RULE REVIEW ANALYSIS

Introduction: THIS RULE REVIEW IS SUBMITTED TO THE BOARD FOR CONSIDERATION AS AN ADOPTED REVIEW

Short Title: Class C (Institutional) Pharmacies

Rule Number: Chapter 291 (§§291.71 – 291.76)


Background: Review of these sections follow the Board's rule review plan.
§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) 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.

(8) 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.
(9) 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).

(10) 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."

(11) 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.

(12) Direct copy--Electronic copy or carbonized copy of a medication order, including a facsimile (FAX), tele-autograph, or a copy transmitted between computers.

(13) 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.

(14) Distribute--The delivery of a prescription drug or device other than by administering or dispensing.

(15) Distributing pharmacist--The pharmacist who checks the medication order prior to distribution.

(16) Downtime--Period of time during which a data processing system is not operable.

(17) 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).

(18) 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.

(19) Expiration date--The date (and time, when applicable) beyond which a product should not be used.

(20) Facility--

(A) a hospital or other in-patient facility that is licensed under Chapter 241 or 577, Health and Safety Code;

(B) a hospice in-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.

(21) 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.

(22) Formulary--List of drugs approved for use in the facility by the committee which performs the pharmacy and therapeutics function for the facility.

(23) 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.

(24) Hard copy--A physical document that is readable without the use of a special device (i.e., cathode ray tube (CRT), microfiche reader, etc).

(25) Hot water--The temperature of water from the pharmacy's sink maintained at a minimum of 105 degrees F (41 degrees C).

(26) Inpatient--A person who is duly admitted to the licensed hospital, or other hospital or facility maintained or operated by the state, 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 which 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. An inpatient includes a person confined in any correctional institution operated by the state of Texas.
(27) 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.

(28) 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) 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.

(31) Part-time pharmacist--A pharmacist either employed or under contract, who routinely works less than full-time.

(32) 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.

(33) 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.

(34) 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.

(35) 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.

(36) 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.

(37) 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.

(38) 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.

(39) 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.

(40) 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.

(41) Quality assurance--The set of activities used to assure that the process used in the preparation of sterile drug products lead to products that meet predetermined standards of quality.

(42) Quality control--The set of testing activities used to determine that the ingredients, components (e.g., containers), and final sterile pharmaceuticals prepared meet predetermined requirements with respect to identity, purity, non-pyrogenicity, and sterility.

(43) Sample--A prescription drug which is not intended to be sold and is intended to promote the sale of the drug.

(44) Texas Controlled Substances Act--The Texas Controlled Substances Act, the Health and Safety Code, Chapter 481, as amended.

(45) 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.

(46) Unusable drugs--Drugs or devices that are unusable for reasons, such as they are adulterated, misbranded, expired, defective, or recalled.

(47) 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 licensed for 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 may distribute prepackaged and prelabeled drugs from a satellite pharmacy in the absence of on-site 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 licensed for 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.

(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.

(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 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.

(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) 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;

(D) participating in the development of a formulary for the facility, subject to approval of the appropriate committee of the facility;

(E) developing a system to assure that drugs to be administered to inpatients are distributed pursuant to an original or direct copy of the practitioner's medication order;

(F) developing a system for the filling and labeling of all containers from which drugs are to be distributed or dispensed;

(G) 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;

(H) 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 pharmaceuticals, and drug delivery devices;
(I) participating in those aspects of the facility's patient care evaluation program which relate to pharmaceutical utilization and effectiveness;

(J) participating in teaching and/or research programs in the facility;

(K) implementing the policies and decisions of the appropriate committee(s) relating to pharmaceutical services of the facility;

(L) 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;

(M) developing a system for the labeling, storage, and distribution of investigational new drugs, including maintenance of 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;

(N) 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;

(O) assuring that a reasonable effort is made to obtain, record, and maintain patient medication records;

(P) 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

(Q) 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;

(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 ensure that the drug is prepared for distribution safely, and accurately as prescribed. In addition, if multiple pharmacists participate in the preparation of medication orders for distribution, each pharmacist shall ensure the safety and accuracy of the portion of the process the pharmacist is performing. 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 drugs and devices pursuant to medication orders;

(ii) compounding and labeling of drugs and devices;

(iii) proper and safe storage of drugs and devices; and

(iv) maintaining proper records for drugs and devices.

(3) Special requirements for compounding.

