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

§291.37 Class A Pharmacies Providing Services Only to Patients in Long-Term Care Facilities

(a) Purpose. The purpose of this section is to provide standards in the conduct, practice activities, and operation of a pharmacy providing services only to patients in long-term care facilities. A pharmacy licensed under this section may not serve the general public or any other type of facility other than those listed in this subsection. A pharmacy licensed under this section may only provide services to patients in a:

(1) healthcare facility regulated under Chapters 242, 247, or 252, Health and Safety Code, provided drugs are administered by licensed, or otherwise authorized by this state, individuals working in the healthcare facility to administer medication;

(2) jail or prison operated by or for the state of Texas, or to patients in a jail or prison operated by local government, provided drugs are administered by licensed, or otherwise authorized by this state, individuals to administer medication.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section shall have the definition set forth in the Act, §551.003.

(1) Accurately as prescribed--Dispensing, delivering, and/or distributing a LTCF drug order:

(A) to the correct patient (or agent of the patient) for whom the drug or device was prescribed;

(B) with the correct drug in the correct strength, quantity, and dosage form ordered by the practitioner; and

(C) with correct labeling (including directions for use) as ordered by the practitioner. Provided, however, that nothing herein shall prohibit pharmacist substitution if substitution is conducted in strict accordance with applicable laws and rules, including Chapters 562 and 563 of the Texas Pharmacy Act.

(2) Act--The Texas Pharmacy Act, Chapters 551 - 566 and 568 - 569, Occupations Code, as amended.

(3) Advanced practice nurse--A registered nurse approved by the Texas Board of Nursing to practice as an advanced practice nurse on the basis of completion of an advanced education program. The term includes a nurse practitioner, a nurse midwife, a nurse anesthetist, and a clinical nurse specialist.

(4) Automated checking device--A device that confirms that the correct drug and strength has been labeled with the correct label for the correct patient prior to delivery of the drug to the patient.

(5) Automated 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.

(6) Automated dispensing systems--A mechanical system located in the prescription department that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, dispensing, and distribution of medications, and which collects, controls, and maintains all transaction information. "Automated dispensing systems" does not mean "Automated compounding or counting devices."

(7) Beyond use date—The date beyond which a product should not be used.

(8) Board--The Texas State Board of Pharmacy.

(9) Data communication device--An electronic device that receives electronic information from one source and transmits or routes it to another (e.g., bridge, router, switch or gateway).

(10) Designated agent--

(A) a licensed nurse, physician assistant, pharmacist, or other individual designated by a practitioner to communicate LTCF orders to a pharmacist;

(B) a licensed nurse, physician assistant, or pharmacist employed in a health care facility to whom the practitioner communicates a LTCF order;

(C) an advanced practice nurse or physician assistant authorized by a practitioner to carry out or sign a LTCF order for dangerous drugs under Chapter 157 of the Medical Practice Act (Subtitle B, Occupations Code); or

(D) a person who is a licensed vocational nurse or has an education equivalent to or greater than that required for a licensed vocational nurse designated by the practitioner to communicate orders for an advanced practice nurse or physician assistant authorized by the practitioner to sign LTCF orders under Chapter 157 of the Medical Practice Act (Subtitle B, Occupations Code).

(11) Dispensing pharmacist--The pharmacist responsible for the final check of the dispensed order before delivery to the patient.

(12) Distribute--The delivery of an ordered drug or device other than by administering or dispensing.

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

(14) Electronic LTCF drug order--A LTCF drug order which is transmitted by an electronic device to the receiver (pharmacy).

(15) 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.

(16) 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.

(17) Hard copy--A physical document that is readable without the use of a special device.

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

(19) Long-term care facility (LTCF)—A healthcare facility regulated under Chapters 242, 247, or 252, Health and Safety Code, provided the drugs are administered by licensed, or otherwise authorized by this state, individuals working in the healthcare facility to administer medication.

(20) LTCF drug order—A prescription or medication drug order for a patient admitted to a long-term care facility.

(21) Medical Practice Act--The Texas Medical Practice Act, Subtitle B, Occupations Code, as amended.

(21) 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.

(22) Part-time pharmacist--A pharmacist who works less than full-time.

(23) Patient med-pak—A package prepared by a pharmacist for a specific patient comprising a series of containers and containing two or more prescribed solid oral dosage forms. The patient med-pak is so designed or each container is so labeled as to indicate the day and time, or period of time, that the contents within each container are to be taken.

(24) 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.

(25) 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.

(26) 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.

(27) Physician assistant--A physician assistant recognized by the Texas Medical Board as having the specialized education and training required under Subtitle B, Chapter 157, Occupations Code, and issued an identification number by the Texas Medical Board.

(28) Prepackaging--The act of repackaging and relabeling quantities of drug products from a manufacturer's original commercial container into a prescription container for dispensing by a pharmacist to the ultimate consumer.

(29) Prescription department--The area of a pharmacy that contains prescription drugs.

(30) 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.

(31) State--One of the 50 United States of America, a U.S. territory, or the District of Columbia.

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

(33) Unit-of-use--A sufficient quantity of a drug product for one normal course of therapy.

