

**TITLE 22. EXAMINING BOARDS**  
**Part 15. Texas State Board of Pharmacy**  
**Chapter 291. Pharmacies**  
**Subchapter D. Institutional Pharmacy (Class C)**

**22 TAC §291.72, §291.73, §291.74, §291.75, §291.76**

The Texas State Board of Pharmacy proposes amendments to §291.72 concerning Definitions, §291.73 concerning Personnel, §291.74 concerning Operational Standards, and §291.75 concerning Records in a Class C (Institutional) Pharmacy and §291.76 concerning Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center. The amendments to §§291.72-291.74 and §291.76, if adopted, will amend the current provisions relating to compounding of sterile pharmaceuticals to match new section §291.26 which outlines new provisions for the compounding of sterile pharmaceuticals. The amendments to §291.75 and §291.76(e), if adopted, will specify that only a pharmacist may verify the receipt of controlled substances by a pharmacy.

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

Ms. Dodson has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the rule will be the establishing of standards for the compounding of non-sterile and sterile pharmaceuticals by pharmacies and stricter controls on the receipt of controlled substances by pharmacies. There is no fiscal impact anticipated for small or large businesses or to other entities who are required to comply with this section.

A public hearing to receive comments on the proposed amendments will be held at 9:00 a.m. on Tuesday, November 18, 2003, at the Health Professions Council Board Room, 333 Guadalupe Street, Tower II, Room 2-225, Austin, Texas 78701. Persons planning to present comments to the Board are asked to provide a written copy of their comments prior to the hearing or bring 20 copies to the hearing. Written comments on the amendments may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, 333 Guadalupe Street, Suite 3-600, Austin, Texas, 78701, FAX: 512/305-8082, E-mail: allison.benz@tsbp.state.tx.us. Comments must be received by 5 p.m., November 12, 2003.

The amendments are proposed under sections 551.002 and 554.051(a) of the Texas Pharmacy Act (Chapters 551-566 and 568-569, Texas Occupations Code). The Board interprets section 551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets section 554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by this rule: Chapters 551-566 and 568-569, Texas Occupations Code.

The agency hereby certifies that the proposed amendments have been reviewed by legal counsel and found to be a valid exercise of the agency's authority.

**§291.72 Definitions.**

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

(1) - (3) (No Change.)

~~[(4) Airborne particulate cleanliness class - The level of cleanliness specified by the maximum allowable number of particles per cubic foot of air as specified in Federal Standard 209E et seq. For example:~~

~~(A) Class 100 is an atmospheric environment which contains less than 100 particles 0.5 microns in diameter per cubic foot of air;~~

~~(B) Class 10,000 is an atmospheric environment which contains less than 10,000 particles 0.5 microns in diameter per cubic foot of air; and~~

~~(C) — Class 100,000 is an atmospheric environment which contains less than 100,000 particles 0.5 microns in diameter per cubic foot of air.~~

~~(5) — Aseptic preparation - The technique involving procedures designed to preclude contamination of drugs, packaging, equipment, or supplies by microorganisms during processing.]~~

~~(4) [(6)] Automated compounding or counting device - An automated device that compounds, measures, counts and/or packages a specified quantity of dosage units of a designated drug product.~~

~~(5) [(7)] Automated medication supply system - a mechanical system that performs operations or activities relative to the storage and distribution of medications for administration and which collects, controls, and maintains all transaction information.~~

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

~~(9) — Biological safety cabinet - Containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel, and environment, according to National Sanitation Foundation (NSF) Standard 49.]~~

~~(6) [(10)] Board - The State Board of Pharmacy.~~

~~(7) [(11)] Certified Pharmacy Technician - A pharmacy technician who:~~

~~(A) - (C) (No Change.)~~

~~[(12) — Clean room - A room in which the concentration of airborne particles is controlled and there are one or more clean zones according to Federal Standard 209E et seq.—~~

~~(13) — Clean zone - A defined space in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class.]~~

~~[(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 or initiative based on the practitioner-patient-pharmacist relationship in the course of professional practice;~~

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

~~(C) — for the purpose of, or as an incident to research, teaching, or chemical analysis and not for sale or dispensing.~~

~~(8) [(15)] Confidential record - Any health-related record that contains information that identifies an individual and that is maintained by a pharmacy or pharmacist, such as a patient medication record, prescription drug order, or medication drug order.~~

~~(9) [(16)] Consultant pharmacist - A pharmacist retained by a facility on a routine basis to consult with the facility in areas that pertain to the practice of pharmacy.~~

~~(17) — Controlled area - A controlled area is the area designated for preparing sterile pharmaceuticals.~~

~~(10) [(18)] Controlled substance - A drug, immediate precursor, or other substance listed in Schedules I-V or Penalty Groups 1-4 of the Texas Controlled Substances Act, as amended, or a drug, immediate precursor, or other substance included in Schedules I-V of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public Law 91-513).~~

~~[(19) — Critical areas - Any area in the controlled area where products or containers are exposed to the environment.—~~

~~(20) — Cytotoxic - A pharmaceutical that has the capability of killing living cells.~~

~~(11) [(21)] Dangerous drug - Any drug or device that is not included in Penalty Groups 1-4 of the controlled Substances Act and that is unsafe for self-medication or any drug or device that bears or is required to bear the legend:~~

~~(A) - (B) (No Change.)~~

~~(12) [(22)] Device - An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part or accessory, that is required under federal or state law to be ordered or prescribed by a practitioner.~~

~~(13) [(23)] Direct copy - Electronic copy or carbonized copy of a medication order, including a facsimile (FAX), tele-autograph, or a copy transmitted between computers.~~

~~(14) [(24)] Dispense - Preparing, packaging, compounding, or labeling for delivery a prescription drug or device in the course of professional practice to an ultimate user or his agent by or pursuant to~~

the lawful order of a practitioner.

**(15)** [~~(25)~~] Distribute - The delivery of a prescription drug or device other than by administering or dispensing.