(A) 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).
(B) Sterile Preparations. All pharmacists engaged in compounding sterile preparations shall meet the training requirements specified in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).

(e) 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) Duties. Duties may include, but need not be limited to, the following functions under the direct supervision of and responsible to a pharmacist:

(A) pre-packing and labeling unit and multiple dose packages, provided a pharmacist supervises and conducts in-process and final checks and affixes his or her signature (first initial and last name or full signature) or electronic signature to the appropriate quality control records;

(B) preparing, packaging, compounding, or labeling prescription drugs pursuant to medication orders, provided a pharmacist supervises and checks the preparation;

(C) bulk compounding or batch preparation provided a pharmacist supervises and conducts in-process and final checks and affixes his or her initials to the appropriate quality control records;

(D) distributing routine orders for stock supplies to patient care areas;

(E) 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 §291.74(e) of this title (relating to Operational Standards);

(F) loading bulk 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 signature (first initial and last name or full signature) or electronic signature to the appropriate quality control records; and

(G) may be allowed access to 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.

(H) compounding sterile preparations pursuant to medication orders provided the pharmacy technicians or pharmacy technician trainees:

(i) have completed the training specified in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations; and

(ii) 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 initials to the label or if batch prepared, to the appropriate quality control records. (The initials are not required on the label if it is maintained in a permanent record of the pharmacy.)

(3) Special requirements for compounding.

(A) 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.
(B) Sterile Preparations. Pharmacy technicians and pharmacy technician trainees engaged in compounding sterile preparations shall meet the training requirements specified in §291.133 of this title.

(4) 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) establishment of policies for procurement of prescription drugs and devices and other products dispensed from the Class C pharmacy;

(2) establishment and 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) 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.

(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, 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.

§291.74 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) If the institutional pharmacy is owned or operated by a hospital management or consulting firm, the following conditions apply.

(A) The pharmacy license application shall list the hospital management or consulting firm as the owner or operator.

(B) The hospital management or consulting firm shall obtain DEA and DPS controlled substance registrations that are issued in their name, unless the following occurs:

(i) the hospital management or consulting firm and the facility cosign a contractual pharmacy service agreement which assigns overall responsibility for controlled substances to the facility; and

(ii) such hospital pharmacy management or consulting firm maintains dual responsibility for the controlled substances.

(3) 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).

(4) A Class C 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 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 pharmacy shall notify the board in writing within 10 days of closing, following the procedures in §291.5 of this title (relating to Closed Pharmacies).

(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 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.

(10) A Class C (Institutional) pharmacy engaged in non-sterile compounding of drug products for inpatients of the hospital shall comply with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-sterile Preparations);
(11) A Class C (Institutional) pharmacy engaged in the compounding of sterile pharmaceuticals shall comply with the provisions of §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).

(12) A Class C (Institutional) 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).

(13) A Class C (Institutional) 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).

(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 shall be maintained within a range compatible with the proper storage of drugs requiring refrigeration.

   (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) typewriter or comparable equipment; and

(2) refrigerator and a system or device (e.g., thermometer) to monitor the temperature and humidity 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, such as:

         (i) Facts and Comparisons with current supplements;

         (ii) United States Pharmacopeia Dispensing Information Volume I (Drug Information for the Healthcare Provider);

         (iii) AHFS Drug Information with current supplements;

         (iv) Remington's Pharmaceutical Sciences; or

         (v) Clinical Pharmacology;

      (3) a current or updated reference on injectable drug products, such as Handbook of Injectable Drugs;

      (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.

(v) The pharmacist shall verify the withdrawal 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 and perform a drug regimen review as specified in subsection (g)(1)(B) of this section after a reasonable interval, but in no event may such interval exceed seven days.

(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 after a reasonable interval, but in no event may such interval exceed seven days.

(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 all of the following conditions:

(i) the pharmacy is owned by a charitable organization described in the Internal Revenue Code of 1986, or by a city, state or county government;

(ii) 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;

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

(iv) the samples are possessed in compliance with the federal Prescription Drug Marketing Act of 1986.

(D) All drugs shall be stored at the proper temperatures, as defined by the following.

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

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

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

(iv) Warm--Any temperature between 30 and 40 degrees Centigrade (86 and 104 degrees Fahrenheit).
(v) Excessive heat--Any temperature above 40 degrees Centigrade (104 degrees Fahrenheit).