(c) Personnel.

(1) Requirements for pharmacist services. A pharmacist shall be accessible at all times to respond to questions and needs of the LTCF. 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.

(2)Pharmacist-in-charge. Each LTCF pharmacy shall have one pharmacist-in-charge who is employed on a full-time basis, who may be the pharmacist-in-charge for only one pharmacy; provided, however, such pharmacist-in-charge may be the pharmacist-in-charge of:

(A) more than one LTCF pharmacy or Class A pharmacy, if the additional pharmacies are not open to provide pharmacy services simultaneously; or

(B) during an emergency, up to two LTCF or Class A pharmacies that are open simultaneously if the pharmacist-in-charge works at least 10 hours per week in each pharmacy for no more than a period of 30 consecutive days.

(C) The pharmacist-in-charge shall comply with the provisions of §291.17 of this title (relating to Inventory Requirements).

(D) The pharmacist-in-charge shall have responsibility for the practice of pharmacy at the pharmacy for which he or she is the pharmacist-in-charge. The pharmacist-in-charge may advise the owner on administrative or operational concerns. The pharmacist-in-charge shall have responsibility for, at a minimum, the following:

(i) education and training of pharmacy technicians and pharmacy technician trainees;

(ii) supervising a system to assure appropriate procurement of prescription drugs and devices and other products dispensed from the pharmacy;

(iii) disposal and distribution of drugs from the pharmacy;

(iv) storage of all materials, including drugs, chemicals, and biologicals;

(v) maintaining records of all transactions of the pharmacy necessary to maintain accurate control over and accountability for all pharmaceutical materials required by applicable state and federal laws and sections;

(vi) supervising a system to assure maintenance of effective controls against the theft or diversion of prescription drugs, and records for such drugs;

(vii) adherence to policies and procedures regarding the maintenance of records in a data processing system such that the data processing system is in compliance with the pharmacy requirements;

(viii) legal operation of the pharmacy, including meeting all inspection and other requirements of all state and federal laws or sections governing the practice of pharmacy; and

(ix) if the pharmacy uses an automated pharmacy dispensing system, shall be responsible for the following:

(I) consulting with the owner concerning adherence to the policies and procedures for system operation, safety, security, accuracy and access, patient confidentiality, prevention of unauthorized access, and malfunction;

(II) inspecting medications in the automated pharmacy dispensing system, at least monthly, for expiration date, misbranding, physical integrity, security, and accountability;

(III) assigning, discontinuing, or changing personnel access to the automated pharmacy dispensing system;

(IV) ensuring that pharmacy technicians, pharmacy technician trainees, and licensed healthcare professionals performing any services in connection with an automated pharmacy dispensing system have been properly trained on the use of the system and can demonstrate comprehensive knowledge of the written policies and procedures for operation of the system; and

(V) ensuring that the automated pharmacy dispensing system is stocked accurately and an accountability record is maintained in accordance with the written policies and procedures of operation.

(3) Owner. The owner of a LTCF 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 pharmacy;

(B) establishment of polices and procedures for the security of the prescription department including the 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.

(4) Pharmacists.

(A) The pharmacist-in-charge shall be assisted by sufficient number of additional licensed pharmacists as may be required to operate the pharmacy competently, safely, and adequately to meet the needs of the patients of the pharmacy.

(B) All pharmacists shall assist the pharmacist-in-charge in meeting his or her responsibilities in ordering, dispensing, and accounting for prescription drugs.

(C) Pharmacists are solely responsible for the direct supervision of pharmacy technicians and pharmacy technician trainees and for designating and delegating duties, other than those listed in subparagraph (G) of this paragraph, to pharmacy technicians and pharmacy technician trainees. Each pharmacist shall be responsible for any delegated act performed by pharmacy technicians and pharmacy technician trainees under his or her supervision.

(D) Pharmacists shall directly supervise pharmacy technicians and pharmacy technician trainees who are entering prescription data into the pharmacy's data processing system by one of the following methods.

(i) Physically present supervision. A pharmacist shall be physically present to directly supervise a pharmacy technician or pharmacy technician trainee who is entering prescription data into the data processing system. Each prescription entered into the data processing system shall be verified at the time of data entry.

(ii) Electronic supervision. A pharmacist may electronically supervise pharmacy technicians or pharmacy technician trainees who are entering prescription data into the data processing system provided the pharmacist:

(I) is on-site, in the LTCF pharmacy where the technician/trainees are located;

(II) has immediate access to any original document containing prescription information or other information related to the dispensing of the order. Such access may be through imaging technology provided the pharmacist has the ability to review the original, hardcopy documents if needed for clarification; and

(III) verifies the accuracy of the data entered information prior to the release of the information to the system for storage and/or generation of the prescription label.

