California Compounding

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California State Board of Pharmacy
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Statutory Mandate

Protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

*California Business and Professions Code section 4001.1*
Ancient History

• Pre-1990
  – California has statutory law allowing pharmacies to compound medications for prescriber office use
  – Regulations in place for “parenteral compounding”
  – Pharmacies can contract to do patient-specific parenteral compounding for another pharmacy

• Early 1990s
  – Regulations developed to define reasonable quantity that a pharmacy may compound for prescriber office use or anticipatory compounding based on prior dispensing of pharmacy
Sterile Injectable Compounding

• 2001-2013
  -- May 2001: CA community pharmacy compounds Betamethasone suspension due to mfg. drug shortage, injuring 30, killing 3
  -- Board establishes specialty compounding license/ with accreditation exemption alternative to licensure. Annual inspection for board licensees
  -- Regs developed, amended: **all** pharmacies compounding injectables must comply with requirements whether or not specially licensed
Early 2012

• Board again amends compounding regs
• Board becomes concerned with substandard compounded products reaching CA, low commitment from accrediting agencies to inspect and enforce board standards
• Drug shortages, especially of hospital medications, are a growing concern
Fall 2012

- The world changes for pharmacy, especially sterile compounding pharmacy
- Immediate inspections of large compounding facilities, sometimes in conjunction with FDA
- Compounding Committee reformed
2013

• Board sponsors legislation (SB 294, Emmerson)
  -- Redefines sterile compounding to include inhalation, eye administration and injectable compounding
  -- Eliminates accreditation as an alternative to board licensure
  -- Inspections by board of CA and nonresident pharmacies
More 2013 Law

- All entities shipping into California must comply with CA provisions
- Recalls reported to board and MedWatch within 12 hours
- Report any discipline or accreditation issues to board
2014

• Regulations for compounding and sterile compounding again under revision
• Board focuses on inspecting hospitals who will require board licenses July 1, as the accreditation exemption expires
• Board will begin out of state inspections
The Numbers
(October 2013)

• Pharmacies 6,928
  – Community 6,434
  – Hospital 494

• Sterile Compounding Pharmacies 269

• Nonresident 499
• Nonresident Sterile Compounding 96
The Inspectors

• The board has 38 inspectors currently
• Effective 7/1/14, the board will have 10 additional inspectors
• We estimate another 700 sterile compounding pharmacies we will have to inspect – we estimate 950 sterile compounding pharmacies licensed by CA
• We will be inspecting out of state – we will call home state EO before coming – all inspections are unannounced
Cease & Desist Orders Issued Since 9/2012

• 2012 – 4 pharmacies (2 out of state)
• 2013 – 7 pharmacies/8 cease & desists and
• 2013 – 6+ pharmacies out of state, shipping into CA without license, told to stop shipping into state
Inspection Findings
(1/1/14 – 3/6/14)

(only CA locations)

290 Sterile Compounding Inspections

135 Hospital

95 Currently accredited or new pharmacies

60 Annual reinspections of current licensed sterile compounders
## Inspection Outcomes
(1/1/14 -- 3/6/14)

- 222 violations were recorded in 86 pharmacies

<table>
<thead>
<tr>
<th>Pharmacy Type</th>
<th>Violations</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital</td>
<td>117</td>
<td>52.7 %</td>
</tr>
<tr>
<td>New LSC Pharmacy</td>
<td>31</td>
<td>14.0 %</td>
</tr>
<tr>
<td>Existing LSC Pharmacy</td>
<td>74</td>
<td>33.3 %</td>
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</tbody>
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Top Violations Discovered in Hospitals (N= 117)

- No Compounding Self Assessment 17 (15.2 %)
- Facility Issues 14 (12.0 %)
- Quality Assurance Issues 15 (12.0 %)
- General Compounding/QA issues 10 (8.5 %)
- Inadequate Compounding Attire 10 (8.5 %)
- Insufficient or Nonexistent Ps & Ps 9 (7.7 %)
- Incomplete Compounding Records 8 (6.8 %)
Top Violations in Non-Hospital Compounding (N= 105)

- Inadequate sterile compounding QA and process validation 21 (20.0%)
- Inadequate Compounding Garb 14 (13.3%)
- Substandard Facility/Equipment 13 (12.4%)
- Inadequate/incomplete Staff Training 11 (11%)
- No compounding Self Assessment 10 (9.5%)
Are Manufactured Medications Trouble Free?

• Pharmacies have been the focus of investigations for substandard compounded medications nationally; however, manufactured drugs are also generating serious issues on the quality of our medications:
  – From July 1, 2013 – March 17, 2014, the board released 273 recall notices from manufacturers or others on drugs being recalled at the pharmacy or patient level
Thank you

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