**(16)** [~~(26)~~] Distributing pharmacist - The pharmacist who checks the medication order prior to distribution.

**(17)** [~~(27)~~] Downtime - Period of time during which a data processing system is not operable.

**(18)** [~~(28)~~] Drug regimen review -  
(A) - (B) (No Change.)

**(19)** [~~(29)~~] Electronic signature - A unique security code or other identifier which specifically identifies the person entering information into a data processing system. A facility which utilizes electronic signatures must:

(A) - (B) (No Change.)

**(20)** [~~(30)~~] Expiration date - The date (and time, when applicable) beyond which a product should not be used.

**(21)** [~~(31)~~] Facility -

(A) - (D) (No Change.)

**(22)** [~~(32)~~] Floor stock - Prescription drugs or devices not labeled for a specific patient and maintained at a nursing station or other hospital department (excluding the pharmacy) for the purpose of administration to a patient of the facility.

**(23)** [~~(33)~~] Formulary - List of drugs approved for use in the facility by the committee which performs the pharmacy and therapeutics function for the facility.

**(24)** [~~(34)~~] Full-time pharmacist - A pharmacist who works in a pharmacy from 30 to 40 hours per week or if the pharmacy is open less than 60 hours per week, one-half of the time the pharmacy is open.

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

**(26)** [~~(36)~~] Inpatient - A person who is duly admitted to the licensed hospital, or other hospital or facility maintained or operated by the state, or who is receiving long term care services or Medicare extended care services in a swing bed on the hospital premise or an adjacent, readily accessible facility which is under the authority of the hospital's governing body. For the purposes of this definition, the term "long term care services" means those services received in a skilled nursing facility which is a distinct part of the hospital and the distinct part is not licensed separately or formally approved as a nursing home by the state, even though it is designated or certified as a skilled nursing facility. An inpatient includes a person confined in any correctional institution operated by the state of Texas.

**(27)** [~~(37)~~] Institutional pharmacy - Area or areas in a facility where drugs are stored, bulk compounded, delivered, compounded, dispensed, and distributed to other areas or departments of the facility, or dispensed to an ultimate user or his or her agent.

**(28)** [~~(38)~~] Investigational new drug - New drug intended for investigational use by experts qualified to evaluate the safety and effectiveness of the drug as authorized by the Food and Drug Administration.

**(29)** [~~(39)~~] Medical Practice Act - The Texas Medical Practice Act, Subtitle B, Occupations Code, as amended.

**(30)** [~~(40)~~] Medication order - A written order from a practitioner or a verbal order from a practitioner or his authorized agent for administration of a drug or device.

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

**(32)** [~~(42)~~] Perpetual inventory - An inventory which documents all receipts and distributions of a drug product, such that an accurate, current balance of the amount of the drug product present in the pharmacy is indicated.

**(33)** [~~(43)~~] Pharmaceutical care - The provision of drug therapy and other pharmaceutical services intended to assist in the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process.

**(34)** [~~(44)~~] Pharmacist-in-charge - Pharmacist designated on a pharmacy license as the pharmacist who has the authority or responsibility for a pharmacy's compliance with laws and rules pertaining to the practice of pharmacy.

**(35)** [~~(45)~~] Pharmacy and therapeutics function - Committee of the medical staff in the facility

which assists in the formulation of broad professional policies regarding the evaluation, selection, distribution, handling, use, and administration, and all other matters relating to the use of drugs and devices in the facility.

**(36)** ~~[(46)]~~ Pharmacy technician - Those individuals utilized in pharmacies whose responsibility it shall be to provide technical services that do not require professional judgment concerned with the preparation and distribution of drugs under the direct supervision of and responsible to a pharmacist. Pharmacy technician includes certified pharmacy technicians, pharmacy technicians, and pharmacy technician trainees.

**(37)** ~~[(47)]~~ Pharmacy technician trainee - a pharmacy technician:

(A) - (B) (No Change.)

**(38)** ~~[(48)]~~ Pre-packaging - The act of re-packaging and re-labeling quantities of drug products from a manufacturer's original container into unit-dose packaging or a multiple dose container for distribution within the facility.

**(39)** ~~[(49)]~~ Prescription drug -

(A) - (C) (No Change.)

**(40)** ~~[(50)]~~ Prescription drug order -

(A) - (B) (No Change.)

~~[(51)]—Process validation—Documented evidence providing a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes.~~

~~(52)—Quality assurance—The set of activities used to assure that the process used in the preparation of sterile drug products lead to products that meet predetermined standards of quality.~~

~~(53)—Quality control—The set of testing activities used to determine that the ingredients, components (e.g., containers), and final sterile pharmaceuticals prepared meet predetermined requirements with respect to identity, purity, non-pyrogenicity, and sterility.]~~

**(41)** ~~[(54)]~~ Sample - A prescription drug which is not intended to be sold and is intended to promote the sale of the drug.

~~[(55)]—Sterile pharmaceutical—A dosage form free from living micro-organisms.]~~

**(42)** ~~[(56)]~~ Texas Controlled Substances Act - The Texas Controlled Substances Act, the Health and Safety Code, Chapter 481, as amended.

**(43)** ~~[(57)]~~ Unit-dose packaging - The ordered amount of drug in a dosage form ready for administration to a particular patient, by the prescribed route at the prescribed time, and properly labeled with name, strength, and expiration date of the drug.

**(44)** ~~[(58)]~~ Unusable drugs - Drugs or devices that are unusable for reasons, such as they are adulterated, misbranded, expired, defective, or recalled.

**(45)** ~~[(59)]~~ Written protocol - A physician's order, standing medical order, standing delegation order, or other order or protocol as defined by rule of the Texas State Board of Medical Examiners under the Texas Medical Practice Act Subtitle B, Chapter 157, Occupations Code.

### **§291.73 Personnel**

(a) (No Change.)

(b) *Pharmacist-in-charge.*

(1) (No Change.)