(iii) Electronic verification of data entry by pharmacy technicians or pharmacy technician trainees. A pharmacist may electronically verify the data entry of order information into a data processing system provided:

(I) a pharmacist is on-site in the LTCF pharmacy where the pharmacy technicians/trainees are located;

(II) the pharmacist electronically conducting the verification is either a:

(-a-) Texas licensed pharmacist; or

(-b-) pharmacist employed by a Class E pharmacy that:

(-1-) has the same owner as the LTCF pharmacy where the pharmacy technicians/trainees are located; or

(-2-) has entered into a written contract or agreement with the pharmacy, which outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations;

(III) the pharmacy establishes controls to protect the privacy and security of confidential records; and

(IV) the pharmacy keeps permanent records of orders electronically verified for a period of two years from the date of verification.

(E) All pharmacists while on duty, shall be responsible for complying with all state and federal laws or rules governing the practice of pharmacy.

(F) A dispensing pharmacist shall be responsible for and ensure that the drug is dispensed and delivered safely, and accurately as prescribed, unless the pharmacy's data processing system can record the identity of each pharmacist involved in a specific portion of the dispensing processing. If the system can track the identity of each pharmacist involved in the dispensing process, each pharmacist involved in the dispensing process shall be responsible for and ensure that the portion of the process the pharmacist is performing results in the safe and accurate dispensing and delivery of the drug as prescribed. The dispensing process shall include, but not be limited to, drug regimen review and verification of accurate LTCF order data entry, including data entry of LTCF orders placed on hold, packaging, preparation, compounding and labeling, and performance of the final check of the dispensed LTCF order.

(G) Duties which may only be performed by a pharmacist are as follows:

(i) receiving oral LTCF drug orders and reducing these orders to writing, either manually or electronically;

(ii) interpreting LTCF drug orders, including the selection of drug products;

(iii) performing the final check of the dispensed order before delivery to the patient to ensure that the order has been dispensed accurately as prescribed;

(iv) communicating to the patient or the patient's agent on his or her request information concerning any prescription drugs dispensed to the patient by the pharmacy;

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

(vi) interpreting patient medication records and performing drug regimen reviews;

(vii) 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; and

(viii) verifying that controlled substances listed on invoices are received by clearly recording his/her initials and date of receipt of the controlled substances.

(H) 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).

(I) 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).

(5) Pharmacy Technicians and Pharmacy Technician Trainees.

(A) All pharmacy technicians and pharmacy technician trainees shall meet the training requirements specified in §297.6 of this title (relating to Pharmacy Technician and Pharmacy Technician Trainee Training).

(B) 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.

(C) All pharmacy technicians and pharmacy technician trainees engaged in compounding sterile preparations shall meet the training requirements specified in §291.133 of this title.

(D) Pharmacy technicians and pharmacy technician trainees may not perform any of the duties listed in paragraph (3)(G) of this subsection.

(E) A pharmacist may delegate to pharmacy technicians and pharmacy technician trainees any nonjudgmental technical duty associated with the preparation and distribution of prescription drugs provided:

(i) a pharmacist verifies the accuracy of all acts, tasks, and functions performed by pharmacy technicians and pharmacy technician trainees;

(ii) pharmacy technicians and pharmacy technician trainees are under the direct supervision of and responsible to a pharmacist; and

(iii) only pharmacy technicians and pharmacy technician trainees who have been properly trained on the use of an automated pharmacy dispensing system and can demonstrate comprehensive knowledge of the written policies and procedures for the operation of the system may be allowed access to the system; and

(F) Pharmacy technicians and pharmacy technician trainees may perform only nonjudgmental technical duties associated with the preparation and distribution of prescription drugs, as follows:

(i) initiating and receiving refill authorization requests;

(ii) entering LTCF order data into a data processing system;

(iii) taking a stock bottle from the shelf for a LTCF order;

(iv) preparing and packaging LTCF drug orders (i.e., counting tablets/capsules, measuring liquids and placing them in the prescription container);

(v) affixing prescription labels and auxiliary labels to the prescription container;

(vi) reconstituting medications;

(vii) prepackaging and labeling prepackaged drugs;

(viii) loading bulk unlabeled drugs into an automated dispensing system provided a pharmacist verifies that the system is properly loaded prior to use;

(ix) compounding non-sterile and sterile LTCF drug orders; and

(x) bulk compounding.

(G) The ratio of on-site pharmacists to pharmacy technicians and pharmacy technician trainees may be 1:3, provided the pharmacist is on-site and at least one of the three is a pharmacy technician. The ratio of pharmacists to pharmacy technician trainees may not exceed 1:2.

(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, 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) A LTCF pharmacy shall register annually or biennially with the board on a pharmacy license application provided by the board, following the procedures specified in §291.1 of this title (relating to Pharmacy License Application).

(B) A LTCF pharmacy which changes ownership shall notify the board within ten days of the change of ownership and apply for a new and separate license as specified in §291.3 of this title (relating to Required Notifications).

(C) A LTCF pharmacy which changes location and/or name shall notify the board within ten days of the change and file for an amended license as specified in §291.3 of this title.

(D) A LTCF pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within ten days of the change, following the procedures in §291.3 of this title.

(E) A LTCF pharmacy shall notify the board in writing within ten days of closing, following the procedures in §291.5 of this title (relating to Closing a Pharmacy).

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

(G) A 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.

(I) A LTCF pharmacy engaged in the compounding of non-sterile preparations shall comply with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

(J) A LTCF pharmacy engaged in the compounding of sterile preparations shall comply with the provisions of §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).

