RULE REVIEW ANALYSIS

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

Short Title: Services Provided by Pharmacies


Background: Review of these sections follow the Board’s rule review plan.
§291.120 General

(a) Purpose. This subchapter applies to all classes of pharmacies except as otherwise noted.

(b) Definitions.

(1) The Texas Pharmacy Act or Act--Subtitle J, other than Chapter 567, Occupations Code, as amended.

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

§291.121 Remote Pharmacy Services

(a) Remote pharmacy services using automated pharmacy systems.

(1) Purpose. The purpose of this section is to provide standards for the provision of pharmacy services by a Class A or Class C pharmacy in a facility that is not at the same location as the Class A or Class C pharmacy through an automated pharmacy system as outlined in §562.109 of the Texas Pharmacy Act.

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

(A) Automated pharmacy system--A mechanical system that dispenses prescription drugs and maintains related transaction information.

(B) Remote site--A facility not located at the same location as a Class A or Class C pharmacy, at which remote pharmacy services are provided using an automated pharmacy dispensing system.

(C) Prepackaging--The act of repackaging and relabeling quantities of drug products from a manufacturer's original commercial container, or quantities of unit dosed drugs, into another cartridge or container for dispensing by a pharmacist using an automated pharmacy system.

(D) Provider pharmacy--The community pharmacy (Class A) or the institutional pharmacy (Class C) providing remote pharmacy services.

(E) Remote pharmacy service--The provision of pharmacy services, including the storage and dispensing of prescription drugs, in remote sites.

(F) Unit dose--An amount of a drug packaged in a dosage form ready for administration to a particular patient, by the prescribed route at the prescribed time, and properly labeled with name, strength, and expiration date of the drug.
(3) General requirements.

(A) A provider pharmacy may provide remote pharmacy services using an automated pharmacy system to a jail or prison operated by or for the State of Texas, a jail or prison operated by local government or a healthcare facility regulated under Chapter 142, 242, 247, or 252, Health and Safety Code, provided drugs are administered by a licensed healthcare professional working in the jail, prison, or healthcare facility.

(B) A provider pharmacy may only provide remote pharmacy services using an automated pharmacy system to inpatients of the remote site.

(C) A provider pharmacy may provide remote pharmacy services at more than one remote site.

(D) Before providing remote pharmacy services, the automated pharmacy system at the remote site must be tested by the provider pharmacy and found to dispense accurately. The provider pharmacy shall make the results of such testing available to the board upon request.

(E) A provider pharmacy which is licensed as an institutional (Class C) pharmacy is required to comply with the provisions of §§291.31 - 291.34 of this title (relating to Definitions, Personnel, Operational Standards, and Records for Class A (Community) Pharmacies) and this section.

(F) The pharmacist-in-charge of the provider pharmacy is responsible for all pharmacy operations involving the automated pharmacy system located at the remote site including supervision of the automated pharmacy system and compliance with this section.

(G) A pharmacist from the provider pharmacy shall be accessible at all times to respond to patient's or other health professionals' questions and needs pertaining to drugs dispensed through the use of the automated pharmacy system. Such access may be through a 24 hour pager service or telephone which is answered 24 hours a day.

(4) Operational standards.

(A) Application for permission to provide pharmacy services using an automated pharmacy system.

(i) A Class A or Class C Pharmacy shall make application to the board to provide remote pharmacy services using an automated pharmacy system. The application shall contain an affidavit with the notarized signatures of the pharmacist-in-charge, and the medical director or the person responsible for the on-site operation of the facility (e.g., administrator, chief operating officer, owner, chief executive officer), and include the following:

(I) the name, address, and license number of the provider pharmacy;

(II) name and address of the facility where the remote pharmacy services will be provided;

(III) a statement indicating that the provider pharmacy and the facility have entered into a written contract or agreement which outlines the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract or agreement in compliance with federal and state laws and regulations; and
(IV) documentation that the automated pharmacy system is located where medications are administered by license healthcare professionals and is:

(-a-) a facility regulated under Chapter 142, 242, 247, or 252, Health and Safety Code; or

(-b-) a jail or prison, operated by the State of Texas or local government.

(ii) Such application shall be resubmitted every two years in conjunction with the application for renewal of the provider pharmacy's license. The renewal petition shall contain the documentation required in clause (i) of this subparagraph except the notarized signature of the medical director or the person responsible for the on-site operation of the facility (e.g., administrator, chief operating officer, owner, chief executive officer) is not required.

(iii) Upon approval of the application, the provider pharmacy will be sent a certificate which must be displayed at the remote site.

(B) Notification requirements.

(i) A provider pharmacy shall notify the board in writing within ten days of a change of location, discontinuance of service, or closure of:

(I) a remote site where an automated pharmacy system is operated by the pharmacy; or

(II) a remote pharmacy service at a remote site.

(ii) A provider pharmacy shall comply with appropriate federal and state controlled substance registrations for each remote site if controlled substances are maintained within an automated pharmacy system at the facility.

(C) Environment/Security.

(i) A provider pharmacy shall only store drugs at a remote site within an automated pharmacy system which is locked by key, combination or other mechanical or electronic means so as to prohibit access by unauthorized personnel.

(ii) An automated pharmacy system shall be under the continuous supervision of a provider pharmacy pharmacist. To qualify as continuous supervision, the pharmacist is not required to be physically present at the site of the automated pharmacy system if the system is supervised electronically by a pharmacist.

(iii) Automated pharmacy systems shall have adequate security and procedures to:

(I) comply with federal and state laws and regulations; and

(II) maintain patient confidentiality.

(iv) Access to the automated pharmacy system shall be limited to pharmacists or personnel who:
(I) are designated in writing by the pharmacist-in-charge; and

(II) have completed documented training concerning their duties associated with the automated pharmacy system.

(v) Drugs shall be stored in compliance with the provisions of §291.15 of this title (relating to Storage of Drugs) and §291.33(f)(2) of this title including the requirements for temperature and handling of outdated drugs.

(D) Prescription dispensing and delivery.

(i) Drugs shall only be dispensed at a remote site through an automated pharmacy system after receipt of an original prescription drug order by a pharmacist at the provider pharmacy in a manner authorized by §291.34(b) of this title.

(ii) A pharmacist at the provider pharmacy shall control all operations of the automated pharmacy system and approve the release of the initial dose of a prescription drug order. Subsequent doses from an approved prescription drug order may be removed from the automated medication system after this initial approval. Any change made in the prescription drug order shall require a new approval by a pharmacist to release the drug.

(iii) A pharmacist at the provider pharmacy shall conduct a drug regimen review as specified in §291.33(c) of this title prior to releasing a prescription drug order to the automated pharmacy system.

(iv) Drugs dispensed by the provider pharmacy through an automated pharmacy system shall comply with the labeling or labeling alternatives specified in §291.33(c) of this title.

(v) An automated pharmacy system used to meet the emergency medication needs for residents of a remote site must comply with the requirements for emergency medication kits in subsection (b) of this section.

(E) Drugs.

(i) Drugs for use in an automated pharmacy system shall be packaged in the original manufacturer's container or be prepackaged in the provider pharmacy and labeled in compliance with the board's prepackaging requirements for the class of pharmacy.

(ii) Drugs dispensed from the automated pharmacy system may be returned to the pharmacy for reuse provided the drugs are in sealed, tamper evident packaging which has not been opened.

(F) Stocking an automated pharmacy system.

(i) Stocking of drugs in an automated pharmacy system shall be completed by a pharmacist, pharmacy technician, or pharmacy technician trainee under the direct supervision of a pharmacist, except as provided in clause (ii) of this subparagraph.

(ii) If the automated pharmacy system uses removable cartridges or containers to hold drugs, the prepackaging of the cartridges or containers shall occur at the provider pharmacy
unless provided by an FDA approved repacker. The prepackaged cartridges or containers may be sent to the remote site to be loaded into the machine by personnel designated by the pharmacist-in-charge provided:

(I) a pharmacist verifies the cartridge or container has been properly filled and labeled;

(II) the individual cartridges or containers are transported to the remote site in a secure, tamper-evident container; and

(III) the automated pharmacy system uses bar-coding, microchip, or other technologies to ensure that the containers are accurately loaded in the automated pharmacy system.

(iii) All drugs to be stocked in the automated pharmacy system shall be delivered to the remote site by the provider pharmacy.

(G) Quality assurance program. A pharmacy that provides pharmacy services through an automated pharmacy system at a remote site shall operate according to a written program for quality assurance of the automated pharmacy system which:

(i) requires continuous supervision of the automated pharmacy system; and

(ii) establishes mechanisms and procedures to routinely test the accuracy of the automated pharmacy system at a minimum of every six months and whenever any upgrade or change is made to the system and documents each such activity.

(H) Policies and procedures of operation.

(i) A pharmacy that provides pharmacy services through an automated pharmacy system at a remote site shall operate according to written policies and procedures. The policy and procedure manual shall include, but not be limited to, the following:

(I) a current list of the name and address of the pharmacist-in-charge and personnel designated by the pharmacist-in-charge to have access to the drugs stored in the automated pharmacy system;

(II) duties which may only be performed by a pharmacist;

(III) a copy of the portion of the written contract or agreement between the pharmacy and the facility which outlines the services to be provided and the responsibilities and accountabilities of each party relating to the operation of the automated pharmacy system in fulfilling the terms of the contract in compliance with federal and state laws and regulations;

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

(V) policies and procedures for:

(-a-) security;

(-b-) operation of the automated pharmacy system;
(-c-) preventative maintenance of the automated pharmacy system;

(-d-) sanitation;

(-e-) storage of drugs;

(-f-) dispensing;

(-g-) supervision;

(-h-) drug procurement;

(-i-) receiving of drugs;

(-j-) delivery of drugs; and

(-k-) recordkeeping.

(ii) A pharmacy that provides pharmacy services through an automated pharmacy system at a remote site shall, at least annually, review its written policies and procedures, revise them if necessary, and document the review.

(iii) A pharmacy providing remote pharmacy services using an automated pharmacy system shall maintain a written plan for recovery from an event which interrupts the ability of the automated pharmacy system to dispense prescription drugs. The written plan for recovery shall include:

(I) planning and preparation for maintaining pharmacy services when an automated pharmacy system is experiencing downtime;

(II) procedures for response when an automated pharmacy system is experiencing downtime; and

(III) procedures for the maintenance and testing of the written plan for recovery.

(5) Records.

(A) Maintenance of records.

(i) Every record required under this section must be:

(I) kept by the provider pharmacy and be available, for at least two years for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies; and

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

(ii) The provider pharmacy shall maintain original prescription drug orders for drugs dispensed from an automated pharmacy system in compliance with §291.34(b) of this title.

(iii) if prescription drug records are maintained in a data processing system, the system shall have a workable (electronic) data retention system which can produce a separate audit trail of drug usage by the provider pharmacy and each remote site for the preceding two years as specified in §291.34(e) of this title.

(B) Prescriptions. Prescription drug orders shall meet the requirements of §291.34(b) of this title.

(C) Records of dispensing. Dispensing records for a prescription drug order shall be maintained by the provider pharmacy in the manner required by §291.34(d) or (e) of this title.

(D) Transaction information.

(i) The automated pharmacy system shall electronically record all transactions involving drugs stored in, removed, or dispensed from the system.

(ii) Records of dispensing from an automated pharmacy system for a patient shall be maintained by the providing pharmacy and include the:

(I) identity of the system accessed;

(II) identification of the individual accessing the system;

(III) date of transaction;

(IV) name, strength, dosage form, and quantity of drug accessed; and

(V) name of the patient for whom the drug was accessed.

(iii) Records of stocking or removal from an automated pharmacy system shall be maintained by the pharmacy and include the:

(I) date;

(II) name, strength, dosage form, and quantity of drug stocked or removed;

(III) name, initials, or identification code of the person stocking or removing drugs from the system;

(IV) name, initials, or identification code of the pharmacist who checks and verifies that the system has been accurately filled;

(E) Patient medication records. Patient medication records shall be created and maintained by the provider pharmacy in the manner required by §291.34(c) of this title.
(F) Inventory.

(i) A provider pharmacy shall:

(I) keep a record of all drugs sent to and returned from a remote site separate from the records of the provider pharmacy and from any other remote site's records; and

(II) keep a perpetual inventory of controlled substances and other drugs required to be inventoried under §291.17 of this title (relating to Inventory Requirements for All Classes of Pharmacies) that are received and dispensed or distributed from each remote site.

(ii) As specified in §291.17 of this title, a provider pharmacy shall conduct an inventory at each remote site. The following is applicable to this inventory.

(I) The inventory of each remote site and the provider pharmacy shall be taken on the same day.

(II) The inventory of each remote site shall be included with, but listed separately from, the drugs of other remote sites and separately from the drugs of the provider pharmacy.

(b) Remote pharmacy services using emergency medication kits.

(1) Purpose. The purpose of this section is to provide standards for the provision of pharmacy services by a Class A or Class C pharmacy in a facility that is not at the same location as the Class A or Class C pharmacy through an emergency medication kit as outlined in §562.108 of the Texas Pharmacy Act.

(2) Definitions. The following words and terms, when used in this subsection, shall have the following meanings, unless the context clearly indicates otherwise. All other words and terms shall have the meanings defined in the Act or §291.31 of this title.

(A) Automated pharmacy system--A mechanical system that dispenses prescription drugs and maintains related transaction information.

(B) Emergency medication kits--Controlled substances and dangerous drugs maintained by a provider pharmacy to meet the emergency medication needs of a resident:

(i) at an institution licensed under Chapter 242 or 252, Health and Safety Code; or

(ii) at an institution licensed under Chapter 242, Health and Safety Code and that is a veterans home as defined by the §164.002, Natural Resources Code, if the provider pharmacy is a United States Department of Veterans Affairs pharmacy or another federally operated pharmacy.

(C) Remote site--A facility not located at the same location as a Class A, Class C, Class E pharmacy or a United States Department of Affairs pharmacy or another federally operated pharmacy, at which remote pharmacy services are provided using an emergency medication kit.
(D) Prepackaging--The act of repackaging and relabeling quantities of drug products from a manufacturer's original commercial container, or quantities of unit dosed drugs, into another cartridge or container for dispensing by a pharmacist using an emergency medication kit.

(E) Provider pharmacy--The community pharmacy (Class A), the institutional pharmacy (Class C), the non-resident (Class E) pharmacy located not more than 20 miles from an institution licensed under Chapter 242 or 252, Health and Safety Code, or the United States Department of Veterans Affairs pharmacy or another federally operated pharmacy providing remote pharmacy services.

(F) Remote pharmacy service--The provision of pharmacy services, including the storage and dispensing of prescription drugs, in remote sites.

(3) General requirements.

(A) A provider pharmacy may provide remote pharmacy services using an emergency medication kit to an institution regulated under Chapter 242, or 252, Health and Safety Code.

(B) A provider pharmacy may provide remote pharmacy services at more than one remote site.

(C) A provider pharmacy shall not place an emergency medication kit in a remote site which already has a kit from another provider pharmacy except as provided by paragraph (4)(B)(iii) of this subsection.

(D) A provider pharmacy which is licensed as an institutional (Class C) or a non-resident (Class E) pharmacy is required to comply with the provisions of §§291.31 - 291.34 of this title and this section.

(E) The pharmacist-in-charge of the provider pharmacy is responsible for all pharmacy operations involving the emergency medication kit located at the remote site including supervision of the emergency medication kit and compliance with this section.

(4) Operational standards.

(A) Application for permission to provide pharmacy services using an emergency medication kit.

(i) A Class A, Class C, or Class E Pharmacy shall make application to the board to provide remote pharmacy services using an emergency medication kit. The application shall contain an affidavit with the notarized signatures of the pharmacist-in-charge, and the medical director or the person responsible for the on-site operation of the facility (e.g., administrator, owner, chief executive officer, chief operating officer), and include the following:

(I) the name, address, and license number of the provider pharmacy;

(II) name and address of the healthcare facility where the remote pharmacy services will be provided;
(III) a statement indicating that the provider pharmacy and the healthcare facility have entered into a written contract or agreement which outlines the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract or agreement in compliance with federal and state laws and regulations;

(IV) documentation that the emergency medication kit is located in a facility regulated under Chapter 242, or 252, Health and Safety Code; and

(V) if applicable, documentation that the emergency kit is located in a facility that is not more than 20 miles from the Class E pharmacy providing the emergency kit.

(ii) Such application shall be resubmitted every two years in conjunction with the application for renewal of the provider pharmacy’s license. The renewal petition shall contain the documentation required in clause (i) of this subparagraph except the notarized signature of the medical director or the person responsible for the on-site operation of the facility (e.g., administrator, owner, chief executive officer, chief operating officer) is not required.

(iii) Upon approval of the application, the provider pharmacy will be sent a certificate which must be displayed at the remote site.

(B) Notification requirements.

(i) A provider pharmacy shall notify the board in writing within ten days of a change of location, discontinuance of service, or closure of:

(I) a remote site where an emergency medication kit is operated by the pharmacy; or

(II) a remote pharmacy service at a remote site.

(ii) A provider pharmacy shall comply with appropriate federal and state controlled substance registrations for each remote site if controlled substances are maintained within an emergency medication kit at the facility.

(iii) If more than one provider pharmacy provides an emergency kit to a remote site, the provider pharmacies must enter into a written agreement as to the emergency medications supplied by each pharmacy. The provider pharmacies shall not duplicate drugs stored in the emergency medication kits. The written agreement shall include reasons why an additional pharmacy is required to meet the emergency medication needs of the residents of the institution.

(C) Environment/Security.

(i) Emergency medication kits shall have adequate security and procedures to:

(I) prohibit unauthorized access;

(II) comply with federal and state laws and regulations; and

(III) maintain patient confidentiality.
(ii) Access to the emergency medication kit shall be limited to pharmacists and licensed healthcare personnel employed by the facility.

(iii) Drugs shall be stored in compliance with the provisions of §291.15 and §291.33(f)(2) of this title including the requirements for temperature and handling outdated drugs.

(D) Prescription dispensing and delivery.

(i) Drugs in the emergency medication kit shall be accessed for administration to meet the emergency medication needs of a resident of the remote site pursuant to an order from a practitioner. The prescription drug order for the drugs used from the emergency medication kit shall be forwarded to the provider pharmacy in a manner authorized by §291.34(b) of this title.

(ii) The remote site shall notify the provider pharmacy of each entry into an emergency medication kit. Such notification shall meet the requirements of paragraph (5)(D)(ii) of this subsection.

(E) Drugs.

(i) The contents of an emergency medication kit:

(I) may consist of dangerous drugs and controlled substances; and

(II) shall be determined by the consultant pharmacist, pharmacist-in-charge of the provider pharmacy, medical director, and the director of nurses and limited to those drugs necessary to meet the resident's emergency medication needs. For the purpose of this subsection, this shall mean a situation in which a drug cannot be supplied by a pharmacy within a reasonable time period.

(ii) When deciding on the drugs to be placed in the emergency medication kit, the consultant pharmacist, pharmacist-in-charge of the provider pharmacy, medical director, and the director of nurses must determine, select, and record a prudent number of drugs for potential emergency incidents based on:

(I) clinical criteria applicable to each facility's demographics;

(II) the facility's census; and

(III) the facility's healthcare environment.

(iii) A current list of the drugs stored in each remote site's emergency medication kit shall be maintained by the provider pharmacy and a copy kept with the emergency medication kit.

(iv) An automated pharmacy system may be used as an emergency medication kit provided the system limits emergency access to only those drugs approved for the emergency medication kit.

(v) Drugs for use in an emergency medication kit shall be packaged in the original manufacturer's container or prepackaged in the provider pharmacy and labeled in compliance with the board's prepackaging requirements for the class of pharmacy.
(F) Stocking emergency medication kits.

(i) Stocking of drugs in an emergency medication kit shall be completed at the provider pharmacy or remote site by a pharmacist, pharmacy technician, or pharmacy technician trainee under the direct supervision of a pharmacist, except as provided in clause (ii) of this subparagraph.

(ii) If the emergency medication kit is an automated pharmacy system which uses bar-coding, microchip, or other technologies to ensure that the containers or unit dose drugs are accurately loaded, the prepackaging of the containers or unit dose drugs shall occur at the provider pharmacy unless provided by a FDA approved repacker. The prepackaged containers or unit dose drugs may be sent to the remote site to be loaded into the machine by personnel designated by the pharmacist-in-charge provided:

(I) a pharmacist verifies the container or unit dose drug has been properly filled and labeled;

(II) the individual containers or unit dose drugs are transported to the remote site in a secure, tamper-evident container; and

(III) the automated pharmacy system uses bar-coding, microchip, or other technologies to ensure that the containers or unit dose drugs are accurately loaded in the automated pharmacy system.

(iii) All drugs to be stocked in the emergency medication kit shall be delivered to the remote site by the provider pharmacy.

(G) Policies and procedures of operation.

(i) A provider pharmacy that provides pharmacy services through an emergency medication kit at a remote site shall operate according to written policies and procedures. The policy and procedure manual shall include, but not be limited to, the following:

(I) duties which may only be performed by a pharmacist;

(II) a copy of the written contract or agreement between the pharmacy and the facility which outlines the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract in compliance with federal and state laws and regulations;

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

(IV) policies and procedures for:

(-a-) security;

(-b-) operation of the emergency medication kit;
(-c-) preventative maintenance of the automated pharmacy system if the emergency medication kit is an automated pharmacy system;

(-d-) sanitation;

(-e-) storage of drugs;

(-f-) dispensing;

(-g-) supervision;

(-h-) drug procurement;

(-i-) receiving of drugs;

(-j-) delivery of drugs; and

(-k-) recordkeeping.

(ii) A pharmacy that provides pharmacy services through an emergency medication kit at a remote site shall, at least annually, review its written policies and procedures, revise them if necessary, and document the review.

