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Review of Classes of Pharmacies

- A – Community
- B – Nuclear
- C – Institutional
- D – Clinic
- E – Non-Resident
- F – FEMCC
- G – Call Center
- H – Limited Prescription Delivery



Review of Classes of Pharmacies

- Pharmacies compounding sterile preparations:
 - A-S
 - C-S
 - E-S



83rd Texas Legislature

- SB 1100
 - Gave TSBP authority to inspect Class E pharmacies and requires the pharmacy to pay all costs associated with the inspection
 - Requires an inspection prior to opening a pharmacy that compounds sterile preparations
 - Requires an inspection before the license can be renewed



83rd Texas Legislature (cont.)

- SB 1
 - Gave TSBP authority to hire 12 new FTEs
 - 5 compliance officers/inspectors
 - 1 field investigator
 - 6 office staff
 - All pharmacies compounding sterile preparations inspected at least annually



§291.133 Pharmacies Compounding Sterile Preparations



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.



Purpose

- The purpose of this section is to provide standards for the:
- 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;
 - 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;
 - compounding and distribution of compounded sterile preparations by a Class A-S pharmacy for a Class C-S pharmacy; and
 - 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.



Training and Education

- Effective September 1, 2015
- All personnel involved in the compounding process are now required to complete an ACPE-approved course in sterile compounding that provides both didactic and experiential training
 - 20 hours for pharmacists
 - 40 hours for pharmacy technicians
- AND on-the-job training of sufficient amount of time to ensure competency in the pharmacy's sterile compounding processes



Training and Education

- Pharmacists/pharmacy technicians must possess knowledge about:
 - aseptic processing;
 - quality control and quality assurance as related to environmental, component, and finished preparation release checks and tests;
 - chemical, pharmaceutical, and clinical properties of drugs;
 - container, equipment, and closure system selection; and
 - sterilization techniques.



Training and Education

- The 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.



Training and Education

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

- two hours of ACPE-accredited continuing education if the individual is engaged in compounding low and medium risk sterile preparations; or
- four hours of ACPE-accredited continuing education if the individual is engaged in compounding high risk sterile preparations.



Training and Education

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

- aseptic technique;
- critical area contamination factors;
- environmental monitoring;
- structure and engineering controls related to facilities;
- equipment and supplies;
- sterile preparation calculations and terminology;
- sterile preparation compounding documentation;
- quality assurance procedures;
- aseptic preparation procedures including proper gowning and gloving technique;
- handling of hazardous drugs, if applicable;
- cleaning procedures; and
- general conduct in the clean room.



Training and Education

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

- every 12 months for low- and medium-risk level compounding; and
 - every six months for high-risk level compounding.
- 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 media-fill challenge testing, and such evaluation documented. Compounding personnel shall not evaluate their own aseptic technique or results of their own media-fill challenge testing.



Training and Education

- Media-fill tests must be conducted at each pharmacy where an individual compounds 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.
- 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.



Training and Education

- Gloved fingertip/thumb sampling
 - No less than three times before initially being allowed to compound
 - Zero colony-forming units growth or the test = failure
 - Repeat test until successful
 - Individuals may not compound until results = zero
 - Pharmacists may supervise pharmacy technicians compounding sterile preparations for no more than 3 days while waiting for results



Commercially Available Products

- Commercially available products may be compounded for dispensing to individual patients or for office use provided the following conditions are met:
 - the commercial product is not reasonably available from normal distribution channels in a timely manner to meet individual patient's needs;
 - the pharmacy maintains documentation that the product is not reasonably available due to a drug shortage or unavailability from the manufacturer; and
 - the prescribing practitioner has requested that the drug be compounded.



Commercially Available Products

- 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.



Low Risk Compounding

Examples of low-risk compounding include the following.

- Single volume transfers of sterile dosage forms from ampules, 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.
- 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.



Medium Risk

Examples of medium-risk compounding. Examples of medium-risk compounding include the following.

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



High Risk

Examples of high-risk compounding. Examples of high-risk compounding include the following.

- Dissolving non-sterile bulk drug powders to make solutions, which will be terminally sterilized.
- 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.
- Measuring and mixing sterile ingredients in non-sterile devices before sterilization is performed.
- 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.



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.



Immediate Use Compounded Sterile Preparations

- 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.
- The compounding procedure occurs continuously without delays or interruptions and does not exceed 1 hour.
- 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.



Immediate Use Compounded Sterile Preparations

- Administration begins not later than one hour following the completion of preparing the compounded sterile preparation.
- 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.
- Hazardous drugs shall not be prepared as immediate use compounded sterile preparations.



Radiopharmaceuticals

- 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.



Radiopharmaceuticals

- 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 clearly separated from routine material-handling procedures and equipment used in preparation activities to avoid any cross-contamination. The preparations shall not require sterilization.



Primary Engineering Control Device

- The pharmacy shall prepare sterile preparations in a primary engineering control device, 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.