(K) A LTCF pharmacy engaged in the provision of remote pharmacy services, including storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of this title (relating to Remote Pharmacy Services).

(L) LTCF pharmacy engaged in centralized LTCF order dispensing and/or LTCF order drug 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) The pharmacy shall be arranged in an orderly fashion and kept clean. All required equipment shall be clean and in good operating condition.

(ii) A LTCF pharmacy shall have a sink with hot and cold running water within the pharmacy, exclusive of restroom facilities, available to all pharmacy personnel and maintained in a sanitary condition.

(iii) The pharmacy shall be properly lighted and ventilated.

(iv) The temperature of the pharmacy shall be maintained within a range compatible with the proper storage of drugs; the temperature of the refrigerator shall be maintained within a range compatible with the proper storage of drugs requiring refrigeration.

(v) Animals, including birds and reptiles, shall not be kept within the pharmacy and in immediately adjacent areas under the control of the pharmacy. This provision does not apply to fish in aquariums, service animals accompanying disabled persons, or animals for sale to the general public in a separate area that is inspected by local health jurisdictions.

(B) Security.

(i) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of prescription drugs, and records for such drugs.

(ii) The prescription department shall be locked by key, combination or other mechanical or electronic means to prohibit unauthorized access when a pharmacist is not on-site except as provided in clause (iii) and (iv) of this subparagraph. The following is applicable:

(I) If the prescription department is closed at any time when the rest of the facility is open, the prescription department must be physically or electronically secured. The security may be accomplished by means such as floor to ceiling walls; walls, partitions, or barriers at least 9 feet 6 inches high; electronically monitored motion detectors; pull down sliders; or other systems or technologies that will secure the prescription department from unauthorized entrance when the prescription department is closed.

(II) The pharmacy's key, combination, or other mechanical or electronic means of locking the pharmacy may not be duplicated without the authorization of the pharmacist-in-charge and owner.

(III) At a minimum, the pharmacy must have a basic alarm system with off-site monitoring and perimeter and motion sensors. The pharmacy may have additional security by video surveillance camera systems.

(iii) Prior to authorizing individuals to enter the prescription department, the pharmacist-in-charge or owner shall designate persons, including other pharmacists, pharmacy personnel and other individuals, who may enter the prescription department to perform functions, other than dispensing functions or LTCF order processing. The pharmacist-in-charge shall maintain written documentation of such individuals. The pharmacy must maintain written documentation of authorized individuals other than individuals employed by the pharmacy who accessed the prescription department when a pharmacist is not on-site.

(iv) The pharmacist-in-charge may designate in writing persons, either by name or by title including such titles as "relief" or "floater" pharmacist, who may unlock the prescription department in emergency situations. An additional key to or instructions on accessing the prescription department may be maintained in a secure location outside the prescription department for use during an emergency or as designated by the pharmacist-in-charge.

(v) Written policies and procedures for the pharmacy's security shall be developed and implemented by the pharmacist-in-charge and/or the owner of the pharmacy. Such polices and procedures may include quarterly audits of controlled substances commonly abused or diverted; perpetual inventories for the comparison of the receipt, dispensing, and distribution of controlled substances; monthly reports from the pharmacy's wholesaler(s) of controlled substances purchased by the pharmacy; opening and closing procedures; product storage and placement; and central management oversight.

(3) LTCF order dispensing and delivery.

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

(B) Pharmaceutical care services.

(i) Drug regimen review.

(I) For the purpose of promoting therapeutic appropriateness, a pharmacist shall, prior to or at the time of dispensing a LTCF drug order, review the patient's medication record. Such review shall at a minimum identify clinically significant:

(-a-) known allergies;

(-b-) rational therapy-contraindications;

(-c-) reasonable dose and route of administration;

(-d-) reasonable directions for use;

(-e-) duplication of therapy;

(-f-) drug-drug interactions;

(-g-) drug-food interactions;

(-h-) drug-disease interactions;

(-i-) adverse drug reactions; and

(-j-) proper utilization, including overutilization or underutilization.

(II) Upon identifying any clinically significant conditions, situations, or items listed in subclause (I) of this clause, the pharmacist shall take appropriate steps to avoid or resolve the problem including consultation with the prescribing practitioner. The pharmacist shall document such occurrences.

(III) The drug regimen review may be conducted by remotely accessing the pharmacy's electronic data base from outside the pharmacy by:

(-a-) an individual Texas licensed pharmacist employee of the pharmacy provided the pharmacy establishes controls to protect the privacy of the patient and the security of confidential records; or

(-b-) a pharmacist employed by a Class E pharmacy provided the pharmacies have entered into a written contract or agreement which outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations.

(IV) Prior to dispensing, any questions regarding a LTCF drug order must be resolved with the prescriber and written documentation of these discussions made and maintained.