(iii) A pharmacy providing remote pharmacy services using an emergency medication kit which is an automated pharmacy system shall maintain a written plan for recovery from an event which interrupts the ability of the automated pharmacy system to provide emergency medications. The written plan for recovery shall include:

(I) planning and preparation for maintaining pharmacy services when an automated pharmacy system is experiencing downtime;

(II) procedures for response when an automated pharmacy system is experiencing downtime; and

(III) procedures for the maintenance and testing of the written plan for recovery.

(5) Records.

(A) Maintenance of records.

(i) Every record required under this section must be:

(I) kept by the provider pharmacy and be available, for at least two years for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies; and

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

(ii) The provider pharmacy shall maintain original prescription drug orders for drugs dispensed from an emergency medication kit in compliance with §291.34(b) of this title.

(B) Prescriptions. Prescription drug orders shall meet the requirements of §291.34(b) of this title.

(C) Records of dispensing. Dispensing records for a prescription drug order shall be maintained by the provider pharmacy in the manner required by §291.34(d) or (e) of this title.

(D) Transaction information.

(i) A prescription drug order shall be maintained by the provider pharmacy as the record of removal of a drug from an emergency medication kit for administration to a patient.

(ii) The remote site shall notify the provider pharmacy electronically or in writing of each entry into an emergency medication kit. Such notification may be included on the prescription drug order or a separate document and shall include the name, strength, and quantity of the drug removed, the time of removal, and the name of the person removing the drug.

(iii) A separate record of stocking, removal, or dispensing for administration from an emergency medication kit shall be maintained by the pharmacy and include the:

(I) date;

(II) name, strength, dosage form, and quantity of drug stocked, removed, or dispensed for administration;

(III) name, initials, or identification code of the person stocking, removing, or dispensing for administration, drugs from the system;

(IV) name, initials, or identification code of the pharmacist who checks and verifies that the system has been accurately filled; and

(V) unique prescription number assigned to the prescription drug order when the drug is administered to the patient.

(E) Inventory.

(i) A provider pharmacy shall:

(I) keep a record of all drugs sent to and returned from a remote site separate from the records of the provider pharmacy and from any other remote site's records; and

(II) keep a perpetual inventory of controlled substances and other drugs required to be inventoried under §291.17 of this title, that are received and dispensed or distributed from each remote site.
(ii) As specified in §291.17 of this title, a provider pharmacy shall conduct an inventory at each remote site. The following is applicable to this inventory.

(I) The inventory of each remote site and the provider pharmacy shall be taken on the same day.

(II) The inventory of each remote site shall be included with, but listed separately from, the drugs of other remote sites and separately from the drugs of the provider pharmacy.

(c) Remote pharmacy services using telepharmacy systems.

(1) Purpose. The purpose of this section is to provide standards for the provision of pharmacy services by a Class A or Class C pharmacy in a healthcare facility that is not at the same location as a Class A or Class C pharmacy through a telepharmacy system as outlined in §562.110 of the Texas Pharmacy Act.

(2) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise. All other words and terms shall have the meanings defined in the Act or §291.31 of this title.

(A) 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.

(B) Provider pharmacy--The community pharmacy (Class A) or the institutional pharmacy (Class C) providing remote pharmacy services.

(C) Remote site--a facility not located at the same location as a Class A or Class C pharmacy, at which remote pharmacy services are provided using a telepharmacy dispensing system.

(D) Remote pharmacy service--The provision of pharmacy services, including the storage and dispensing of prescription drugs, drug regimen review, and patient counseling, at a remote site.

(E) Still image capture--A specific image captured electronically from a video or other image capture device.

(F) Store and forward--A video or still image record which is saved electronically for future review.

(G) Telepharmacy system--A system that monitors the dispensing of prescription drugs and provides for related drug use review and patient counseling services by an electronic method which shall include the use of the following types of technology:

(i) audio and video;

(ii) still image capture; and

(iii) store and forward.
(H) Unit-of-use--A sufficient quantity of a drug for one normal course of therapy as determined by the pharmacist-in-charge and the prescribing practitioner(s) at the healthcare facility.

(3) General requirements.

(A) A provider pharmacy may provide remote pharmacy services using a telepharmacy system to:

(i) a rural health clinic regulated under 42 U.S.C. Section 1395x(aa), as amended;

(ii) a health center as defined by 42 U.S.C. Section 254b, as amended; or

(iii) healthcare facility located in a medically underserved area as defined by state or federal law.

(B) A provider pharmacy may not provide remote pharmacy services if a Class A (Community) or Class C (Institutional) pharmacy that dispenses prescription drug orders to outpatients is located in the same community. For the purposes of this subsection a community is defined as:

(i) the census tract in which the remote site is located, if the remote site is located in a Metropolitan Statistical Area (MSA) as defined by the United States Census Bureau in the most recent U.S. Census; or

(ii) within 10 miles of the remote site, if the remote site is not located in a MSA.

(C) The provider pharmacy shall have sufficient pharmacists on duty such that each pharmacist may supervise no more than three remote sites that are simultaneously open to provide services. An exception to the supervision limit may be granted by the board in situations where the provider has documented a need for a pharmacist to supervise additional remote sites and has demonstrated that appropriate safeguards are in place to assure proper supervision of each remote site.

(D) Before providing remote pharmacy service, the telepharmacy system at the off-site facility must be tested by the provider pharmacy and found to operate properly. The provider pharmacy shall make the results of such testing available to the board upon request.

(E) A provider pharmacy which is licensed as an institutional (Class C) pharmacy is required to comply with the provisions of §§291.31 - 291.34 of this title and this section.

(F) The pharmacist-in-charge of the provider pharmacy is responsible for all operations at the remote site including supervision of the telepharmacy system and compliance with this section.

(4) Operational standards.

(A) Application to provide pharmacy services using a telepharmacy system.

(i) A Class A or class C Pharmacy shall make application to the board to provide remote pharmacy services using a telepharmacy system. The application shall contain an affidavit with
the notarized signatures of pharmacist-in-charge, and the medical director or the person responsible for the on-site operation of the facility (e.g., administrator, owner, chief executive officer, chief operating officer), and include the following:

(I) the name, address, and license number of the provider pharmacy;

(II) name and address of the healthcare facility where the remote pharmacy services will be provided;

(III) a statement indicating that the provider pharmacy and the healthcare facility have entered into a written contract or agreement which outlines the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract or agreement in compliance with federal and state laws and regulations;

(IV) documentation that the healthcare facility is:

(-a-) a rural health clinic regulated under 42 U.S.C. Section 1395x(aa), as amended;

(-b-) a health center as defined by 42 U.S.C. Section 254b, as amended; or

(-c-) located in a medically underserved area as defined by state or federal law; and

(V) documentation that a Class A (Community) or Class C (Institutional) Pharmacy that dispenses prescriptions drug orders to out-patients is not located within the community, as defined in paragraph (3)(B) of this subsection, where the remote site is located.

(ii) Such application shall be resubmitted every two years in conjunction with the renewal of the provider pharmacy's license. The renewal application shall contain the documentation required in clause (i) of this subparagraph except the notarized signature of the medical director or the person responsible for the on-site operation of the facility (e.g., administrator, owner, chief executive officer, chief operating officer) is not required.

(iii) On approval of the application, the provider pharmacy will be sent a registration certificate, which must be displayed at the remote site.

(B) Notification requirements.

(i) A provider pharmacy shall notify the board in writing within ten days of a change of location, discontinuance of service, or closure of:

(I) a remote site where a telepharmacy system is operated by the pharmacy; or

(II) a remote pharmacy service at a remote site.

(ii) A provider pharmacy shall comply with appropriate federal and state controlled substance registrations for each remote site, if controlled substances are maintained.

(C) Environment/Security.
(i) A remote site shall be under the continuous supervision of a provider pharmacy pharmacist at all times the site is open to provide pharmacy services. To qualify as continuous supervision, the pharmacist is not required to be physically present at the remote site and shall supervise electronically through the use of the following types of technology:

(I) audio and video;

(II) still image capture; and

(III) store and forward.

(ii) Drugs shall be stored in compliance with the provisions of §291.15 and §291.33(f)(2) of this title including the requirements for temperature and handling of outdated drugs.

(iii) Drugs for use in the telepharmacy system shall be stored in an area that is:

(I) separate from any other drugs used by the healthcare facility; and

(II) locked by key, combination or other mechanical or electronic means, so as to prohibit access by unauthorized personnel.

(iv) Access to the area where drugs are stored at the remote site and operation of the telepharmacy system shall be limited to pharmacists employed by the provider pharmacy or personnel who:

(I) are licensed healthcare providers pharmacy technicians or pharmacy technician trainees;

(II) are designated in writing by the pharmacist-in-charge; and

(III) have completed documented training concerning their duties associated with the telepharmacy pharmacy system.

(v) Remote sites shall have adequate security and procedures to:

(I) comply with federal and state laws and regulations; and

(II) maintain patient confidentiality.

(vi) The provider pharmacy shall have procedures that specify that drugs may only be delivered to the remote site by the provider pharmacy and shall:

(I) be shipped in a sealed container with a list of drugs delivered;

(II) signed for on receipt by an employee of the healthcare facility;

(III) be quarantined in a locked area, if personnel designated to receive the drugs by the pharmacist-in-charge is not available; and
(IV) be checked by personnel designated by the pharmacist-in-charge to verify that drugs sent by the provider pharmacy were actually received. The designated person who checks the order shall document the verification by signing and dating the list of drugs delivered.

(D) Prescription dispensing and delivery.

(i) Drugs shall only be dispensed at the remote site through a telepharmacy system after receipt of an original prescription drug order by a pharmacist at the provider pharmacy in the manner authorized by §291.34(b) of this title.

(ii) Drugs may be dispensed by the provider pharmacy through a telepharmacy system at a remote site only in unit-of-use containers that are:

(I) prepackaged in suitable containers at the provider pharmacy and appropriately labeled as specified in §291.33(c)(6) of this title; or

(II) in original manufacturer's containers.

(iii) The following duties shall be performed only by a pharmacist at the provider pharmacy:

(I) receiving an oral prescription drug order;

(II) interpret the prescription drug order;

(III) verify the accuracy of prescription data entry;

(IV) select the drug product;

(V) interpret the patient's medication record and conduct a drug regimen review as specified in clause (iv) of this subparagraph;

(VI) authorize the telepharmacy system to print a prescription label at the remote site as specified in clause (v) of this subparagraph;

(VII) perform the final check of the dispensed prescription as specified in clause (vi) of this subparagraph to ensure that the prescription drug order has been dispensed accurately as prescribed;

(VIII) counsel the patient as specified clause (vii) of this subparagraph.

(iv) A pharmacist at the provider pharmacy shall conduct a drug regimen review as specified in §291.33(c) of this title prior to delivery of the dispensed prescription to the patient or patient's agent.

(v) The dispensed prescription shall be labeled at the remote site with the information specified in §291.33(c) of this title except that:

(I) the label shall contain both the name, address, and phone number of the provider pharmacy and the name and address of the remote site; and
(II) the unique identification number of the prescription on the label shall in some manner identify the remote site which dispensed the prescription using a telepharmacy system.

(vi) A pharmacist at the provider pharmacy shall perform the final check of the dispensed prescription before delivery to the patient to ensure that the prescription has been dispensed accurately as prescribed. This final check shall be accomplished through a visual check using electronic methods.

(vii) A pharmacist at the provider pharmacy shall counsel the patient or patient's agent as specified in §291.33(c) of this title. This counseling may be performed using electronic methods. Non-pharmacist personnel may not ask questions of a patient or patient's agent which are intended to screen and/or limit interaction with the pharmacist.

(viii) If the remote site has direct access to the provider pharmacy's data processing system, only a pharmacist, pharmacy technician, or pharmacy technician trainee may enter prescription information into the data processing system. The original prescription shall be sent to the provider pharmacy and a pharmacist shall verify the accuracy of the data entry.

(ix) Drugs which require reconstitution through the addition of a specified amount of water may be dispensed by the remote site only if a pharmacy technician, pharmacy technician trainee, or licensed healthcare provider reconstitutes the product.

(E) Quality assurance program. A pharmacy that provides pharmacy services through a telepharmacy system at a remote site shall operate according to a written program for quality assurance of the telepharmacy system which:

(i) requires continuous supervision of the telepharmacy system at all times the site is open to provide pharmacy services; and

(ii) establishes mechanisms and procedures to routinely test the operation of the telepharmacy system at a minimum of every six months and whenever any upgrade or change is made to the system and documents each such activity.

(F) Policies and procedures.

(i) A pharmacy that provides pharmacy services through a telepharmacy system at a remote site shall operate according to written policies and procedures. The policy and procedure manual shall include, but not be limited to, the following:

(I) a current list of the name and address of the pharmacist-in-charge and personnel designated by the pharmacist-in-charge to have:

(-a-) have access to the area where drugs are stored at the remote site; and

(-b-) operate the telepharmacy system;

(II) duties which may only be performed by a pharmacist;

(III) a copy of the written contact or agreement between the provider pharmacy and the healthcare facility which outlines the services to be provided and the responsibilities and
accountabilities of each party in fulfilling the terms of the contract or agreement in compliance with federal and state laws and regulations;

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

(V) policies and procedures for:

(-a-) security;
(-b-) operation of the telepharmacy system;
(-c-) sanitation;
(-d-) storage of drugs;
(-e-) dispensing;
(-f-) supervision;
(-g-) drug and/or device procurement;
(-h-) receiving of drugs and/or devices;
(-i-) delivery of drugs and/or devices; and
(-j-) recordkeeping

(ii) A pharmacy that provides pharmacy services through a telepharmacy system at a remote site shall, at least annually, review its written policies and procedures, revise them if necessary, and document the review.

(iii) A pharmacy providing remote pharmacy services through a telepharmacy system shall maintain a written plan for recovery from an event which interrupts the ability of a pharmacist to electronically supervise the telepharmacy system and the dispensing of prescription drugs at the remote site. The written plan for recovery shall include:

(I) a statement that prescription drugs shall not be dispensed at the remote site, if a pharmacist is not able to electronically supervise the telepharmacy system and the dispensing of prescription drugs;

(II) procedures for response when a telepharmacy system is experiencing downtime; and

(III) procedures for the maintenance and testing of the written plan for recovery.

(5) Records.

(A) Maintenance of records.

(i) Every record required under this section must be:
(I) kept by the provider pharmacy and be available, for at least two years for inspecting and
copying by the board or its representative and to other authorized local, state, or federal law
enforcement agencies; and

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

(ii) The provider pharmacy shall maintain original prescription drug orders for medications
dispensed from a remote site using a telepharmacy system in the manner required by
§291.34(b) of this title.

(iii) If prescription drug records are maintained in a data processing system, the system shall
have a workable (electronic) data retention system which can produce a separate audit trail of
drug usage by the provider pharmacy and by each remote site for the preceding two years as
specified in §291.34(e) of this title.

(B) Prescriptions. Prescription drug orders shall meet the requirements of §291.34(b) of this
title.

(C) Patient medication records. Patient medication records shall be created and maintained
at the provider pharmacy in the manner required by §291.34(c) of this title.

(D) Inventory.

(i) A provider pharmacy shall:

(I) keep a record of all drugs sent to and returned from a remote site separate from the
records of the provider pharmacy and from any other remote site's records;

(II) keep a perpetual inventory of controlled substances and other drugs required to be
inventoried under §291.17 of this title, that are received and dispensed or distributed from each
remote site.

(ii) As specified in §291.17 of this title. A provider pharmacy shall conduct an inventory at
each remote site. The following is applicable to this inventory.

(I) The inventory of each remote site and the provider pharmacy shall be taken on the
same day.

(II) The inventory of each remote site shall be included with, but listed separately from, the
drugs of other remote sites and separately from the drugs at the provider pharmacy.

§291.123 Central Prescription Drug or Medication Order Processing

(a) Purpose.
(1) The purpose of this section is to provide standards for centralized prescription drug or medication order processing by a Class A (Community), Class C (Institutional), or Class E (Non-Resident) pharmacy.

(2) Any facility established for the purpose of processing prescription drug or medication drug orders shall be licensed as a Class A, Class C, or Class E pharmacy under the Act. However, nothing in this subsection shall prohibit an individual pharmacist employee who is licensed in Texas from remotely accessing the pharmacy’s electronic data base from outside the pharmacy in order to process prescription or medication drug orders, provided the pharmacy establishes controls to protect the privacy and security of confidential records.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section shall have the definition set out in the Act. Centralized prescription drug or medication order processing—the processing of a prescription drug or medication orders by a Class A, Class C, or Class E pharmacy on behalf of another pharmacy, a health care provider, or a payor. Centralized prescription drug or medication order processing does not include the dispensing of a prescription drug order but includes any of the following:

(1) receiving, interpreting, or clarifying prescription drug or medication drug orders;
(2) data entering and transferring of prescription drug or medication order information;
(3) performing drug regimen review;
(4) obtaining refill and substitution authorizations;
(5) interpreting clinical data for prior authorization for dispensing;
(6) performing therapeutic interventions; and
(7) providing drug information concerning a patient's prescription.

(c) Operational Standards.

(1) General requirements.

(A) A Class A, Class C, or Class E Pharmacy may outsource prescription drug or medication order processing to another Class A, Class C, or Class E pharmacy provided the pharmacies:

(i) have:

(I) the same owner; or

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

(ii) share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to process a non-dispensing function.
(B) A pharmacy that performs centralized prescription drug or medication order processing shall comply with the provisions applicable to the class of pharmacy contained in either §§291.31 - 291.35 of this title (relating to Definitions, Personnel, Operational Standards, Records, and Official Prescription Requirements in Class A (Community) Pharmacies), or §§291.72 - 291.75 of this title (relating to Definitions, Personnel, Operational Standards, and Records in a Class C (Institutional) Pharmacy), or §§291.102 - 291.105 of this title (relating to Definitions, Personnel, Operational Standards, and Records in a Class E (Non-Resident Pharmacy) to the extent applicable for the specific processing activity and this section including:

(i) duties which must be performed by a pharmacist; and

(ii) supervision requirements for pharmacy technicians and pharmacy technician trainees.

(2) Notifications to patients.

(A) A pharmacy that outsources prescription drug or medication order processing to another pharmacy shall prior to outsourcing their prescription:

(i) notify patients that prescription processing may be outsourced to another pharmacy; and

(ii) give the name of that pharmacy; or if the pharmacy is part of a network of pharmacies under common ownership and any of the network pharmacies may process the prescription, the patient shall be notified of this fact. Such notification may be provided through a one-time written notice to the patient or through use of a sign in the pharmacy.

(B) The provisions of this paragraph do not apply to patients in facilities where drugs are administered to patients by a person required to do so by the laws of the state (i.e., hospitals or nursing homes).

(3) Policy and Procedures. A policy and procedure manual as it relates to central processing shall be maintained at all pharmacies involved in central processing and be available for inspection. Each pharmacy is required to maintain only those portions of the policy and procedure manual that relate to that pharmacy’s operations. The manual shall:

(A) outline the responsibilities of each of the pharmacies;

(B) include a list of the name, address, telephone numbers, and all license/registration numbers of the pharmacies involved in centralized prescription drug or medication order processing; and

(C) include policies and procedures for:

(i) protecting the confidentiality and integrity of patient information;

(ii) maintenance of appropriate records to identify the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist or pharmacy technician who performed any processing;

(iii) complying with federal and state laws and regulations;
(iv) operating a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems; and

(v) annually reviewing the written policies and procedures and documenting such review.

(d) Records. All pharmacies shall maintain appropriate records which identify, by prescription drug or medication order, the name(s), initials, or identification code(s) of each pharmacist, pharmacy technician, or pharmacy technician trainee who performs a processing function for a prescription drug or medication order. Such records may be maintained:

1. separately by each pharmacy and pharmacist; or

2. in a common electronic file as long as the records are maintained in such a manner that the data processing system can produce a printout which lists the functions performed by each pharmacy and pharmacist.

§291.125 Centralized Prescription Dispensing

(a) Purpose. The purpose of this section is to provide standards for centralized prescription dispensing by a Class A (Community), Class C (Institutional) pharmacy, or Class E (Non-Resident) Pharmacy.

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

1. Central fill pharmacy—a Class A, Class A-S, Class C, Class C-S, Class E, or Class E-S pharmacy that prepares prescription drug orders for dispensing pursuant to a valid prescription transmitted to the central fill pharmacy by an outsourcing pharmacy.

2. Centralized prescription dispensing—the dispensing or refilling of a prescription drug order by a Class A, Class C, or Class E pharmacy at the request of another Class A or Class C pharmacy and the return of the dispensed prescriptions to the outsourcing pharmacy for delivery to the patient or patient’s agent, or at the request of the outsourcing pharmacy for direct delivery to the patient.

3. Outsourcing pharmacy—a Class A or Class C pharmacy that transmits a prescription drug order to a central fill pharmacy to be dispensed by the central fill pharmacy.

(c) Operational standards.

1. General requirements.

(A) A Class A or Class C pharmacy may outsource prescription drug order dispensing to a central fill pharmacy provided the pharmacies:

(i) have:
(I) the same owner; or

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

(ii) share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to dispense or process a prescription drug order.

(B) The pharmacist-in-charge of the central fill pharmacy shall ensure that:

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

(ii) the dispensed prescriptions are shipped in containers which are sealed in a manner as to show evidence of opening or tampering.

(C) A Class A or Class C central fill pharmacy shall comply with the provisions of §§291.31 - 291.35 of this title (relating to Definitions, Personnel, Operational Standards, Records, and Official Prescription Requirements in Community Pharmacy (Class A) and this section.

(D) A Class E central fill pharmacy shall comply with §§291.101 - 291.105 of this title (relating to Purpose, Definitions, Personnel, Operational Standards, and Records in Non-resident Pharmacy (Class E) and this section.