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

(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 substitute, 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 substitution; and

(iv) the practitioner authorizes pharmacists in the facility to substitute 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 pre-packaging the drug.

(iii) Records of pre-packaging 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 pre-packaged 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 pharmaceuticals 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;

(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) Supportive personnel may not receive verbal 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 inpatient medication;

(XXVI) preparation and distribution of sterile pharmaceuticals;

(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, drug delivery systems, and first dose monitoring;

(XXXI) drug labeling;

(XXXII) recordkeeping;

(XXXIII) quality assurance/quality control;

(XXXIV) duties and education and training of professional and nonprofessional staff; and

(XXXV) emergency preparedness plan, to include continuity of patient therapy and public safety.

(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) 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 from the emergency room.

(A) 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.

(i) 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.

(ii) 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.

(iii) 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.

(iv) 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.

(v) 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.

(vi) 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.

(vii) 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.

(B) If the patient has been admitted to the emergency room of a hospital and a practitioner telephones an order for a dangerous drug to be supplied, the following is applicable.

(i) Dangerous drugs may only be supplied to patients of hospitals after the normal business hours of local pharmacies and when pharmacy services are not reasonably available to the patient.

(ii) The practitioner shall cosign any order for a dangerous drug which is telephoned to the hospital emergency room within 72 hours.

(iii) The practitioner shall have a previous patient/physician relationship with the patient admitted to the emergency room.

(iv) The dangerous drugs may only be supplied in accordance with the system of control and accountability for drugs 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.

(v) Only dangerous drugs 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 of the nature and type to meet the immediate needs of emergency room patients.

(vi) The dangerous drugs 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.

(vii) At any time of delivery of the dangerous drugs, a licensed nurse shall complete the label with at least the following information:

(I) name, address, and phone number of the facility;

(II) date supplied;

(III) name of the practitioner;

(IV) name of the patient;

(V) directions for use;
(VI) brand name and strength of the dangerous drug; or if no brand name, then the generic name, strength, and the name of the manufacturer or distributor of the dangerous drug;

(VII) quantity supplied; and

(VIII) unique identification number.

(viii) A licensed nurse shall give the appropriately labeled, prepackaged dangerous drug to the patient and explain the correct use of the drug.

(ix) A perpetual record of dangerous drugs 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 if no brand name, then the generic name, strength, and the name of the manufacturer or distributor of the dangerous drug;

(V) quantity supplied; and

(VI) unique identification number.

(x) 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.

(C) Prior to implementing the procedures for supplying dangerous drugs to emergency room patients of a hospital on the telephone order of a practitioner, as specified in subparagraph (B) of this paragraph, the hospital shall notify the board of its intent to implement this policy. Such notification shall be signed by the hospital administrator, medical director, and pharmacist-in-charge and contain the following information:

(i) the hours the hospital pharmacy is open for pharmacy services; and

(ii) documentation of the lack of pharmacy services after normal business hours of the hospital pharmacy.

(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 bulk or unlabeled drugs only by a pharmacist or by pharmacy technicians 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 bulk or 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 filled through the use of 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) 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 bulk 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 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 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 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 Schedule 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, e.g., microfilm or microfiche, 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 of this title (relating to Records), and §291.35 of this title (relating to Official Prescription Records), contained in Community Pharmacy (Class A).

(2) Outpatient prescriptions, including, but not limited to, furlough and discharge prescriptions, that are written by the practitioner must be written on a form which meets the requirements of the Act, §562.006. 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 the Texas controlled substances regulations, 37 TAC §13.74 (relating to Exceptions to Use of Forms). Outpatient prescriptions for Schedule II controlled substances that are exempted from the official prescription requirement must be manually signed by the practitioner.

(c) Inpatient 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 order 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 inpatient 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.

(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.

(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.
(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) signature (first initial and last name or full signature) 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 Schedule 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) signature (first initial and last name or full signature) 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 back-up systems. The facility shall maintain a back-up copy of information stored in the data processing system using disk, tape, or other electronic back-up system and update this back-up 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, nalbuphine (e.g., Nubain), tripelennamine (e.g., PBZ) and carisoprodol (e.g., Soma). 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, nalbuphine (e.g., Nubain), tripelennamine (e.g., PBZ), and carisoprodol (e.g., Soma) to the pharmacy.

(A) Each time a controlled substance, nalbuphine (e.g., Nubain), tripelennamine (e.g., PBZ), or carisoprodol (e.g., Soma) 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 CRT display, 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 these 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.