(ii) Other pharmaceutical care services. Other pharmaceutical care services which may be provided by pharmacists include, but are not limited to, the following:

(I) managing drug therapy as delegated by a practitioner as allowed under the provisions of the Medical Practices;

(II) administering immunizations and vaccinations under written protocol of a physician;

(III) managing patient compliance programs;

(IV) providing preventative health care services; and

(V) providing case management of patients who are being treated with high-risk or high-cost drugs, or who are considered "high risk" due to their age, medical condition, family history, or related concern.

(C) Generic Substitution. A pharmacist may dispense a generically equivalent drug product and shall comply with the provisions of §309.3 of this title (relating to Generic Substitution).

(D) Therapeutic Drug Interchange. A switch to a drug providing a similar therapeutic response to the one prescribed shall not be made without prior approval of the prescribing practitioner. This subparagraph does not apply to generic substitution.

(E) Prescription containers. A drug dispensed pursuant to a LTCF drug order shall be dispensed in an appropriate container as specified by the manufacturer.

(F) Labeling. At the time of delivery of the drug, the dispensing container shall bear a label with at least the following information:

(i) pharmacy name and address;

(ii) unique identification number of the LTCF order;

(iii) name and strength of the drug dispensed;

(iv) name of the patient;

(v) name of the prescribing practitioner and, if applicable, the name of the advanced practice nurse, physician assistant, or pharmacist who signed the LTCF drug order;

(vi) if the drug is dispensed in a container other than the manufacturer's original container, the date after which the medication should not be used or beyond-use-date. Unless otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date the drug is dispensed or the manufacturer's expiration date, whichever is earlier. The beyond-use-date may be placed on the prescription label or on a flag label attached to the container. A beyond-use-date is not required on the label of a LTCF container dispensed to a person at the time of release from prison or jail if the LTCF container is for not more than a 10-day supply of medication; and

(vii) the directions for use and cautionary statements, if any, contained on the LTCF drug order or required by law.

(G) Returning Undelivered Medication to Stock.

(i) As specified in §431.021(w), Health and Safety Code, a pharmacist may not accept an unused prescription or drug, in whole or in part, for the purpose of resale or re-dispensing to any person after the prescription or drug has been originally dispensed, or sold except as provided in §291.8 of this title (relating to Return of Prescription Drugs). LTCF orders that have not been picked up by or delivered to the patient or patient's agent may be returned to the pharmacy's stock for dispensing.

(ii) A pharmacist shall evaluate the quality and safety of the prescriptions to be returned to stock.

(iii) Prescriptions returned to stock for dispensing shall not be mixed within the manufacturer's container.

(iv) Prescriptions returned to stock for dispensing should be used as soon as possible and stored in the dispensing container. The expiration date of the medication shall be the lesser of one year from the dispensing date on the prescription label or the manufacturer's expiration date if dispensed in the manufacturer's original container.

(v) At the time of dispensing, the prescription medication shall be placed in a new prescription container and not dispensed in the previously labeled container unless the label can be completely removed. However, if the medication is in the manufacturer's original container, the pharmacy label must be removed so that no confidential patient information is released.

(4) Equipment and supplies. LTCF pharmacies dispensing LTCF drug orders shall have the following equipment and supplies:

(A) data processing system including a printer or comparable equipment;

(B) refrigerator;

(C) adequate supply of air, water, and light-resistant, and if applicable, glass containers;

(D) adequate supply of prescription, poison, and other applicable labels;

(E) appropriate equipment necessary for the proper preparation of LTCF drug orders; and

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

(5) 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; and

(iv) Federal Controlled Substances Act and rules (or official publication describing the requirements of the Federal Controlled Substances Act and rules);

(B) at least one current or updated reference from each of the following categories:

(i) 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) a general information reference text, such as:

(I) Facts and Comparisons with current supplements;

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

(III) Clinical Pharmacology;

(IV) American Hospital Formulary Service with current supplements; or

(V) Remington's Pharmaceutical Sciences; and

(C) basic antidote information and the telephone number of the nearest Regional Poison Control Center.

(6) Drugs.

(A) Procurement 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 relative to such responsibility.

(ii) Prescription drugs and devices and nonprescription Schedule V controlled substances shall be stored within the prescription department or a locked storage area.

(iii) All drugs shall be stored at the proper temperature, as defined in the USP/NF and §291.15 of this title (relating to Storage of Drugs).

(B) Out-of-date drugs or devices.

(i) Any drug or device bearing an expiration date shall not be dispensed beyond the expiration date of the drug or device.

(ii) Outdated drugs or devices shall be removed from dispensing stock and shall be quarantined together until such drugs or devices are disposed of properly.

(C) Samples. LTCF pharmacies may not sell, purchase, trade or possess prescription drug samples, unless the pharmacy meets the requirements as specified in §291.16 of this title (relating to Samples).

(7) Prepackaging of drugs.

(A) Drugs may be prepackaged in quantities suitable for internal distribution only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist.

(B) 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 lot number;

(iii) facility’s beyond use date; and

(iv) quantity of the drug, if the quantity is greater than one.

(C) Records of prepackaging shall be maintained to show:

(i) name of the drug, strength, and dosage form;

(ii) facility's lot number;

(iii) manufacturer or distributor;

(iv) manufacturer's lot number;

(v) manufacturer’s expiration date;

(vi) quantity per prepackaged unit;

(vii) number of prepackaged units;

(viii) date packaged;

(ix) name, initials, or electronic signature of the prepacker; and

(x) signature, or electronic signature of the responsible pharmacist.