(2) Notifications to patients.

(A) A pharmacy that outsources prescription dispensing to a central fill pharmacy shall:

(i) prior to outsourcing the prescription:

(I) notify patients that their prescription may be outsourced to a central fill pharmacy; and

(ii) if the prescription is delivered directly to the patient by the central fill pharmacy and not returned to the outsourcing pharmacy, place on the prescription container or on a separate sheet delivered with the prescription container, in both English and Spanish, the local, and if applicable, the toll-free telephone number of the pharmacy and the statement: "Written information about this prescription has been provided for you. Please read this information before you take the medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions at (insert the pharmacy's local and toll-free telephone numbers)."
(B) The provisions of this paragraph do not apply to patients in facilities where drugs are administered to patients by a person required to do so by the laws of the state (e.g., hospitals or nursing homes).

(3) Prescription Labeling. The central fill pharmacy shall place on the prescription label, the name and address of the outsourcing pharmacy and a unique identifier (i.e., the central fill pharmacy's DEA registration number or, if the pharmacy does not have a DEA registration number, the central fill pharmacy's Texas license number) indicating that the prescription was dispensed by the central fill pharmacy; and comply with all other labeling requirements in §291.33 of this title.

(4) Policies and Procedures. A policy and procedure manual as it relates to centralized dispensing shall be maintained at both pharmacies and be available for inspection. Each pharmacy is required to maintain only those portions of the policy and procedure manual that relate to that pharmacy's operations. The manual shall:

(A) outline the responsibilities of each of the pharmacies;

(B) include a list of the name, address, telephone numbers, and all license/registration numbers of the pharmacies involved in centralized prescription dispensing; and

(C) include policies and procedures for:

(i) notifying patients that their prescription may be outsourced to a central fill pharmacy for dispensing and providing the name of that pharmacy;

(ii) protecting the confidentiality and integrity of patient information;

(iii) dispensing prescription drug orders when the dispensed order is not received or the patient comes in before the order is received;

(iv) complying with federal and state laws and regulations;

(v) operating a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems; and

(vi) annually reviewing the written policies and procedures and documenting such review.

(d) Records.

(1) Records may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided:

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

(B) the data processing system is capable of producing a hard copy of the record upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.
(2) Each pharmacy shall comply with all the laws and rules relating to the maintenance of
records and be able to produce an audit trail showing all prescriptions dispensed by the
pharmacy.

(3) The outsourcing pharmacy shall maintain records which indicate the:

(A) date:

(i) the request for dispensing was transmitted to the central fill pharmacy; and

(ii) the dispensed prescription was received by the outsourcing pharmacy, including the
method of delivery (e.g., private, common, or contract carrier) and the name of the person
accepting delivery; and

(B) name, address, license number, and the unique identifier of the central fill pharmacy.

(4) The central fill pharmacy shall maintain records which indicate the:

(A) date the prescription was shipped to the outsourcing pharmacy or the patient;

(B) name and address where the prescription was shipped;

(C) method of delivery (e.g., private, common, or contract carrier); and

(D) name, address, and license number of the outsourcing pharmacy.

§291.127 Emergency Remote Pharmacy License

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

(1) Emergency remote pharmacy--A pharmacy not located at the same Texas location as a
home pharmacy at which pharmacy services are provided during an emergency situation.

(2) Emergency situation--An emergency caused by a natural or manmade disaster or any other
exceptional situation that causes an extraordinary demand for pharmacy services.

(3) Home pharmacy--A currently licensed Class A (Community), Class C (Institutional), or
Class D (Clinic) pharmacy that is providing emergency pharmacy services through an
emergency remote pharmacy.

(b) Emergency remote pharmacy license. In an emergency situation, the board may grant a
holder of a Class A (Community), Class C (Institutional), or Class D (Clinic) pharmacy license,
the authority to operate a pharmacy and provide pharmacy services at an alternate location.
The following is applicable for the emergency remote pharmacy.
(1) The emergency remote pharmacy will not be issued a separate pharmacy license, but shall operate under the license of the home pharmacy. To qualify for an emergency remote pharmacy license, the applicant must submit an application including the following information:

(A) license number, name, address, and phone number of the home pharmacy;
(B) name, address, and phone number of the emergency remote pharmacy;
(C) name and Texas pharmacist license number of the pharmacist-in-charge of the home pharmacy and of the pharmacist-in-charge of the emergency remote pharmacy; and
(D) any other information required by the board.

(2) The board will notify the home pharmacy of the approval of an emergency remote pharmacy license.

(3) The emergency remote pharmacy license shall be valid for a period as determined by the board not to exceed six months. The executive director of the board, in his/her discretion, may renew the remote license for an additional six months, if the emergency situation still exists and the holder of the license shows good cause for emergency remote pharmacy to continue operation.

(4) The emergency remote pharmacy shall have a written contract or agreement with the home pharmacy which outlines the services to be provided and the responsibilities and accountabilities of the remote and home pharmacy in fulfilling the terms of the contract or agreement in compliance with federal and state laws and regulations.

(5) The home pharmacy shall designate a pharmacist to serve as the pharmacist-in-charge of the emergency remote pharmacy.

(6) The emergency remote pharmacy shall comply with the rules for the class of pharmacy under which the home pharmacy is licensed. A Class A pharmacy shall comply with the rules under Subchapter B of this chapter titled Community Pharmacy (Class A). A Class C pharmacy shall comply with the rules under Subchapter D of this chapter titled Institutional Pharmacy (Class C). A Class D pharmacy shall comply with the rules under Subchapter E of this chapter titled Clinic Pharmacy (Class D).

(7) The records of services provided at the emergency remote pharmacy shall be:

(A) kept by the home pharmacy and be available, for at least two years from the date of provision of the service, for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies; and
(B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format if specifically requested by the board or its representative. Failure to provide the records set out in this section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.
§291.129  Satellite Pharmacy

(a) Purpose. The purpose of this section is to create a new class of pharmacy for the provision of pharmacy services by a Class A or Class C pharmacy in a location that is not at the same location as a Class A or Class C pharmacy through a satellite pharmacy and to provide standards for the operation of this class of pharmacy established under §560.053 of the Texas Pharmacy Act.

(b) Definitions. The following words and terms, when used in the section, shall have the following meanings, unless the context clearly indicates otherwise. All other words and terms shall have the meanings defined in the Act or §291.31 of this title.

(1) Provider pharmacy--The Class A or Class C pharmacy providing satellite pharmacy services.

(2) Satellite pharmacy--A facility not located at the same location as a Class A or Class C pharmacy at which satellite pharmacy services are provided.

(3) Satellite pharmacy services--The provision of pharmacy services, including the storage and delivery of prescription drugs, in an alternate location.

(c) General requirements.

(1) A Class A or Class C provider pharmacy may establish a satellite pharmacy in a location that is not at the same location as a Class A or Class C pharmacy.

(2) The pharmacist-in-charge of the provider pharmacy is responsible for all pharmacy operations involving the satellite pharmacy including supervision of satellite pharmacy personnel and compliance with this section.

(3) A satellite pharmacy may not store bulk drugs and may only store prescription medications that have been previously verified and dispensed by the provider pharmacy.

(4) A Class C pharmacy that is a provider pharmacy dispensing outpatient prescriptions for a satellite pharmacy shall comply with the provisions of §§291.31 - 291.34 of this title (relating to Definitions, Personnel, Operational Standards, and Records for Class A (Community) pharmacies) and this section.

(5) The provider pharmacy and the satellite pharmacy must have:

   (A) the same owner; and

   (B) share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to process a non-dispensing function.

(d) Personnel.

(1) All individuals working at the satellite pharmacy shall be employees of the provider pharmacy and must report their employment to the board as such.
(2) A satellite pharmacy shall have sufficient pharmacists on duty to operate the satellite pharmacy competently, safely, and adequately to meet the needs of the patients of the pharmacy.

(3) Pharmacists are solely responsible for the direct supervision of pharmacy technicians and pharmacy technician trainees and for designating and delegating duties, other than those listed in paragraph (7) of this subsection, to pharmacy technicians and pharmacy technician trainees. Each pharmacist:

(A) shall verify the accuracy of all acts, tasks, and functions performed by pharmacy technicians and pharmacy technician trainees; and

(B) shall be responsible for any delegated act performed by pharmacy technicians and pharmacy technician trainees under his or her supervision.

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

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

(6) A pharmacist shall ensure that the drug is dispensed and delivered safely and accurately as prescribed. A pharmacist shall ensure the safety and accuracy of the portion of the process the pharmacist is performing.

(7) Duties, in a satellite pharmacy, that may only be performed by a pharmacist are as follows:

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

(B) interpreting or clarifying prescription drug orders;

(C) communicating to the patient or patient's agent information about the prescription drug or device which in the exercise of the pharmacist's professional judgment, the pharmacist deems significant, as specified in §291.33(c) of this title;

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

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

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

(G) performing a specific act of drug therapy management for a patient delegated to a pharmacist by a written protocol from a physician licensed in this state in compliance with the Medical Practice Act.
(8) Pharmacy technicians and pharmacy technician trainees may not perform any of the duties listed in paragraph (7) of this subsection. However, a pharmacist may delegate to pharmacy technicians and pharmacy technician trainees any nonjudgmental technical duty associated with the preparation and distribution of prescription drugs provided:

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

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

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

(A) initiating and receiving refill authorization requests;

(B) entering prescription data into a data processing system; and

(C) reconstituting medications.

(10) In a satellite pharmacy, the ratio of pharmacists to pharmacy technicians/pharmacy technician trainees may be 1:3, provided at least one of the three is a pharmacy technician and not a pharmacy technician trainee.

(11) All satellite pharmacy personnel shall wear identification tags or badges that bears the person's name and identifies him or her as a pharmacist, pharmacist intern, pharmacy technician, or pharmacy technician trainee.

(e) Operational requirements.

(1) Application for permission to provide satellite pharmacy services.

(A) A Class A or Class C pharmacy shall make application to the board to provide satellite pharmacy services. The application shall contain an affidavit with the notarized signatures of the pharmacist-in-charge and the person responsible for the on-site operation of the facility where the satellite pharmacy will be located and include the following:

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

(ii) the name and address of the facility where the satellite pharmacy will be located;

(iii) anticipated date of opening and hours of operation; and

(iv) copy of the lease agreement or if the location of the satellite pharmacy is owned by the applicant, a notarized statement certifying such location ownership.

(B) Such application shall be resubmitted every two years in conjunction with the application for renewal of the provider pharmacy's license. The renewal petition shall contain the documentation required in subparagraph (A) of this paragraph except the notarized signature of
the person responsible for the on-site operation of the facility where the satellite pharmacy will be located.

(C) Upon approval of the application, the provider pharmacy will be sent a certificate which must be displayed at the satellite pharmacy.

(2) Notification requirements.

(A) A provider pharmacy shall notify the board in writing within ten days of a change of location, discontinuance of service, or closure of a satellite pharmacy that is operated by the pharmacy.

(B) A provider pharmacy shall comply with appropriate federal and state controlled substance registrations for each satellite pharmacy if controlled substances are maintained at the satellite pharmacy.

(3) Environment.

(A) The satellite pharmacy shall be arranged in an orderly fashion and kept clean. All required equipment shall be clean and in good operating condition.

(B) A satellite pharmacy shall contain an area which is suitable for confidential patient counseling.

(i) Such counseling area shall:

(I) be easily accessible to both patient and pharmacists and not allow patient access to prescription drugs;

(II) be designed to maintain the confidentiality and privacy of the pharmacist/patient communication.

(ii) In determining whether the area is suitable for confidential patient counseling and designed to maintain the confidentiality and privacy of the pharmacist/patient communication, the board may consider factors such as the following:

(I) the proximity of the counseling area to the check-out or cash register area;

(II) the volume of pedestrian traffic in and around the counseling area;

(III) the presence of walls or other barriers between the counseling area and other areas of the pharmacy; and

(IV) any evidence of confidential information being overheard by persons other than the patient or patient's agent or the pharmacist or agents of the pharmacist.

(C) The satellite pharmacy shall be properly lighted and ventilated.

(D) The temperature of the satellite pharmacy shall be maintained within a range compatible with the proper storage of drugs in compliance with the provisions of §291.15 of this title.
(relating to storage of drugs). The temperature of the refrigerator shall be maintained within a range compatible with the proper storage of drugs requiring refrigeration.

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

(4) Security.

(A) A satellite pharmacy shall be under the continuous, physically present supervision of a pharmacist at all times the satellite pharmacy is open to provide pharmacy services.

(B) The satellite pharmacy shall be enclosed by walls, partitions or other means of floor-to-ceiling enclosure. In addition, to the security requirements outlined in §291.33(b)(2) of this title, satellite pharmacies shall have adequate security and procedures to

(i) prohibit unauthorized access;

(ii) comply with federal and state regulations; and

(iii) maintain patient confidentiality.

(C) Access to the satellite pharmacy shall be limited to pharmacists, pharmacy technicians, and pharmacy technician trainees employed by the provider pharmacy and who are designated in writing by the pharmacist-in-charge.

(D) The provider pharmacy shall have procedures that specify that prescriptions may only be delivered to the satellite pharmacy by the provider pharmacy and shall:

(i) be delivered in a sealed container with a list of the prescriptions delivered;

(ii) signed for on receipt by the pharmacist at the satellite pharmacy;

(iii) be checked by personnel designated by the pharmacist-in-charge to verify that the prescriptions sent by the provider pharmacy were actually received. The designated person who checks the order shall document the verification by signing and dating the list of prescriptions delivered.

(5) Prescription dispensing and delivery. A satellite pharmacy shall comply with the requirements outlines in §291.33(c) of this title with regard to prescription dispensing and delivery.

(6) Equipment and supplies. A satellite pharmacy shall have the following equipment and supplies:

(A) typewriter or comparable equipment;

(B) refrigerator, if storing drugs requiring refrigeration;
(C) metric-apothecary weight and measure conversion charts.

(7) Library. A reference library shall be maintained by the satellite pharmacy that includes the following in hard-copy or electronic format:

(A) current copies of the following:

(i) Texas Pharmacy Act and rules;

(ii) Texas Dangerous Drug Act and rules;

(iii) Texas Controlled Substances Act and rules; and

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

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

(i) patient information:

(I) United States Pharmacopeia Dispensing Information, Volume II (Advice to the Patient);

or

(II) a reference text or information leaflets which provide patient information;

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

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

(I) Facts and Comparisons with current supplements;

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

(III) Clinical Pharmacology;

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

(V) Remington's Pharmaceutical Sciences; and

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

(f) Records.

(1) Maintenance of records.
(A) Every record required to be kept and §291.34 of this title and under this section shall be;

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

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

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

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

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

(C) Prescription drug orders shall be maintained by the provider pharmacy in the manner
required by §291.34(d) or (e) of this title.

(2) Prescriptions.

(A) Prescription drug orders shall meet the requirements of §291.34(b) of this title.

(B) The provider pharmacy must maintain appropriate records to identify the name(s), initials,
or identification code(s) and specific activity(ies) of each pharmacist, pharmacy technician, or
pharmacy technician trainee who performed any processing at the satellite pharmacy.

(C) A provider pharmacy shall keep a record of all prescriptions sent and returned between
the pharmacies separate from the records of the provider pharmacy and from any other satellite
pharmacy’s records.

(D) A satellite pharmacy shall keep a record of all prescriptions received and returned
between the pharmacies.

§291.131 Pharmacies Compounding Non-Sterile Preparations

(a) Purpose. Pharmacies compounding non-sterile preparations, prepackaging pharmaceutical
products and distributing those products shall comply with all requirements for their specific
license classification and this section. The purpose of this section is to provide standards for
the:
(1) compounding of non-sterile preparations pursuant to a prescription or medication order for a patient from a practitioner in Class A (Community), Class C (Institutional), and Class E (Non-resident) pharmacies;

(2) compounding, dispensing, and delivery of a reasonable quantity of a compounded non-sterile preparation in a Class A (Community), Class C (Institutional), and Class E (Non-resident) pharmacies to a practitioner’s office for office use by the practitioner;

(3) compounding and distribution of compounded non-sterile preparations by a Class A (Community) pharmacy for a Class C (Institutional) pharmacy; and

(4) compounding of non-sterile preparations by a Class C (Institutional) pharmacy and the distribution of the compounded preparations to other Class C (Institutional) pharmacies under common ownership.

(b) Definitions. In addition to the definitions for specific license classifications, the following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Beyond-use date—The date or time after which the compounded non-sterile preparation shall not be stored or transported or begin to be administered to a patient. The beyond-use date is determined from the date or time when the preparation was compounded.

(2) Component—Any ingredient intended for use in the compounding of a drug preparation, including those that may not appear in such preparation.

(3) Compounding—The preparation, mixing, assembling, packaging, or labeling of a drug or device:

(A) as the result of a practitioner’s prescription drug or medication order, based on the practitioner-patient-pharmacist relationship in the course of professional practice;

(B) for administration to a patient by a practitioner as the result of a practitioner’s initiative based on the practitioner-patient-pharmacist relationship in the course of professional practice;

(C) in anticipation of prescription drug or medication orders based on routine, regularly observed prescribing patterns; or

(D) for or as an incident to research, teaching, or chemical analysis and not for sale or dispensing, except as allowed under §562.154 or Chapter 563 of the Occupations Code.

(4) Hot water—The temperature of water from the pharmacy’s sink maintained at a minimum of 105 degrees F (41 degrees C).

(5) Reasonable quantity—An amount of a compounded drug that:

(A) does not exceed the amount a practitioner anticipates may be used in the practitioner’s office or facility before the beyond use date of the drug;
(B) is reasonable considering the intended use of the compounded drug and the nature of the practitioner’s practice; and

(C) for any practitioner and all practitioners as a whole, is not greater than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality, and purity of the compounded drug that are consistent with United States Pharmacopeia guidelines and accreditation practices.

(6) SOPs--Standard operating procedures.


(c) Personnel.

(1) Pharmacist-in-charge. In addition to the responsibilities for the specific class of pharmacy, the pharmacist-in-charge shall have the responsibility for, at a minimum, the following concerning non-sterile compounding:

(A) determining that all personnel involved in non-sterile compounding possess the education, training, and proficiency necessary to properly and safely perform compounding duties undertaken or supervised;

(B) determining that all personnel involved in non-sterile compounding obtain continuing education appropriate for the type of compounding done by the personnel;

(C) assuring that the equipment used in compounding is properly maintained;

(D) maintaining an appropriate environment in areas where non-sterile compounding occurs; and

(E) assuring that effective quality control procedures are developed and followed.

(2) Pharmacists. Special requirements for non-sterile compounding.

(A) All pharmacists engaged in compounding shall:

(i) possess the education, training, and proficiency necessary to properly and safely perform compounding duties undertaken or supervised; and

(ii) obtain continuing education appropriate for the type of compounding done by the pharmacist.

(B) A pharmacist shall inspect and approve all components, drug product containers, closures, labeling, and any other materials involved in the compounding process.

(C) A pharmacist shall review all compounding records for accuracy and conduct in-process and final checks to ensure that errors have not occurred in the compounding process.

(D) A pharmacist is responsible for the proper maintenance, cleanliness, and use of all equipment used in the compounding process.
(3) Pharmacy technicians and pharmacy technician trainees. All pharmacy technicians and pharmacy technician trainees engaged in non-sterile compounding shall:

(A) possess the education, training, and proficiency necessary to properly and safely perform compounding duties undertaken;

(B) obtain continuing education appropriate for the type of compounding done by the pharmacy technician or pharmacy technician trainee; and

(C) perform compounding duties under the direct supervision of and responsible to a pharmacist.

(4) Training.

(A) All training activities shall be documented and covered by appropriate SOPs as outlined in subsection (d)(8)(A) of this section.

(B) All personnel involved in non-sterile compounding shall be well trained and must participate in continuing relevant training programs.

(d) Operational Standards.

(1) General requirements.

(A) Non-sterile drug preparations may be compounded in licensed pharmacies:

(i) upon presentation of a practitioner’s prescription drug or medication order based on a valid pharmacist/patient/prescriber relationship;

(ii) in anticipation of future prescription drug or medication orders based on routine, regularly observed prescribing patterns; or

(iii) in reasonable quantities for office use by a practitioner and for use by a veterinarian.

(B) Non-sterile compounding in anticipation of future prescription drug or medication orders must be based upon a history of receiving valid prescriptions issued within an established pharmacist/patient/prescriber relationship, provided that in the pharmacist's professional judgment the quantity prepared is stable for the anticipated shelf time.

(i) The pharmacist’s professional judgment shall be based on the criteria used to determine a beyond-use date outlined in paragraph (5)(C) of this subsection.

(ii) Documentation of the criteria used to determine the stability for the anticipated shelf time must be maintained and be available for inspection.

(iii) Any preparation compounded in anticipation of future prescription drug or medication orders shall be labeled. Such label shall contain:
(I) name and strength of the compounded preparation or list of the active ingredients and strengths;

(II) facility's lot number;

(III) beyond-use date as determined by the pharmacist using appropriate documented criteria as outlined in paragraph (5)(C) of this subsection; and

(IV) quantity or amount in the container.

(C) Commercially available products may be compounded for dispensing to individual patients provided the following conditions are met:

(i) the commercial product is not reasonably available from normal distribution channels in a timely manner to meet patient's needs;

(ii) the pharmacy maintains documentation that the product is not reasonably available due to a drug shortage or unavailability from the manufacturer; and

(iii) the prescribing practitioner has requested that the drug be compounded as described in subparagraph (D) of this paragraph.

