast guard, or marine corps of the United States or a reserve unit of one of those branches of the armed forces.

(3) Military service member--A person who is on active duty.

(4) Military spouse--A person who is married to a military service member.

(5) Military veteran--A person who has served on active duty and who was discharged or released from active duty.

(b) Alternative registration procedure. For the purpose of §55.004, Occupations Code, a military service member, military veteran, or military spouse may complete the following alternative procedures to apply for a pharmacy technician registration if the applicant holds a current registration issued by another state that is similar in scope of practice to the registration in this state and is in good standing with that state's licensing authority or within the five years preceding the application date held a pharmacy technician registration in this state.

(1) Provisional registration. On receipt by the board of an application for a pharmacy technician registration in accordance with this subsection, the board shall issue a provisional registration to the applicant while the board processes the application. A provisional registrations issued under this subsection expires on the earlier of:

(A) the date the board approves or denies the provisional registration holder's application for the registration; or

(B) the 180th date after the date the provisional registration is issued.

(2) An applicant who holds a current registration as a pharmacy technician issued by another state but does not have a current pharmacy technician certification certificate shall meet the requirements for registration as a pharmacy technician trainee as specified in §297.3 of this chapter (relating to Registration Requirements).

(3) An applicant who held a pharmacy technician registration in Texas that expired within the five years preceding the application date who meets the following requirements may be granted a pharmacy technician registration. The applicant:

(A) shall complete the Texas application for registration that includes the following:

(i) name;

(ii) addresses, phone numbers, date of birth, and social security number; and
(iii) any other information requested on the application;
(B) shall provide documentation to include:
(i) military identification indicating that the applicant is a military service member, military veteran, or military dependent, if a military spouse; and
(ii) marriage certificate, if the applicant is a military spouse; applicant's spouse is on active duty status;
(C) be exempt from the application fees paid to the board set forth in §297.4(a) and (b)(2) of this chapter (relating to Fees);
(D) shall meet all necessary requirements in order for the board to access the criminal history records information, including submitting fingerprint information and such criminal history check does not reveal any charge or conviction for a crime that §281.64 of this title (relating to Sanctions for Criminal Offenses) indicates a sanction of denial, revocation, or suspension; and
(E) is not required to have a current pharmacy technician certification certificate.

(c) Expedited registration procedure. For the purpose of §55.005, Occupations Code, a military service member, military veteran or military spouse may complete the following expedited procedures to apply for a pharmacy technician registration if the applicant holds a current registration issued by another state that is similar in scope of practice to the registration in this state and is in good standing with that state's licensing authority or within the five years preceding the application date held a pharmacy technician registration in this state.

(1) The applicant shall:
(A) have a high school or equivalent diploma (e.g., GED), or be working to achieve a high school or equivalent diploma. For the purpose of this clause, an applicant for registration may be working to achieve a high school or equivalent diploma for no more than two years;
(B) have taken and passed a pharmacy technician certification examination approved by the board and have a current certification certificate;
(C) complete the Texas application for registration that includes the following information:
(i) name;
(ii) addresses, phone numbers, date of birth, and social security number; and
(iii) any other information requested on the application;
(D) meet all requirements necessary in order for the Board to access the criminal history record information, including submitting fingerprint information and paying the required fees; and
(E) shall be exempt from the registration fee as specified in §297.4(b)(2) of this chapter.

(2) Once an applicant has successfully completed all requirements of registration, and the board has determined there are no grounds to refuse registration, the applicant shall be notified of registration as a registered pharmacy technician and of his or her pharmacy technician registration number.

(3) All applicants for renewal of an expedited pharmacy technician registration issued to a military service member, military veteran, or military spouse shall comply with the renewal procedures as specified in §297.3 of this chapter.

(d) Registration renewal. As specified in §55.003, Occupations Code, a military service member who holds a pharmacy technician registration is entitled to two years of additional time to complete any requirements related to the renewal of the military service member's registration.

(1) A military service member who fails to renew their pharmacy technician registration in a timely manner because the individual was serving as a military service member shall submit to the board:
(A) name, address, and registration number of the pharmacy technician;
(B) military identification indicating that the individual is a military service member; and
(C) a statement requesting up to two years of additional time to complete the renewal.

(2) A military service member specified in paragraph (1) of this subsection shall be exempt from fees specified in §297.3(d)(3) of this chapter.

(3) A military service member specified in paragraph (1) of this subsection is entitled to two additional years of time to complete the continuing education requirements specified in §297.8 of this title (relating to Continuing Education Requirements).

(e) Interim registration for military service member or military spouse. In accordance with §55.0041, Occupations Code, a military service member or military spouse may be issued an interim pharmacy technician registration if the member or spouse currently holds a registration similar in scope of practice issued by the licensing authority of another state and is in good standing with that licensing authority as specified in §55.0042, Occupations Code.

(1) Before engaging in pharmacy technician duties, the military service member or military spouse shall submit an application that includes:

(A) a copy of the member's military orders showing relocation to this state;

(B) if the applicant is a military spouse, a copy of the military spouse's marriage certificate; and;

(C) a notarized affidavit affirming under penalty of perjury that:

(i) the applicant is the person described and identified in the application;

(ii) all statements in the application are true, correct, and complete;

(iii) the applicant understands the scope of practice for a pharmacy technician registration in this state and will not perform outside of that scope of practice; and

(iv) the applicant is in good standing in each state in which the applicant holds or has held a pharmacy technician registration.

(2) A military service member or military spouse applying for an interim registration under this subsection may not engage in pharmacy technician duties in this state until issued an interim pharmacy technician registration.

(3) For a military service member or military spouse applying for an interim registration under this subsection, the board shall:

(A) determine whether the state in which the applicant is registered issues registrations similar in scope of practice to a pharmacy technician registration issued by the board; and

(B) notify the applicant that:

(i) the board is issuing the interim registration;

(ii) the application is incomplete; or

(iii) the board is unable to issue the interim registration because a pharmacy technician registration issued by the board is not similar in scope of practice to the applicant's registration.

(4) A military service member or military spouse may engage in pharmacy technician duties under an interim registration issued under this subsection only for the period during which the military service member or, with respect to a military spouse, the military service member to whom the spouse is married is stationed at a military installation in this state.

(5) In the event of a divorce or similar event that affects a person's status as a military spouse, the former spouse may continue to engage in pharmacy technician duties under an interim registration issued under this subsection until the third anniversary of the date the spouse submitted the application required under paragraph (1) of this subsection.

(6) While engaged in pharmacy technician duties in this state, the military service member or military spouse shall comply with all other laws and regulations applicable to practicing as a pharmacy technician in this state.

(f) Relationship to federal law. This section establishes requirements and procedures authorized or required by Texas Occupations Code, Chapter 55, and does not modify or alter rights that may be provided under federal law.

§297.11 Temporary Emergency Registration

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

(1) Emergency situation--An emergency caused by a natural or manmade disaster or any other exceptional situation that causes an extraordinary demand for pharmacist services.

(2) State--One of the 50 United States of America, the District of Columbia, and Puerto Rico.