(D) Stock packages, repackaged units, and control records shall be quarantined together until checked/released by the pharmacist.

(8) Customized patient medication packages.

(A) Purpose. In lieu of dispensing two or more prescribed drug products in separate containers, a pharmacist may provide a customized patient medication package (patient med-pak).

(B) Label. The patient med-pak shall bear a label stating:

(i) pharmacy by name and address;

(ii) unique identification number of the LTCF order;

(iii) names and strengths of the drugs dispensed;

(iv) name of the patient;

(v) date of dispensing;

(vi) initials or an identification code of the dispensing pharmacist; However, the label is not required to include the initials or identification code of the dispensing pharmacist if the identity of the dispensing pharmacist is recorded in the pharmacy's data processing system. The record of the identity of the dispensing pharmacist shall not be altered in the pharmacy's data processing system.

(vii) name of the prescribing practitioner and, if applicable, the name of the advanced practice nurse , physician assistant, or pharmacist who signed the LTCF drug order;

(viii) if the drug is dispensed in a container other than the manufacturer's original container, the date after which the LTCF order should not be used or beyond-use-date. Unless otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date the drug is dispensed or the manufacturer's expiration date, whichever is earlier. The beyond-use-date may be placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is not required on the label of a LTCF order dispensed to a person at the time of release from prison or jail if the LTCF container is for not more than a 10-day supply of medication; and

(ix) for each drug product, the directions for use and cautionary statements, if any, contained on the LTCF drug order or required by law.

(C) Labeling. The patient med-pak shall be accompanied by a med-guide, in the event that any drug contained therein is required to be dispensed with such guide as accompanying labeling. Alternatively, such required information may be incorporated into a single, overall educational guide provided by the pharmacist for the total patient med-pak.

(D) Packaging. In the absence of more stringent packaging requirements for any of the drug products contained therein, each container of the patient med-pak shall comply with official packaging standards. Each container shall be either not reclosable or so designed as to show evidence of having been opened.

(E) Guidelines. It is the responsibility of the dispensing pharmacist when preparing a patient med-pak, to take into account any applicable compendial requirements or guidelines and the physical and chemical compatibility of the dosage forms placed within each container, as well as any therapeutic incompatibilities that may attend the simultaneous administration of the drugs.

(F) Recordkeeping. In addition to any individual prescription filing requirements, a record of each patient med-pak shall be made and filed. Each record shall contain, as a minimum:

(i) the name and address of the patient;

(ii) the unique identification number for the patient med-pak itself and a separate unique identification number for each of the LTCF drug orders for each of the drug products contained therein;

(iii) the name of the manufacturer or distributor and lot number for each drug product contained therein;

(iv) information identifying or describing the design, characteristics, or specifications of the patient med-pak sufficient to allow subsequent preparation of an identical patient med-pak for the patient;

(v) the date of preparation of the patient med-pak and the beyond-use date that was assigned; and

(vi) any special labeling instructions.

(vii) the initials or an identification code of the dispensing pharmacist.

(9) Automated devices and systems.

(A) Automated compounding or counting devices. If a pharmacy uses automated compounding or counting devices:

(i) 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;

(ii) the devices may be loaded with bulk or unlabeled drugs only by a pharmacist or by pharmacy technicians/trainees under the direction and direct supervision of a pharmacist;

(iii) 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;

(iv) 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) manufacturer’s 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

(v) 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 clause (iv) of this subparagraph.

(B) Automated dispensing systems.

(i) Authority to use automated dispensing systems. A pharmacy may use an automated dispensing system to fill LTCF drug orders provided that:

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

(II) the automated dispensing system has been tested by the pharmacy and found to dispense accurately. The pharmacy shall make the results of such testing available to the Board upon request; and

(III) the pharmacy will make the automated dispensing system available for inspection by the board for the purpose of validating the accuracy of the system.

(ii) Quality assurance program. A pharmacy which uses an automated dispensing system to fill LTCF drug orders shall operate according to a written program for quality assurance of the automated pharmacy dispensing system which:

(I) requires continuous monitoring of the automated dispensing system; and

(II) establishes mechanisms and procedures to test the accuracy of the automated dispensing system at least every six months and whenever any upgrade or change is made to the system and documents each such activity.

(iii) Policies and procedures of operation.

(I) When an automated dispensing system is used to fill LTCF drug orders, it shall be operated according to written policies and procedures of operation. The policies and procedures of operation shall include the following:

(-a-) provide for a pharmacist's review, approval, and accountability for the transmission of each original or new LTCF drug order to the automated pharmacy dispensing system before the transmission is made;

(-b-) stocking of the automated dispensing system;

(-c-) require prior to use, that a pharmacist checks, verifies, and documents that the automated pharmacy dispensing system has been accurately filled each time the system is stocked;

(-d-) provide an accountability record to be maintained which documents all transactions relative to stocking and removing medications from the automated dispensing system;

(-e-) require a prospective drug regimen review is conducted as specified in paragraph (3)(B)(i) of this subsection; and

(-f-) establish and make provisions for documentation of a preventative maintenance program for the automated dispensing system.