(D) A pharmacy may not compound preparations that are essentially copies of commercially available products (e.g., the preparation is dispensed in a strength that is only slightly different from a commercially available product) unless the prescribing practitioner specifically orders the strength or dosage form and specifies why the patient needs the particular strength or dosage form of the preparation. The prescribing practitioner shall provide documentation of a patient specific medical need and the preparation produces a clinically significant therapeutic response (e.g. the physician requests an alternate product due to hypersensitivity to excipients or preservative in the FDA-approved product, or the physician requests an effective alternate dosage form) or if the drug product is not commercially available. The unavailability of such drug product must be documented prior to compounding. The methodology for documenting unavailability includes maintaining a copy of the wholesaler's notification showing back-ordered, discontinued, or out-of-stock items. This documentation must be available in hard-copy or electronic format for inspection by the board.

(E) A pharmacy may enter into an agreement to compound and dispense prescription/medication orders for another pharmacy provided the pharmacy complies with the provisions of §291.125 of this title (relating to Centralized Prescription Dispensing).

(F) Compounding pharmacies/pharmacists may advertise and promote the fact that they provide non-sterile prescription compounding services, which may include specific drug products and classes of drugs.

(G) A pharmacy may not compound veterinary preparations for use in food producing animals except in accordance with federal guidelines.

(H) A pharmacist may add flavoring to a prescription at the request of a patient, the patient's agent, or the prescriber. The pharmacist shall label the flavored prescription with a beyond-use-date that shall be no longer than fourteen days if stored in a refrigerator unless otherwise
documented. Documentation of beyond-use-dates longer than fourteen days shall be maintained by the pharmacy electronically or manually and made available to agents of the board on request. A pharmacist may not add flavoring to an over-the-counter product at the request of a patient or patient's agent unless the pharmacist obtains a prescription for the over-the-counter product from the patient's practitioner.

(2) Library. In addition to the library requirements of the pharmacy's specific license classification, a pharmacy shall maintain a current copy, in hard-copy or electronic format, of Chapter 795 of the USP/NF concerning Pharmacy Compounding Non-Sterile Preparations.

(3) Environment.

(A) Pharmacies regularly engaging in compounding shall have a designated and adequate area for the safe and orderly compounding of non-sterile preparations, including the placement of equipment and materials. Pharmacies involved in occasional compounding shall prepare an area prior to each compounding activity which is adequate for safe and orderly compounding.

(B) Only personnel authorized by the responsible pharmacist shall be in the immediate vicinity of a drug compounding operation.

(C) A sink with hot and cold running water, exclusive of rest room facilities, shall be accessible to the compounding areas and be maintained in a sanitary condition. Supplies necessary for adequate washing shall be accessible in the immediate area of the sink and include:

(i) soap or detergent; and

(ii) air-driers or single-use towels.

(D) If drug products which require special precautions to prevent contamination, such as penicillin, are involved in a compounding operation, appropriate measures, including dedication of equipment for such operations or the meticulous cleaning of contaminated equipment prior to its use for the preparation of other drug products, must be used in order to prevent cross-contamination.

(4) Equipment and Supplies. The pharmacy shall:

(A) have a Class A prescription balance, or analytical balance and weights which shall be properly maintained and subject to periodic inspection by the Texas State Board of Pharmacy; and

(B) have equipment and utensils necessary for the proper compounding of prescription drug or medication orders. Such equipment and utensils used in the compounding process shall be:

(i) of appropriate design and capacity, and be operated within designed operational limits;

(ii) of suitable composition so that surfaces that contact components, in-process material, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the desired result;
(iii) cleaned and sanitized immediately prior and after to each use; and

(iv) routinely inspected, calibrated (if necessary), or checked to ensure proper performance.

(5) Labeling. In addition to the labeling requirements of the pharmacy’s specific license classification, the label dispensed or distributed pursuant to a prescription drug or medication order shall contain the following.

(A) The generic name(s) or the official name(s) of the principal active ingredient(s) of the compounded preparation.

(B) A statement that the preparation has been compounded by the pharmacy. (An auxiliary label may be used on the container to meet this requirement).

(C) A beyond-use date after which the compounded preparation should not be used. The beyond-use date shall be determined as outlined in Chapter 795 of the USP/NF concerning Pharmacy Compounding Non-Sterile Preparations including the following:

(i) The pharmacist shall consider:

(I) physical and chemical properties of active ingredients;

(II) use of preservatives and/or stabilizing agents;

(III) dosage form;

(IV) storage containers and conditions; and

(V) scientific, laboratory, or reference data from a peer reviewed source and retained in the pharmacy. The reference data should follow the same preparation instructions for combining raw materials and packaged in a container with similar properties.

(ii) In the absence of stability information applicable for a specific drug or preparation, the following maximum beyond-use dates are to be used when the compounded preparation is packaged in tight, light-resistant containers and stored at controlled room temperatures.

(I) Nonaqueous liquids and solid formulations (Where the manufactured drug product is the source of active ingredient): 25% of the time remaining until the product’s expiration date or 6 months, whichever is earlier.

(II) Water-containing formulations (Prepared from ingredients in solid form): Not later than 14 days when refrigerated between 2 - 8 degrees Celsius (36 - 46 degrees Fahrenheit).

(III) All other formulations: Intended duration of therapy or 30 days, whichever is earlier.

(iii) Beyond-use date limits may be exceeded when supported by valid scientific stability information for the specific compounded preparation.

(6) Written drug information. Written information about the compounded preparation or its major active ingredient(s) shall be given to the patient at the time of dispensing. A statement
which indicates that the preparation was compounded by the pharmacy must be included in this written information. If there is no written information available, the patient should be advised that the drug has been compounded and how to contact a pharmacist, and if appropriate the prescriber, concerning the drug.

(7) Drugs, components, and materials used in non-sterile compounding.

(A) Drugs used in non-sterile compounding shall be a USP/NF grade substances manufactured in an FDA-registered facility.

(B) If USP/NF grade substances are not available, or when food, cosmetics, or other substances are, or must be used, the substance shall be of a chemical grade in one of the following categories:

(i) Chemically Pure (CP);

(ii) Analytical Reagent (AR); or

(iii) American Chemical Society (ACS); or

(iv) Food Chemical Codex; or

(C) If a drug, component or material is not purchased from a FDA-registered facility, the pharmacist shall establish purity and stability by obtaining a Certificate of Analysis from the supplier and the pharmacist shall compare the monograph of drugs in a similar class to the Certificate of Analysis.

(D) A manufactured drug product may be a source of active ingredient. Only manufactured drugs from containers labeled with a batch control number and a future expiration date are acceptable as a potential source of active ingredients. When compounding with manufactured drug products, the pharmacist must consider all ingredients present in the drug product relative to the intended use of the compounded preparation.

(E) All components shall be stored in properly labeled containers in a clean, dry area, under proper temperatures.

(F) Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the compounded drug product beyond the desired result.

(G) Components, drug product containers, and closures shall be rotated so that the oldest stock is used first.

(H) Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded drug product.

(I) A pharmacy may not compound a preparation that contains ingredients appearing on a federal Food and Drug Administration list of drug products withdrawn or removed from the market for safety reasons.
(8) Compounding process.

(A) All significant procedures performed in the compounding area shall be covered by written SOPs designed to ensure accountability, accuracy, quality, safety, and uniformity in the compounding process. At a minimum, SOPs shall be developed for:

(i) the facility;

(ii) equipment;

(iii) personnel;

(iv) preparation evaluation;

(v) quality assurance;

(vi) preparation recall;

(vii) packaging; and

(viii) storage of compounded preparations.

(B) Any compounded preparation with an official monograph in the USP/NF shall be compounded, labeled, and packaged in conformity with the USP/NF monograph for the drug.

(C) Any person with an apparent illness or open lesion that may adversely affect the safety or quality of a drug product being compounded shall be excluded from direct contact with components, drug product containers, closures, any materials involved in the compounding process, and drug products until the condition is corrected.

(D) Personnel engaged in the compounding of drug preparations shall wear clean clothing appropriate to the operation being performed. Protective apparel, such as coats/jackets, aprons, hair nets, gowns, hand or arm coverings, or masks shall be worn as necessary to protect personnel from chemical exposure and drug preparations from contamination.

(E) At each step of the compounding process, the pharmacist shall ensure that components used in compounding are accurately weighed, measured, or subdivided as appropriate to conform to the formula being prepared.

(9) Quality Assurance.

(A) Initial formula validation. Prior to routine compounding of a non-sterile preparation, a pharmacy shall conduct an evaluation that shows that the pharmacy is capable of compounding a product that contains the stated amount of active ingredient(s).

(B) Finished preparation checks. The prescription drug and medication orders, written compounding procedure, preparation records, and expended materials used to make compounded non-sterile preparations shall be inspected for accuracy of correct identities and
amounts of ingredients, packaging, labeling, and expected physical appearance before the non-sterile preparations are dispensed.

(10) Quality Control.

(A) The pharmacy shall follow established quality control procedures to monitor the quality of compounded drug preparations for uniformity and consistency such as capsule weight variations, adequacy of mixing, clarity, or pH of solutions. When developing these procedures, pharmacy personnel shall consider the provisions of Chapter 795, concerning Pharmacy Compounding Non-Sterile Preparations, Chapter 1075, concerning Good Compounding Practices, and Chapter 1160, concerning Pharmaceutical Calculations in Prescription Compounding contained in the current USP/NF. Such procedures shall be documented and be available for inspection.

(B) Compounding procedures that are routinely performed, including batch compounding, shall be completed and verified according to written procedures. The act of verification of a compounding procedure involves checking to ensure that calculations, weighing and measuring, order of mixing, and compounding techniques were appropriate and accurately performed.

(C) Unless otherwise indicated or appropriate, compounded preparations are to be prepared to ensure that each preparation shall contain not less than 90.0 percent and not more than 110.0 percent of the theoretically calculated and labeled quantity of active ingredient per unit weight or volume and not less than 90.0 percent and not more than 110.0 percent of the theoretically calculated weight or volume per unit of the preparation.

(e) Records.

(1) Maintenance of records. Every record required by this section shall be:

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

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

(2) Compounding records.

(A) Compounding pursuant to patient specific prescription drug or medication orders. Compounding records for all compounded preparations shall be maintained by the pharmacy electronically or manually as part of the prescription drug or medication order, formula record, formula book, or compounding log and shall include:

(i) the date of preparation;
(ii) a complete formula, including methodology and necessary equipment which includes the
brand name(s) of the raw materials, or if no brand name, the generic name(s) and name(s) of
the manufacturer(s) of the raw materials and the quantities of each;

(iii) signature or initials of the pharmacist or pharmacy technician or pharmacy technician
trainee performing the compounding;

(iv) signature or initials of the pharmacist responsible for supervising pharmacy technicians
or pharmacy technician trainees and conducting in-process and final checks of compounded
preparations if pharmacy technicians or pharmacy technician trainees perform the compounding
function;

(v) the quantity in units of finished preparations or amount of raw materials;

(vi) the container used and the number of units prepared;

(vii) a reference to the location of the following documentation which may be maintained with
other records, such as quality control records:

(I) the criteria used to determine the beyond-use date; and

(II) documentation of performance of quality control procedures. Documentation of the
performance of quality control procedures is not required if the compounding process is done
pursuant to a patient specific order and involves the mixing of two or more commercially
available oral liquids or commercially available preparations when the final product is intended
for external use.

(B) Compounding records when batch compounding or compounding in anticipation of future
prescription drug or medication orders.

(i) Master work sheet. A master work sheet shall be developed and approved by a
pharmacist for preparations prepared in batch. Once approved, a duplicate of the master work
sheet shall be used as the preparation work sheet from which each batch is prepared and on
which all documentation for that batch occurs. The master work sheet shall contain at a
minimum:

(I) the formula;

(II) the components;

(III) the compounding directions;

(IV) a sample label;

(V) evaluation and testing requirements;

(VI) specific equipment used during preparation; and

(VII) storage requirements.
(ii) Preparation work sheet. The preparation work sheet for each batch of preparations shall document the following:

(I) identity of all solutions and ingredients and their corresponding amounts, concentrations, or volumes;

(II) lot number or each component;

(III) component manufacturer/distributor or suitable identifying number;

(IV) container specifications;

(V) unique lot or control number assigned to batch;

(VI) beyond use date of batch-prepared preparations;

(VII) date of preparation;

(VIII) name, initials, or electronic signature of the person(s) involved in the preparation;

(IX) name, initials, or electronic signature of the responsible pharmacist;

(X) finished preparation evaluation and testing specifications, if applicable; and

(XI) comparison of actual yield to anticipated or theoretical yield, when appropriate.

(f) Office Use Compounding and Distribution of Compounded Preparations to Class C Pharmacies or Veterinarians in Accordance With §563.054 of the Act.

(1) General.

(A) A pharmacy may dispense and deliver a reasonable quantity of a compounded preparation to a practitioner for office use by the practitioner in accordance with this subsection.

(B) A Class A (Community) pharmacy is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute non-sterile compounded preparations to a Class C (Institutional) pharmacy.

(C) A Class C (Institutional) pharmacy is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute non-sterile compounded preparations that the Class C pharmacy has compounded for other Class C pharmacies under common ownership.

(D) To dispense and deliver a compounded preparation under this subsection, a pharmacy must:

(i) verify the source of the raw materials to be used in a compounded drug;

(ii) comply with applicable United States Pharmacopoeia guidelines, including the testing requirements, and the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191);
(iii) enter into a written agreement with a practitioner for the practitioner's office use of a compounded preparation;

(iv) comply with all applicable competency and accrediting standards as determined by the board; and

(v) comply with the provisions of this subsection.

(2) Written Agreement. A pharmacy that provides non-sterile compounded preparations to practitioners for office use or to another pharmacy shall enter into a written agreement with the practitioner or pharmacy. The written agreement shall:

(A) address acceptable standards of practice for a compounding pharmacy and a practitioner and receiving pharmacy that enter into the agreement including a statement that the compounded preparations may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity except as authorized by §563.054 of the Act;

(B) require the practitioner or receiving pharmacy to include on a patient’s chart, medication order, or medication administration record the lot number and beyond-use date of a compounded preparation administered to a patient; and

(C) describe the scope of services to be performed by the pharmacy and practitioner or receiving pharmacy, including a statement of the process for:

(i) a patient to report an adverse reaction or submit a complaint; and

(ii) the pharmacy to recall batches of compounded preparations.

(3) Recordkeeping.

(A) Maintenance of Records.

(i) Records of orders and distribution of non-sterile compounded preparations to a practitioner for office use or to a Class C (Institutional) pharmacy for administration to a patient shall:

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

(II) maintained separately from the records of products dispensed pursuant to a prescription or medication order; and

(III) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy or its representative. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format. Failure to provide the records set out in this subsection, either on site or within 72 hours for whatever reason, constitutes prima facie evidence of failure to keep and maintain records.
(ii) Records may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided the data processing system is capable of producing a hard copy of the record upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.

(B) Orders. The pharmacy shall maintain a record of all non-sterile compounded preparations ordered by a practitioner for office use or by a Class C pharmacy for administration to a patient. The record shall include the following information:

(i) date of the order;

(ii) name, address, and phone number of the practitioner who ordered the preparation and if applicable, the name, address and phone number of the Class C pharmacy ordering the preparation; and

(iii) name, strength, and quantity of the preparation ordered.

(C) Distributions. The pharmacy shall maintain a record of all non-sterile compounded preparations distributed pursuant to an order to a practitioner for office use or by a Class C pharmacy for administration to a patient. The record shall include the following information:

(i) date the preparation was compounded;

(ii) date the preparation was distributed;

(iii) name, strength and quantity in each container of the preparation;

(iv) pharmacy's lot number;

(v) quantity of containers shipped; and

(vi) name, address, and phone number of the practitioner or Class C pharmacy to whom the preparation is distributed.

(D) Audit Trail.

(i) The pharmacy shall store the order and distribution records of preparations for all non-sterile compounded preparations ordered by and or distributed to a practitioner for office use or by a Class C pharmacy for administration to a patient in such a manner as to be able to provide an audit trail for all orders and distributions of any of the following during a specified time period.

(I) any strength and dosage form of a preparation (by either brand or generic name or both);

(II) any ingredient;

(III) any lot number;

(IV) any practitioner;
(V) any facility; and

(VI) any pharmacy, if applicable.

(ii) The audit trail shall contain the following information:

(I) date of order and date of the distribution;

(II) practitioner's name, address, and name of the Class C pharmacy, if applicable;

(III) name, strength and quantity of the preparation in each container of the preparation;

(IV) name and quantity of each active ingredient;

(V) quantity of containers distributed; and

(VI) pharmacy's lot number;

(4) Labeling. The pharmacy shall affix a label to the preparation containing the following information:

(A) name, address, and phone number of the compounding pharmacy;

(B) the statement: "For Institutional or Office Use Only--Not for Resale"; or if the preparation is distributed to a veterinarian the statement: "Compounded Preparation";

(C) name and strength of the preparation or list of the active ingredients and strengths;

(D) pharmacy's lot number;

(E) beyond-use date as determined by the pharmacist using appropriate documented criteria;

(F) quantity or amount in the container;

(G) appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and

(H) device-specific instructions, where appropriate.

(g) Recall Procedures.

(1) The pharmacy shall have written procedures for the recall of any compounded non-sterile preparations provided to a patient, to a practitioner for office use, or a pharmacy for administration. Written procedures shall include, but not be limited to the requirements as specified in paragraph (3) of this subsection.

(2) The pharmacy shall immediately initiate a recall of any non-sterile preparation compounded by the pharmacy upon identification of a potential or confirmed harm to a patient.

(3) In the event of a recall, the pharmacist-in-charge shall ensure that:
(A) each practitioner, facility, and/or pharmacy to which the preparation was distributed is notified, in writing, of the recall;  
(B) each patient to whom the preparation was dispensed is notified, in writing, of the recall;  
(C) if the preparation is prepared as a batch, the board is notified of the recall, in writing;  
(D) if the preparation is distributed for office use, the Texas Department of State Health Services, Drugs and Medical Devices Group, is notified of the recall, in writing;  
(E) the preparation is quarantined; and  
(F) the pharmacy keeps a written record of the recall including all actions taken to notify all parties and steps taken to ensure corrective measures.

§291.133 Pharmacies Compounding Sterile Preparations  
(a) Purpose. Pharmacies compounding sterile preparations, prepackaging pharmaceutical products, and distributing those products shall comply with all requirements for their specific license classification and this section. The purpose of this section is to provide standards for the:  
(1) compounding of sterile preparations pursuant to a prescription or medication order for a patient from a practitioner in Class A-S, Class B, Class C-S, and Class E-S pharmacies;  
(2) compounding, dispensing, and delivery of a reasonable quantity of a compounded sterile preparation in Class A-S, Class B, Class C-S, and Class E-S pharmacies to a practitioner’s office for office use by the practitioner;  
(3) compounding and distribution of compounded sterile preparations by a Class A-S pharmacy for a Class C-S pharmacy; and  
(4) compounding of sterile preparations by a Class C-S pharmacy and the distribution of the compounded preparations to other Class C or Class C-S pharmacies under common ownership.  
(b) Definitions. In addition to the definitions for specific license classifications, the following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.  
(1) ACPE--Accreditation Council for Pharmacy Education.  
(2) Airborne particulate cleanliness class--The level of cleanliness specified by the maximum allowable number of particles per cubic meter of air as specified in the International Organization of Standardization (ISO) Classification Air Cleanliness (ISO 14644-1). For example:
(A) ISO Class 5 (formerly Class 100) is an atmospheric environment that contains less than 2537 3,520 particles 0.5 microns in diameter per cubic meter of air (formerly stated as 100 particles 2538 0.5 microns in diameter per cubic foot of air); and

(B) ISO Class 7 (formerly Class 10,000) is an atmospheric environment that contains less 2541 than 352,000 particles 0.5 microns in diameter per cubic meter of air (formerly stated as 10,000 2542 particles 0.5 microns in diameter per cubic foot of air); and

(C) ISO Class 8 (formerly Class 100,000) is an atmospheric environment that contains less 2545 than 3,520,000 particles 0.5 microns in diameter per cubic meter of air (formerly stated as 2546 100,000 particles 0.5 microns in diameter per cubic foot of air).

(3) Ancillary supplies--Supplies necessary for the preparation and administration of compounded sterile preparations.

(4) Ante-area--An ISO Class 8 or better area where personnel may perform hand hygiene and 2552 garbing procedures, staging of components, order entry, labeling, and other high-particulate 2554 generating activities. It is also a transition area that:

(A) provides assurance that pressure relationships are constantly maintained so that air flows 2556 from clean to dirty areas; and

(B) reduces the need for the heating, ventilating and air conditioning (HVAC) control system 2558 to respond to large disturbances.

(5) Aseptic Processing--A mode of processing pharmaceutical and medical preparations that 2562 involves the separate sterilization of the preparation and of the package (containers-closures or 2564 packaging material for medical devices) and the transfer of the preparation into the container 2565 and its closure under at least ISO Class 5 conditions.

(6) Automated compounding device--An automated device that compounds, measures, and/or 2568 packages a specified quantity of individual components in a predetermined sequence for a 2569 designated sterile preparation.

(7) Batch--A specific quantity of a drug or other material that is intended to have uniform 2571 character and quality, within specified limits, and is produced during a single preparation cycle.

(8) Batch preparation compounding--Compounding of multiple sterile preparation units, in a 2574 single discrete process, by the same individual(s), carried out during one limited time period. 2575 Batch preparation/compounding does not include the preparation of multiple sterile preparation 2576 units pursuant to patient specific medication orders.

(9) Beyond-use date--The date or time after which the compounded sterile preparation shall 2579 not be stored or transported or begin to be administered to a patient. The beyond-use date is 2580 determined from the date or time the preparation is compounded.

(10) Biological Safety Cabinet, Class II--A ventilated cabinet for personnel, product or 2583 preparation, and environmental protection having an open front with inward airflow for personnel 2584 protection, downward HEPA filtered laminar airflow for product protection, and HEPA filtered 2585 exhausted air for environmental protection.
(11) Buffer Area--An ISO Class 7 or, if a Class B pharmacy, ISO Class 8 or better, area where the primary engineering control area is physically located. Activities that occur in this area include the preparation and staging of components and supplies used when compounding sterile preparations.

