Sterile Compounding Inspections

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TEXAS STATE BOARD OF PHARMACY

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Licensing of Pharmacies

- The Texas State Board of Pharmacy licenses all pharmacies located in:
  - Texas (Community, Hospital, etc.); and
  - Other states, if the pharmacies dispense and ship prescription drugs to Texas residents.

Texas Pharmacy Act

- The Texas Pharmacy Act specifies that:
  - New sterile compounding pharmacies may not open until inspected; and
  - Existing sterile compounding pharmacies may <u>NOT</u> renew their Biennial registration unless they have:
    - Been inspected as specified by the Board rules; and
    - If located in a state other than Texas, reimbursed the Board for all expenses incurred by the Board in inspecting the pharmacy.

Texas Pharmacy Act (cont.)

- The Texas Pharmacy Act requires:
  - A pharmacy that compounds a sterile product to notify the Board:
    - Immediately of any adverse effects reported to the pharmacy or known by the pharmacy to be potentially attributable to a sterile product compounded by the pharmacy; and
    - Not later than 24-hours after the pharmacy issues a recall for a sterile product compounded by the pharmacy.

Training of **Pharmacists** that Compound Sterile Pharmaceuticals

- All pharmacists who compound sterile preparations or supervise pharmacy technicians compounding sterile preparations must complete through a single course, a minimum of 20 hours of instruction and experience in the areas listed in the rules.

Pharmacists' Training

- The pharmacists' training must be obtained through completion of a:
  - Recognized course in an accredited college of pharmacy; or
  - Course sponsored by an ACPE accredited provider covering the items listed in Board rules.

Training of **Pharmacy Technicians** that Compound Sterile Pharmaceuticals

- Pharmacy technicians must have completed a 40-hour course provided by an ACPE approved provider covering the items listed in Board rules.

Inspections of Sterile Compounding Pharmacies (FY2015)

# OF PHARMACIES THAT COMPOUND STERILE PRODUCTS			
	Class A-S	Class C-S	Class E-S	Totals
	144	128	66	338

Note: Pharmacies located within Texas are inspected by TSBP staff.
Pharmacies located in a state other than Texas are inspected by TSBP staff or by inspectors contracted and trained by TSBP.

FY2015 Inspection Violations

Inspection Violations (Warning Notices Issued)	
Unsanitary	32
Improper Environment	137
Incomplete QA/QC	99
No/Incomplete P&P Manual	237
No/Inadequate Preparation Area	165
Cytoxic/Bio Procedures	2

Problem Inspections

- If an inspector finds problems that he/she considers a danger to the public, the pharmacy is given the opportunity to <u>voluntary cease</u> the problem activity.

- If the pharmacy refuses to cease the activity, a <u>temporary suspension</u> hearing to immediately suspend the license of the pharmacy will be scheduled.

Testing of Compounded Products

SUMMARY OF COMPOUNDED SAMPLE TESTING PROGRAM FY 2011 – FY 2015						
	FY2011	**FY2012**	**FY2013**	**FY2014**	**FY2015**	**5-Yr. Avg.**
Total # Samples Tested	37	28	58	124	193	88
# Non-Sterile Samples Tested	27	20	9	7	24	17
# Potency Failures	4	2	1	2	5	3
# Sterile Samples Tested	10	8	49	117	169	71
# Potency Failures	4	1	2	9	24	0
# Sterility Failures	0	1**	0	0	0	<1
# Fungal Failures*	N/A	N/A	0	0	0	0
# Endotoxin Failures	0	0	0	0	0	0

*Fungal Testing began in FY2012   **Nasal product