(II) A pharmacy which uses an automated dispensing system to fill LTCF drug orders shall, at least annually, review its written policies and procedures, revise them if necessary, and document the review.

(C) Final check of prescriptions dispensed using an automated dispensing system. For the purpose of subsection (c)(4)(F)(iv) of this section, a pharmacist must perform the final check of all prescriptions prior to delivery to the patient to ensure that the prescription is dispensed accurately as prescribed.

(i) This final check shall be considered accomplished if:

(I) a check of the final product is conducted by a pharmacist after the automated system has completed the prescription and prior to delivery to the patient; or

(II) the following checks are conducted by a pharmacist:

(-a-) if the automated pharmacy dispensing system contains bulk stock drugs, a pharmacist verifies that those drugs have been accurately stocked as specified in subparagraph (B)(iii)(I)(-d-) of this paragraph; and

(-b-) a pharmacist checks the accuracy of the data entry of each original or new LTCF drug order entered into the automated pharmacy dispensing system.

(ii) If the final check is accomplished as specified in clause (i)(II) of this subparagraph, the following additional requirements must be met.

(I) The dispensing process must be fully automated from the time the pharmacist releases the prescription to the automated system until a completed, labeled prescription ready for delivery to the patient is produced.

(II) The pharmacy has conducted initial testing and has a continuous quality assurance program which documents that the automated pharmacy dispensing system dispenses accurately as specified in subparagraph (B)(i) and (ii) of this paragraph.

(III) The automated pharmacy dispensing system documents and maintains:

(-a-) the name(s), initials, or identification code(s) of each pharmacist responsible for the checks outlined in clause (i)(II) of this subparagraph; and

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

(IV) The pharmacy establishes mechanisms and procedures to test the accuracy of the automated pharmacy dispensing system at least every month rather than every six months as specified in subparagraph (B)(ii) of this paragraph.

(D) Automated checking device.

(i) For the purpose of (c)(4)(F) of this section, the final check of a dispensed prescription 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:

(-a-) the prepackaged drug or unit-of-use container, such as metered-dose inhalers, insulin pens, topical creams or ointments, or ophthalmic or otic preparations, used to fill the order is checked by a pharmacist who verifies that the drug is labeled and packaged accurately; and

(-b-) a pharmacist checks the accuracy of each original or new LTCF drug order.

(II) the prescription is dispensed, labeled, and made ready for delivery to the patient in compliance with LTCF pharmacy rules; and

(ii) Prior to delivery to the patient:

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

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

(iii) If the final check is accomplished as specified in clause (ii) of this subparagraph, 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:

(-a-) the name(s), initials, or identification code(s) of each pharmacist responsible for the checks outlined in clause (ii)(I) of this subparagraph; and

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

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

(e) Records.

(1) Maintenance of records.

(A) Every inventory or other record required to be kept under the provisions of this section (relating to Class A Pharmacies Providing Services Only to Patients in Long-Term Care Facilities) 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 to 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 section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(B) Records of controlled substances listed in Schedule 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 system or direct imaging system provided:

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

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

(2) Patient records of the pharmacy

(A) Original LTCF drug orders. Each original order shall bear the following information:

(i) patient name and facility;

(ii) drug name and strength,

(iii) directions for use;

(iv) date of dispensing;

(v) name of the prescriber; and

(vi) signature or electronic signature of the practitioner or that of his or her authorized agent in compliance with 21 CFR 1311.100 of the Code of Federal Regulations.

(B) Patient medication records (PMR).

(i) A patient medication record system shall be maintained by the pharmacy for patients to whom LTCF drug orders are dispensed.

(ii) The patient medication record system shall provide for the immediate retrieval of information for the previous 12 months which is necessary for the dispensing pharmacist to conduct a prospective drug regimen review at the time a LTCF drug order is presented for dispensing.

(iii) The pharmacist-in-charge shall assure that a reasonable effort is made to obtain and record in the patient medication record at least the following information:

(I) full name of the patient for whom the drug is ordered;

(II) facility address of the patient;

(III) patient's age or date of birth;

(IV) patient's gender;

(V) any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs currently being used by the patient which may relate to prospective drug regimen review;

(VI) pharmacist's comments relevant to the individual's drug therapy, including any other information unique to the specific patient or drug; and

(VII) a list of all LTCF drug orders dispensed (new and refill) to the patient by the pharmacy during the last two years. Such list shall contain the following information:

(-a-) date dispensed;

(-b-) name, strength, and quantity of the drug dispensed;

(-c-) prescribing practitioner's name;

(-d-) unique identification number of the LTCF order; and

(-e-) name or initials of the dispensing pharmacists.

(iv) A patient medication record shall be maintained in the pharmacy for two years. If patient medication records are maintained in a data processing system, all of the information specified in this subsection shall be maintained in a readily retrievable form for two years and information for the previous 12 months shall be maintained on-line. A patient medication record must contain documentation of any modification, change, or manipulation to the record.