(12) Clean room--A room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear are not exceeded for a specified cleanliness class.

(13) Component--Any ingredient intended for use in the compounding of a drug preparation, including those that may not appear in such preparation.

(14) Compounding--The preparation, mixing, assembling, packaging, or labeling of a drug or device:

(A) as the result of a practitioner's prescription drug or medication order based on the practitioner-patient-pharmacist relationship in the course of professional practice;

(B) for administration to a patient by a practitioner as the result of a practitioner’s initiative based on the practitioner-patient-pharmacist relationship in the course of professional practice;

(C) in anticipation of prescription drug or medication orders based on routine, regularly observed prescribing patterns; or

(D) for or as an incident to research, teaching, or chemical analysis and not for sale or dispensing, except as allowed under §562.154 or Chapter 563 of the Occupations Code.

(15) Compounding Aseptic Isolator--A form of barrier isolator specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment shall not occur unless it has first passed through a microbial retentive filter (HEPA minimum).

(16) Compounding Aseptic Containment Isolator--A compounding aseptic isolator designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where volatile hazardous drugs are prepared, the exhaust air from the isolator should be appropriately removed by properly designed building ventilation.

(17) Compounding Personnel--A pharmacist, pharmacy technician, or pharmacy technician trainee who performs the actual compounding; a pharmacist who supervises pharmacy technicians or pharmacy technician trainees compounding sterile preparations, and a pharmacist who performs an intermediate or final verification of a compounded sterile preparation.
(18) Critical Area--An ISO Class 5 environment.

(19) Critical Sites--A location that includes any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampules, needle hubs) exposed and at risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination. Risk of microbial particulate contamination of the critical site increases with the size of the openings and exposure time.

(20) 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.

(21) Direct Compounding Area--A critical area within the ISO Class 5 primary engineering control where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.

(22) Disinfectant--An agent that frees from infection, usually a chemical agent but sometimes a physical one, and that destroys disease-causing pathogens or other harmful microorganisms but may not kill bacterial and fungal spores. It refers to substances applied to inanimate objects.

(23) First Air--The air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.

(24) Hazardous Drugs--Drugs that, studies in animals or humans indicate exposure to the drugs, have a potential for causing cancer, development or reproductive toxicity, or harm to organs. For the purposes of this chapter, radiopharmaceuticals are not considered hazardous drugs.

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

(26) HVAC--Heating, ventilation, and air conditioning.

(27) Immediate use--A sterile preparation that is not prepared according to USP 797 standards (i.e., outside the pharmacy and most likely not by pharmacy personnel) which shall be stored for no longer than one hour after completion of the preparation.

(28) IPA--Isopropyl alcohol (2-propanol).

(29) Labeling--All labels and other written, printed, or graphic matter on an immediate container of an article or preparation or on, or in, any package or wrapper in which it is enclosed, except any outer shipping container. The term "label" designates that part of the labeling on the immediate container.

(30) Media-Fill Test--A test used to qualify aseptic technique of compounding personnel or processes and to ensure that the processes used are able to produce sterile preparation without microbial contamination. During this test, a microbiological growth medium such as Soybean-Casein Digest Medium is substituted for the actual drug preparation to simulate admixture compounding. The issues to consider in the development of a media-fill test are the following:
media-fill procedures, media selection, fill volume, incubation, time and temperature, inspection of filled units, documentation, interpretation of results, and possible corrective actions required.

(31) Multiple-Dose Container--A multiple-unit container for articles or preparations intended for potential administration only and usually contains antimicrobial preservatives. The beyond-use date for an opened or entered (e.g., needle-punctured) multiple-dose container with antimicrobial preservatives is 28 days, unless otherwise specified by the manufacturer.

(32) Negative Pressure Room--A room that is at a lower pressure compared to adjacent spaces and, therefore, the net flow of air is into the room.

(33) Office use--The administration of a compounded drug to a patient by a practitioner in the practitioner's office or by the practitioner in a health care facility or treatment setting, including a hospital, ambulatory surgical center, or pharmacy in accordance with Chapter 562 of the Act, or for administration or provision by a veterinarian in accordance with §563.054 of the Act.

(34) Pharmacy Bulk Package--A container of a sterile preparation for potential use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes. The closure shall be penetrated only one time after constitution with a suitable sterile transfer device or dispensing set, which allows measured dispensing of the contents. The pharmacy bulk package is to be used only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area).

(35) Prepackaging--The act of repackaging and relabeling quantities of drug products from a manufacturer's original container into unit dose packaging or a multiple dose container for distribution within a facility licensed as a Class C pharmacy or to other pharmacies under common ownership for distribution within those facilities. The term as defined does not prohibit the prepackaging of drug products for use within other pharmacy classes.

(36) Preparation or Compounded Sterile Preparation--A sterile admixture compounded in a licensed pharmacy or other healthcare-related facility pursuant to the order of a licensed prescriber. The components of the preparation may or may not be sterile products.

(37) Primary Engineering Control--A device or room that provides an ISO Class 5 environment for the exposure of critical sites when compounding sterile preparations. Such devices include, but may not be limited to, laminar airflow workbenches, biological safety cabinets, compounding aseptic isolators, and compounding aseptic containment isolators.

(38) Product--A commercially manufactured sterile drug or nutrient that has been evaluated for safety and efficacy by the U.S. Food and Drug Administration (FDA). Products are accompanied by full prescribing information, which is commonly known as the FDA-approved manufacturer's labeling or product package insert.

(39) Positive Control--A quality assurance sample prepared to test positive for microbial growth.

(40) Quality assurance--The set of activities used to ensure that the process used in the preparation of sterile drug preparations lead to preparations that meet predetermined standards of quality.
(41) Quality control--The set of testing activities used to determine that the ingredients, components (e.g., containers), and final compounded sterile preparations prepared meet predetermined requirements with respect to identity, purity, non-pyrogenicity, and sterility.

(42) Reasonable quantity--An amount of a compounded drug that:

(A) does not exceed the amount a practitioner anticipates may be used in the practitioner's office or facility before the beyond use date of the drug;

(B) is reasonable considering the intended use of the compounded drug and the nature of the practitioner's practice; and

(C) for any practitioner and all practitioners as a whole, is not greater than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality, and purity of the compounded drug that are consistent with United States Pharmacopeia guidelines and accreditation practices.

(43) Segregated Compounding Area--A designated space, either a demarcated area or room, that is restricted to preparing low-risk level compounded sterile preparations with 12-hour or less beyond-use date. Such area shall contain a device that provides unidirectional airflow of ISO Class 5 air quality for preparation of compounded sterile preparations and shall be void of activities and materials that are extraneous to sterile compounding.

(44) Single-dose container--A single-unit container for articles or preparations intended for parenteral administration only. It is intended for a single use. A single-dose container is labeled as such. Examples of single-dose containers include pre-filled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when so labeled.

(45) SOPs--Standard operating procedures.

(46) Sterilizing Grade Membranes--Membranes that are documented to retain 100% of a culture of 107 microorganisms of a strain of Brevundimonas (Pseudomonas) diminuta per square centimeter of membrane surface under a pressure of not less than 30 psi (2.0 bar). Such filter membranes are nominally at 0.22-micrometer or 0.2-micrometer nominal pore size, depending on the manufacturer's practice.

(47) Sterilization by Filtration--Passage of a fluid or solution through a sterilizing grade membrane to produce a sterile effluent.

(48) Terminal Sterilization--The application of a lethal process, e.g., steam under pressure or autoclaving, to sealed final preparation containers for the purpose of achieving a predetermined sterility assurance level of usually less than 10-6 or a probability of less than one in one million of a non-sterile unit.

(49) Unidirectional Flow--An airflow moving in a single direction in a robust and uniform manner and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area.

(c) Personnel.

(1) Pharmacist-in-charge.

(A) General. The pharmacy shall have a pharmacist-in-charge in compliance with the specific license classification of the pharmacy.

(B) Responsibilities. In addition to the responsibilities for the specific class of pharmacy, the pharmacist-in-charge shall have the responsibility for, at a minimum, the following concerning the compounding of sterile preparations:

(i) developing a system to ensure that all pharmacy personnel responsible for compounding and/or supervising the compounding of sterile preparations within the pharmacy receive appropriate education and training and competency evaluation;

(ii) determining that all personnel involved in compounding sterile preparations obtain continuing education appropriate for the type of compounding done by the personnel;

(iii) supervising a system to ensure appropriate procurement of drugs and devices and storage of all pharmaceutical materials including pharmaceuticals, components used in the compounding of sterile preparations, and drug delivery devices;

(iv) ensuring that the equipment used in compounding is properly maintained;

(v) developing a system for the disposal and distribution of drugs from the pharmacy;

(vi) developing a system for bulk compounding or batch preparation of drugs;

(vii) developing a system for the compounding, sterility assurance, quality assurance, and quality control of sterile preparations; and

(viii) if applicable, ensuring that the pharmacy has a system to dispose of hazardous waste in a manner so as not to endanger the public health.

(2) Pharmacists.

(A) General.

(i) A pharmacist is responsible for ensuring that compounded sterile preparations are accurately identified, measured, diluted, and mixed and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed.

(ii) A pharmacist shall inspect and approve all components, drug preparation containers, closures, labeling, and any other materials involved in the compounding process.

(iii) A pharmacist shall review all compounding records for accuracy and conduct periodic in-process checks as defined in the pharmacy’s policy and procedures.
(iv) A pharmacist shall review all compounding records for accuracy and conduct a final check.

(v) A pharmacist is responsible for ensuring the proper maintenance, cleanliness, and use of all equipment used in the compounding process.

(vi) A pharmacist shall be accessible at all times, 24 hours a day, to respond to patients’ and other health professionals’ questions and needs.

(B) Initial training and continuing education.

(i) All pharmacists who compound sterile preparations or supervise pharmacy technicians and pharmacy technician trainees compounding sterile preparations shall comply with the following:

(I) complete through a single course, a minimum of 20 hours of instruction and experience in the areas listed in paragraph (4)(D) of this subsection. Such training shall be obtained through completion of a recognized course in an accredited college of pharmacy or a course sponsored by an ACPE accredited provider;

(II) complete a structured on-the-job didactic and experiential training program at this pharmacy which provides sufficient hours of instruction and experience in the facility’s sterile compounding processes and procedures. Such training may not be transferred to another pharmacy unless the pharmacies are under common ownership and control and use a common training program; and

(III) possess knowledge about:

(-a-) aseptic processing;

(-b-) quality control and quality assurance as related to environmental, component, and finished preparation release checks and tests;

(-c-) chemical, pharmaceutical, and clinical properties of drugs;

(-d-) container, equipment, and closure system selection; and

(-e-) sterilization techniques.

(ii) The required experiential portion of the training programs specified in this subparagraph must be supervised by an individual who is actively engaged in performing sterile compounding and is qualified and has completed training as specified in this paragraph or paragraph (3) of this subsection.

(iii) In order to renew a license to practice pharmacy, during the previous licensure period, a pharmacist engaged in sterile compounding shall complete a minimum of:

(I) two hours of ACPE-accredited continuing education relating to one or more of the areas listed in paragraph (4)(D) of this subsection if the pharmacist is engaged in compounding low and medium risk sterile preparations; or
(II) four hours of ACPE-accredited continuing education relating to one or more of the areas listed in paragraph (4)(D) of this subsection if the pharmacist is engaged in compounding high risk sterile preparations.

(3) Pharmacy technicians and pharmacy technician trainees.

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

(B) Initial training and continuing education.

(i) Pharmacy technicians and pharmacy technician trainees may compound sterile preparations provided the pharmacy technicians and/or pharmacy technician trainees are supervised by a pharmacist as specified in paragraph (2) of this subsection.

(ii) All pharmacy technicians and pharmacy technician trainees who compound sterile preparations for administration to patients shall:

(I) have initial training obtained either through completion of:

(-a-) a single course, a minimum of 40 hours of instruction and experience in the areas listed in paragraph (4)(D) of this subsection. Such training shall be obtained through completion of a course sponsored by an ACPE accredited provider which provides 40 hours of instruction and experience; or

(-b-) a training program which is accredited by the American Society of Health-System Pharmacists.

(II) and

(-a-) complete a structured on-the-job didactic and experiential training program at this pharmacy which provides sufficient hours of instruction and experience in the facility’s sterile compounding processes and procedures. Such training may not be transferred to another pharmacy unless the pharmacies are under common ownership and control and use a common training program; and

(-b-) possess knowledge about:

(-1-) aseptic processing;

(-2-) quality control and quality assurance as related to environmental, component, and finished preparation release checks and tests;

(-3-) chemical, pharmaceutical, and clinical properties of drugs;

(-4-) container, equipment, and closure system selection; and

(-5-) sterilization techniques.
(iii) Individuals enrolled in training programs accredited by the American Society of Health-System Pharmacists may compound sterile preparations in a licensed pharmacy provided the:

(I) compounding occurs only during times the individual is assigned to a pharmacy as a part of the experiential component of the American Society of Health-System Pharmacists training program;

(II) individual is under the direct supervision of and responsible to a pharmacist who has completed training as specified in paragraph (2) of this subsection; and

(III) supervising pharmacist conducts periodic in-process checks as defined in the pharmacy’s policy and procedures; and

(IV) supervising pharmacist conducts a final check.

(iv) The required experiential portion of the training programs specified in this subparagraph must be supervised by an individual who is actively engaged in performing sterile compounding, is qualified and has completed training as specified in paragraph (2) of this subsection or this paragraph.

(v) In order to renew a registration as a pharmacy technician, during the previous registration period, a pharmacy technician engaged in sterile compounding shall complete a minimum of:

(I) two hours of ACPE accredited continuing education relating to one or more of the areas listed in paragraph (4)(D) of this subsection if the pharmacy technician is engaged in compounding low and medium risk sterile preparations; or

(II) four hours of ACPE accredited continuing education relating to one or more of the areas listed in paragraph (4)(D) of this subsection if pharmacy technician is engaged in compounding high risk sterile preparations.

(4) Evaluation and testing requirements.

(A) All pharmacy personnel preparing sterile preparations shall be trained conscientiously and skillfully by expert personnel through multimedia instructional sources and professional publications in the theoretical principles and practical skills of aseptic manipulations, garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 environmental conditions, and cleaning and disinfection procedures before beginning to prepare compounded sterile preparations.

(B) All pharmacy personnel preparing sterile preparations shall perform didactic review and pass written and media-fill testing of aseptic manipulative skills initially followed by:

(i) every 12 months for low- and medium-risk level compounding; and

(ii) every six months for high-risk level compounding.
(C) Pharmacy personnel who fail written tests or whose media-fill test vials result in gross microbial colonization shall:

(i) be immediately re-instructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies; and

(ii) not be allowed to compound sterile preparations for patient use until passing results are achieved.

(D) The didactic and experiential training shall include instruction, experience, and demonstrated proficiency in the following areas:

(i) aseptic technique;

(ii) critical area contamination factors;

(iii) environmental monitoring;

(iv) structure and engineering controls related to facilities;

(v) equipment and supplies;

(vi) sterile preparation calculations and terminology;

(vii) sterile preparation compounding documentation;

(viii) quality assurance procedures;

(ix) aseptic preparation procedures including proper gowning and gloving technique;

(x) handling of hazardous drugs, if applicable;

(xi) cleaning procedures; and

(xii) general conduct in the clean room.

(E) The aseptic technique of each person compounding or responsible for the direct supervision of personnel compounding sterile preparations shall be observed and evaluated by expert personnel as satisfactory through written and practical tests, and challenge testing, and such evaluation documented. Compounding personnel shall not evaluate their own aseptic technique or results of their own media-fill challenge testing.

(F) Media-fill tests must be conducted at each pharmacy where an individual compounds low or medium risk sterile preparations. If pharmacies are under common ownership and control, the media-fill testing may be conducted at only one of the pharmacies provided each of the pharmacies are operated under equivalent policies and procedures and the testing is conducted under the most challenging or stressful conditions. In addition, each pharmacy must maintain documentation of the media-fill test. No preparation intended for patient use shall be compounded by an individual until the on-site media-fill tests indicate that the individual can competently perform aseptic procedures, except that a pharmacist may temporarily compound
sterile preparations and supervise pharmacy technicians compounding sterile preparations
without media-fill tests provided the pharmacist completes the on-site media-fill tests within
seven days of commencing work at the pharmacy.

(G) Media-fill tests must be conducted at each pharmacy where an individual compounds
high risk sterile preparations. No preparation intended for patient use shall be compounded by
an individual until the on-site media-fill tests indicate that the individual can competently perform
aseptic procedures, except that a pharmacist may temporarily compound sterile preparations
and supervise pharmacy technicians compounding sterile preparations without media-fill tests
provided the pharmacist completes the on-site media-fill tests within seven days of commencing
work at the pharmacy.

(H) Media-fill tests procedures for assessing the preparation of specific types of sterile
preparations shall be representative of the most challenging or stressful conditions encountered
by the pharmacy personnel being evaluated and, if applicable, for sterilizing high-risk level
compounded sterile preparations.

(I) Media-fill challenge tests simulating high-risk level compounding shall be used to verify the
capability of the compounding environment and process to produce a sterile preparation.

(J) Commercially available sterile fluid culture media, such as Soybean-Casein Digest
Medium shall be able to promote exponential colonization of bacteria that are most likely to be
transmitted to compounding sterile preparations from the compounding personnel and
environment. Media-filled vials are generally incubated at 20 to 25 degrees Celsius or at 30 to
35 degrees Celsius for a minimum of 14 days. If two temperatures are used for incubation of
media-filled samples, then these filled containers should be incubated for at least 7 days at each
temperature. Failure is indicated by visible turbidity in the medium on or before 14 days.

(K) The pharmacist-in-charge shall ensure continuing competency of pharmacy personnel
through in-service education, training, and media-fill tests to supplement initial training.
Personnel competency shall be evaluated:

(i) during orientation and training prior to the regular performance of those tasks;

(ii) whenever the quality assurance program yields an unacceptable result;

(iii) whenever unacceptable techniques are observed; and

(iv) at least on an annual basis for low- and medium-risk level compounding, and every six
months for high-risk level compounding.

(L) The pharmacist-in-charge shall ensure that proper hand hygiene and garbing practices of
compounding personnel are evaluated prior to compounding, supervising, or verifying sterile
preparations intended for patient use and whenever an aseptic media fill is performed.

(i) Sampling of compounding personnel glove fingertips shall be performed for all risk level
compounding.
(ii) All compounding personnel shall demonstrate competency in proper hand hygiene and
garbing procedures and in aseptic work practices (e.g., disinfection of component surfaces,
routine disinfection of gloved hands).

(iii) Sterile contact agar plates shall be used to sample the gloved fingertips of compounding
personnel after garbing in order to assess garbing competency and after completing the media-
fill preparation (without applying sterile 70% IPA).

(iv) The visual observation shall be documented and maintained to provide a permanent
record and long-term assessment of personnel competency.

(v) All compounding personnel shall successfully complete an initial competency evaluation
and gloved fingertip/thumb sampling procedure no less than three times before initially being
allowed to compound sterile preparations for patient use. Immediately after the compounding
personnel completes the hand hygiene and garbing procedure (i.e., after donning of sterile
gloves and before any disinfecting with sterile 70% IPA), the evaluator will collect a gloved
fingertip and thumb sample from both hands of the compounding personnel onto agar plates or
media test paddles by having the individual lightly touching each fingertip onto the agar. The
test plates or test paddles will be incubated for the appropriate incubation period and at the
appropriate temperature. Results of the initial gloved fingertip evaluations shall indicate zero
colony-forming units (0 CFU) growth on the agar plates or media test paddles, or the test shall
be considered a failure. In the event of a failed gloved fingertip test, the evaluation shall be
repeated until the individual can successfully don sterile gloves and pass the gloved fingertip
evaluation, defined as zero CFUs growth. No preparation intended for patient use shall be
compounded by an individual until the results of the initial gloved fingertip evaluation indicate
that the individual can competently perform aseptic procedures except that a pharmacist may
temporarily supervise pharmacy technicians compounding sterile preparations while waiting for
the results of the evaluation for no more than three days.

(vi) Re-evaluation of all compounding personnel shall occur at least annually for
compounding personnel who compound low and medium risk level preparations and every six
months for compounding personnel who compound high risk level preparations. Results of
gloved fingertip tests conducted immediately after compounding personnel complete a
compounding procedure shall indicate no more than 3 CFUs growth, or the test shall be
considered a failure, in which case, the evaluation shall be repeated until an acceptable test can
be achieved (i.e., the results indicated no more than 3 CFUs growth).

(M) The pharmacist-in-charge shall ensure surface sampling shall be conducted in all ISO
classified areas on a periodic basis. Sampling shall be accomplished using contact plates at the
conclusion of compounding. The sample area shall be gently touched with the agar surface by
rolling the plate across the surface to be sampled.

(5) Documentation of Training. The pharmacy shall maintain a record of the training and
continuing education on each person who compounds sterile preparations. The record shall
contain, at a minimum, a written record of initial and in-service training, education, and the
results of written and practical testing and media-fill testing of pharmacy personnel. The record
shall be maintained and available for inspection by the board and contain the following
information:

(A) name of the person receiving the training or completing the testing or media-fill tests;
(B) date(s) of the training, testing, or media-fill challenge testing;

(C) general description of the topics covered in the training or testing or of the process validated;

(D) name of the person supervising the training, testing, or media-fill challenge testing; and

(E) signature or initials of the person receiving the training or completing the testing or media-fill challenge testing and the pharmacist-in-charge or other pharmacist employed by the pharmacy and designated by the pharmacist-in-charge as responsible for training, testing, or media-fill challenge testing of personnel.