(b) Emergency Temporary Pharmacy Technician Registration. In an emergency situation, the board may grant a pharmacy technician who holds a current registration in another state an emergency temporary pharmacy technician registration to practice in Texas. The following is applicable for the emergency temporary pharmacy technician registration.

(1) An applicant for an emergency temporary pharmacy technician registration under this section must hold a current pharmacy technician registration in another state and that registration and other registrations held by the applicant in any other state may not be suspended, revoked, canceled, surrendered, or otherwise restricted for any reason.

(2) To qualify for an emergency temporary pharmacy technician registration, the applicant must submit an application including the following information:

(A) name, address, and phone number of the applicant; and

(B) any other information the required by the board.

(3) An emergency temporary pharmacy technician registration shall be valid for a period as determined by the board not to exceed six months. The executive director of the board, in his/her discretion, may renew the registration for an additional six months, if the emergency situation still exists.

(c) Exception. This section is not applicable to pharmacy technicians enrolled in a volunteer health registry maintained by the Texas Department of State Health Services.

CHAPTER 303 – DESTRUCTION OF DRUGS

§303.1 Destruction of Dispensed Drugs

(a) Drugs dispensed to patients in health care facilities or institutions.

(1) Destruction by the consultant pharmacist. The consultant pharmacist, if in good standing with the Texas State Board of Pharmacy, is authorized to destroy dangerous drugs dispensed to patients in health care facilities or institutions. A consultant pharmacist may destroy controlled substances as allowed to do so by federal laws or rules of the Drug Enforcement Administration. Dangerous drugs may be destroyed provided the following conditions are met.

(A) A written agreement exists between the facility and the consultant pharmacist.

(B) The drugs are inventoried and such inventory is verified by the consultant pharmacist. The following information shall be included on this inventory:

(i) name and address of the facility or institution;

(ii) name and pharmacist license number of the consultant pharmacist;

(iii) date of drug destruction;

(iv) date the prescription was dispensed;

(v) unique identification number assigned to the prescription by the pharmacy;

(vi) name of dispensing pharmacy;

(vii) name, strength, and quantity of drug;

(viii) signature of consultant pharmacist destroying drugs;

(ix) signature of the witness(es); and

(x) method of destruction.

(C) The signature of the consultant pharmacist and witness(es) to the destruction and the method of destruction specified in subparagraph (B) of this paragraph may be on a cover sheet attached to the inventory and not on each individual inventory sheet, provided the cover sheet contains a statement indicating the number of inventory pages that are attached and each of the attached pages are initialed by the consultant pharmacist and witness(es).

(D) The drugs are destroyed in a manner to render the drugs unfit for human consumption and disposed of in compliance with all applicable state and federal requirements.

(E) The actual destruction of the drugs is witnessed by one of the following:

(i) a commissioned peace officer;

(ii) an agent of the Texas State Board of Pharmacy;

(iii) an agent of the Texas Health and Human Services Commission, authorized by the Texas State Board of Pharmacy to destroy drugs;

(iv) an agent of the Texas Department of State Health Services, authorized by the Texas State Board of Pharmacy to destroy drugs; or

(v) any two individuals working in the following capacities at the facility:

(I) facility administrator;

(II) director of nursing;

(III) acting director of nursing; or

(IV) licensed nurse.

(F) If the actual destruction of the drugs is conducted at a location other than the facility or institution, the consultant pharmacist and witness(es) shall retrieve the drugs from the facility or institution, transport, and destroy the drugs at such other location.

(2) Destruction by a waste disposal service. A consultant pharmacist may utilize a waste disposal service to destroy dangerous drugs dispensed to patients in health care facilities or institutions. A consultant pharmacist may destroy controlled substances, including any dangerous drugs comingled with the controlled substances in a shared container, as allowed to do so by federal laws or rules of the Drug Enforcement Administration.

Dangerous drugs not comingled with controlled substances may be transferred to a waste disposal service for destruction provided the following conditions are met.

(A) The waste disposal service is in compliance with applicable rules of the Texas Commission on Environmental Quality and United States Environmental Protection Agency relating to waste disposal.

(B) The consultant pharmacist seals the container of drugs in the presence of the facility administrator and the director of nursing or one of the other witnesses listed in paragraph (1)(E) of this subsection as follows:

(i) tamper resistant tape is placed on the container in such a manner that any attempt to reopen the container will result in the breaking of the tape; and

(ii) the signature of the consultant pharmacist is placed over this tape seal.

(C) The sealed container is maintained in a secure area at the facility or institution until transferred to the waste disposal service by the consultant pharmacist, facility administrator, director of nursing, or acting director of nursing.

(D) A record of the transfer to the waste disposal service is maintained. Such record shall contain the following information:

(i) date of the transfer;

(ii) signature of the person who transferred the drugs to the waste disposal service;

(iii) name and address of the waste disposal service; and

(iv) signature of the employee of the waste disposal service who receives the container.

(E) The waste disposal service shall provide the facility with proof of destruction of the sealed container. Such proof of destruction shall contain the date, location, and method of destruction of the container.

(3) Record retention. All records required in this subsection shall be maintained by the consultant pharmacist at the health care facility or institution for two years from the date of destruction.

(b) Drugs returned to a pharmacy. A pharmacist in a pharmacy may accept and destroy dangerous drugs that have been previously dispensed to a patient and returned to a pharmacy by the patient or an agent of the patient. A pharmacist may accept controlled substances that have been previously dispensed to a patient as allowed by federal laws of the Drug Enforcement Administration. The following procedures shall be followed in destroying dangerous drugs.

(1) The dangerous drugs shall be destroyed in a manner to render the drugs unfit for human consumption and disposed of in compliance with all applicable state and federal requirements.

(2) Documentation shall be maintained that includes the following information:

(A) name and address of the dispensing pharmacy;

(B) unique identification number assigned to the prescription, if available;

(C) name and strength of the dangerous drug; and

(D) signature of the pharmacist.

§303.2 Disposal of Stock Prescription Drugs

(a) Definition of stock. "Stock" as used in these sections means dangerous drugs or controlled substances which are packaged in the original manufacturer's container.

(b) Disposal of stock dangerous drugs. A pharmacist, licensed by the board, is authorized to destroy stock dangerous drugs owned by a licensed pharmacy if such dangerous drugs are destroyed in a manner to render the drugs unfit for human consumption and disposed of in compliance with all applicable state and federal requirements.

(c) Disposal of stock controlled substances. A pharmacist, licensed by the board, shall dispose of stock controlled substances owned by a licensed pharmacy in accordance with procedures authorized by the Federal and Texas Controlled Substances Acts and sections adopted pursuant to such Acts.

§303.3 Records

All inventory records and forms of disposed drugs shall be maintained for two years from the date of transfer, disposal, or destruction and be available for inspection by an agent of the board, Texas Department of Public Safety, Drug Enforcement Administration, or any other agent authorized to inspect such records.

CHAPTER 309 – SUBSTITUTION OF DRUG PRODUCTS

§309.1 Objective

These sections govern the substitution of lower-priced generically equivalent drug products for certain brand name drug products and the substitution of interchangeable biological products for certain biological products.

§309.2 Definitions

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section shall have the definition set out in the Act, §551.003 and Chapter 562.