(v) Nothing in this subsection shall be construed as requiring a pharmacist to obtain, record, and maintain patient information other than LTCF drug order information when a patient or patient's agent refuses to provide the necessary information for such patient medication records.

(C) General requirements for records maintained in a data processing system.

(i) Noncompliance with data processing requirements. If a LTCF 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 back-up systems. The pharmacy 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.

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

(I) Records of distribution and return for all controlled substances and nalbuphine (e.g., Nubain). 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 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.

(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.

(v) 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.

(vi) Data processing system downtime. In the event that a LTCF 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) Records Relating to Dispensing Errors.

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

(ii) If a dispensing error occurs, the following is applicable.

(I) Original LTCF drug orders:

(-a-) shall not be destroyed and must be maintained in accordance with paragraph (1) of this subsection; and

(-b-) shall not be altered. Altering includes placing a label or any other item over any of the information on the LTCF drug order (e.g., a dispensing tag or label that is affixed to back of a LTCF drug order must not be affixed on top of another dispensing tag or label in such a manner as to obliterate the information relating to the error).

(II) LTCF drug order records maintained in a data processing system:

(-a-) shall not be deleted and must be maintained in accordance with paragraph (1) of this subsection

(-b-) may be changed only in compliance with paragraph (2)(B) of this subsection; and

(-c-) if the error involved incorrect data entry into the pharmacy's data processing system, this record must be either voided or cancelled in the data processing system, so that the incorrectly entered LTCF drug order may not be dispensed, or the data processing system must be capable of maintaining an audit trail showing any changes made to the data in the system.

(E) Transfer of LTCF order information. For the purpose of dispensing, the transfer of original LTCF order information is permissible between pharmacies, subject to the following requirements.

(i) The transfer of original LTCF order information for controlled substances listed in Schedule III, IV, or V is permissible between pharmacies on a one-time basis only.

(ii) The transfer of original LTCF order information for dangerous drugs is permissible between pharmacies without limitation up to the number of originally authorized refills.

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

(iv) Both the original and the transferred LTCF orders are maintained for a period of two years from the date of last refill.

(v) The pharmacist or pharmacist intern transferring the LTCF order information shall ensure the following occurs:

(I) the LTCF order is voided in the data processing system; and

(II) the following information is stored with the invalidated LTCF order in the data processing system:

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

(-b-) the name of the pharmacist or pharmacist intern receiving the LTCF order information;

(-c-) the name of the pharmacist or pharmacist intern transferring the LTCF order information; and

(-d-) the date of the transfer.

(vi) The pharmacist or pharmacist intern receiving the transferred LTCF order information shall ensure the following occurs:

(I) the LTCF record indicates the prescription was a transfer; and

(II) the following information is stored with the LTCF order in the data processing system:

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

(-b-) original prescription number;

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

(-d-) name of the pharmacist or pharmacist intern transferring the LTCF order information.

(vii) LTCF orders may not be transferred by non-electronic means during periods of downtime except on consultation with and authorization by a prescribing practitioner; provided however, during downtime, a hard copy of a LTCF order may be made available for informational purposes only, to the patient, a pharmacist or pharmacist intern, and the prescription may be read to a pharmacist or pharmacist intern by telephone.

(viii) The original LTCF order shall be invalidated in the data processing system for purposes of filling or refilling, but shall be maintained in the data processing system for refill history purposes.

(ix) If the data processing system does not have the capacity to store all the information required in clauses (v) and (vi) of this subparagraph, the pharmacist is required to record this information on the original or transferred LTCF order.

(x) The data processing system shall have a mechanism to prohibit the transfer or refilling of controlled substance LTCF orders which have been previously transferred.

(F) Electronic transfer of LTCF order information between pharmacies. Pharmacies electronically accessing the same LTCF order records may electronically transfer prescription information if the following requirements are met.

(i) The original order is voided and the following information is documented in the records of the transferring pharmacy:

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

(II) the name of the pharmacist or pharmacist intern receiving the LTCF order information; and

(III) the date of the transfer.

(ii) Pharmacies not owned by the same person may electronically access the same LTCF order records, provided the owner or chief executive officer of each pharmacy signs an agreement allowing access to such LTCF order records.

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

(G) A pharmacist or pharmacist intern may not refuse to transfer original LTCF order information to another pharmacist or pharmacist intern who is acting on behalf of a patient and who is making a request for this information as specified in subparagraphs (E) and (F) of this paragraph.

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

(A) 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);

(B) 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;

(C) records of electronic orders of schedule II controlled substances maintained in compliance with 21 CFR Part 1305;

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

(E) 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;

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

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

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

(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 the sections in this chapter, including, but not limited to, the following:

(i) reports of theft or significant loss of controlled substances to DEA, Department of Public Safety, and the board;

(ii) notifications 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.

(4) 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 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.

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

(iii) The records to be maintained at the central record location shall not include executed DEA order forms, LTCF 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 72 hours of written request of a board agent.

(5) Ownership of pharmacy records. For the purposes of these sections, a pharmacy licensed under the Act is the only entity which may legally own and maintain LTCF order records.