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

(A) -(B) (No Change.)

~~[(C)] developing a system for the compounding, sterility assurance, quality assurance and quality control of sterile pharmaceuticals compounded within the institutional pharmacy;~~

~~[(D)] developing a system to assure that all pharmacy personnel responsible for compounding and/or supervising the compounding of sterile pharmaceuticals within the pharmacy receive appropriate education and training and competency evaluation;]~~

**(C)** ~~[(E)]~~ providing written guidelines and approval of the procedure to assure that all pharmaceutical requirements are met when any part of preparing, sterilizing, and labeling of sterile pharmaceuticals is not performed under direct pharmacy supervision;

~~[(F)] developing a system for bulk compounding or batch preparation of drugs;]~~

~~[(G)] establishing specifications for procurement and storage of all pharmaceutical~~

materials including pharmaceuticals, components used in the compounding of pharmaceuticals, and drug delivery devices;

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

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

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

**(G)** [(+)] assuring that the pharmacy maintains and makes available a sufficient inventory of antidotes and other emergency drugs as well as current antidote information, telephone numbers of regional poison control center and other emergency assistance organizations, and such other materials and information as may be deemed necessary by the appropriate committee of the facility;

**(H)** [(+)] maintaining records of all transactions of the institutional pharmacy as may be required by applicable law, state and federal, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials including pharmaceuticals, components used in the compounding of pharmaceuticals, and drug delivery devices;

**(I)** [(+)] participating in those aspects of the facility's patient care evaluation program which relate to pharmaceutical utilization and effectiveness;

**(J)** [(+)] participating in teaching and/or research programs in the facility;

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

**(L)** [(+)] providing effective and efficient messenger or delivery service to connect the institutional pharmacy with appropriate areas of the facility on a regular basis throughout the normal workday of the facility;

**(M)** [(+)] developing a system for the labeling, storage, and distribution of investigational new drugs, including maintenance of information in the pharmacy and nursing station where such drugs are being administered, concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interactions and symptoms of toxicity of investigational new drugs;

**(N)** [(+)] assuring that records in a data processing system are maintained such that the data processing system is in compliance with Class C (Institutional) pharmacy requirements;

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

**(P)** [(+)] assuring the legal operation of the pharmacy, including meeting all inspection and other requirements of all state and federal laws or rules governing the practice of pharmacy; and

**(Q)** [(+)] if the pharmacy uses an automated medication supply system, shall be responsible for the following:

(i) - (v) (No change.)

(c) (No Change.)

(d) *Pharmacists.*

(1) - (2) (No change.)

**(3) Special requirements for compounding.**

**(A) Non-Sterile Pharmaceuticals. All pharmacists engaged in compounding non-sterile pharmaceuticals shall meet the training requirements specified in §291.25 of this title (relating to Pharmacies Compounding Non-sterile Pharmaceuticals).**

**(B) Sterile Pharmaceuticals. All pharmacists engaged in compounding non-sterile pharmaceuticals shall meet the training requirements specified in §291.26 of this title (relating to Pharmacies Compounding Sterile Pharmaceuticals).**

(e) *Pharmacy technicians.*

(1) (No Change.)

(2) *Duties.* [(A) General.] Duties may include, but need not be limited to, the following functions under the direct supervision of and responsible to a pharmacist:

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

**(B)** [(+)] preparing, packaging, compounding, or labeling prescription drugs pursuant to

medication orders, provided a pharmacist supervises and checks the preparation;

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

**(D)** [(iv)] distributing routine orders for stock supplies to patient care areas;

**(E)** [(v)] entering medication order and drug distribution information into a data processing system, provided judgmental decisions are not required and a pharmacist checks the accuracy of the information entered into the system prior to releasing the order or in compliance with the absence of pharmacist requirements contained in §291.74(e) of this title (relating to Operational Standards);

**(F)** [(vi)] loading bulk unlabeled drugs into an automated compounding or counting device provided a pharmacist supervises, verifies that the system was properly loaded prior to use, and affixes his or her signature (first initial and last name or full signature) or electronic signature to the appropriate quality control records; and

**(G)** [(vii)] may be allowed access to automated medication supply systems after proper training on the use of the automated medication supply system and demonstration of comprehensive knowledge of the written policies and procedures for its operation.

~~**(B)**—*Sterile pharmaceuticals.*~~

~~(i)——Only pharmacy technicians who have completed the training specified in subsection (f) of this section may compound sterile pharmaceuticals pursuant to medication orders providing a pharmacist who has completed the training specified in subsection (f) of this section supervises, conducts in-process and final checks, and affixes his or her initials to the label or if batch prepared, to the appropriate quality control records. (The initials are not required on the label if it is maintained in a permanent record of the pharmacy).~~

~~(ii)——Effective January 1, 2001, pharmacy technicians may compound sterile pharmaceuticals pursuant to medication orders provided the pharmacy technicians:~~

~~(I)——are certified pharmacy technicians or technician trainees;—~~

~~(II)——Have Completed The Training Specified in Subsection (F) of This~~

~~Section; and~~

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

**(3) Special requirements for compounding.**

**(A) *Non-Sterile Pharmaceuticals.* All pharmacy technicians engaged in compounding non-sterile pharmaceuticals shall meet the training requirements specified in §291.25 of this title.**

**(B) *Sterile Pharmaceuticals.* Pharmacy technicians may compound sterile pharmaceuticals pursuant to medication orders provided the pharmacy technicians:**

**(i) are certified pharmacy technicians or technician trainees;**

**(ii) have completed the training specified in subsection (f) of this**

**section; and**

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

**(4) [(3)] Procedures.**

(A) - (B) (No Change.)

**(5) [(4)] Training.**

(A) - (E) (No Change.)

**(6) [(5)] Training program. Pharmacy technician training shall be outlined in a training manual. Such training manual shall, at a minimum, contain the following:**

(A) - (B) (No Change.)