Personal Cleansing and Garbing

- Hand cleansing
 - Waterless alcohol-based surgical hand scrub
 - Sterile powder-free gloves
- Hazardous preparations
 - Double glove; or
 - Single gloves – chemotherapy rated



Conditions Receiving "Warning Notices" FY2015



Number of Inspections

Class	FY2015	% of FY2015 Inspections
Class A Pharmacies	2,275	76%
Class A-S	144	5%
Class B Pharmacies	5	<1%
Class C Pharmacies	268	9%
Class C-S	128	4%
Class D Pharmacies	95	3%
Class F Pharmacies	61	2%
Class G Pharmacies	15	<1%
Totals	2,991	100%

Warning Notices

Class	# Pharmacies Receiving WN	% Receiving WN
Class A	992	77%
Class A-S	84	6%
Class B	2	<1%
Class C	80	6%
Class C-S	87	7%
Class D	31	2%
Class F	17	1%
Class G	0	N/A
Totals	1,293	100%

Most Common Warning Notices (All Classes of Pharmacy)

Violation	Number of WN Issued*
Records	731
Sterile Preparations	647
Pharmacy Technicians	564
Drug/Stock Environment	421
Prescriptions	335
Inventory	319

* One pharmacy may receive multiple Warning Notice violations.

**Most Common Warning Notices
(All Classes of Pharmacy) cont.**

Condition	Number of WN Issued	Total
Records		731
Records Not Available	314	
Absence of R.Ph. Record	66	
Rx Not Separated	17	
Rx Records Not Numerical Order	25	
Improper Transfer of RX copies	3	
Invoices Not Separated/Retrievable	122	
Records for Non-Sterile Compounds	169	
No Written Information on RX	10	

**Most Common Warning Notices
(All Classes of Pharmacy) cont.**

Condition	Number of WN Issued	Total
Sterile Preparations		647
No/Incomplete QA/QC	99	
No/Incomplete P&P Manual	237	
No/Inadequate Preparation Area	165	
IV Preparation	131	
No DUR	13	
Cytotoxic/Bio Procedures	2	

Quality Assurance

- Formula validation
- Finished preparation release checks and tests
- Environmental testing
 - Viable and nonviable sampling test
 - Pressure differential monitoring
 - Viable air sampling
 - Compounding accuracy checks



Quality Control

- Verification of compounding accuracy and sterility
 - Follow established quality control procedures to monitor environment and quality
 - Use provisions of USP
 - Document procedures and



Most Common Warning Notices (All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
Pharmacy Technicians		564
No/Incomplete Training	510	
No/Improper Supervision	19	
Improper Registration	29	
No Name Tags	6	

Most Common Warning Notices (All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
Drug Stock/Environment		421
Improper Environment	137	
Out-of-Date Drug Stock	158	
Security	65	
Unsanitary	32	
Improper Drug Storage	20	
Area for Non-Sterile Compounding	7	
Violation of Limited Formulary	2	

**Most Common Warning Notices
(All Classes of Pharmacy) cont.**

Condition	Number of WN Issued	Total
Prescriptions		335
Lack Proper Information	159	
Prescription Label Incorrect	136	
Official Rx Non-Compliance	40	

**Most Common Warning Notices
(All Classes of Pharmacy) cont.**

Condition	Number of WN Issued	Total
Inventory		319
No Annual Inventory	84	
No Change of Ownership Inventory	5	
No Change of PIC Inventory	35	
Incomplete Inventory	194	
Improper Drug Destruction	1	

**Violations NOT Resulting
in Warning Notices**

- Individuals performing technician duties without an active registration.
- Technicians performing technician duties with no pharmacist on site.
- Technicians performing pharmacist-only duties with no pharmacist on site (results in emergency temporary suspension hearing).
- Pharmacists who do not verbally counsel a patient on a new prescription.



Violations NOT Resulting in Warning Notices

- Pharmacy is not able to produce 2 consecutive annual inventories.
- PIC falsifies response to a Warning Notice.
- Pharmacies dispensing/shipping prescription drugs into other states without holding a pharmacy license in that state.
- Pharmacies compounding sterile preparations without proper licensure (e.g., Class A who should have a Class A-S pharmacy license).



Violations NOT Resulting in Warning Notices

- Egregious Conditions
 - Dispensing CII's pursuant to prescriptions not issued on an Official Form;
 - Excessive quantity of out-of-date stock (i.e., more than 25% of the inventory);
 - Pharmacy closed and did not notify TSBP of closing;
 - Operating without a PIC for an extended period of time (i.e., 3 months or more).



Violations NOT Resulting in Warning Notices

- Continuing threat – For example:
 - Impaired pharmacist on duty; or
 - Sterile compounding pharmacies who have extensive non-compliance with Board Rule 291.133 and will not voluntarily agree to "cease and desist" sterile compounding until conditions have been corrected.
- Both of these scenarios would result in an Emergency Temporary Suspension Hearing.



Thank You!



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Final Reminders

- Receiving Credit
- Look for the quiz and evaluation to be posted in your Lifelong Learning Account 5-7 days from now
- You will have 30 days from the date they are posted to complete them.
- Complete these items to generate your certificate, which can be accessed at any time through your Lifelong Learning Account.

Trouble accessing your Lifelong Learning Account?

Questions about your attendance?

Call the help desk:
1-800-215-0641
Select Option 1

Please note: This course is accepted by the Texas State Board of Pharmacy for both general credit and as fulfilling the law requirement. However, it is NOT ACPE certified and will not appear in your CPE Monitor account.



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Thank You!

Thank you for your attendance!

If you have additional compliance-related questions, please call the TSBP Compliance Line at 512-305-8070.

For questions about today's presentation, please email us at:

educationcoordinator@pharmacy.texas.gov



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