(d) Operational Standards.

(1) General Requirements.

(A) Sterile preparations may be compounded:

(i) upon presentation of a practitioner's prescription drug or medication order based on a valid pharmacist/patient/prescriber relationship;

(ii) in anticipation of future prescription drug or medication orders based on routine, regularly observed prescribing patterns; or

(iii) in reasonable quantities for office use by a practitioner and for use by a veterinarian.

(B) Sterile compounding in anticipation of future prescription drug or medication orders must be based upon a history of receiving valid prescriptions issued within an established pharmacist/patient/prescriber relationship, provided that in the pharmacist's professional judgment the quantity prepared is stable for the anticipated shelf time.

(i) The pharmacist's professional judgment shall be based on the criteria used to determine a beyond-use date outlined in paragraph (6)(G) of this subsection.

(ii) Documentation of the criteria used to determine the stability for the anticipated shelf time must be maintained and be available for inspection.

(iii) Any preparation compounded in anticipation of future prescription drug or medication orders shall be labeled. Such label shall contain:

(I) name and strength of the compounded preparation or list of the active ingredients and strengths;

(II) facility's lot number;

(III) beyond-use date as determined by the pharmacist using appropriate documented criteria as outlined in paragraph (6)(G) of this subsection;

(IV) quantity or amount in the container;
(V) appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and

(VI) device-specific instructions, where appropriate.

(C) Commercially available products may be compounded for dispensing to individual patients or for office use provided the following conditions are met:

(i) the commercial product is not reasonably available from normal distribution channels in a timely manner to meet individual patient's needs;

(ii) the pharmacy maintains documentation that the product is not reasonably available due to a drug shortage or unavailability from the manufacturer; and

(iii) the prescribing practitioner has requested that the drug be compounded as described in subparagraph (D) of this paragraph.

(D) A pharmacy may not compound preparations that are essentially copies of commercially available products (e.g., the preparation is dispensed in a strength that is only slightly different from a commercially available product) unless the prescribing practitioner specifically orders the strength or dosage form and specifies why the individual patient needs the particular strength or dosage form of the preparation or why the preparation for office use is needed in the particular strength or dosage form of the preparation. The prescribing practitioner shall provide documentation of a patient specific medical need and the preparation produces a clinically significant therapeutic response (e.g., the physician requests an alternate preparation due to hypersensitivity to excipients or preservative in the FDA-approved product, or the physician requests an effective alternate dosage form) or if the drug product is not commercially available. The unavailability of such drug product must be documented prior to compounding. The methodology for documenting unavailability includes maintaining a copy of the wholesaler’s notification showing back-ordered, discontinued, or out-of-stock items. This documentation must be available in hard-copy or electronic format for inspection by the board.

(E) A pharmacy may enter into an agreement to compound and dispense prescription/medication orders for another pharmacy provided the pharmacy complies with the provisions of §291.125 of this title (relating to Centralized Prescription Dispensing).

(F) Compounding pharmacies/pharmacists may advertise and promote the fact that they provide sterile prescription compounding services, which may include specific drug preparations and classes of drugs.

(G) A pharmacy may not compound veterinary preparations for use in food producing animals except in accordance with federal guidelines.

(H) Compounded sterile preparations, including hazardous drugs and radiopharmaceuticals, shall be prepared only under conditions that protect the pharmacy personnel in the preparation and storage areas.
(2) Microbial Contamination Risk Levels. Risk Levels for sterile compounded preparations shall be as outlined in Chapter 797, Pharmacy Compounding--Sterile Preparations of the USP/NF and as listed in this paragraph.

(A) Low-risk level compounded sterile preparations.

(i) Low-Risk conditions. Low-risk level compounded sterile preparations are those compounded under all of the following conditions.

(I) The compounded sterile preparations are compounded with aseptic manipulations entirely within ISO Class 5 or better air quality using only sterile ingredients, products, components, and devices.

(II) The compounding involves only transfer, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile products and not more than two entries into any one sterile container or package (e.g., bag, vial) of sterile product or administration container/device to prepare the compounded sterile preparation.

(III) Manipulations are limited to aseptically opening ampuls, penetrating disinfected stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and containers for storage and dispensing.

(IV) For a low-risk preparation, in the absence of passing a sterility test the storage periods cannot exceed the following periods: before administration the compounded sterile preparation is stored properly and are exposed for not more than 48 hours at controlled room temperature, for not more than 14 days if stored at a cold temperature, and for 45 days if stored in a frozen state between minus 25 degrees Celsius and minus 10 degrees Celsius. For delayed activation device systems, the storage period begins when the device is activated.

(ii) Examples of Low-Risk Compounding. Examples of low-risk compounding include the following.

(I) Single volume transfers of sterile dosage forms from ampuls, bottles, bags, and vials using sterile syringes with sterile needles, other administration devices, and other sterile containers. The solution content of ampules shall be passed through a sterile filter to remove any particles.

(II) Simple aseptic measuring and transferring with not more than three packages of manufactured sterile products, including an infusion or diluent solution to compound drug admixtures and nutritional solutions.

(B) Low-Risk Level compounded sterile preparations with 12-hour or less beyond-use date. Low-risk level compounded sterile preparations are those compounded pursuant to a physician's order for a specific patient under all of the following conditions.

(i) The compounded sterile preparations are compounded in compounding aseptic isolator or compounding aseptic containment isolator that does not meet the requirements described in paragraph (7)(C) or (D) of this subsection (relating to Primary Engineering Control Device) or
the compounded sterile preparations are compounded in laminar airflow workbench or a biological safety cabinet that cannot be located within the buffer area.

(ii) The primary engineering control device shall be certified and maintain ISO Class 5 for exposure of critical sites and shall be located in a segregated compounding area restricted to sterile compounding activities that minimizes the risk of contamination of the compounded sterile preparation.

(iii) The segregated compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or that is adjacent to construction sites, warehouses, or food preparation.

(iv) For a low-risk preparation compounded as described in clauses (i) - (iii) of this subparagraph, administration of such compounded sterile preparations must commence within 12 hours of preparation or as recommended in the manufacturers' package insert, whichever is less. However, the administration of sterile radiopharmaceuticals, with documented testing of chemical stability, may be administered beyond 12 hours of preparation.

(C) Medium-risk level compounded sterile preparations.

(i) Medium-Risk Conditions. Medium-risk level compounded sterile preparations, are those compounded aseptically under low-risk conditions and one or more of the following conditions exists.

(I) Multiple individual or small doses of sterile products are combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions.

(II) The compounding process includes complex aseptic manipulations other than the single-volume transfer.

(III) The compounding process requires unusually long duration, such as that required to complete the dissolution or homogenous mixing (e.g., reconstitution of intravenous immunoglobulin or other intravenous protein products).

(IV) The compounded sterile preparations do not contain broad spectrum bacteriostatic substances and they are administered over several days (e.g., an externally worn infusion device).

(V) For a medium-risk preparation, in the absence of passing a sterility test the storage periods cannot exceed the following time periods: before administration, the compounded sterile preparations are properly stored and are exposed for not more than 30 hours at controlled room temperature, for not more than 9 days at a cold temperature, and for 45 days in solid frozen state between minus 25 degrees Celsius and minus 10 degrees Celsius.

(ii) Examples of medium-risk compounding. Examples of medium-risk compounding include the following.

(I) Compounding of total parenteral nutrition fluids using a manual or automated device during which there are multiple injections, detachments, and attachments of nutrient source
products to the device or machine to deliver all nutritional components to a final sterile container.

(II) Filling of reservoirs of injection and infusion devices with more than three sterile drug products and evacuations of air from those reservoirs before the filled device is dispensed.

(III) Filling of reservoirs of injection and infusion devices with volumes of sterile drug solutions that will be administered over several days at ambient temperatures between 25 and 40 degrees Celsius (77 and 104 degrees Fahrenheit).

(IV) Transfer of volumes from multiple ampuls or vials into a single, final sterile container or product.

(D) High-risk level compounded sterile preparations.

(i) High-risk Conditions. High-risk level compounded sterile preparations are those compounded under any of the following conditions.

(I) Non-sterile ingredients, including manufactured products not intended for sterile routes of administration (e.g., oral) are incorporated or a non-sterile device is employed before terminal sterilization.

(II) Any of the following are exposed to air quality worse than ISO Class 5 for more than 1 hour:

(-a-) sterile contents of commercially manufactured products;

(-b-) CSPs that lack effective antimicrobial preservatives; and

(-c-) sterile surfaces of devices and containers for the preparation, transfer, sterilization, and packaging of CSPs.

(III) Compounding personnel are improperly garbed and gloved.

(IV) Non-sterile water-containing preparations are exposed no more than 6 hours before being sterilized.

(V) It is assumed, and not verified by examination of labeling and documentation from suppliers or by direct determination, that the chemical purity and content strength of ingredients meet their original or compendial specifications in unopened or in opened packages of bulk ingredients.

(VI) For a sterilized high-risk level preparation, in the absence of passing a sterility test, the storage periods cannot exceed the following time periods: before administration, the compounded sterile preparations are properly stored and are exposed for not more than 24 hours at controlled room temperature, for not more than 3 days at a cold temperature, and for 45 days in solid frozen state between minus 25 degrees Celsius and minus 10 degrees Celsius.

(VII) All non-sterile measuring, mixing, and purifying devices are rinsed thoroughly with sterile, pyrogen-free water, and then thoroughly drained or dried immediately before use for
high-risk compounding. All high-risk compounded sterile solutions subjected to terminal
sterilization are prefiltered by passing through a filter with a nominal pore size not larger than
1.2 micron preceding or during filling into their final containers to remove particulate matter.
Sterilization of high-risk level compounded sterile preparations by filtration shall be performed
with a sterile 0.2 micrometer or 0.22 micrometer nominal pore size filter entirely within an ISO
Class 5 or superior air quality environment.

(ii) Examples of high-risk compounding. Examples of high-risk compounding include the
following.

(I) Dissolving non-sterile bulk drug powders to make solutions, which will be terminally
sterilized.

(II) Exposing the sterile ingredients and components used to prepare and package
compounded sterile preparations to room air quality worse than ISO Class 5 for more than one
hour.

(III) Measuring and mixing sterile ingredients in non-sterile devices before sterilization is
performed.

(IV) Assuming, without appropriate evidence or direct determination, that packages of bulk
ingredients contain at least 95% by weight of their active chemical moiety and have not been
contaminated or adulterated between uses.

(3) Immediate Use Compounded Sterile Preparations. For the purpose of emergency or
immediate patient care, such situations may include cardiopulmonary resuscitation, emergency
room treatment, preparation of diagnostic agents, or critical therapy where the preparation of the
compounded sterile preparation under low-risk level conditions would subject the patient to
additional risk due to delays in therapy. Compounded sterile preparations are exempted from
the requirements described in this paragraph for low-risk level compounded sterile preparations
when all of the following criteria are met.

(A) Only simple aseptic measuring and transfer manipulations are performed with not more
than three sterile non-hazardous commercial drug and diagnostic radiopharmaceutical drug
products, including an infusion or diluent solution, from the manufacturers' original containers
and not more than two entries into any one container or package of sterile infusion solution or
administration container/device.

(B) Unless required for the preparation, the compounding procedure occurs continuously
without delays or interruptions and does not exceed 1 hour.

(C) During preparation, aseptic technique is followed and, if not immediately administered,
the finished compounded sterile preparation is under continuous supervision to minimize the
potential for contact with nonsterile surfaces, introduction of particulate matter of biological
fluids, mix-ups with other compounded sterile preparations, and direct contact of outside
surfaces.

(D) Administration begins not later than one hour following the completion of preparing the
compounded sterile preparation.
(E) When the compounded sterile preparations is not administered by the person who prepared it, or its administration is not witnessed by the person who prepared it, the compounded sterile preparation shall bear a label listing patient identification information such as name and identification number(s), the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact 1-hour beyond-use time and date.

(F) If administration has not begun within one hour following the completion of preparing the compounded sterile preparation, the compounded sterile preparation is promptly and safely discarded. Immediate use compounded sterile preparations shall not be stored for later use.

(G) Hazardous drugs shall not be prepared as immediate use compounded sterile preparations.

(4) Single-dose and multiple dose containers.

(A) Opened or needle punctured single-dose containers, such as bags bottles, syringes, and vials of sterile products shall be used within one hour if opened in worse than ISO Class 5 air quality. Any remaining contents must be discarded.

(B) Single-dose containers, including single-dose large volume parenteral solutions and single-dose vials, exposed to ISO Class 5 or cleaner air may be used up to six hours after initial needle puncture.

(C) Opened single-dose fusion sealed containers shall not be stored for any time period.

(D) Multiple-dose containers may be used up to 28 days after initial needle puncture unless otherwise specified by the manufacturer.

(5) Library. In addition to the library requirements of the pharmacy's specific license classification, a pharmacy shall maintain current or updated copies in hard-copy or electronic format of each of the following:

(A) a reference text on injectable drug preparations, such as Handbook on Injectable Drug Products;

(B) a specialty reference text appropriate for the scope of pharmacy services provided by the pharmacy, e.g., if the pharmacy prepares hazardous drugs, a reference text on the preparation of hazardous drugs; and

(C) the United States Pharmacopeia/National Formulary containing USP Chapter 71, Sterility Tests, USP Chapter 85, Bacterial Endotoxins Test, Pharmaceutical Compounding--Nonsterile Preparations, USP Chapter 795, USP Chapter 797, Pharmaceutical Compounding--Sterile Preparations, and USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding; and

(D) any additional USP/NF chapters applicable to the practice of the pharmacy (e.g., USP Chapter 800, Hazardous Drugs--Handling in Healthcare Settings, USP Chapter 823, Positron Emission Tomography Drugs for Compounding, Investigational, and Research Uses).
(6) Environment. Compounding facilities shall be physically designed and environmentally controlled to minimize airborne contamination from contacting critical sites.

(A) Low and Medium Risk Preparations. A pharmacy that prepares low- and medium-risk preparations shall have a clean room for the compounding of sterile preparations that is constructed to minimize the opportunities for particulate and microbial contamination. The clean room shall:

(i) be clean, well lit, and of sufficient size to support sterile compounding activities;

(ii) be maintained at a temperature of 20 degrees Celsius or cooler and at a humidity below 60%;

(iii) be used only for the compounding of sterile preparations;

(iv) be designed such that hand sanitizing and gOWning occurs outside the buffer area but allows hands-free access by compounding personnel to the buffer area;

(v) have non-porous and washable floors or floor covering to enable regular disinfection;

(vi) be ventilated in a manner to avoid disruption from the HVAC system and room cross-drafts;

(vii) have walls, ceilings, floors, fixtures, shelving, counters, and cabinets that are smooth, impervious, free from cracks and crevices (e.g., coved), non-shedding and resistant to damage by disinfectant agents;

(viii) have junctures of ceilings to walls coved or caulked to avoid cracks and crevices;

(ix) have drugs and supplies stored on shelving areas above the floor to permit adequate floor cleaning;

(x) contain only the appropriate compounding supplies and not be used for bulk storage for supplies and materials. Objects that shed particles shall not be brought into the clean room. A Class B pharmacy may use low-linting absorbent materials in the primary engineering control device;

(xi) contain an ante-area that contains a sink with hot and cold running water that enables hands-free use with a closed system of soap dispensing to minimize the risk of extrinsic contamination. A Class B pharmacy may have a sink with hot and cold running water that enables hands-free use with a closed system of soap dispensing immediately outside the ante-area if antiseptic hand cleansing is performed using a waterless alcohol-based surgical hand scrub with persistent activity following manufacturers’ recommendations once inside the ante-area; and

(xii) contain a buffer area. The following is applicable for the buffer area.

(I) There shall be some demarcation designation that delineates the ante-area from the buffer area. The demarcation shall be such that it does not create conditions that could adversely affect the cleanliness of the area.
(II) The buffer area shall be segregated from surrounding, unclassified spaces to reduce the risk of contaminants being blown, dragged, or otherwise introduced into the filtered unidirectional airflow environment, and this segregation should be continuously monitored.

(III) A buffer area that is not physically separated from the ante-area shall employ the principle of displacement airflow as defined in Chapter 797, Pharmaceutical Compounding—Sterile Preparations, of the USP/NF, with limited access to personnel.

(IV) The buffer area shall not contain sources of water (i.e., sinks) or floor drains other than distilled or sterile water introduced for facilitating the use of heat block wells for radiopharmaceuticals.

(B) High-risk Preparations.

(i) In addition to the requirements in subparagraph (A) of this paragraph, when high-risk preparations are compounded, the primary engineering control shall be located in a buffer area that provides a physical separation, through the use of walls, doors and pass-throughs and has a minimum differential positive pressure of 0.02 to 0.05 inches water column.

(ii) Presterilization procedures for high-risk level compounded sterile preparations, such as weighing and mixing, shall be completed in no worse than an ISO Class 8 environment.

(C) Automated compounding device.

(i) General. If automated compounding devices are used, the pharmacy shall have a method to calibrate and verify the accuracy of automated compounding devices used in aseptic processing and document the calibration and verification on a daily basis, based on the manufacturer's recommendations, and review the results at least weekly.

(ii) Loading bulk drugs into automated compounding devices.

(I) Automated compounding device may be loaded with bulk drugs only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist.

(II) The label of an automated compounding device container shall indicate the brand name and strength of the drug; or if no brand name, then the generic name, strength, and name of the manufacturer or distributor.

(III) Records of loading bulk drugs into an automated compounding device shall be maintained to show:

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

(-b-) manufacturer or distributor;

(-c-) manufacturer’s lot number;

(-d-) manufacturer’s expiration date;
(-e-) quantity added to the automated compounding device;

(-f-) date of loading;

(-g-) name, initials, or electronic signature of the person loading the automated compounding device; and

(-h-) name, initials, or electronic signature of the responsible pharmacist.

(IV) The automated compounding device shall not be used until a pharmacist verifies that the system is properly loaded and affixes his or her signature or electronic signature to the record specified in subclause (III) of this clause.

(D) Hazardous drugs. If the preparation is hazardous, the following is also applicable.

(i) Hazardous drugs shall be prepared only under conditions that protect personnel during preparation and storage.

(ii) Hazardous drugs shall be stored separately from other inventory in a manner to prevent contamination and personnel exposure.

(iii) All personnel involved in the compounding of hazardous drugs shall wear appropriate protective apparel, such as gowns, face masks, eye protection, hair covers, shoe covers or dedicated shoes, and appropriate gloving at all times when handling hazardous drugs, including receiving, distribution, stocking, inventorying, preparation, for administration and disposal.

(iv) Appropriate safety and containment techniques for compounding hazardous drugs shall be used in conjunction with aseptic techniques required for preparing sterile preparations.

(v) Disposal of hazardous waste shall comply with all applicable local, state, and federal requirements.

(vi) Prepared doses of hazardous drugs must be dispensed, labeled with proper precautions inside and outside, and distributed in a manner to minimize patient contact with hazardous agents.

(E) Blood-labeling procedures. When compounding activities require the manipulation of a patient's blood-derived material (e.g., radiolabeling a patient's or donor's white blood cells), the manipulations shall be performed in a ISO Class 5 biological safety cabinet located in a buffer area and shall be clearly separated from routine material-handling procedures and equipment used in preparation activities to avoid any cross-contamination. The preparations shall not require sterilization.

(F) Cleaning and disinfecting the sterile compounding areas. The following cleaning and disinfecting practices and frequencies apply to direct and contiguous compounding areas, which include ISO Class 5 compounding areas for exposure of critical sites as well as buffer areas, ante-areas, and segregated compounding areas.
(i) The pharmacist-in-charge is responsible for developing written procedures for cleaning and disinfecting the direct and contiguous compounding areas and assuring the procedures are followed.

(ii) These procedures shall be conducted at the beginning of each work shift, before each batch preparation is started, when there are spills, and when surface contamination is known or suspected resulting from procedural breaches, and every 30 minutes during continuous compounding of individual compounded sterile preparations, unless a particular compounding procedure requires more than 30 minutes to complete, in which case, the direct compounding area is to be cleaned immediately after the compounding activity is completed.

(iii) Before compounding is performed, all items shall be removed from the direct and contiguous compounding areas and all surfaces are cleaned by removing loose material and residue from spills, followed by an application of a residue-free disinfecting agent (e.g., IPA), which is allowed to dry before compounding begins. In a Class B pharmacy, objects used in preparing sterile radiopharmaceuticals (e.g., dose calibrator) which cannot be reasonably removed from the compounding area shall be sterilized with an application of a residue-free disinfection agent.

(iv) Work surfaces in the buffer areas and ante-areas, as well as segregated compounding areas, shall be cleaned and disinfected at least daily. Dust and debris shall be removed when necessary from storage sites for compounding ingredients and supplies using a method that does not degrade the ISO Class 7 or 8 air quality.

(v) Floors in the buffer area, ante-area, and segregated compounding area are cleaned by mopping with a cleaning and disinfecting agent at least once daily when no aseptic operations are in progress. Mopping shall be performed by trained personnel using approved agents and procedures described in the written SOPs. It is incumbent on compounding personnel to ensure that such cleaning is performed properly.

(vi) In the buffer area, ante-area, and segregated compounding area, walls, ceilings, and shelving shall be cleaned and disinfected monthly. Cleaning and disinfecting agents shall be used with careful consideration of compatibilities, effectiveness, and inappropriate or toxic residues.

(vii) All cleaning materials, such as wipers, sponges, and mops, shall be non-shedding, and dedicated to use in the buffer area, ante-area, and segregated compounding areas and shall not be removed from these areas except for disposal. Floor mops may be used in both the buffer area and ante-area, but only in that order. If cleaning materials are reused, procedures shall be developed that ensure that the effectiveness of the cleaning device is maintained and that repeated use does not add to the bio-burden of the area being cleaned.