(1) Act--The Texas Pharmacy Act, Occupations Code, Subtitle J, as amended.

(2) Biological product--A virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

(3) Biosimilar--A biological product that is highly similar to the reference product notwithstanding minor differences in clinically inactive components and there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

(4) Data communication device--An electronic device that receives electronic information from one source and transmits or routes it to another (e.g., bridge, router, switch, or gateway).

(5) Electronic prescription drug order--A prescription drug order which is transmitted by an electronic device to the receiver (pharmacy).

(6) Generically equivalent--A drug that is pharmaceutically equivalent and therapeutically equivalent to the drug prescribed.

(7) Interchangeable--Referencing a biological product that is:

(A) biosimilar to the reference product and can be expected to produce the same clinical result as the reference product in any given patient; and if the biological product is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product; or

(B) designated as therapeutically equivalent to another product by the United States Food and Drug Administration in the most recent edition or supplement of the United States Food and Drug Administration's references.

(8) Pharmaceutically equivalent--Drug products that have identical amounts of the same active chemical ingredients in the same dosage form and that meet the identical compendial or other applicable standards of strength, quality, and purity according to the United States Pharmacopoeia or another nationally recognized compendium.

(9) Reference product--A single biological product against which a biological product is evaluated and is found to be biosimilar.

(10) Therapeutically equivalent--Pharmaceutically equivalent drug products that, if administered in the same amounts, will provide the same therapeutic effect, identical in duration and intensity.

(11) Original prescription--The:

(A) original written prescription drug orders; or

(B) original oral or electronic prescription drug orders reduced to writing either manually or electronically.

(12) 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, therapeutic optometrist, or veterinarian but excluding a person licensed under this subtitle;
(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 registered nurse or physician assistant to whom a physician has delegated the authority to carry out or sign prescription drug orders under §§157.0511, 157.0512, or 157.054, Occupations Code.

§309.3 Substitution Requirements

(a) General requirements. In accordance with Chapter 562 of the Act, a pharmacist may dispense a generically equivalent drug or interchangeable biological product if:

(1) the generic drug or interchangeable biological product costs the patient less than the prescribed drug product;
(2) the patient does not refuse the substitution; and
(3) the practitioner does not certify on the prescription form that a specific prescribed brand is medically necessary as specified in a dispensing directive described in subsection (c) of this section.

(b) Prescription format for written prescription drug orders.

(1) A written prescription drug order issued in Texas may:
(A) be on a form containing a single signature line for the practitioner; and
(B) contain the following reminder statement on the face of the prescription: "A generically equivalent drug product may be dispensed unless the practitioner hand writes the words 'Brand Necessary' or 'Brand Medically Necessary' on the face of the prescription."
(2) A pharmacist may dispense a prescription that is not issued on the form specified in paragraph (1) of this subsection, however, the pharmacist may dispense a generically equivalent drug or interchangeable biological product unless the practitioner has prohibited substitution through a dispensing directive in compliance with subsection (c)(1) of this section.
(3) The prescription format specified in paragraph (1) of this subsection does not apply to the following types of prescription drug orders:
(A) prescription drug orders issued by a practitioner in a state other than Texas;
(B) prescriptions for dangerous drugs issued by a practitioner in the United Mexican States or the Dominion of Canada; or
(C) prescription drug orders issued by practitioners practicing in a federal facility provided they are acting in the scope of their employment.
(4) In the event of multiple prescription orders appearing on one prescription form, the practitioner shall clearly identify to which prescription(s) the dispensing directive(s) apply. If the practitioner does not clearly indicate to which prescription(s) the dispensing directive(s) apply, the pharmacist may substitute on all prescriptions on the form.

(c) Dispensing directive.

(1) General requirements. The following is applicable to the dispensing directive outlined in this subsection.
(A) When a prescription is issued for a brand name product that has no generic equivalent product, the pharmacist must dispense the brand name product. If a generic equivalent or interchangeable biological product becomes available, a pharmacist may substitute the generically equivalent or interchangeable

biological product unless the practitioner has specified on the initial prescription that the brand name product is medically necessary.

(B) If the practitioner has prohibited substitution through a dispensing directive in compliance with this subsection, a pharmacist shall not substitute a generically equivalent drug or interchangeable biological product unless the pharmacist obtains verbal or written authorization from the practitioner, notes such authorization on the original prescription drug order, and notifies the patient in accordance with §309.4 of this title (relating to Patient Notification).

(2) Written prescriptions.

(A) A practitioner may prohibit the substitution of a generically equivalent drug or interchangeable biological product for a brand name drug product by writing across the face of the written prescription, in the practitioner's own handwriting, the phrase "brand necessary" or "brand medically necessary."

(B) The dispensing directive shall:

(i) be in a format that protects confidentiality as required by the Health Insurance Portability and Accountability Act of 1996 (29 U.S.C. Section 1181 et seq.) and its subsequent amendments; and

(ii) comply with federal and state law, including rules, with regard to formatting and security requirements.

(C) The dispensing directive specified in this paragraph may not be preprinted, rubber stamped, or otherwise reproduced on the prescription form.

(D) A practitioner may prohibit substitution on a written prescription only by following the dispensing directive specified in this paragraph. Two-line prescription forms, check boxes, or other notations on an original prescription drug order which indicate "substitution instructions" are not valid methods to prohibit substitution, and a pharmacist may substitute on these types of written prescriptions.

(3) Oral Prescriptions.

(A) If a prescription drug order is transmitted orally, and the practitioner or practitioner's agent prohibited substitution by specifying "brand necessary" or "brand medically necessary," a notation of any substitution instructions by the practitioner or practitioner's agent shall be made on the file copy of the prescription drug order. Such file copy may follow the one-line format indicated in subsection (b)(1) of this section, or any other format that clearly indicates the substitution instructions.

(B) If the practitioner's or practitioner's agent does not clearly indicate that the brand name is medically necessary, the pharmacist may substitute a generically equivalent drug or interchangeable biological product.

(C) To prohibit substitution on an oral prescription reimbursed through the medical assistance program specified in 42 C.F.R., §447.331:

(i) the practitioner or the practitioner's agent shall orally indicate that the brand is medically necessary; and

(ii) the practitioner shall mail or fax a written prescription to the pharmacy which complies with the dispensing directive for written prescriptions specified in paragraph (1) of this subsection within 30 days.

(4) Electronic prescription drug orders.

(A) To prohibit substitution, the practitioner or practitioner's agent shall clearly indicate substitution instructions in the electronic prescription drug order.

(B) If the practitioner or practitioner's agent does not indicate or does not clearly indicate in the electronic prescription drug order that the brand is necessary, the pharmacist may substitute a generically equivalent drug or interchangeable biological product.

(C) To prohibit substitution on an electronic prescription drug order reimbursed through the medical assistance program specified in 42 C.F.R., §447.331, the practitioner shall comply with state and federal laws.

(5) Prescriptions issued by out-of-state, Mexican, Canadian, or federal facility practitioners.

(A) The dispensing directive specified in this subsection does not apply to the following types of prescription drug orders:

(i) prescription drug orders issued by a practitioner in a state other than Texas;

(ii) prescriptions for dangerous drugs issued by a practitioner in the United Mexican States or the Dominion of Canada; or

(iii) prescription drug orders issued by practitioners practicing in a federal facility provided they are acting in the scope of their employment.