(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 Texas State Board of Pharmacy, 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 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 on-line data entry as soon as the system is available for use again.

(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.

(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) If the distribution is for a Schedule I or II controlled substance, the following is applicable.

(A) The pharmacy, practitioner or other registrant who is receiving the controlled substances shall issue copy 1 and copy 2 of a DEA order form (DEA 222) to the distributing pharmacy.

(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.

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

(1) a permanent log of the initials or identification codes which will identify 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);

(2) copy 3 of DEA order form (DEA 222) which has been properly dated, initialed, and filed, and all copies of each unaccepted or defective order form and any attached statements or other documents;

(3) a hard copy of the power of attorney to sign DEA 222 order forms (if applicable);

(4) suppliers' invoices of dangerous drugs and controlled substances; a pharmacist shall verify that the controlled drugs listed on the invoices were actually received by clearly recording his/her initials and the actual date of receipt of the controlled substances;

(5) suppliers' credit memos for controlled substances and dangerous drugs;

(6) a hard copy of inventories required by §291.17 of this title (relating to Inventory Requirements) 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;

(7) hard copy reports of surrender or destruction of controlled substances and/or dangerous drugs to an appropriate state or federal agency;

(8) a hard copy Schedule V nonprescription register book;

(9) records of distribution of controlled substances and/or dangerous drugs to other pharmacies, practitioners, or registrants; and

(10) a hard copy of any notification required by the Texas Pharmacy Act or these sections including, but not limited to, the following:

(A) reports of theft or significant loss of controlled substances to DEA, DPS, 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, medication, 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 the Drug Enforcement Administration as required by Title 21, Code of Federal Regulations, §1304.04(a), and submits a copy of this written notification to
the Texas State Board of Pharmacy. Unless the registrant is informed by the divisional director of the Drug Enforcement Administration that permission to keep central records is denied, the pharmacy may maintain central records commencing 14 days after receipt of notification by the divisional director.

(B) The pharmacy maintains a copy of the notification required in subparagraph (A) of this paragraph.

(C) The records to be maintained at the central record location shall not include executed DEA order forms, prescription drug orders, or controlled substance inventories, which shall be maintained at the pharmacy.

(2) Dangerous drug records. Invoices and financial data for dangerous drugs may be maintained at a central location.

(3) Access to records. If the records are kept on microfilm, computer media, or in any form requiring special equipment to render the records easily readable, the pharmacy shall provide access to such equipment with the records.

(4) Delivery of records. The pharmacy agrees to deliver all or any part of such records to the pharmacy location within two business days of written request of a board agent or any other authorized official.

§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, Chapters 551 - 566 and 568 - 569, Occupations Code, as amended.

(2) Ambulatory surgical center (ASC)--A freestanding facility that is licensed by the Texas Department of State Health Services to provide surgical services to patients who do not require overnight hospital care.

(3) Automated drug dispensing system--An automated device that measures, counts, and/or packages a specified quantity of dosage units for a designated drug product.

(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 ASC 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 Schedule I - V of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public Law 91-513).
(7) Direct copy--Electronic copy or carbonized copy of a medication order including a facsimile (FAX), tele-autograph, or a copy transmitted between computers.

(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., cathode ray tube (CRT), microfiche reader, 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--A written order from a practitioner or a verbal 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) A written order from a practitioner or 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.

(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, the 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) establishment of specifications for procurement and storage of all materials, including drugs, chemicals, and biologicals;

(ii) participation in the development of a formulary for the ASC, subject to approval of the appropriate committee of the ASC;

(iii) distribution of drugs to be administered to inpatients pursuant to an original or direct copy of 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 inpatient 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) 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) participation in those aspects of the ASC’s patient care evaluation program which relate to pharmaceutical material utilization and effectiveness;

(viii) participation in teaching and/or research programs in the ASC;

(ix) implementation of the policies and decisions of the appropriate committee(s) relating to pharmaceutical services of the ASC;

(x) 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, storage, and distribution of investigational new drugs, including maintenance of 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; and

(xiii) maintenance of 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.

(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 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) selection of prescription drugs and/or devices and/or suppliers; and

(iii) interpreting patient profiles.

(C) Special requirements for compounding.

(i) 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).