~~[(f)——Special education, training, and evaluation requirements for pharmacy personnel compounding or responsible for the direct supervision of pharmacy personnel compounding sterile pharmaceuticals:~~

~~(1)——General:~~

(A) — All pharmacy personnel preparing sterile pharmaceuticals shall receive didactic and experiential training and competency evaluation through demonstration, testing (written or practical) — as outlined by the pharmacist-in-charge and described in the policy and procedure or training manual. Such training shall include instruction and experience in the following areas:

- (i) — aseptic technique;
- (ii) — critical area contamination factors;
- (iii) — environmental monitoring;
- (iv) — facilities;
- (v) — equipment and supplies;
- (vi) — sterile pharmaceutical calculations and terminology;
- (vii) — sterile pharmaceutical compounding documentation;
- (viii) — quality assurance procedures;
- (ix) — aseptic preparation procedures, including proper gowning and gloving

technique;

- (x) — the handling of cytotoxic and hazardous drugs; and
- (xi) — general conduct in the controlled area.

(B) — The aseptic technique of each person compounding or responsible for the direct supervision of personnel compounding sterile pharmaceuticals shall be observed and evaluated as satisfactory through written or practical tests and process validation and such evaluation documented.

(C) — Although process validation may be incorporated into the experiential portion of a training program, process validation must be conducted at each pharmacy where an individual compounds sterile pharmaceuticals. No product intended for patient use shall be compounded by an individual until the on-site process validation test indicates that the individual can competently perform aseptic procedures, except that a pharmacist may compound sterile pharmaceuticals and supervise pharmacy technicians compounding sterile pharmaceuticals without process validation provided the pharmacist:

(i) — has completed a recognized course in an accredited college of pharmacy or a course sponsored by an American Council on Pharmaceutical Education approved provider which provides 20 hours of instruction and experience in the areas listed in this paragraph; and

(ii) — completes the on-site process validation within seven days of commencing work at the pharmacy.

(D) — Process validation procedures for assessing the preparation of specific types of sterile pharmaceuticals shall be representative of all types of manipulations, products, and batch sizes that personnel preparing that type of pharmaceutical are likely to encounter.

(E) — The pharmacist-in-charge shall assure continuing competency of pharmacy personnel through in-service education, training, and process validation 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.

(2) — Pharmacists:

(A) — All pharmacists who compound sterile pharmaceuticals or supervise pharmacy technicians compounding sterile pharmaceuticals shall:

(i) — complete through a single course, a minimum 20 hours of instruction and experience in the areas listed in paragraph (1) of this subsection. Such training may be evidenced by either:

(I) — completion of a structured on-the-job didactic and experiential training program at this pharmacy which provides 20 hours of instruction and experience in the areas listed in paragraph (1) of this subsection. Such training may not be transferred to another pharmacy unless the pharmacies are under common ownership and control and use a common training program; or

(II) — completion of a recognized course in an accredited college of pharmacy or a course sponsored by an American Council on Pharmaceutical Education approved provider which provides 20 hours of instruction and experience in the areas listed in paragraph (1) of this subsection; and

(ii) — possess knowledge about:

(I) — aseptic processing;

(II) — quality control and quality assurance as related to environmental, component, and end-product testing;

(III) — chemical, pharmaceutical, and clinical properties of drugs;

(IV) — container, equipment, and closure system selection; and

(V) — sterilization techniques.

(B) — The required experiential portion of the training programs specified in this paragraph must be supervised by an individual who has already completed training as specified in paragraph (2) or (3) of this subsection.

(3) — Pharmacy technicians. In addition to the qualifications and training outlined in subsection (e) of this section, all pharmacy technicians who compound sterile pharmaceuticals shall:

(A) — have a high school or equivalent education;

(B) — either:

(i) — complete through a single course, a minimum of 40 hours of instruction and experience in the areas listed in paragraph (1) of this subsection. Such training may be obtained through the:

(I) — completion of a structured on-the-job didactic and experiential training program at this pharmacy which provides 40 hours of instruction and experience in the areas listed in paragraph (1) of this subsection. Such training may not be transferred to another pharmacy unless the pharmacies are under common ownership and control and use a common training program; or

(II) — completion of a course sponsored by an ACPE approved provider which provides 40 hours of instruction and experience in the areas listed in paragraph (1) of this subsection; or

(ii) — complete a training program which is accredited by the American Society of Health-System Pharmacists (formerly the American Society of Hospital Pharmacists). Individuals enrolled in training programs accredited by the American Society of Health-System Pharmacists may compound sterile pharmaceuticals in a licensed pharmacy provided:

(I) — the 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) — the 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) — the supervising pharmacist conducts in-process and final checks;

and

(C) — on January 1, 2001, discontinue preparation of sterile pharmaceuticals if the technician has not taken and passed the National Pharmacy Technician Certification Exam or other examination approved during an open meeting by the Board. Such pharmacy technicians may continue to compound sterile pharmaceuticals during the interim between the effective date of these rules and January 1, 2001, if they maintain documentation of completion of the training specified in subparagraph (B) of this paragraph.

(D) — acquire the required experiential portion of the training programs specified in this paragraph under the supervision of an individual who has already completed training as specified in this paragraph or paragraph (2) of this subsection.

(4) — Documentation of Training. A written record of initial and in-service training and the results of written or practical testing and process validation of pharmacy personnel shall be maintained and contain the following information:

(A) — name of the person receiving the training or completing the testing or process validation;

(B) — date(s) of the training, testing, or process validation;—

(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 process validation; and

(E) — signature (first initial and last name or full signature) of the person receiving the training or completing the testing or process validation 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 process validation of personnel.]~~

**(f)** ~~[(g)]~~ *Identification of pharmacy personnel.* All pharmacy personnel shall wear an identification tag or badge which bears the person's name and identifies him or her by title or function as follows:

(1) - (3) (No Change.)