(B) A pharmacist may not substitute on prescription drug orders identified in subparagraph (A) of this paragraph unless the practitioner has authorized substitution on the prescription drug order. If the practitioner has not authorized substitution on the written prescription drug order, a pharmacist shall not substitute a generically equivalent drug product unless:

(i) the pharmacist obtains verbal or written authorization from the practitioner (such authorization shall be noted on the original prescription drug order); or

(ii) the pharmacist obtains written documentation regarding substitution requirements from the State Board of Pharmacy in the state, other than Texas, in which the prescription drug order was issued. The following is applicable concerning this documentation.

(I) The documentation shall state that a pharmacist may substitute on a prescription drug order issued in such other state unless the practitioner prohibits substitution on the original prescription drug order.

(II) The pharmacist shall note on the original prescription drug order the fact that documentation from such other state board of pharmacy is on file.

(III) Such documentation shall be updated yearly.

(d) Refills.

(1) Original substitution instructions. All refills shall follow the original substitution instructions unless otherwise indicated by the practitioner or practitioner's agent.

(2) Narrow therapeutic index drugs.

(A) The board and the Texas Medical Board shall establish a joint committee to recommend to the board a list of narrow therapeutic index drugs and the rules, if any, by which this paragraph applies to those drugs. The committee must consist of an equal number of members from each board. The committee members shall select a member of the committee to serve as presiding officer for a one year term. The presiding officer may not represent the same board as the presiding officer's predecessor.

(B) The board, on the recommendation of the joint committee, has determined that no drugs shall be included on a list of narrow therapeutic index drugs as defined in §562.014, Occupations Code.

(i) The board has specified in §309.7 of this title (relating to dispensing responsibilities) that for drugs listed in the publication, pharmacist shall use as a basis for determining generic equivalency, Approved Drug Products with Therapeutic Equivalence Evaluations and current supplements published by the Federal Food and Drug Administration, within the limitations stipulated in that publication. For drugs listed in the publications, pharmacists may only substitute products that are rated therapeutically equivalent in the Approved Drug Products with Therapeutic Equivalence Evaluations and current supplements.

(ii) Practitioners may prohibit substitution through a dispensing directive in compliance with subsection (c) of this section.

(C) The board shall reconsider the contents of the list if:

(i) the Federal Food and Drug Administration determines a new equivalence classification which indicates that certain drug products are equivalent but special notification to the patient and practitioner is required when substituting these products; or

(ii) any interested person petitions the board to reconsider the list. If the board receives a petition to include a drug on the list, the joint committee specified in subparagraph (A) of this paragraph shall review the request and make a recommendation to the board.

§309.4 Patient Notification

(a) Substitution notification. Before delivery of a prescription for a generically equivalent drug or interchangeable biological product as authorized by Chapter 562, Subchapter A of the Act, a pharmacist must:

(1) personally, or through his or her agent or employee inform the patient or the patient's agent that a less expensive generically equivalent drug or interchangeable biological product is available for the brand prescribed; and ask the patient or the patient's agent to choose between the generically equivalent drug or interchangeable biological product and the brand prescribed.

(2) A pharmacist shall offer the patient or the patient's agent the option of paying for a prescription drug at a lower price instead of paying the amount of the copayment under the patient's prescription drug insurance plan if the price of the prescribed drug is lower than the amount of the patient's copayment.

(b) Exceptions. A pharmacy is not required to comply with the provisions of subsection (a) of this section:

(1) in the case of the refill of a prescription for which the pharmacy previously complied with subsection (a) of this section with regard to the same patient or patient's agent; or

(2) if the patient's physician or physician's agent advises the pharmacy that:

(A) the physician has informed the patient or the patient's agent that a less expensive generically equivalent drug or interchangeable biological product is available for the brand prescribed; and

(B) the patient or the patient's agent has chosen either the brand prescribed or the less expensive generically equivalent drug or interchangeable biological product.

(c) Notification by pharmacies delivering prescriptions by mail.

(1) A pharmacy that supplies a prescription by mail is considered to have complied with the provision of subsection (a) of this section if the pharmacy includes on the prescription order form completed by the patient or the patient's agent language that clearly and conspicuously:

(A) states that if a less expensive generically equivalent drug or interchangeable biological product is available for the brand prescribed, the patient or the patient's agent may choose between the generically equivalent drug or interchangeable biological product and the brand prescribed; and

(B) allows the patient or the patient's agent to indicate the choice of the generically equivalent drug or interchangeable biological product or the brand prescribed.

(2) If the patient or patient's agent fails to indicate otherwise to a pharmacy on the prescription order form under paragraph (1) of this subsection, the pharmacy may dispense a generically equivalent drug or interchangeable biological product.

(d) Inpatient notification exemption. Institutional pharmacies shall be exempt from the labeling provisions and patient notification requirements of §562.006 and §562.009 of the Act, as respects drugs distributed pursuant to medication orders.

§309.5 Communication with Prescriber

(a) Not later than the third business day after the date of dispensing a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescribing practitioner the specific product provided to the patient, including the name of the product and the manufacturer or national drug code number.

(b) The communication must be conveyed by making an entry into an interoperable electronic medical records system or through electronic prescribing technology or a pharmacy benefit management system or a pharmacy record, which may include information submitted for the payment of claims, that a pharmacist reasonably concludes is electronically accessible by the prescribing practitioner. Otherwise, the pharmacist or the pharmacist's designee shall communicate the biological product dispensed to the prescribing practitioner, using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication is not required if:

(1) there is no interchangeable biological product approved by the United States Food and Drug Administration for the product prescribed; or
(2) a refill prescription is not changed from the product dispensed on the prior filling of the prescription.

§309.6 Records

(a) When the pharmacist dispenses a generically equivalent drug or interchangeable biological product pursuant to the Subchapter A, Chapter 562 of the Act, the following information shall be noted on the original prescription or in the pharmacy's data processing system:
(1) any substitution instructions communicated orally to the pharmacist by the practitioner or practitioner's agent or a notation that no substitution instructions were given; and
(2) the name and strength of the actual drug product dispensed shall be noted on the original or hard-copy prescription drug order. The name shall be either:
(A) the brand name and strength; or
(B) the generic name or the name of the interchangeable biological product, strength, and name of the manufacturer or distributor of such generic drug or interchangeable biological product. (The name of the manufacturer or distributor may be reduced to an abbreviation or initials, provided the abbreviation or initials are sufficient to identify the manufacturer or distributor. For combination drug products having no brand name, the principal active ingredients shall be indicated on the prescription.)

(b) If a pharmacist refills a prescription drug order with a generically equivalent product or interchangeable biological product from a different manufacturer or distributor than previously dispensed, the pharmacist shall record on the prescription drug order the information required in subsection (a) of this section for the product dispensed on the refill.
(c) If a pharmacy utilizes patient medication records for recording prescription information, the information required in subsections (a) and (b) of this section shall be recorded on the patient medication records.
(d) The National Drug Code (NDC) of a drug or any other code may be indicated on the prescription drug order at the discretion of the pharmacist, but such code shall not be used in place of the requirements of subsections (a) and (b) of this section.