(viii) Supplies and equipment removed from shipping cartons must be wiped with a disinfecting agent, such as sterile IPA. After the disinfectant is sprayed or wiped on a surface to be disinfected, the disinfectant shall be allowed to dry, during which time the item shall not be used for compounding purposes. However, if sterile supplies are received in sealed pouches, the pouches may be removed as the supplies are introduced into the ISO Class 5 area without the need to disinfect the individual sterile supply items. No shipping or other external cartons may be taken into the buffer area or segregated compounding area.
(ix) Storage shelving emptied of all supplies, walls, and ceilings are cleaned and disinfected at planned intervals, monthly, if not more frequently.

(x) Cleaning must be done by personnel trained in appropriate cleaning techniques.

(xi) Proper documentation and frequency of cleaning must be maintained and shall contain the following:

(I) date and time of cleaning;

(II) type of cleaning performed; and

(III) name of individual who performed the cleaning.

(G) Security requirements. The pharmacist-in-charge may authorize personnel to gain access to that area of the pharmacy containing dispensed sterile preparations, in the absence of the pharmacist, for the purpose of retrieving dispensed prescriptions to deliver to patients. If the pharmacy allows such after-hours access, the area containing the dispensed sterile preparations shall be an enclosed and lockable area separate from the area containing undispensed prescription drugs. A list of the authorized personnel having such access shall be in the pharmacy’s policy and procedure manual.

(H) Storage requirements and beyond-use dating.

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

(ii) Beyond-use dating.

(I) Beyond-use dates for compounded sterile preparations shall be assigned based on professional experience, which shall include careful interpretation of appropriate information sources for the same or similar formulations.

(II) Beyond-use dates for compounded sterile preparations that are prepared strictly in accordance with manufacturers' product labeling must be those specified in that labeling, or from appropriate literature sources or direct testing.

(III) When assigning a beyond-use date, compounding personnel shall consult and apply drug-specific and general stability documentation and literature where available, and they should consider the nature of the drug and its degradation mechanism, the container in which it is packaged, the expected storage conditions, and the intended duration of therapy.

(IV) The sterility and storage and stability beyond-use date for attached and activated container pairs of drug products for intravascular administration shall be applied as indicated by the manufacturer.

(7) Primary engineering control device. The pharmacy shall prepare sterile preparations in a primary engineering control device (PEC), such as a laminar air flow hood, biological safety cabinet, compounding aseptic isolator (CAI), or compounding aseptic containment isolator.
(CACI) which is capable of maintaining at least ISO Class 5 conditions for 0.5 micrometer particles while compounding sterile preparations.

(A) Laminar air flow hood. If the pharmacy is using a laminar air flow hood as its PEC, the laminar air flow hood shall:

(i) be located in the buffer area and placed in the buffer area in a manner as to avoid conditions that could adversely affect its operation such as strong air currents from opened doors, personnel traffic, or air streams from the heating, ventilating and air condition system;

(ii) be certified by a qualified independent contractor according to the appropriate Controlled Environment Testing Association (CETA) standard (CAG-003-2006) for operational efficiency at least every six months and whenever the device or room is relocated or altered or major service to the facility is performed;

(iii) have pre-filters inspected periodically and replaced as needed, in accordance with written policies and procedures and the manufacturer’s specification, and the inspection and/or replacement date documented; and

(iv) be located in a buffer area that has a minimum differential positive pressure of 0.02 to 0.05 inches water column. A buffer area that is not physically separated from the ante-area shall employ the principle of displacement airflow as defined in Chapter 797, Pharmaceutical Compounding:—Sterile Preparations, of the USP/NF, with limited access to personnel.

(B) Biological safety cabinet.

(i) If the pharmacy is using a biological safety cabinet as its PEC for the preparation of hazardous sterile compounded preparations, the biological safety cabinet shall be a Class II or III vertical flow biological safety cabinet located in an ISO Class 7 area that is physically separated from other preparation areas. The area for preparation of sterile chemotherapeutic preparations shall:

(I) have not less than 0.01 inches water column negative pressure to the adjacent positive pressure ISO Class 7 or better ante-area; and

(II) have a pressure indicator that can be readily monitored for correct room pressurization.

(ii) Pharmacies that prepare a low volume of hazardous drugs, are not required to comply with the provisions of clause (i) of this subparagraph if the pharmacy uses a device that provides two tiers of containment (e.g., closed-system vial transfer device within a BSC).

(iii) If the pharmacy is using a biological safety cabinet as its PEC for the preparation of non-hazardous sterile compounded preparations, the biological safety cabinet shall:

(I) be located in the buffer area and placed in the buffer area in a manner as to avoid conditions that could adversely affect its operation such as strong air currents from opened doors, personnel traffic, or air streams from the heating, ventilating and air condition system;

(II) be certified by a qualified independent contractor according to the International Organization of Standardization (ISO) Classification of Particulate Matter in Room Air (ISO
14644-1) for operational efficiency at least every six months and whenever the device or room is
relocated or altered or major service to the facility is performed, in accordance with the
manufacturer's specifications and test procedures specified in the Institute of Environmental
Sciences and Technology (IEST) document IEST-RP-CC002.3;

(III) have pre-filters inspected periodically and replaced as needed, in accordance with
written policies and procedures and the manufacturer's specification, and the inspection and/or
replacement date documented; and

(IV) be located in a buffer area that has a minimum differential positive pressure of 0.02 to
0.05 inches water column.

(C) Compounding aseptic isolator.

(i) If the pharmacy is using a compounding aseptic isolator (CAI) as its PEC, the CAI shall
provide unidirectional airflow within the main processing and antechambers, and be placed in an
ISO Class 7 buffer area unless the isolator meets all of the following conditions:

(I) The isolator must provide isolation from the room and maintain ISO Class 5 during
dynamic operating conditions including transferring ingredients, components, and devices into
and out of the isolator and during preparation of compounded sterile preparations.

(II) Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure
site must maintain ISO Class 5 levels during compounding operations.

(III) The CAI must be validated according to CETA CAG-002-2006 standards.

(IV) The pharmacy shall maintain documentation from the manufacturer that the isolator
meets this standard when located in worse than ISO Class 7 environments.

(ii) If the isolator meets the requirements in clause (i) of this subparagraph, the CAI may be
placed in a non-ISO classified area of the pharmacy; however, the area shall be segregated
from other areas of the pharmacy and shall:

(I) be clean, well lit, and of sufficient size;

(II) be used only for the compounding of low- and medium-risk, non-hazardous sterile
preparations;

(III) be located in an area of the pharmacy with non-porous and washable floors or floor
covering to enable regular disinfection; and

(IV) be an area in which the CAI is placed in a manner as to avoid conditions that could
adversely affect its operation.

(iii) In addition to the requirements specified in clauses (i) and (ii) of this subparagraph, if the
CAI is used in the compounding of high-risk non-hazardous preparations, the CAI shall be
placed in an area or room with at least ISO 8 quality air so that high-risk powders weighed in at
least ISO-8 air quality conditions, compounding utensils for measuring and other compounding
(D) Compounding aseptic containment isolator.

(i) If the pharmacy is using a compounding aseptic containment isolator as its PEC for the preparation of low- and medium-risk hazardous drugs, the CACI shall be located in a separate room away from other areas of the pharmacy and shall:

(I) provide at least 0.01 inches water column negative pressure compared to the other areas of the pharmacy;

(II) provide unidirectional airflow within the main processing and antechambers, and be placed in an ISO Class 7 buffer area, unless the CACI meets all of the following conditions.

(-a-) The isolator must provide isolation from the room and maintain ISO Class 5 during dynamic operating conditions including transferring ingredients, components, and devices into and out of the isolator and during preparation of compounded sterile preparations.

(-b-) Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site must maintain ISO Class 5 levels during compounding operations.

(-c-) The CACI must be validated according to CETA CAG-002-2006 standards.

(-d-) The pharmacy shall maintain documentation from the manufacturer that the isolator meets this standard when located in worse than ISO Class 7 environments.

(ii) If the CACI meets all conditions specified in clause (i) of this subparagraph, the CACI shall not be located in the same room as a CAI, but shall be located in a separate room in the pharmacy, that is not required to maintain ISO classified air. The room in which the CACI is located shall provide a minimum of 0.01 inches water column negative pressure compared with the other areas of the pharmacy and shall meet the following requirements:

(I) be clean, well lit, and of sufficient size;

(II) be maintained at a temperature of 20 degrees Celsius or cooler and a humidity below 60%;

(III) be used only for the compounding of hazardous sterile preparations;

(IV) be located in an area of the pharmacy with walls, ceilings, floors, fixtures, shelving, counters, and cabinets that are smooth, impervious, free from cracks and crevices, non-shedding and resistant to damage by disinfectant agents; and

(V) have non-porous and washable floors or floor covering to enable regular disinfection.

(iii) If the CACI is used in the compounding of high-risk hazardous preparations, the CACI shall be placed in an area or room with at least ISO 8 quality air so that high-risk powders, weighed in at least ISO-8 air quality conditions, are not exposed to lesser air quality prior to the completion of compounding and packaging of the high-risk preparation.
(iv) Pharmacies that prepare a low volume of hazardous drugs, are not required to comply with the provisions of clauses (i) and (iii) of this subparagraph if the pharmacy uses a device that provides two tiers of containment (e.g., CACI that is located in a non-negative pressure room).

(8) Additional Equipment and Supplies. Pharmacies compounding sterile preparations shall have the following equipment and supplies:

(A) a calibrated system or device (i.e., thermometer) to monitor the temperature to ensure that proper storage requirements are met, if sterile preparations are stored in the refrigerator;

(B) a calibrated system or device to monitor the temperature where bulk chemicals are stored;

(C) a temperature-sensing mechanism suitably placed in the controlled temperature storage space to reflect accurately the true temperature;

(D) if applicable, a Class A prescription balance, or analytical balance and weights. Such balance shall be properly maintained and subject to periodic inspection by the Texas State Board of Pharmacy;

(E) equipment and utensils necessary for the proper compounding of sterile preparations. Such equipment and utensils used in the compounding process shall be:

(i) of appropriate design, appropriate capacity, and be operated within designed operational limits;

(ii) of suitable composition so that surfaces that contact components, in-process material, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug preparation beyond the desired result;

(iii) cleaned and sanitized immediately prior to and after each use; and

(iv) routinely inspected, calibrated (if necessary), or checked to ensure proper performance;

(F) appropriate disposal containers for used needles, syringes, etc., and if applicable, hazardous waste from the preparation of hazardous drugs and/or biohazardous waste;

(G) appropriate packaging or delivery containers to maintain proper storage conditions for sterile preparations;

(H) infusion devices, if applicable; and

(I) all necessary supplies, including:

(i) disposable needles, syringes, and other supplies for aseptic mixing;

(ii) disinfectant cleaning solutions;
(iii) sterile 70% isopropyl alcohol;
(iv) sterile gloves, both for hazardous and non-hazardous drug compounding;
(v) sterile alcohol-based or water-less alcohol based surgical scrub;
(vi) hand washing agents with bactericidal action;
(vii) disposable, lint free towels or wipes;
(viii) appropriate filters and filtration equipment;
(ix) hazardous spill kits, if applicable; and
(x) masks, caps, coveralls or gowns with tight cuffs, shoe covers, and gloves, as applicable.

(9) Labeling.

(A) Prescription drug or medication orders. In addition to the labeling requirements for the pharmacy’s specific license classification, the label dispensed or distributed pursuant to a prescription drug or medication order shall contain the following:

(i) the generic name(s) or the official name(s) of the compounded sterile preparation;

(ii) for outpatient prescription orders other than sterile radiopharmaceuticals, a statement that the compounded sterile preparation has been compounded by the pharmacy. (An auxiliary label may be used on the container to meet this requirement);

(iii) a beyond-use date. The beyond-use date shall be determined as outlined in Chapter 797, Pharmacy Compounding--Sterile Preparations of the USP/NF, and paragraph (7)(G) of this subsection;

(B) Batch. If the sterile preparation is compounded in a batch, the following shall also be included on the batch label:

(i) unique lot number assigned to the batch;

(ii) quantity;

(iii) appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and

(iv) device-specific instructions, where appropriate.

(C) Pharmacy bulk package. The label of a pharmacy bulk package shall:

(i) state prominently "Pharmacy Bulk Package--Not for Direct Infusion;"
(ii) contain or refer to information on proper techniques to help ensure safe use of the
preparation; and

(iii) bear a statement limiting the time frame in which the container may be used once it has
been entered, provided it is held under the labeled storage conditions.

(10) Written drug information for prescription drug orders only. Written information about the
compounded preparation or its major active ingredient(s) shall be given to the patient at the time
of dispensing a prescription drug order. A statement which indicates that the preparation was
compounded by the pharmacy must be included in this written information. If there is no written
information available, the patient shall be advised that the drug has been compounded and how
to contact a pharmacist, and if appropriate, the prescriber, concerning the drug. This paragraph
does not apply to the preparation of radiopharmaceuticals.

(11) Pharmaceutical Care Services. In addition to the pharmaceutical care requirements for the
pharmacy’s specific license classification, the following requirements for sterile preparations
compounded pursuant to prescription drug orders must be met. This paragraph does not apply
to the preparation of radiopharmaceuticals.

(A) Primary provider. There shall be a designated physician primarily responsible for the
patient’s medical care. There shall be a clear understanding between the physician, the patient,
and the pharmacy of the responsibilities of each in the areas of the delivery of care, and the
monitoring of the patient. This shall be documented in the patient medication record (PMR).

(B) Patient training. The pharmacist-in-charge shall develop policies to ensure that the patient
and/or patient’s caregiver receives information regarding drugs and their safe and appropriate
use, including instruction when applicable, regarding:

(i) appropriate disposition of hazardous solutions and ancillary supplies;

(ii) proper disposition of controlled substances in the home;

(iii) self-administration of drugs, where appropriate;

(iv) emergency procedures, including how to contact an appropriate individual in the event of
problems or emergencies related to drug therapy; and

(v) if the patient or patient’s caregiver prepares sterile preparations in the home, the
following additional information shall be provided:

(I) safeguards against microbial contamination, including aseptic techniques for
compounding intravenous admixtures and aseptic techniques for injecting additives to premixed
intravenous solutions;

(II) appropriate storage methods, including storage durations for sterile pharmaceuticals
and expirations of self-mixed solutions;

(III) handling and disposition of premixed and self-mixed intravenous admixtures; and
(IV) proper disposition of intravenous admixture compounding supplies such as syringes, vials, ampules, and intravenous solution containers.

(C) Pharmacist-patient relationship. It is imperative that a pharmacist-patient relationship be established and maintained throughout the patient's course of therapy. This shall be documented in the patient's medication record (PMR).

(D) Patient monitoring. The pharmacist-in-charge shall develop policies to ensure that:

(i) the patient's response to drug therapy is monitored and conveyed to the appropriate health care provider;

(ii) the first dose of any new drug therapy is administered in the presence of an individual qualified to monitor for and respond to adverse drug reactions; and

(iii) reports of adverse events with a compounded sterile preparation are reviewed promptly and thoroughly to correct and prevent future occurrences.

(12) Drugs, components, and materials used in sterile compounding.

(A) Drugs used in sterile compounding shall be a USP/NF grade substances manufactured in an FDA-registered facility.

(B) If USP/NF grade substances are not available shall be of a chemical grade in one of the following categories:

(i) Chemically Pure (CP);

(ii) Analytical Reagent (AR);

(iii) American Chemical Society (ACS); or

(iv) Food Chemical Codex.

(C) If a drug, component or material is not purchased from a FDA-registered facility, the pharmacist shall establish purity and stability by obtaining a Certificate of Analysis from the supplier and the pharmacist shall compare the monograph of drugs in a similar class to the Certificate of Analysis.

(D) All components shall:

(i) be manufactured in an FDA-registered facility; or

(ii) in the professional judgment of the pharmacist, be of high quality and obtained from acceptable and reliable alternative sources; and

(iii) stored in properly labeled containers in a clean, dry area, under proper temperatures.
(E) Drug preparation containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the compounded drug preparation beyond the desired result.

(F) Components, drug preparation containers, and closures shall be rotated so that the oldest stock is used first.

(G) Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded drug preparation.

(H) A pharmacy may not compound a preparation that contains ingredients appearing on a federal Food and Drug Administration list of drug products withdrawn or removed from the market for safety reasons.

(13) Compounding process.

(A) Standard operating procedures (SOPs). All significant procedures performed in the compounding area shall be covered by written SOPs designed to ensure accountability, accuracy, quality, safety, and uniformity in the compounding process. At a minimum, SOPs shall be developed and implemented for:

(i) the facility;
(ii) equipment;
(iii) personnel;
(iv) preparation evaluation;
(v) quality assurance;
(vi) preparation recall;
(vii) packaging; and
(viii) storage of compounded sterile preparations.

(B) USP/NF. Any compounded formulation with an official monograph in the USP/NF shall be compounded, labeled, and packaged in conformity with the USP/NF monograph for the drug.

(C) Personnel Cleansing and Garbing.

(i) Any person with an apparent illness or open lesion, including rashes, sunburn, weeping sores, conjunctivitis, and active respiratory infection, that may adversely affect the safety or quality of a drug preparation being compounded shall be excluded from working in ISO Class 5, ISO Class 7, and ISO Class 8 compounding areas until the condition is remedied.

(ii) Before entering the buffer area, compounding personnel must remove the following:
(I) personal outer garments (e.g., bandanas, coats, hats, jackets, scarves, sweaters, vests);

(II) all cosmetics, because they shed flakes and particles; and

(III) all hand, wrist, and other body jewelry or piercings (e.g., earrings, lip or eyebrow piercings) that can interfere with the effectiveness of personal protective equipment (e.g., fit of gloves and cuffs of sleeves).

(iii) The wearing of artificial nails or extenders is prohibited while working in the sterile compounding environment. Natural nails shall be kept neat and trimmed.

(iv) Personnel shall don personal protective equipment and perform hand hygiene in an order that proceeds from the dirtiest to the cleanest activities as follows:

(I) Activities considered the dirtiest include donning of dedicated shoes or shoe covers, head and facial hair covers (e.g., beard covers in addition to face masks), and face mask/eye shield. Eye shields are optional unless working with irritants like germicidal disinfecting agents or when preparing hazardous drugs.

(II) After donning dedicated shoes or shoe covers, head and facial hair covers, and face masks, personnel shall perform a hand hygiene procedure by removing debris from underneath fingernails using a nail cleaner under running warm water followed by vigorous hand washing. Personnel shall begin washing arms at the hands and continue washing to elbows for at least 30 seconds with either a plain (non-antimicrobial) soap, or antimicrobial soap, and water while in the ante-area. Hands and forearms to the elbows shall be completely dried using lint-free disposable towels, an electronic hands-free hand dryer, or a HEPA filtered hand dryer.

(III) After completion of hand washing, personnel shall don clean non-shedding gowns with sleeves that fit snugly around the wrists and enclosed at the neck.

(IV) Once inside the buffer area or segregated compounding area, and prior to donning sterile powder-free gloves, antiseptic hand cleansing shall be performed using a waterless alcohol-based surgical hand scrub with persistent activity following manufacturers' recommendations. Hands shall be allowed to dry thoroughly before donning sterile gloves.

(V) Sterile gloves that form a continuous barrier with the gown shall be the last item donned before compounding begins. Sterile gloves shall be donned using proper technique to ensure the sterility of the glove is not compromised while donning. The cuff of the sterile glove shall cover the cuff of the gown at the wrist. When preparing hazardous preparations, the compounder shall double glove or shall use single gloves ensuring that the gloves are sterile powder-free chemotherapy-rated gloves. Routine application of sterile 70% IPA shall occur throughout the compounding day and whenever non-sterile surfaces are touched.

(v) When compounding personnel shall temporarily exit the buffer area during a work shift, the exterior gown, if not visibly soiled, may be removed and retained in the ante-area, to be re-donned during that same work shift only. However, shoe covers, hair and facial hair covers, face mask/eye shield, and gloves shall be replaced with new ones before re-entering the buffer area along with performing proper hand hygiene.
(vi) During high-risk compounding activities that precede terminal sterilization, such as weighing and mixing of non-sterile ingredients, compounding personnel shall be garbed and gloved the same as when performing compounding in an ISO Class 5 environment. Properly garbed and gloved compounding personnel who are exposed to air quality that is either known or suspected to be worse than ISO Class 7 shall re-garb personal protective equipment along with washing their hands properly, performing antiseptic hand cleansing with a sterile 70% IPA-based or another suitable sterile alcohol-based surgical hand scrub, and donning sterile gloves upon re-entering the ISO Class 7 buffer area.

(vii) When compounding aseptic isolators or compounding aseptic containment isolators are the source of the ISO Class 5 environment, at the start of each new compounding procedure, a new pair of sterile gloves shall be donned within the CAI or CACI. In addition, the compounding personnel should follow the requirements as specified in this subparagraph, unless the isolator manufacturer can provide written documentation based on validated environmental testing that any components of personal protective equipment or cleansing are not required.

(14) Quality Assurance.

(A) Initial Formula Validation. Prior to routine compounding of a sterile preparation, a pharmacy shall conduct an evaluation that shows that the pharmacy is capable of compounding a preparation that is sterile and that contains the stated amount of active ingredient(s).

(i) Low risk preparations.

(I) Quality assurance practices include, but are not limited to the following:

(-a-) Routine disinfection and air quality testing of the direct compounding environment to minimize microbial surface contamination and maintain ISO Class 5 air quality.

(-b-) Visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments and goggles.

(-c-) Review of all orders and packages of ingredients to ensure that the correct identity and amounts of ingredients were compounded.

(-d-) Visual inspection of compounded sterile preparations, except for sterile radiopharmaceuticals, to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling.