#### **§291.74 Operational Standards**

(a) *Licensing requirements.*

(1) - (8) (No Change.)

(9) A Class C pharmacy, licensed under the Act, §560.051(a)(3), which also operates another type of pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(1) (Community Pharmacy (Class A)) or the Act, §560.051(a)(2) (Nuclear Pharmacy (Class B)), is not required to secure a license for the such other type of pharmacy; provided, however, such licensee is required to comply with the provisions of §291.31 of this title (relating to Definitions), §291.32 of this title (relating to Personnel), §291.33 of this title (relating to Operational Standards), §291.34 of this title (relating to Records), **and** §291.35 of this title (relating to **Official** [Triplicate] Prescription Records), [~~and §291.36 of this title (relating to Class A Pharmacies Compounding Sterile Pharmaceuticals),~~] contained in Community Pharmacy (Class A), or §291.51 of this title (relating to Purpose), §291.52 of this title (relating to Definitions), §291.53 of this title (relating to Personnel), §291.54 of this title (relating to Operational Standards), and §291.55 of this title (relating to Records), contained in Nuclear Pharmacy (Class B), to the extent such sections are applicable to the operation of the pharmacy.

(10) A Class C (**Institutional**) pharmacy engaged in non-sterile compounding of drug products for inpatients of the hospital shall comply with the provisions of **§291.25 of this title (relating to Pharmacies compounding Non-Sterile Pharmaceuticals)** [~~§§291.31 - 291.34 of this title to the extent such rules are applicable to non-sterile compounding of drug products~~].

**(11) A Class C (Institutional) pharmacy engaged in the compounding of sterile pharmaceuticals shall comply with the provisions of §291.26 of this title (relating to Pharmacies compounding Sterile Pharmaceuticals).**

~~(12) [(11)]~~ A Class C (Institutional) pharmacy engaged in the provision of remote pharmacy services, including storage and dispensing of prescription drugs, shall comply with the provisions of §291.20 of this title (relating to Remote Pharmacy Services).

~~(13) [(12)]~~ A Class C (Institutional) pharmacy engaged in centralized prescription dispensing and/or prescription drug or medication order processing shall comply with the provisions of §291.37 of this title (relating to Centralized Prescription Dispensing) and/or §291.38 of this title (relating to Centralized Prescription Drug or Medication Order Processing).

(b) *Environment.*

(1) (No Change.)

~~[(2) Special requirements for the compounding of sterile pharmaceuticals in the institutional pharmacy:]~~

~~[(A) — If the institutional pharmacy compounds sterile pharmaceuticals, the following is applicable:]~~

~~[(i) — Aseptic environment control device(s). The institutional pharmacy shall prepare sterile pharmaceuticals in an appropriate aseptic environmental control device(s) or area, such as a laminar air flow hood, biological safety cabinet, or clean room, which is capable of maintaining at least Class 100 conditions during normal activity. Such aseptic environmental control device(s) shall:]~~

~~[(t) — be certified by an independent contractor according to Federal Standard 209E et seq for operational efficiency at least every six months or when it is relocated; and]~~

~~[(tt) — have pre-filters inspected periodically and replaced as needed, in accordance with written policies and procedures, and the inspection and/or replacement date documented:]~~

~~[(ii) — Controlled area. The institutional pharmacy shall have a designated controlled area for the compounding of sterile pharmaceuticals that is functionally separate from areas for the preparation of non-sterile pharmaceuticals and is constructed to minimize the opportunities for particulate and microbial contamination. This controlled area for the preparation of sterile pharmaceuticals shall:]~~

~~[(t) — have a controlled environment that is aseptic or contains an~~

aseptic environmental control device(s);]

~~[(II) — be clean, well lighted, and of sufficient size to support sterile~~

~~compounding activities;]~~

~~[(III) — be used only for the compounding of sterile pharmaceuticals;]~~

~~[(IV) — be designed to avoid outside traffic and air flow and be ventilated in a manner not interfering with aseptic environmental control conditions;]~~

~~[(V) — have drugs and supplies stored on shelving areas above the floor to permit adequate floor cleaning;]~~

~~[(VI) — have non-porous and washable floors or floor covering to enable regular disinfection;]~~

~~[(VII) — have hard cleanable walls and ceilings (acoustical ceiling tiles that are coated with an acrylic paint are acceptable); and]~~

~~[(VIII) — contain only the appropriate compounding supplies and not be used for bulk storage for supplies and materials.]~~

~~[(iii) — End-product evaluation:]~~

~~[(t) — The responsible pharmacist shall verify that the sterile pharmaceutical was compounded accurately with respect to the use of correct ingredients, quantities, containers, and reservoirs.]~~

~~[(II) — End product sterility testing according to policies and procedures, which include a statistically valid sampling plan and acceptance criteria for the sampling and testing, shall be performed if deemed appropriate by the pharmacist-in-charge.]~~

~~[(III) — The pharmacist-in-charge shall establish a mechanism for recalling all products of a specific batch if end-product testing procedures yield unacceptable results.]~~

~~[(B) — Cytotoxic drugs. In addition to the requirements specified in subparagraph (A) of this paragraph, if the product is also cytotoxic, the following is applicable:]~~

~~[(i) — General:]~~

~~[(t) — All personnel involved in the compounding of cytotoxic products shall wear appropriate protective apparel, such as masks, gloves, and gowns or coveralls with tight cuffs.]~~

~~[(II) — Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with aseptic techniques required for preparing sterile pharmaceuticals.]~~

~~[(III) — Disposal of cytotoxic waste shall comply with all applicable local, state, and federal requirements.]~~

~~[(IV) — Prepared doses of cytotoxic drugs must be dispensed, labeled with proper precautions inside and outside, and distributed in a manner to minimize contact with cytotoxic agents.]~~

~~[(ii) — Aseptic environment control device(s).]~~

~~[(t) — Cytotoxic drugs must be prepared in a vertical flow biological safety cabinet.]~~

