Sterile Compounding Inspections

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Texas State Board of Pharmacy

FDA’s 2016 Inter-governmental Working Meeting on Pharmacy Compounding
September 21, 2016
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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.
The Texas Pharmacy Act specifies that:

- New sterile compounding pharmacies may not open until inspected; and

- Existing sterile compounding pharmacies may NOT 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.
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)

<table>
<thead>
<tr>
<th>Class A-S</th>
<th>Class C-S</th>
<th>Class E-S</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>144</td>
<td>128</td>
<td>66</td>
<td>338</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Inspection Violations</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(Warning Notices Issued)</td>
<td></td>
</tr>
<tr>
<td>Unsanitary</td>
<td>32</td>
</tr>
<tr>
<td>Improper Environment</td>
<td>137</td>
</tr>
<tr>
<td>Incomplete QA/QC</td>
<td>99</td>
</tr>
<tr>
<td>No/Incomplete P&amp;P Manual</td>
<td>237</td>
</tr>
<tr>
<td>No/Inadequate Preparation Area</td>
<td>165</td>
</tr>
<tr>
<td>Cytoxic/Bio Procedures</td>
<td>2</td>
</tr>
</tbody>
</table>

**Total Violations:** 641
Problem Inspections

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

If the pharmacy refuses to cease the activity, a temporary suspension 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**

<table>
<thead>
<tr>
<th></th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Total # Samples Tested</strong></td>
<td>37</td>
<td>28</td>
<td>58</td>
<td>124</td>
<td>193</td>
<td>88</td>
</tr>
<tr>
<td><strong># Non-Sterile Samples Tested</strong></td>
<td>27</td>
<td>20</td>
<td>9</td>
<td>7</td>
<td>24</td>
<td>17</td>
</tr>
<tr>
<td><strong># Potency Failures</strong></td>
<td>4</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td><strong># Sterile Samples Tested</strong></td>
<td>10</td>
<td>8</td>
<td>49</td>
<td>117</td>
<td>169</td>
<td>71</td>
</tr>
<tr>
<td><strong># Potency Failures</strong></td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>4</td>
<td>9</td>
<td>24</td>
</tr>
<tr>
<td><strong># Sterility Failures</strong></td>
<td>0</td>
<td>1**</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>&lt;1</td>
</tr>
<tr>
<td><strong># Fungal Failures</strong></td>
<td>N/A</td>
<td>N/A</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong># Endotoxin Failures</strong></td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

*Fungal Testing began in FY2012  **Nasal product