(ii) Sterile Preparations. All pharmacists engaged in compounding sterile preparations shall meet the training requirements specified in §291.133 of this title (relating to Pharmacies Compounding 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. 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 in-process and final checks and affixes his or her signature or electronic signature to the appropriate quality control records;

(ii) preparing, packaging, compounding, or labeling prescription drugs pursuant to medication orders, provided a pharmacist supervises and checks the preparation;

(iii) compounding non-sterile and sterile preparations pursuant to medication orders; and

(I) have completed the training specified in §291.26 of this title (relating to Pharmacies Compounding Sterile Pharmaceuticals); and

(II) are supervised by a pharmacist who has completed the sterile products training specified in §291.26 of this title, conducts in-process and final checks, and affixes his or her initials to the label or if batch prepared, to the appropriate quality control records. (The initials are not required on the label if it is maintained in a permanent record of the pharmacy.)

(iv) bulk compounding, provided a pharmacist supervises and conducts in-process and final checks and affixes his or her initials to the appropriate quality control records;

(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)(E) and (F) of this section;
(vii) maintaining inventories of drug supplies;

(viii) maintaining pharmacy records; and

(ix) loading bulk unlabeled drugs into an automated drug dispensing system provided a pharmacist supervises, verifies that the system was properly loaded prior to use, and affixes his or her signature or electronic signature to the appropriate quality control records.

(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 working in a Class A pharmacy.

(D) Special requirements for compounding.

(i) 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.

(ii) Sterile Preparations. All pharmacy technicians and pharmacy technician trainees engaged in compounding 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) establishment of policies for procurement of prescription drugs and devices and other products dispensed from the ASC pharmacy;

(B) establishment and maintenance of effective controls against the theft or diversion of prescription drugs;

(C) 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;

(D) providing the pharmacy with the necessary equipment and resources commensurate with its level and type of practice; and

(E) 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.

(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 trainee a registered 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) Licensing requirements.

(A) An ASC pharmacy shall register annually 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) If the ASC pharmacy is owned or operated by a pharmacy management or consulting firm, the following conditions apply.

   (i) The pharmacy license application shall list the pharmacy management or consulting firm as the owner or operator.

   (ii) The pharmacy management or consulting firm shall obtain DEA and DPS controlled substances registrations that are issued in the name of the firm, unless the following occur:

      (I) the pharmacy management or consulting firm and the facility cosign a contractual pharmacy service agreement which assigns overall responsibility for controlled substances to the facility; and

      (II) such pharmacy management or consulting firm maintains dual responsibility for the controlled substances.

(C) 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).

(D) 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.

(E) 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.

(F) 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 Closed Pharmacies).

(G) 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.

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

(J) An ASC pharmacy engaged in non-sterile compounding of drug products for inpatients of the hospital shall comply with the provisions of §291.131 of this title.

(K) An ASC pharmacy engaged in the compounding of sterile pharmaceuticals shall comply with the provisions of §291.133 of this title.

(L) 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).

(M) 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 Centralized 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) Only authorized personnel may have access to storage areas for prescription drugs and/or devices.

(ii) All storage areas for prescription drugs and/or devices shall be locked by key or combination, so as to prevent access by unauthorized personnel.
(iii) 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 prescription drugs and/or devices.

(3) Equipment and supplies. Ambulatory surgical centers supplying drugs for postoperative use shall have the following equipment and supplies:

(A) typewriter or comparable equipment; and

(B) adequate supply of child-resistant, moisture-proof, and light-proof containers;

(C) adequate supply of prescription labels and other applicable identification labels;

(4) Library. A reference library shall be maintained which 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;

(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) 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;

(ii) General information. 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) AHFS Drug Information with current supplements;

(IV) Remington's Pharmaceutical Sciences; or

(V) Clinical Pharmacology;

(C) a current or updated reference on injectable drug products, such as Handbook of Injectable Drugs;

(D) basic antidote information and the telephone number of the nearest regional poison control center.
(E) if the pharmacy compounds sterile preparations, specialty references appropriate for the scope of services provided by the pharmacy, e.g., if the pharmacy prepares cytotoxic drugs, a reference text on the preparation of cytotoxic drugs, such as Procedures for Handling Cytotoxic Drugs.

(F) metric-apothecary weight and measure conversion charts.

(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 all of the following conditions:

(I) the pharmacy is owned by a charitable organization described in the Internal Revenue Code of 1986, or by a city, state or county government;

(II) 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;

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

(IV) the samples are possessed in compliance with the federal Prescription Drug Marketing Act of 1986.