~~[(II) — If the vertical flow biological safety cabinet is also used to prepare non-cytotoxic sterile pharmaceuticals, the cabinet must be thoroughly cleaned prior to its use to prepare non-cytotoxic sterile pharmaceuticals.]~~

~~(2) [(3)] Security requirements.~~

~~(A) - (C) (No Change.)~~

(c) *Equipment and supplies.* [(1)] Institutional pharmacies distributing medication orders shall have the following equipment:

~~(1) [(A)] typewriter or comparable equipment; and~~

~~(2) [(B)] refrigerator and a system or device (e.g., thermometer) to monitor the temperature daily to ensure that proper storage requirements are met.~~

~~[(2) — If the institutional pharmacy compounds medication orders which require the use of a balance, a Class A prescription balance or analytical balance with weights. Such balance shall be properly maintained and inspected at least every three years by the appropriate authority as prescribed by local, state, or federal law or regulations.]~~

~~[(3) — If the institutional pharmacy compounds sterile pharmaceuticals, the pharmacy shall have the following equipment:]~~

- ~~[(A) — appropriate disposal containers for used needles, syringes, etc., and if applicable, cytotoxic waste from the preparation of chemotherapeutic agents, cytotoxic waste;]~~
- ~~[(B) — infusion devices, if applicable;]~~
- ~~[(C) — all necessary supplies, including:]~~
  - ~~[(i) — disposable needles, syringes, and other supplies for aseptic mixing;]~~
  - ~~[(ii) — disinfectant cleaning solutions;]~~
  - ~~[(iii) — hand washing agents with bacteriocidal action;]~~
  - ~~[(iv) — disposable, lint free towels or wipes;]~~
  - ~~[(v) — appropriate filters and filtration equipment;]~~
  - ~~[(vi) — cytotoxic spill kits, if applicable; and]~~
  - ~~[(vii) — masks, caps, coveralls or gowns with tight cuffs, shoe covers, and gloves,~~

~~as applicable.]~~

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

(1) - (4) (No Change.)

~~[(5) — if the pharmacy compounds sterile pharmaceuticals, specialty references appropriate for the scope of services provided by the pharmacy, e.g., if the pharmacy prepares cytotoxic drugs, a reference text on the preparation of cytotoxic drugs, such as Procedures for Handling Cytotoxic Drugs;]~~

~~**(5)** [(6)] metric-apothecary weight and measure conversion charts.~~

(e) (No Change.)

(f) *Drugs.*

(1) - (3) (No Change.)

~~[(4) — Sterile pharmaceuticals compounded in the pharmacy:]~~

~~[(A) — Batch preparation:~~

~~(i) — Master work sheet. A master work sheet shall be developed and approved by a pharmacist for each batch of sterile pharmaceuticals to be prepared. 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) — sterilization method(s), if applicable;]~~

~~[(vii) — storage requirements; and]~~

~~[(viii) — specific equipment used during aseptic preparation (e.g., specific automated compounding device).]~~

~~(ii) — Preparation work sheet. The preparation work sheet for each batch of sterile pharmaceuticals shall document the following:]~~

~~[(i) — identity of all solutions and ingredients and their corresponding amounts, concentrations, or volumes;]~~

~~[(ii) — manufacturer lot number for each component;]~~

~~[(iii) — component manufacturer 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 products;]~~

~~[(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;]~~

~~and]~~

~~[(xi) — comparison of actual yield to anticipated yield, when appropriate.]~~

~~[(B) — Labeling. The label of each sterile pharmaceutical shall bear at a minimum:]~~

~~(i) — for patient-specific products, the patient's name and location or~~

identification number;]

~~[(iii) — for batch prepared products, the unique lot or control number assigned to the batch;]~~

~~[(iii) — all solution and ingredient names, amounts, strengths, and concentrations, when applicable;]~~

~~[(iv) — expiration date and time, when applicable;]~~

~~[(v) — directions for use, including infusion rate, when appropriate;]~~

~~[(vi) — name or initials of the person preparing the product and, if prepared by supportive personnel, the name or initials of the pharmacist who checked and released the final product. (This information is not required on the label if it is maintained in a permanent record of the pharmacy);]~~

~~[(vii) — appropriate ancillary instructions such as storage instructions or cautionary statements, including cytotoxic warning labels where appropriate; and]~~

~~[(viii) — device-specific instructions, when appropriate.]~~

~~[(C) — Expiration date:]~~

~~[(i) — The expiration date assigned shall be based on currently available drug stability information and sterility considerations or appropriate in-house or contract service stability testing.]~~

~~[(ii) — Sources of drug stability information shall include the following:]~~

~~[(I) — references (e.g., Remington's Pharmaceutical Sciences, Handbook on Injectable Drugs);]~~

~~[(II) — manufacturer recommendations; and]~~

~~[(III) — reliable, published research.]~~

~~[(iii) — When interpreting published drug stability information, the pharmacist shall consider all aspects of the final sterile product being prepared (e.g., drug reservoir, drug concentration, storage conditions).]~~

~~[(iv) — Methods used for establishing expiration dates shall be documented.]~~

~~[(D) — Quality control. There shall be a documented, ongoing quality control program that monitors and evaluates personnel performance, equipment and facilities. Procedures shall be in place to assure that the pharmacy is capable of consistently preparing pharmaceuticals which are sterile and stable. Quality control procedures shall include, but are not limited to, the following:]~~

~~[(i) — recall procedures;]~~

~~[(ii) — storage and dating; and]~~

~~[(iii) — documentation of appropriate functioning of refrigerator, freezer and other equipment;]~~

~~[(iv) — documentation of aseptic environmental control device(s) certification at least every six months and the regular replacement of pre-filters as necessary; and]~~

~~[(v) — a process to evaluate and confirm the quality of the prepared pharmaceutical product.]~~