§309.7 Dispensing Responsibilities

(a) The determination of the drug product to be substituted as authorized by the Subchapter A, Chapter 562 of the Act, is the professional responsibility of the pharmacist, and the pharmacist may not dispense any product that does not meet the requirements of the Subchapter A, Chapter 562 of the Act.
(b) Pharmacists shall use as a basis for the determination of generic equivalency or interchangeability as defined in the Subchapter A, Chapter 562 of the Act, most recent edition or supplement of the United States Food and Drug Administration's references (e.g., the Orange Book or Purple Book).
(c) Pharmacists. For drugs not listed in the Orange Book, pharmacists shall use their professional judgment to determine generic equivalency.
(d) Pharmacists shall use Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations (Purple Book) and current supplements published by the Federal Food and Drug Administration, within the limitations stipulated in that publication, to determine biosimilarity to or interchangeability with a reference biological product.

§309.8 Advertising of Generic Drugs by Pharmacies

Prescription drug advertising comparing generic drugs or biological products and brand name drugs or biological products is subject to the §554.054 of the Act and in compliance with federal law.

CHAPTER 311 – CODE OF CONDUCT

§311.1 Procedures

(a) Complaints alleging violations of the Board Code of Conduct by a board employee shall be submitted in writing to the executive director. If a board member is notified of a complaint against an employee, the board member shall direct the complainant to file a written complaint with the executive director. Complaints filed against a peace officer employee must comply with §614.023 of the Government Code (relating to Copy of Complaint to be Given to Officer or Employee).

(b) The executive director shall notify the employee's supervisor that a complaint has been filed against the employee. The supervisor shall provide the employee with written notice that a complaint has been filed, which contains the date the complaint was filed and a description of the complaint. An anonymous complaint or a complaint filed by e-mail will not be considered a valid complaint for the purposes of this section.

(c) In order for a complaint concerning violations of the Code of Conduct to be considered valid, such complaint shall contain the following information:

(1) the date the complaint is filed;
(2) the date the violation occurred;
(3) the complainant's name, address, and telephone number;
(4) the name of the board employee;
(5) detailed description of the alleged violation;
(6) any written documentation or name of witnesses to the alleged violation; and
(7) the signature of the complainant.

(d) The executive director shall acknowledge receipt of the complaint in writing to the complainant. Such acknowledgment may include a request for additional information concerning the complaint or questions about the occurrence or statements.

(e) In reviewing the complaint, the executive director may contact the complainant if necessary and shall conduct a personal interview with the employee and give the employee ample opportunity to present evidence to support his or her explanation of the circumstances surrounding the complaint. The employee shall have the right to submit any relevant records, materials, comments, and documents to the executive director for review. Additionally, the employee has the right to review all documents and records involving the complaint. The employee may request the executive director to allow the board's legal counsel to advise the employee of his or her rights.

(f) Upon completing the review of the complaint and relevant statements or documents, the executive director shall render a decision concerning the complaint within 10 days and provide written notification of the decision to the employee, and his or her supervisor within five days of rendering the decision. The executive director shall notify the complainant of the disposition of the complaint. If the disposition of the complaint affects the employee's employment status, the employee has the right to exercise the board's grievance procedure.

(g) Complaints alleging violations of the Board Code of Conduct by the executive director shall be directed to the president of the board. The procedures set out in this section shall be followed in disposing of such complaints; provided, however, that for the purposes of this subsection, where the term "executive director" appears in the procedures set out in this section, the term "president of the board" shall be substituted therefor.

§311.2 Procedures Regarding Complaints Filed against Board Members

(a) The following procedures are applicable with regard to complaints against a board member, if the complaint alleges violations of the laws and rules governing the practice of pharmacy.

(1) The complaint shall be reviewed by the executive director, who may refer the complaint to the appropriate board staff for handling, or if deemed necessary, the executive director may refer the complaint to another agency.

(2) If the complaint is investigated and the investigation produces evidence of a violation of the laws or rules regarding the practice of pharmacy, the board staff shall determine if the complaint merits the institution of disciplinary action. This decision shall be made in consultation with one board member who shall be a

pharmacist, but who shall not be the subject of the complaint; the board member shall be the president of the board, unless such person is unable to serve because he or she does not meet the criteria of this paragraph or for some other valid reason. If the president is unable to serve, the order of succession shall be vice-president, then treasurer. If none of the pharmacist officers are able to serve, then the board president or designee shall designate another pharmacist board member to serve.

(b) If after consultation with the board member described in subsection (a)(2) of this section, the determination is made that the complaint merits the institution of disciplinary action, the following is applicable.

(1) The complaint shall be directed to the assistant attorney general assigned to the board. The Office of the Attorney General should then assign an assistant attorney general to prosecute the complaint in accordance with board rules.

(2) The board's legal counsel shall act as a liaison between the board's staff and the attorney general's office. The board's legal counsel shall ensure that the board's staff provides any information or assistance requested by the attorney general's office.

(3) The board member shall be sent a preliminary notice letter and offered the opportunity to attend an informal conference for the purpose of settling the matter through an informal conference.

(c) If the board member accepts the opportunity to attend an informal conference, the conference participants shall be as follows:

(1) the assistant attorney general assigned to the case, who shall conduct the informal conference;

(2) the board member who is the subject of the complaint and/or his or her legal counsel;

(3) board staff, as necessary or required; and

(4) one board member, who shall be the same person who was initially consulted about the complaint, as described in subsection (a)(2) of this section, provided, however, if that board member is unable to serve for some valid reason, the board member that shall attend the informal conference shall be a pharmacist, but who shall not be the subject of the complaint; the board member designated to attend the informal conference shall be the president of the board, unless such person is unable to serve because he or she does not meet the criteria of this paragraph or for some other valid reason. If the president is unable to serve, the order of succession shall be vice-president, then treasurer. If none of the pharmacist officers are able to serve, then the board president or designee shall designate another pharmacist board member to attend the informal conference.

(d) The case shall proceed to hearing, if the board member who is the subject of the complaint waives his or her right to attend an informal conference, or if after an informal conference is conducted, the case is not dismissed or the board member does not accept the recommendation for settlement.

(e) If the case proceeds to hearing, the following procedures are applicable:

(1) the assistant attorney general assigned to the case shall prosecute the hearing with the hearings officer presiding;

(2) the hearings officer shall then draft an officer's report which discusses the evidence and contains proposed findings of fact and conclusions of law. The hearings officer shall, as authorized by law, recommend a sanction if he or she determines one is necessary; and

(3) at the next scheduled board meeting, after the hearing officer has issued a proposal and all parties have accepted and replied, the following is applicable.

(A) The board, absent the board member who is the subject of the complaint, shall vote to:

(i) accept or reject each proposed finding of fact and conclusion of law; and

(ii) accept or reject the recommended sanction, if applicable.

(B) If the board rejects the recommended sanction, the board shall then vote on the sanction they deem appropriate.

(C) If the board determines that additional evidence is needed, they can vote to remand the case for further hearing, as provided by law.