(iv) All drugs shall be stored at the proper temperatures, as defined by the following terms.

(I) Room temperature--temperature maintained between 15 degrees Celsius (59 degrees Fahrenheit) and 30 degrees Celsius (86 degrees Fahrenheit).

(II) Cool--temperature between 8 degrees Celsius (46 degrees Fahrenheit) and 15 degrees Celsius (59 degrees Fahrenheit). An article for which storage in a cool place is directed may, alternatively, be stored in a refrigerator unless otherwise specified on the labeling.

(III) Refrigerate--temperature that is thermostatically maintained between 2 degrees Celsius (36 degrees Fahrenheit) and 8 degrees Celsius (46 degrees Fahrenheit).

(IV) Freeze--temperature that is thermostatically maintained between minus 20 degrees Celsius (minus 4 degrees Fahrenheit) and minus 10 degrees Celsius (14 degrees Fahrenheit).

(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 ambulatory surgical center.
(ii) The pharmacist-in-charge or consultant pharmacist shall be a full voting member of any committee which involves pharmaceutical services.

(C) Prepackaging of drugs and loading of bulk unlabeled drugs into automated drug dispensing system.

(i) Prepackaging of drugs.

(I) Drugs may be prepackaged in quantities suitable for internal distribution only by a pharmacist or 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 unlabeled drugs into automated drug dispensing systems.

(I) Automated drug dispensing systems may be loaded with bulk unlabeled 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 drug dispensing system 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 unlabeled drugs into an automated drug dispensing system shall be maintained to show:

(-a-) name of the drug, strength, and dosage form;
(-b-) manufacturer or distributor;
(-c-) manufacturer's lot number;
(-d-) expiration date;
(-e-) date of loading;
(-f-) name, initials, or electronic signature of the person loading the automated drug dispensing system; and
(-g-) signature or electronic signature of the responsible pharmacist.

(IV) The automated drug dispensing system 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.

(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.

(B) Drugs may be distributed only pursuant to the original or a direct copy of the practitioner's medication order.

(C) Pharmacy technicians and pharmacy technician trainees may not receive oral medication orders.

(D) 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.

(E) 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 taken;

(V) time and date; and

(VI) signature or electronic signature of person making withdrawal.

(iv) The original or direct copy of the medication order 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.

(F) 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 drugs and devices; the record shall meet the same requirements as specified in subparagraph (E)(iii) of this paragraph.

(iv) The pharmacist shall verify each distribution after a reasonable interval, but in no event may such interval exceed seven days.

(7) Floor stock. In facilities using a floor stock method of drug distribution, 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; 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) A pharmacist shall verify the withdrawal according to the following schedule.

(i) In facilities with a full-time pharmacist, the withdrawal shall be verified as soon as practical, but in no event more than 72 hours from the time of such withdrawal.
(ii) In facilities with a part-time or consultant pharmacist, the withdrawal shall be verified after a reasonable interval, but in no event may such interval exceed seven days.

(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 drug dispensing systems; and

(T) use of data processing systems.

(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 ambulatory surgical center.
(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 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 by the practitioner, 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 every seven days.

(e) Records.
(1) Maintenance of records.

(A) Every inventory or other record required to be kept under the provisions of this section (relating to Institutional Pharmacy (Class C)) 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 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 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 Schedules I and II shall be maintained separately 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 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.

(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, e.g., microfilm or microfiche, 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.

(2) Outpatient records.

(A) Only a registered pharmacist may receive, certify, and receive prescription drug orders.

(B) Outpatient records shall be maintained as provided in §291.34 and §291.35 of this title contained in Community Pharmacy (Class A).

(C) Outpatient prescriptions, including, but not limited to, discharge prescriptions, that are written by the practitioner, must be written on a form which meets the requirements of the Act, §562.006. Medication order forms or copies thereof do not meet the requirements for outpatient forms.

(D) Controlled substances listed in Schedule II must be written on an electronic 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 the Texas Controlled Substances Rules, 37 TAC §13.74. Outpatient prescriptions for Schedule II controlled substances that are exempted from the official prescription requirement must be manually signed by the practitioner.

(3) Inpatient records.
(A) Each original 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 ASC.

(B) Original medication orders shall be maintained with the medication administration record in the medical records of the patient.

(C) Controlled substances records shall be maintained as follows.

(i) All records for controlled substances shall be maintained in a readily retrievable manner.