~~[(E) — Quality assurance:]~~

~~[(i) — There shall be a documented, ongoing quality assurance program for monitoring and evaluating personnel performance and patient outcomes to assure an efficient drug delivery process, patient safety, and positive clinical outcomes.]~~

~~[(ii) — There shall be documentation of quality assurance audits at regular, planned intervals including infection control, sterile technique, delivery systems/times, order transcription accuracy, drug administration systems, adverse drug reactions and drug therapy appropriateness, as applicable.]~~

~~[(iii) — A plan for corrective action of problems identified by quality assurance audits shall be developed which includes procedures for documentation of identified problems and action taken.]~~

~~[(iv) — A periodic evaluation of the effectiveness of the quality assurance activities shall be completed and documented.]~~

**(4) [(5)]** Sterile pharmaceuticals prepared in a location other than the pharmacy. A distinctive supplementary label shall be affixed to the container of any admixture. The label shall bear at a minimum:

(A) patient's name and location;

(B) name and amount of drug(s) added;

- (C) name of the basic solution;
- (D) name or identifying code of person who prepared admixture; and
- (E) expiration date of solution.

**(5) [(6)] Distribution.**

- (A) - (B) (No Change.)

(g) - (j) (no Change.)

**§291.75 Records**

(a) - (d) (No Change.)

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

(1) - (3) (No Change.)

(4) suppliers' invoices of dangerous drugs and controlled substances; **a pharmacist** ~~[pharmacists or other responsible individuals]~~ shall verify that the controlled drugs listed on the invoices were actually received by clearly recording **his/her** ~~[their]~~ initials and the actual date of receipt of the controlled substances;

(5) - (10) (No Change.)

(f) - (g) (No Change.)

**§291.76 Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center**

(a) - (b) (No Change.)

(c) *Personnel.*

(1) *Pharmacist-in-charge.*

(A) (No Change.)

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

~~(i) preparation and sterilization of parenteral medications compounded within the ASC pharmacy;~~

~~(ii) admixture of parenteral products, including education and training of nursing personnel concerning incompatibility and provision of proper incompatibility information when the admixture of parenteral products is not performed within the ASC pharmacy;~~

~~(iii) bulk compounding of drugs;~~

**(i) [(iv)]** establishment of specifications for procurement and storage of all materials, including drugs, chemicals, and biologicals;

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

**(iii) [(vi)]** distribution of drugs to be administered to inpatients pursuant to an original or direct copy of the practitioner's medication order;

**(iv) [(vii)]** filling and labeling all containers from which drugs are to be distributed or dispensed;

**(v) [(viii)]** maintaining and making available a sufficient inventory of antidotes and other emergency drugs, both in the pharmacy and inpatient care areas, as well as current antidote information, telephone numbers of regional poison control center and other emergency assistance organizations, and such other materials and information as may be deemed necessary by the appropriate committee of the ASC;

**(vi) [(ix)]** records of all transactions of the ASC pharmacy as may be required by applicable state and federal law, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials;

**(vii) [(x)]** participation in those aspects of the ASC's patient care evaluation program which relate to pharmaceutical material utilization and effectiveness;

**(viii) [(xi)]** participation in teaching and/or research programs in the ASC;

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

**(x) [(xiii)]** effective and efficient messenger and delivery service to connect the ASC pharmacy with appropriate areas of the ASC on a regular basis throughout the normal workday of the ASC;

**(xi) [(xiv)]** labeling, storage, and distribution of investigational new drugs,

including maintenance of information in the pharmacy and nursing station where such drugs are being administered, concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interactions, and symptoms of toxicity of investigational new drugs;

(xii) ~~[xv]~~ meeting all inspection and other requirements of the Texas Pharmacy Act and this subsection; and

(xiii) ~~[(xvi)]~~ maintenance of records in a data processing system such that the data processing system is in compliance with the requirements for a Class C (institutional) pharmacy located in a freestanding ASC.

(2) (No change.)

(3) *Pharmacists.*

(A) - (B) (No Change.)

(C) **Special requirements for compounding.**

(i) **Non-Sterile Pharmaceuticals. All pharmacists engaged in compounding non-sterile pharmaceuticals shall meet the training requirements specified in §291.25 of this title (relating to Pharmacies Compounding Non-Sterile Pharmaceuticals).**

(ii) **Sterile Pharmaceuticals. All pharmacists engaged in compounding non-sterile pharmaceuticals shall meet the training requirements specified in §291.26 of this title (relating to Pharmacies Compounding Sterile Pharmaceuticals).** ~~[Special requirements. All pharmacists who compound sterile parenteral and/or enteral products shall meet minimal standards of training and experience in the preparation, sterilization, and admixture of parenteral and/or enteral products; such standards of training and experience may be evidenced by either:~~

(i) ~~documentation of completion of a minimum of 20 hours of on-the-job training in the preparation, sterilization, and admixture of parenteral and/or enteral products; or~~

(ii) ~~documentation of completion of a recognized course in an accredited college of pharmacy or a course sponsored by an ACPE approved provider. The course must provide a minimum of 20 hours of education or experience in the preparation, sterilization, and admixture of parenteral and/or enteral products.~~

(4) *Pharmacy technicians.*

(A) - (C) (No Change.)

(D) *Training.*

(i) Pharmacy technicians shall complete initial training as outlined by the pharmacist-in-charge which includes on-the-job training and related education commensurate with the tasks they are to perform, prior to the regular performance of those tasks.

~~[(ii) Pharmacy technicians who prepare sterile parenteral and/or enteral products shall complete an additional 40 hours of on-the-job training in the preparation, sterilization, and admixture of sterile parenteral and/or enteral products.]~~

(ii) ~~[(iii)]~~ The pharmacist-in-charge shall assure continuing competence of pharmacy technicians through in-service education and training to supplement initial training.

(iii) ~~[(iv)]~~ A written record of initial and in-service training of pharmacy technicians shall be maintained and contain the following information:

(I) - (V) (No Change.)