(f) For the purposes of this section, a board member is defined as any individual who is serving on the board on the date of the receipt of the complaint, or any individual who has previously served on the board, if the complaint is filed within two years from the date the board member's official duties ended.

CHAPTER 315 – CONTROLLED SUBSTANCES

§315.1 Definitions - Effective September 1, 2016

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

(1) TCSA--The Texas Controlled Substances Act (Texas Health and Safety Code, Chapter 481).

(2) Advanced practice registered nurse--A registered nurse licensed by the Texas Board of Nursing to practice as an advanced practice registered nurse on the basis of completion of an advanced educational program. The term includes a nurse practitioner, nurse midwife, nurse anesthetist, and clinical nurse specialist. The term is synonymous with "advanced nurse practitioner" and "advanced practice nurse."

(3) Day--A calendar day unless the context clearly indicates a business day.

(4) Drug Enforcement Administration (DEA)--The Federal Drug Enforcement Administration.

(5) Electronic transmission--The transmission of information in electronic form such as computer to computer, electronic device to computer, e-mail, or the transmission of the exact visual image of a document by way of electronic media.

(6) Emergency situation--A situation described in the Code of Federal Regulations, Title 21, §1306.11(d).

(7) Individual practitioner--A physician, dentist, veterinarian, optometrist, podiatrist, or other individual licensed, registered, or otherwise permitted to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

(8) Institutional practitioner--A hospital or other person (other than an individual practitioner) licensed, registered, or otherwise permitted to dispense a controlled substance in the course of professional practice, but does not include a pharmacy.

(9) Locum tenen--An individual practitioner who practices in a temporary position in this state and licensed by the appropriate Texas state licensing board.

(10) Long-term care facility (LTCF)--An establishment licensed as such by the Texas Department of Aging and Disability Services.

(11) NDC #--A National Drug Code number.

(12) Physician assistant--An individual licensed as such by the Texas Physician Assistant Board.

(13) Record--A notification, order form, statement, invoice, prescription, inventory information, or other document for the acquisition or disposal of a controlled substance, precursor, or apparatus in any manner by a registrant or permit holder under a record keeping or inventory requirement of federal law, the TCSA, or this chapter.

(14) Reportable prescription--A prescription for a controlled substance:

(A) listed in Schedule II through V; and

(B) not excluded from this chapter by a rule adopted under the TCSA, §481.0761(b).

(15) Temporary controlled substances registration (TCSR)--A controlled substances registration issued to a locum tenen or a health practitioner for a period of time not to exceed 90 days.

§315.2 Official Prescription Form - Effective September 1, 2016

(a) A practitioner may order official prescription forms from the board only if the practitioner is registered by the DEA to prescribe a Schedule II controlled substance.

(b) The board is the sole source for the official prescription forms.

(c) This subsection applies only to an institutional practitioner who is employed by a hospital or other training institution. An institutional practitioner authorized by a hospital or institution to prescribe a Schedule II controlled substance under the DEA registration of the hospital or institution may order official prescription forms under this section if:

(1) the practitioner prescribes a controlled substance in the usual course of the practitioner's training, teaching program, or employment at the hospital or institution;

(2) the appropriate state health regulatory agency has assigned an institutional permit or similar number to the practitioner; and

(3) the hospital or institution:

(A) maintains a current list of each institutional practitioner and each assigned institutional permit number; and

(B) makes the list available to another registrant or a member of a state health regulatory or law enforcement agency for the purpose of verifying the authority of the practitioner to prescribe the substance.

(d) An advanced practice registered nurse or physician assistant operating under a prescriptive authority agreement pursuant to Texas Occupations Code, Chapter 157 may order official prescription forms under this section if authority to prescribe has been delegated by a physician. Upon withdrawal of the delegating physician's authority such forms are void and must be returned to the board.

§315.3 Prescriptions

(a) Schedule II Prescriptions.

(1) Except as provided by subsection (e) of this section, a practitioner, as defined in, §481.002(39)(A) of the TCSA, must issue a written prescription for a Schedule II controlled substance only on an official Texas prescription form or through an electronic prescription that meets all requirements of the TCSA. This subsection also applies to a prescription issued in an emergency situation.

(2) A practitioner who issues a written prescription for any quantity of a Schedule II controlled substance must complete an official prescription form.

(3) Except as provided by subsection (f) of this section, a practitioner may issue multiple written prescriptions authorizing a patient to receive up to a 90-day supply of a Schedule II controlled substance provided:

(A) each prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice;

(B) the practitioner provides written instructions on each prescription, other than the first prescription if the practitioner intends for that prescription to be filled immediately, indicating the earliest date on which a pharmacy may dispense each prescription; and

(C) the practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse.

(4) A schedule II prescription must be dispensed no later than 30 days after the date of issuance or, if the prescription is part of a multiple set of prescriptions, issued on the same day, no later than 30 days after the earliest date on which a pharmacy may dispense the prescription as indicated on each prescription.

(5) A person dispensing a Schedule II controlled substance prescription shall provide written notice on the safe disposal of controlled substance prescription drugs that includes information on locations at which Schedule II controlled substance prescription drugs are accepted for safe disposal. In lieu of listing those locations, the notice may alternatively provide the address of an Internet website specified by the board that provides a searchable database of locations at which Schedule II controlled substance prescription drugs are accepted for safe disposal. The written notice may be provided to the patient in an electronic format, such as by e-mail, if the patient or patient's agent requests the notice in an electronic format and the request is documented. Such written notice is not required if:

(A) the Schedule II controlled substance prescription drug is dispensed at a pharmacy or other location that:

(i) is authorized to take back those drugs for safe disposal; and

(ii) regularly accepts those drugs for safe disposal; or

(B) the dispenser provides to the person to whom the Schedule II controlled substance prescription drug is dispensed, at the time of dispensation and at no cost to the person:

(i) a mail-in pouch for surrendering unused controlled substance prescription drugs; or

(ii) chemicals to render any unused drugs unusable or non-retrievable.

(b) Schedules III through V Prescriptions.

(1) A practitioner, as defined §§481.002(39)(A), (C), (D) of the TCSA, may use prescription forms and order forms through individual sources. A practitioner may issue, or allow to be issued by a person under the practitioner's direction or supervision, a Schedule III through V controlled substance on a prescription form for a valid medical purpose and in the course of medical practice.

(2) Except as provided in subsection (f) of this section, Schedule III through V prescriptions may be refilled up to five times within six months after date of issuance.

(c) Electronic prescribing.

(1) A practitioner is permitted to issue and to dispense an electronic controlled substance prescription only in accordance with the requirements of the Code of Federal Regulations, Title 21, Part 1311.

(2) Effective January 1, 2021, a prescription for a controlled substance is not required to be issued electronically and may be issued in writing if the prescription is issued:

(A) in circumstances in which electronic prescribing is not available due to temporary technological or electronic failure;

(B) by a practitioner to be dispensed by a pharmacy located outside this state; or

(C) in any other circumstance described in §481.0755(a) of the TCSA.