(ii) Controlled substances records shall be maintained in a manner to establish receipt and distribution of all controlled substances.

(D) Records of controlled substances listed in Schedule II shall be maintained as follows.

(i) 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.

(ii) An ASC pharmacy shall maintain a perpetual inventory of any controlled substance listed in Schedule II.

(iii) Distribution records for Schedule II - V controlled substances floor stock shall include the following information:

(I) patient's name;

(II) practitioner who ordered 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 controlled substance;

(VI) returns to the pharmacy; and

(VII) waste (waste is required to be witnessed and cosigned, manually or electronically, by another individual).

(E) Floor stock records shall be maintained as follows.

(i) Distribution records for Schedules III - V controlled substances floor stock shall include the following information:
(I) patient's name;

(II) practitioner who ordered controlled substance;

(III) name of controlled substance, dosage form, and strength;

(IV) time and date of administration to patient;

(V) quantity administered;

(VI) signature or electronic signature of 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).

(ii) The record required by clause (i) of this subparagraph shall be maintained separately from patient records.

(iii) 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.

(F) General requirements for records maintained in a data processing system are as follows.

(i) 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.

(ii) 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 to assure that data is not lost due to system failure.

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

(I) Records of distribution and return for all controlled substances, nalbuphine (Nubain), and tripelennamine (PBZ). A pharmacy that changes or discontinues use of a data processing system must:

(-a-) transfer the records to the new data processing system; or

(-b-) purge the records to a printout which contains the same information as required on the audit trail printout as specified in subparagraph (G)(ii) of this paragraph. 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:

(-a-) transfer the records to the new data processing system; or

(-b-) 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.
(iv) 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.

(G) Data processing system maintenance of records for the distribution and return of all controlled substances, nalbuphine (Nubain), or tripelennamine (PBZ) to the pharmacy.

(i) Each time a controlled substance, nalbuphine (Nubain), or tripelennamine (PBZ) is distributed from or returned to the pharmacy, a record of such distribution or return shall be entered into the data processing system.

(ii) 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 CRT display, the following shall also be included on the printout:

(-a-) prescribing or attending practitioner's address; and

(-b-) practitioner's DEA registration number, if the medication order is for a controlled substance.

(iii) An audit trail printout for each strength and dosage form of these 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.

(iv) 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.

(H) 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.

(I) Data processing system downtime. 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 on-line 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 dispense 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) If the distribution is for a Schedule I or II controlled substance, the following is applicable.

(i) 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 222C) to the distributing pharmacy.

(ii) The distributing pharmacy shall:

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

(II) maintain Copy 1 of the DEA order form (DEA 222C) at the pharmacy for two years; and

(III) forward Copy 2 of the DEA order form (DEA 222C) to the divisional office of the Drug Enforcement Administration.

(5) Other records. Other records to be maintained by the pharmacy include:

(A) a permanent log of the initials or identification codes which will identify 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) Copy 3 of DEA order form (DEA 222C), which has been properly dated, initialed, and filed, and all copies of each unaccepted or defective order form and any attached statements or other documents;

(C) a hard copy of the power of attorney to sign DEA 222C order forms (if applicable);

(D) 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;

(E) supplier’s credit memos for controlled substances and dangerous drugs;

(F) 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;
(G) hard-copy reports of surrender or destruction of controlled substances and/or dangerous drugs to an appropriate state or federal agency;

(H) a hard-copy Schedule V nonprescription register book;

(I) records of distribution of controlled substances and/or dangerous drugs to other pharmacies, practitioners, or registrants; and

(J) a hard 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, DPS, 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 the Drug Enforcement Administration as required by the Code of Federal Regulations, Title 21, §1304(a), and submits a copy of this written notification to the Texas State Board of Pharmacy. Unless the registrant is informed by the divisional director of the Drug Enforcement Administration that permission to keep central records is denied, the pharmacy may maintain central records commencing 14 days after receipt of notification by the divisional director.

(ii) The pharmacy maintains a copy of the notification required in this subparagraph.

(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.

(7) 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.
(B) Confidential records are privileged and may be released only to:

(i) the patient or the patient's agent;

(ii) 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;

(iii) the board or to a person or another state or federal agency authorized by law to receive the confidential record;

(iv) 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.);

(v) a person employed by a state agency that licenses a practitioner, if the person is performing the person's official duties; or

(vi) an insurance carrier or other third party payor authorized by a patient to receive such information.