(E) **Special requirements for compounding.**

(i) **Non-Sterile Pharmaceuticals. All pharmacy technicians engaged in compounding non-sterile pharmaceuticals shall meet the training requirements specified in §291.25 of this title.**

(ii) **Sterile Pharmaceuticals. Pharmacy technicians may compound sterile pharmaceuticals pursuant to medication orders provided the pharmacy technicians:**

(I) **are certified pharmacy technicians or technician trainees;**

(II) **have completed the training specified in subsection (f) of this**

**section; and**

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

(5) (No Change.)

(d) Operational standards.

(1) Licensing requirements.

(A) - (H) (No Change.)

(I) An ASC pharmacy, licensed under the Act, §560.051(a)(3), concerning institutional pharmacy (Class C), which also operates another type of pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(1), concerning community pharmacy (Class A), or the Act, §560.051(a)(2), concerning nuclear pharmacy (Class B), is not required to secure a license for the other type of pharmacy; provided, however, such license is required to comply with the provisions of §291.31 of this title (relating to Definitions), §291.32 of this title (relating to Personnel), §291.33 of this title (relating to Operational Standards), §291.34 of this title (relating to Records), **and** §291.35 of this title (relating to **(Official)** [Triplicate] Prescription Records), ~~and §291.36 of this title (relating to Class A Pharmacies Dispensing Sterile Products)~~ contained in Community Pharmacy (Class A), or §291.51 of this title (relating to Purpose), §291.52 of this title (relating to Definitions), §291.53 of this title (relating to Personnel), §291.54 of this title (relating to Operational Standards), and §291.55 of this title (relating to Records), contained in Nuclear Pharmacy (Class B), to the extent such sections are applicable to the operation of the pharmacy.

**(J) An ASC pharmacy engaged in non-sterile compounding of drug products for inpatients of the hospital shall comply with the provisions of §291.25 of this title.**

**(K) An ASC pharmacy engaged in the compounding of sterile pharmaceuticals shall comply with the provisions of §291.26 of this title.**

**(L) An ASC pharmacy engaged in the provision of remote pharmacy services, including storage and dispensing of prescription drugs, shall comply with the provisions of §291.20 of this title (relating to Remote Pharmacy Services).**

**(M) An ASC pharmacy engaged in centralized prescription dispensing and/or prescription drug or medication order processing shall comply with the provisions of §291.37 of this title (relating to Centralized Prescription Dispensing) and/or §291.38 of this title (relating to Centralized Prescription Drug or Medication Order Processing).**

(2) Environment.

(A) (No Change.)

(B) *Special requirements.*

(i) The ASC pharmacy shall have locked storage for Schedule II controlled substances and other controlled drugs requiring additional security.

(ii) The ASC pharmacy shall have a designated area for the storage of poisons and externals separate from drug storage areas.

~~[(iii) If the ASC pharmacy prepares sterile products, the ASC pharmacy shall have a designated area for the laminar air flow hood for the preparation of sterile products, which shall:~~

~~(I) be designed to avoid outside traffic and air flow;~~

~~(II) have cleanable surfaces, walls, and floors;~~

~~(III) be ventilated in a manner not interfering with laminar flow hood~~

~~conditions; and~~

~~(IV) not be used for bulk storage for supplies and materials.]~~

(C) (No Change.)

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

(A) - (C) (No Change.)

~~[(D) special equipment according to the following requirements which shall be maintained:~~

~~(i) if the ASC pharmacy compounds prescriptions or medication orders, a Class A prescription balance or analytical balance with weights. Such balance shall be properly maintained and inspected at least every three years by the appropriate authority as prescribed by local, state, or federal law or regulations; and~~

~~(ii) if the ASC pharmacy prepares sterile parenteral and enteral products, an annually certified laminar air flow hood and other equipment necessary for manipulation of sterile products.]~~

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

(A) current copies of the following:

- (i) Texas Pharmacy Act and rules;
- (ii) Texas Dangerous Drug Act and rules;
- (iii) Texas Controlled Substances Act and rules;
- (iv) Federal Controlled Substances Act and rules or official publication

describing the requirements of the Federal Controlled Substances Act and rules;

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

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

(ii) **General information.** A general information reference text, such as:

**(I)** [(i)] Facts and Comparisons with current supplements;

**(II)** [(ii)] United States Pharmacopeia Dispensing Information

Volume I (Drug Information for the Healthcare Provider);

**(III)** [(iii)] AHFS Drug Information with current supplements;

**(IV)** [(iv)] Remington's Pharmaceutical Sciences; or

**(V)** [(v)] **Clinical Pharmacology;** [Micromedex;]

(C) **a current or updated reference on injectable drug products, such as Handbook of Injectable Drugs;** [a reference on injectable drug products, such as, Handbook on Injectable Drugs (if sterile parenteral or enteral products are compounded in the facility);]

(D) basic antidote information and the telephone number of the nearest regional poison control center.

(E) **if the pharmacy compounds sterile pharmaceuticals, specialty references appropriate for the scope of services provided by the pharmacy, e.g., if the pharmacy prepares cytotoxic drugs, a reference text on the preparation of cytotoxic drugs, such as Procedures for Handling Cytotoxic Drugs.**

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

(5) Drugs.

(A) - (C) (No Change.)

~~[(D) — IV admixtures. Policies shall be established by the pharmacist-in-charge, with approval of the appropriate committee, which govern the proper preparation and sterility assurance of parenteral products compounded within the ambulatory surgical center.]~~

(6) - (9) (No Change.)

(e) Records.

(1) - (4) (No Change.)

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

(A) - (C) (No Change.)

(D) suppliers' invoices of dangerous drugs and controlled substances; **a pharmacist** ~~[pharmacists or other responsible individuals]~~ shall verify that the controlled drugs listed on the invoices were actually received by clearly recording **his/her** ~~[their]~~ initials and the actual date of receipt of the controlled substances;

(E) - (J) (No Change.)

(6) - (7) (No Change.)