(3) A prescriber may apply for a waiver from the electronic prescribing requirement by:

(A) submitting a waiver request form to the agency that issued the license, certification, or registration to the prescriber, including any information requested on the form; and

(B) demonstrating circumstances necessitating a waiver from the requirement, including:

(i) economic hardship, as determined by the agency that issued the license, registration, or certification to the prescriber on a prescriber/by prescriber basis, taking into account factors including:

(I) any special situational factors affecting either the cost of compliance or ability to comply;

(II) the likely impact of compliance on profitability or viability; and

(III) the availability of measures that would mitigate the economic impact of compliance;

(ii) technological limitations not reasonably within the control of the prescriber; or

(iii) other exceptional circumstances demonstrated by the prescriber.

(C) A waiver may be issued to a prescriber for a period of one year as specified in Chapter 481 of the Texas Controlled Substances Act. A prescriber may reapply for a subsequent waiver not earlier than the 30th day before the date the waiver expires if the circumstances that necessitated the waiver continue.

(d) Controlled substance prescriptions may not be postdated.

(e) Advanced practice registered nurses or physician assistants may only use the official prescription forms issued with their name, address, phone number, and DEA numbers, and the delegating physician's name and DEA number.

(f) Opioids for the treatment of acute pain.

(1) For the treatment of acute pain, as defined in §481.07636 of the TCSA, a practitioner may not:

(A) issue a prescription for an opioid in an amount that exceeds a 10-day supply; or

(B) provide for a refill of the opioid prescription.

(2) Paragraph (1) of this subsection does not apply to a prescription for an opioid approved by the U.S. Food and Drug Administration for the treatment of substance addiction that is issued by a practitioner for the treatment of substance addiction.

(3) A dispenser is not subject to criminal, civil, or administrative penalties for dispensing or refusing to dispense a controlled substance under a prescription that exceed the limits provided by paragraph (1) of this subsection.

§315.4 Exceptions to Use of Form - Effective September 1, 2016

(a) An official prescription form is not required for a medication order written for a patient who is admitted to a hospital at the time the medication order is written and dispensed.

(1) A practitioner may dispense or cause to be dispensed a Schedule II controlled substance to a patient who:

(A) is admitted to the hospital; and

(B) will require an emergency quantity of a controlled substance upon release from the hospital.

(2) Under paragraph (1) of this subsection, the controlled substance:

(A) may only be dispensed in a properly labeled container; and

(B) may not be more than a seven-day supply or the minimum amount needed for proper treatment of the patient until the patient can obtain access to a pharmacy, whichever is less.

(b) Subsection (a) of this section applies to a patient who is admitted to a hospital, including a patient:

(1) admitted to:

(A) a general hospital, special hospital, licensed ambulatory surgical center, surgical suite in a dental school, or veterinary medical school; or

(B) a hospital clinic or emergency room, if the clinic or emergency room is under the control, direction, and administration as an integral part of a general or special hospital;

(2) receiving treatment with a Schedule II controlled substance from a member of a Life Flight or similar medical team or an emergency medical ambulance crew or a paramedic-emergency medical technician operating as an extension of an emergency room of a general or special hospital; or

(3) receiving treatment with a Schedule II controlled substance while the patient is an inmate incarcerated in a correctional facility operated by the Texas Department of Criminal Justice or a correctional facility operating in accordance with the Health Services Plan adopted by the Texas Commission on Jail Standards.

(c) Subsection (a) of this section applies to an animal admitted to an animal hospital, including an animal that is a permanent resident of a zoo, wildlife park, exotic game ranch, wildlife management program, or state or federal research facility.

(d) An official prescription form is not required in a long-term care facility (LTCF) if:

(1) an individual administers the substance to an inpatient from the facility's medical emergency kit;

(2) the individual administering the substance is an authorized practitioner or an agent acting under the practitioner's order; and

(3) the facility maintains the proper records as required for an emergency medical kit in an LTCF.

(e) An official prescription form is not required when a therapeutic optometrist administers a topical ocular pharmaceutical agent in compliance with:

(1) the Texas Optometry Act; and

(2) a rule adopted by the Texas Optometry Board under the authority of the Texas Optometry Act.

§315.5 Pharmacy Responsibility - Generally

(a) Upon receipt of a properly completed prescription form, a dispensing pharmacist must:

(1) if the prescription is for a Schedule II controlled substance, ensure the date the prescription is presented is not later than 30 days after the date of issuance;

(2) if multiple prescriptions are issued by the prescribing practitioner allowing up to a 90-day supply of Schedule II controlled substances, ensure each prescription is neither dispensed prior to the earliest date intended by the practitioner nor dispensed beyond 30 days from the earliest date the prescription may be dispensed;

(3) record the date dispensed and the pharmacy prescription number;

(4) indicate whether the pharmacy dispensed to the patient a quantity less than the quantity prescribed; and

(5) if issued on an official prescription form, record the following information, if different from the prescribing practitioner's information:

(A) the brand name or, if none, the generic name of the controlled substance dispensed; or

(B) the strength, quantity, and dosage form of the Schedule II controlled substance used to prepare the mixture or compound.

(b) The prescription presented for dispensing is void, and a new prescription is required, if:

(1) the prescription is for a Schedule II controlled substance, 30 days after issuance, or 30 days after any earliest dispense date; or

(2) the prescription is for a Schedule III, IV, or V controlled substance, more than six months after issuance or has been dispensed five times during the six months after issuance.

§315.6 Pharmacy Responsibility - Electronic Reporting

(a) Not later than the next business day after the date a controlled substance prescription is dispensed, a pharmacy must electronically submit to the board any data elements indicated as required by the board's Data Submission Guide for Dispensers.

(b) A pharmacy must electronically correct dispensing data submitted to the board within seven business days of identifying an omission, error, or inaccuracy in previously submitted dispensing data.

(c) If a pharmacy does not dispense any controlled substance prescriptions, the pharmacy must electronically submit to the board a zero report indicating that no controlled substances were dispensed every seven days. If the pharmacy subsequently begins dispensing controlled substances, the pharmacy must begin reporting as specified in subsection (a) of this section.

(d) A pharmacy that does not dispense controlled substances may request a waiver of the zero reporting requirements by submitting a waiver request form and providing any information requested on the form. If the pharmacy subsequently begins dispensing controlled substances, the waiver is no longer valid, and the pharmacy must begin reporting as specified in subsection (a) of this section.

§315.7 Pharmacy Responsibility - Oral, Telephonic, or Emergency Prescription - Effective September 1, 2016

(a) If a pharmacy dispenses a controlled substance pursuant to an orally or telephonically communicated prescription from a practitioner or the practitioner's designated agent, the prescription must be promptly reduced to writing, including the information required:

(1) by law for a standard prescription; and

(2) by law and this subchapter for an official prescription, if issued for a Schedule II controlled substance in an emergency situation.

(b) After dispensing a Schedule II controlled substance pursuant to an orally or telephonically communicated prescription, the dispensing pharmacy must:

(1) maintain the written record created under subsection (a) of this section;

(2) note the emergency nature of the prescription;

(3) upon receipt from the practitioner, attach the original official prescription to the orally or telephonically communicated prescription; and

(4) retain both documents in the pharmacy records.