(II) Example of a Media-Fill Test Procedure. This, or an equivalent test, is performed at least annually by each person authorized to compound in a low-risk level under conditions that closely simulate the most challenging or stressful conditions encountered during compounding of low-risk level sterile preparations. Once begun, this test is completed without interruption within an ISO Class 5 air quality environment. Three sets of four 5-milliliter aliquots of sterile Soybean-Casein Digest Medium are transferred with the same sterile 10-milliliter syringe and vented needle combination into separate sealed, empty, sterile 30-milliliter clear vials (i.e., four 5-milliliter aliquots into each of three 30-milliliter vials). Sterile adhesive seals are aseptically affixed to the rubber closures on the three filled vials. The vials are incubated within a range of 20 - 35 degrees Celsius for a minimum of 14 days. Failure is indicated by visible turbidity in the medium on or before 14 days. The media-fill test must include a positive-control sample.
(ii) Medium risk preparations.

(I) Quality assurance procedures for medium-risk level compounded sterile preparations include all those for low-risk level compounded sterile preparations, as well as a more challenging media-fill test passed annually, or more frequently.

(II) Example of a Media-Fill Test Procedure. This, or an equivalent test, is performed at least annually under conditions that closely simulate the most challenging or stressful conditions encountered during compounding. This test is completed without interruption within an ISO Class 5 air quality environment. Six 100-milliliter aliquots of sterile Soybean-Casein Digest Medium are aseptically transferred by gravity through separate tubing sets into separate evacuated sterile containers. The six containers are then arranged as three pairs, and a sterile 10-milliliter syringe and 18-gauge needle combination is used to exchange two 5-milliliter aliquots of medium from one container to the other container in the pair. For example, after a 5-milliliter aliquot from the first container is added to the second container in the pair, the second container is agitated for 10 seconds, then a 5-milliliter aliquot is removed and returned to the first container in the pair. The first container is then agitated for 10 seconds, and the next 5-milliliter aliquot is transferred from it back to the second container in the pair. Following the two 5-milliliter aliquot exchanges in each pair of containers, a 5-milliliter aliquot of medium from each container is aseptically injected into a sealed, empty, sterile 10-milliliter clear vial, using a sterile 10-milliliter syringe and vented needle. Sterile adhesive seals are aseptically affixed to the rubber closures on the three filled vials. The vials are incubated within a range of 20 - 35 degrees Celsius for a minimum of 14 days. Failure is indicated by visible turbidity in the medium on or before 14 days. The media-fill test must include a positive-control sample.

(iii) High risk preparations.

(I) Procedures for high-risk level compounded sterile preparations include all those for low-risk level compounded sterile preparations. In addition, a media-fill test that represents high-risk level compounding is performed twice a year by each person authorized to compound high-risk level compounded sterile preparations.

(II) Example of a Media-Fill Test Procedure Compounded Sterile Preparations Sterilized by Filtration. This test, or an equivalent test, is performed under conditions that closely simulate the most challenging or stressful conditions encountered when compounding high-risk level compounded sterile preparations. Note: Sterility tests for autoclaved compounded sterile preparations are not required unless they are prepared in batches of more than 25 units. This test is completed without interruption in the following sequence:

(-a-) Dissolve 3 grams of non-sterile commercially available Soybean-Casein Digest Medium in 100 milliliters of non-bacteriostatic water to make a 3% non-sterile solution.

(-b-) Draw 25 milliliters of the medium into each of three 30-milliliter sterile syringes. Transfer 5 milliliters from each syringe into separate sterile 10-milliliter vials. These vials are the positive controls to generate exponential microbial growth, which is indicated by visible turbidity upon incubation.

(-c-) Under aseptic conditions and using aseptic techniques, affix a sterile 0.2-micron porosity filter unit and a 20-gauge needle to each syringe. Inject the next 10 milliliters from each
syringe into three separate 10-milliliter sterile vials. Repeat the process for three more vials. Label all vials, affix sterile adhesive seals to the closure of the nine vials, and incubate them at 20 to 35 degrees Celsius for a minimum of 14 days. Inspect for microbial growth over 14 days as described in Chapter 797 Pharmaceutical Compounding--Sterile Preparations, of the USP/NF.

(III) Filter Integrity Testing. Filters need to undergo testing to evaluate the integrity of filters used to sterilize high-risk preparations, such as Bubble Point Testing or comparable filter integrity testing. Such testing is not a replacement for sterility testing and shall not be interpreted as such. Such test shall be performed after a sterilization procedure on all filters used to sterilize each high-risk preparation or batch preparation and the results documented. The results should be compared with the filter manufacturer’s specification for the specific filter used. If a filter fails the integrity test, the preparation or batch must be sterilized again using new unused filters.

(B) Finished preparation release checks and tests.

(i) All high-risk level compounded sterile preparations that are prepared in groups of more than 25 identical individual single-dose packages (such as ampuls, bags, syringes, and vials), or in multiple dose vials for administration to multiple patients, or are exposed longer than 12 hours at 2 - 8 degrees Celsius and longer than six hours at warmer than 8 degrees Celsius before they are sterilized shall be tested to ensure they are sterile and do not contain excessive bacterial endotoxins as specified in Chapter 71, Sterility Tests of the USP/NF before being dispensed or administered.

(ii) All compounded sterile preparations, except for sterile radiopharmaceuticals, that are intended to be solutions must be visually examined for the presence of particulate matter and not administered or dispensed when such matter is observed.

(iii) The prescription drug and medication orders, written compounding procedure, preparation records, and expended materials used to make compounded sterile preparations at all contamination risk levels shall be inspected for accuracy of correct identities and amounts of ingredients, aseptic mixing and sterilization, packaging, labeling, and expected physical appearance before they are dispensed or administered.

(iv) Written procedures for checking compounding accuracy shall be followed for every compounded sterile preparation during preparation, in accordance with pharmacy’s policies and procedures, and immediately prior to release, including label accuracy and the accuracy of the addition of all drug products or ingredients used to prepare the finished preparation and their volumes or quantities. A pharmacist shall ensure that components used in compounding are accurately weighed, measured, or subdivided as appropriate to conform to the formula being prepared.

(C) Environmental Testing.

(i) Viable and nonviable environmental sampling testing. Environmental sampling shall occur, at a minimum, every six months as part of a comprehensive quality management program and under any of the following conditions:

(I) as part of the commissioning and certification of new facilities and equipment;
(II) following any servicing of facilities and equipment;
(III) as part of the re-certification of facilities and equipment;
(IV) in response to identified problems with end products or staff technique; or
(V) in response to issues with compounded sterile preparations, observed compounding
personnel work practices, or patient-related infections (where the compounded sterile
preparation is being considered as a potential source of the infection).

(ii) Total particle counts. Certification that each ISO classified area (e.g., ISO Class 5, 7, and
8), is within established guidelines shall be performed no less than every six months and
whenever the equipment is relocated or the physical structure of the buffer area or ante-area
has been altered. All certification records shall be maintained and reviewed to ensure that the
controlled environments comply with the proper air cleanliness, room pressures, and air
changes per hour. Testing shall be performed by qualified operators using current, state-of-the-art equipment, with results of the following:

(I) ISO Class 5 - not more than 3520 particles 0.5 micrometer and larger size per cubic
meter of air;
(II) ISO Class 7 - not more than 352,000 particles of 0.5 micrometer and larger size per
cubic meter of air for any buffer area; and
(III) ISO Class 8 - not more than 3,520,000 particles of 0.5 micrometer and larger size per
cubic meter of air for any ante-area.

(iii) Pressure differential monitoring. A pressure gauge or velocity meter shall be installed to
monitor the pressure differential or airflow between the buffer area and the ante-area and
between the ante-area and the general environment outside the compounding area. The results
shall be reviewed and documented on a log at least every work shift (minimum frequency shall
be at least daily) or by a continuous recording device. The pressure between the ISO Class 7 or
ISO Class 8 and the general pharmacy area shall not be less than 0.02 inch water column.

(iv) Sampling plan. An appropriate environmental sampling plan shall be developed for
airborne viable particles based on a risk assessment of compounding activities performed.
Selected sampling sites shall include locations within each ISO Class 5 environment and in the
ISO Class 7 and 8 areas and in the segregated compounding areas at greatest risk of
contamination. The plan shall include sample location, method of collection, frequency of
sampling, volume of air sampled, and time of day as related to activity in the compounding area
and action levels.

(v) Viable air sampling. Evaluation of airborne microorganisms using volumetric collection
methods in the controlled air environments shall be performed by properly trained individuals for
all compounding risk levels. For low-, medium-, and high-risk level compounding, air sampling
shall be performed at locations that are prone to contamination during compounding activities
and during other activities such as staging, labeling, gowning, and cleaning. Locations shall
include zones of air backwash turbulence within the laminar airflow workbench and other areas
where air backwash turbulence may enter the compounding area. For low-risk level
compounded sterile preparations within 12-hour or less beyond-use-date prepared in a primary
engineering control that maintains an ISO Class 5, air sampling shall be performed at locations
inside the ISO Class 5 environment and other areas that are in close proximity to the ISO Class
5 environment during the certification of the primary engineering control.

(vi) Air sampling frequency and process. Air sampling shall be performed at least every 6
months as a part of the re-certification of facilities and equipment. A sufficient volume of air shall
be sampled and the manufacturer's guidelines for use of the electronic air sampling equipment
followed. At the end of the designated sampling or exposure period for air sampling activities,
the microbial growth media plates are recovered and their covers secured and they are inverted
and incubated at a temperature and for a time period conducive to multiplication of
microorganisms. Sampling data shall be collected and reviewed on a periodic basis as a means
of evaluating the overall control of the compounding environment. If an activity consistently
shows elevated levels of microbial growth, competent microbiology or infection control
personnel shall be consulted. A colony forming unit (cfu) count greater than 1 cfu per cubic
meter of air for ISO Class 5, greater than 10 cfu per cubic meter of air for ISO Class 7, and
greater than 100 cfu per cubic meter of air for ISO Class 8 or worse should prompt a re-
evaluation of the adequacy of personnel work practices, cleaning procedures, operational
procedures, and air filtration efficiency within the aseptic compounding location. An investigation
into the source of the contamination shall be conducted. The source of the problem shall be
eliminated, the affected area cleaned, and resampling performed. Counts of cfu are to be used
as an approximate measure of the environmental microbial bioburden. Action levels are
determined on the basis of cfu data gathered at each sampling location and trended over time.
Regardless of the number of cfu identified in the pharmacy, further corrective actions will be
dictated by the identification of microorganisms recovered by an appropriate credentialed
laboratory of any microbial bioburden captured as a cfu using an impaction air sampler. Highly
pathogenic microorganisms (e.g., gram-negative rods, coagulase positive staphylococcus,
molds and yeasts) can be potentially fatal to patient receiving compounded sterile preparations
and must be immediately remedied, regardless of colony forming unit count, with the
assistance, if needed, of a competent microbiologist, infection control professional, or industrial
hygienist.

(vii) Compounding accuracy checks. Written procedures for checking compounding
accuracy shall be followed for every compounded sterile preparation during preparation and
immediately prior to release, including label accuracy and the accuracy of the addition of all
drug products or ingredients used to prepare the finished preparation and their volumes or
quantities. At each step of the compounding process, the pharmacist shall ensure that
components used in compounding are accurately weighed, measured, or subdivided as
appropriate to conform to the formula being prepared.

(15) Quality control.

(A) Quality control procedures. The pharmacy shall follow established quality control
procedures to monitor the compounding environment and quality of compounded drug
preparations for conformity with the quality indicators established for the preparation. When
developing these procedures, pharmacy personnel shall consider the provisions of USP
Chapter 71, Sterility Tests, USP Chapter 85, Bacterial Endotoxins Test, Pharmaceutical
Compounding-Non-sterile Preparations, USP Chapter 795, USP Chapter 797, Pharmaceutical
Compounding--Sterile Preparations, USP Chapter 800, Hazardous Drugs--Handling in
Healthcare Settings, USP Chapter 823, Positron Emission Tomography Drugs for
Compounding, Investigational, and Research Uses, USP Chapter 1160, Pharmaceutical
Calculations in Prescription Compounding, and USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding of the current USP/NF. Such procedures shall be documented and be available for inspection.

(B) Verification of compounding accuracy and sterility.

(i) The accuracy of identities, concentrations, amounts, and purities of ingredients in compounded sterile preparations shall be confirmed by reviewing labels on packages, observing and documenting correct measurements with approved and correctly standardized devices, and reviewing information in labeling and certificates of analysis provided by suppliers.

(ii) If the correct identity, purity, strength, and sterility of ingredients and components of compounded sterile preparations cannot be confirmed such ingredients and components shall be discarded immediately. Any compounded sterile preparation that fails sterility testing following sterilization by one method (e.g., filtration) is to be discarded and not subjected to a second method of sterilization.

(iii) If individual ingredients, such as bulk drug substances, are not labeled with expiration dates, when the drug substances are stable indefinitely in their commercial packages under labeled storage conditions, such ingredients may gain or lose moisture during storage and use and shall require testing to determine the correct amount to weigh for accurate content of active chemical moieties in compounded sterile preparations.

(e) Records. Any testing, cleaning, procedures, or other activities required in this subsection shall be documented and such documentation shall be maintained by the pharmacy.

(1) Maintenance of records. Every record required under this section must be:

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

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

(2) Compounding records.

(A) Compounding pursuant to patient specific prescription drug orders or medication orders. Compounding records for all compounded preparations shall be maintained by the pharmacy and shall include:

(i) the date and time of preparation;

(ii) a complete formula, including methodology and necessary equipment which includes the brand name(s) of the raw materials, or if no brand name, the generic name(s) or official name and name(s) of the manufacturer(s) or distributor of the raw materials and the quantities of
each; however, if the sterile preparation is compounded according to the manufacturer’s labeling instructions, then documentation of the formula is not required;

(iii) written or electronic signature or initials of the pharmacist or pharmacy technician or pharmacy technician trainee performing the compounding;

(iv) written or electronic signature or initials of the pharmacist responsible for supervising pharmacy technicians or pharmacy technician trainees and conducting finals checks of compounded pharmaceuticals if pharmacy technicians or pharmacy technician trainees perform the compounding function;

(v) the container used and the number of units of finished preparation prepared; and

(vi) a reference to the location of the following documentation which may be maintained with other records, such as quality control records:

(I) the criteria used to determine the beyond-use date; and

(II) documentation of performance of quality control procedures.

(B) Compounding records when batch compounding or compounding in anticipation of future prescription drug or medication orders.

(i) Master work sheet. A master work sheet shall be developed and approved by a pharmacist for preparations prepared in batch. Once approved, a duplicate of the master work sheet shall be used as the preparation work sheet from which each batch is prepared and on which all documentation for that batch occurs. The master work sheet shall contain at a minimum:

(I) the formula;

(II) the components;

(III) the compounding directions;

(IV) a sample label;

(V) evaluation and testing requirements;

(VI) specific equipment used during preparation; and

(VII) storage requirements.

(ii) Preparation work sheet. The preparation work sheet for each batch of preparations shall document the following:

(I) identity of all solutions and ingredients and their corresponding amounts, concentrations, or volumes;

(II) lot number for each component;
(III) component manufacturer/distributor or suitable identifying number;

(IV) container specifications (e.g., syringe, pump cassette);

(V) unique lot or control number assigned to batch;

(VI) expiration date of batch-prepared preparations;

(VII) date of preparation;

(VIII) name, initials, or electronic signature of the person(s) involved in the preparation;

(IX) name, initials, or electronic signature of the responsible pharmacist;

(X) finished preparation evaluation and testing specifications, if applicable; and

(XI) comparison of actual yield to anticipated or theoretical yield, when appropriate.

(f) Office Use Compounding and Distribution of Sterile Compounded Preparations

(1) General.

(A) A pharmacy may compound, dispense, deliver, and distribute a compounded sterile preparation as specified in Subchapter D, Texas Pharmacy Act Chapter 562.

(B) A Class A-S pharmacy is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute sterile compounded preparations to a Class C or Class C-S pharmacy.

(C) A Class C-S pharmacy is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute sterile compounded preparations that the Class C-S pharmacy has compounded for other Class C or Class C-S pharmacies under common ownership.

(D) To compound and deliver a compounded preparation under this subsection, a pharmacy must:

(i) verify the source of the raw materials to be used in a compounded drug;

(ii) comply with applicable United States Pharmacopoeia guidelines, including the testing requirements, and the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191);

(iii) enter into a written agreement with a practitioner for the practitioner’s office use of a compounded preparation;

(iv) comply with all applicable competency and accrediting standards as determined by the board; and
(v) comply with the provisions of this subsection.

(E) This subsection does not apply to Class B pharmacies compounding sterile radiopharmaceuticals that are furnished for departmental or physicians’ use if such authorized users maintain a Texas radioactive materials license.

(2) Written Agreement. A pharmacy that provides sterile compounded preparations to practitioners for office use or to another pharmacy shall enter into a written agreement with the practitioner or pharmacy. The written agreement shall:

(A) address acceptable standards of practice for a compounding pharmacy and a practitioner and receiving pharmacy that enter into the agreement including a statement that compounded drugs may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity except to a veterinarian as authorized by §563.054 of the Act;

(B) require the practitioner or receiving pharmacy to include on a patient’s chart, medication order or medication administration record the lot number and beyond-use date of a compounded preparation administered to a patient;

(C) describe the scope of services to be performed by the pharmacy and practitioner or receiving pharmacy, including a statement of the process for:

(i) a patient to report an adverse reaction or submit a complaint; and

(ii) the pharmacy to recall batches of compounded preparations.

(3) Recordkeeping.

(A) Maintenance of Records.

(i) Records of orders and distribution of sterile compounded preparations to a practitioner for office use or to an institutional pharmacy for administration to a patient shall:

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

(II) maintained separately from the records of preparations dispensed pursuant to a prescription or medication order; and

(III) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy or its representative. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format. Failure to provide the records set out in this subsection, either on site or within 72 hours for whatever reason, constitutes prima facie evidence of failure to keep and maintain records.

(ii) Records may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided the data processing system is capable of
producing a hard copy of the record upon the request of the board, its representative, or other
authorized local, state, or federal law enforcement or regulatory agencies.

(B) Orders. The pharmacy shall maintain a record of all sterile compounded preparations
ordered by a practitioner for office use or by an institutional pharmacy for administration to a
patient. The record shall include the following information:

(i) date of the order;

(ii) name, address, and phone number of the practitioner who ordered the preparation and if
applicable, the name, address and phone number of the institutional pharmacy ordering the
preparation; and

(iii) name, strength, and quantity of the preparation ordered.

(C) Distributions. The pharmacy shall maintain a record of all sterile compounded
preparations distributed pursuant to an order to a practitioner for office use or by an institutional
pharmacy for administration to a patient. The record shall include the following information:

(i) date the preparation was compounded;

(ii) date the preparation was distributed;

(iii) name, strength and quantity in each container of the preparation;

(iv) pharmacy's lot number;

(v) quantity of containers shipped; and

(vi) name, address, and phone number of the practitioner or institutional pharmacy to whom
the preparation is distributed.

(D) Audit Trail.

(i) The pharmacy shall store the order and distribution records of preparations for all sterile
compounded preparations ordered by and or distributed to a practitioner for office use or by a
pharmacy licensed to compound sterile preparations for administration to a patient in such a
manner as to be able to provide an audit trail for all orders and distributions of any of the
following during a specified time period:

(I) any strength and dosage form of a preparation (by either brand or generic name or
both);

(II) any ingredient;

(III) any lot number;

(IV) any practitioner;

(V) any facility; and
(VI) any pharmacy, if applicable.

(ii) The audit trail shall contain the following information:

(I) date of order and date of the distribution;

(II) practitioner's name, address, and name of the institutional pharmacy, if applicable;

(III) name, strength and quantity of the preparation in each container of the preparation;

(IV) name and quantity of each active ingredient;

(V) quantity of containers distributed; and

(VI) pharmacy's lot number.

(4) Labeling. The pharmacy shall affix a label to the preparation containing the following information:

(A) name, address, and phone number of the compounding pharmacy;

(B) the statement: "For Institutional or Office Use Only--Not for Resale"; or if the preparation is distributed to a veterinarian the statement: "Compounded Preparation";

(C) name and strength of the preparation or list of the active ingredients and strengths;

(D) pharmacy's lot number;

(E) beyond-use date as determined by the pharmacist using appropriate documented criteria;

(F) quantity or amount in the container;

(G) appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and

(H) device-specific instructions, where appropriate.

(g) Recall Procedures.

(1) The pharmacy shall have written procedures for the recall of any compounded sterile preparation provided to a patient, to a practitioner for office use, or a pharmacy for administration. Written procedures shall include, but not be limited to the requirements as specified in paragraph (3) of this subsection.

(2) The pharmacy shall immediately initiate a recall of any sterile preparation compounded by the pharmacy upon identification of a potential or confirmed harm to a patient.

(3) In the event of a recall, the pharmacist-in-charge shall ensure that:
(A) each practitioner, facility, and/or pharmacy to which the preparation was distributed is notified, in writing, of the recall;

(B) each patient to whom the preparation was dispensed is notified, in writing, of the recall;

(C) the board is notified of the recall, in writing, not later than 24 hours after the recall is issued;

(D) if the preparation is distributed for office use, the Texas Department of State Health Services, Drugs and Medical Devices Group, is notified of the recall, in writing;

(E) the preparation is quarantined; and

(F) the pharmacy keeps a written record of the recall including all actions taken to notify all parties and steps taken to ensure corrective measures.

(4) If a pharmacy fails to initiate a recall, the board may require a pharmacy to initiate a recall if there is potential for or confirmed harm to a patient.

(5) A pharmacy that compounds sterile preparations shall notify the board immediately of any adverse effects reported to the pharmacy or that are known by the pharmacy to be potentially attributable to a sterile preparation compounded by the pharmacy.