(c) A pharmacy that dispenses Schedule III, IV, or V controlled substances pursuant to an orally or telephonically communicated prescription must inform the prescribing practitioner in the event of an emergency refill of the prescription.

(d) All records generated under this section must be maintained for two years from the date the substance was dispensed.

§315.8 Pharmacy Responsibility - Modification of Prescription - Effective September 1, 2016

The pharmacy is responsible for documenting the following information regarding a modified prescription:

(1) date the change or adding of information was authorized;

(2) information that was authorized to be added or changed;

(3) name of the prescribing practitioner granting the authorization; and

(4) initials or identification code of the pharmacist.

§315.9 Pharmacy Responsibility - Out-of-State Practitioner

(a) A Schedule II controlled substance prescription issued by a practitioner in another state may be dispensed if:

(1) the practitioner is authorized by the other state to prescribe the substance;

(2) the pharmacy has a plan approved by and on file with the board allowing the activity; and

(3) the pharmacy processes and submits the prescription according to the reporting requirements approved in the plan.

(b) The pharmacy may dispense a prescription for a Schedule III through V controlled substance issued by a practitioner in another state if the practitioner is authorized by the other state to prescribe the substance.

§315.10 Return of Unused Official Prescription Form - Effective September 1, 2016

(a) An unused official prescription form is invalid and the practitioner or another person acting on behalf of the practitioner must return the unused form to the board with an appropriate explanation not later than the 30th day after the date:

(1) the practitioner's license to practice, DEA number is canceled, revoked, suspended, denied, or surrendered or amended to exclude the handling of all Schedule II controlled substances; or

(2) the practitioner is deceased.

(b) An individual who is an institutional practitioner must return an unused official prescription form to the administrator of the hospital or other training institution upon completion or termination of the individual's training at the hospital or institution. The administrator must return an unused official prescription form to the board not later than the 30th day after the date the individual completes or terminates all training programs.

(c) No individual may continue to use an official prescription form issued under an institutional practitioner's DEA number or similar number after the individual has been properly and individually licensed as a practitioner by the appropriate state health regulatory agency.

§315.11 Release of Prescription Data

(a) A person listed under §481.076(a) of the TCSA must show proper need for the information when requesting the release of prescription data. The showing of proper need is ongoing.

(b) A pharmacist may delegate access to prescription data to a pharmacist-intern, pharmacy technician, or pharmacy technician trainee, as defined by Texas Occupations Code, §551.003, employed at the pharmacy and acting under the direction of the pharmacist.

(c) A practitioner may delegate access to prescription data to an employee or other agent of the practitioner and acting at the direction of the practitioner.

§315.12 Schedule III through V Prescription Forms - Effective September 1, 2016

(a) A practitioner, as defined in the TCSA, §481.002(39)(A), (C), and (D), may use prescription forms ordered through individual sources or through an electronic prescription that includes the controlled substances registration number issued by the United States Drug Enforcement Administration and meets all requirements of the TCSA.

(b) If a written prescription form is to be used to prescribe a controlled substance the dispensing practitioner must be registered with the DEA under both state and federal law to prescribe controlled substances.

§315.13 Official Prescription Form

(a) Accountability. A practitioner who obtains from the board an official prescription form is accountable for each numbered form.

(b) Prohibited acts. A practitioner may not:

(1) allow another practitioner to use the individual practitioner's official prescription form;

(2) pre-sign an official prescription blank;

(3) post-date an official prescription; or

(4) leave an official prescription blank in a location where the practitioner should reasonably believe another could steal or misuse a prescription.

(c) While not in use. While an official prescription blank is not in immediate use, a practitioner may not maintain or store the book at a location so the book is easily accessible for theft or other misuse.

(d) Voided. A practitioner must account for each voided official prescription form by sending the voided form to the board.

(e) Types of forms. Forms may be single or multiple copy forms as provided by the board.

§315.14 Official Prescription - Effective September 1, 2016

(a) Report lost forms. Not later than close of business on the day of discovery, a practitioner must report a lost or stolen official prescription form to:

(1) the local police department or sheriff's office in an effective manner; and

(2) the board.

(b) Recovery report. Not later than close of business on the day of recovery of an official prescription form previously reported lost or stolen, a practitioner must, before using the recovered form, notify:

(1) the local law enforcement agency to which the matter was originally reported; and

(2) the board.

(c) Replacement/lost form. Not later than the close of business on the day that an official prescription is replaced or reported lost, with or without a replacement, the prescribing practitioner, or designated agent, shall report to the board the following:

(1) patient name, address, date of birth or age;

(2) all drug information; and

(3) official prescription form control number.

§315.15 Access Requirements

(a) Effective March 1, 2020, a pharmacist before dispensing an outpatient prescription for an opioid, benzodiazepine, barbiturate, or carisoprodol for a patient shall consult the Texas Prescription Monitoring Program (PMP) database to review the patient's controlled substance history. The dispensing pharmacist of an outpatient prescription shall be responsible for the review of the PMP database prior to dispensing the prescription, unless the pharmacy has designated another pharmacist whose identity has been recorded in the pharmacy's data processing system as responsible for PMP review.

(b) The duty to consult the PMP database as described in subsection (a) of this section does not apply in the following circumstances:

(1) the prescribing individual practitioner is a veterinarian;

(2) it is clearly noted in the prescription record that the patient has a diagnosis of cancer or sickle cell disease or is in hospice care; or

(3) the pharmacist is unable to access the PMP after making and documenting a good faith effort to do so.

(c) If a pharmacist uses pharmacy management systems that integrate data from the PMP, a review of the pharmacy management system with the integrated data shall be deemed compliant with the review of the PMP database as required under §481.0764(a) of the Texas Health and Safety Code and in subsection (a) of this section.

(d) Pharmacists and pharmacy technicians acting at the direction of a pharmacist may only access information contained in the PMP as authorized in §481.076 of Texas Controlled Substances Act. A person who is authorized to access the PMP may only do so utilizing that person's assigned identifier (i.e., login and password) and may not use the assigned identifier of another person. Unauthorized access of PMP information is a violation of Texas Controlled Substances Act, the Texas Pharmacy Act, and board rules.

§315.16 Patient Access to Prescription Monitoring Program Prescription Record

(a) A patient, the patient's parent or legal guardian if the patient is a minor, or the patient's legal guardian if the patient is an incapacitated person as defined by §1002.017(2) of the Estates Code, may obtain a copy of the patient's prescription record, including a list of persons who have accessed that record, as authorized in §481.076(a)(9) of the Texas Controlled Substances Act, by submitting the following to the board:

(1) a completed, notarized patient data request form, including any information or supporting documentation requested on the form;

(2) a copy of the requestor's driver's license or other state photo identity card issued by the state's Department of Motor Vehicles;

(3) if requesting as a parent or legal guardian of the patient, a copy of the patient's birth certificate or the order of guardianship over the patient; and

(4) a $50 fee.

(b) The board shall deliver the requested records to the requestor via certified mail to the address listed on the requestor's driver's license or other state photo identity card issued by the state's Department of Motor Vehicles. If the requestor does not have a mailbox at the listed address, the board shall deliver the records to the requestor at the listed address via a trackable delivery service and the requestor shall be responsible for the cost.