

California Compounding

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California State Board of Pharmacy

March 21, 2014

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 allows 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

	Violations	
Hospital	117	52.7 %
New LSC Pharmacy	31	14.0 %
Existing LSC Pharmacy	74	33.3 %

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%)



euro-pro

causation

In the event of Food Fire-up
keep door closed

Toast
Keep Warm



250
200
150



Stay On

60
50
Min



Form

GLY

0724-08

9274

Humco

HEP

TECH

ST FOR

DA

EXTR

Life

ACETONE

HOUSEHOLD

173 mL

CHEMICAL MFG. CORP.

FERRIC SULFATE SOLUTION

GARDENA CALIFORNIA 90247

IPT

DEVELOPMENT

Dimethylsulfoxide

Analyzed REAGENT

9274

PHILIPSON

POLO

20

1 GALLO

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30 CAP

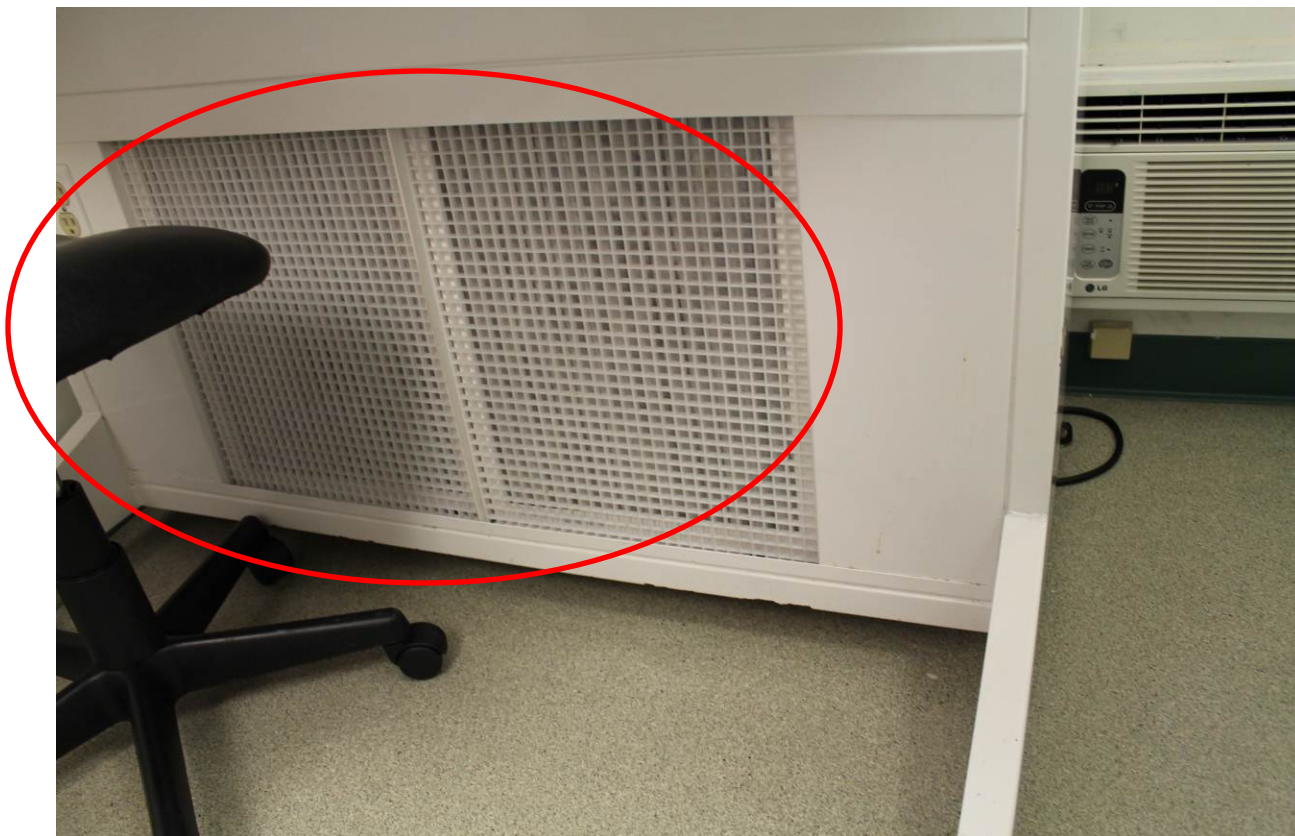
PHARMACY

AMERICAN

NORTH PLUM



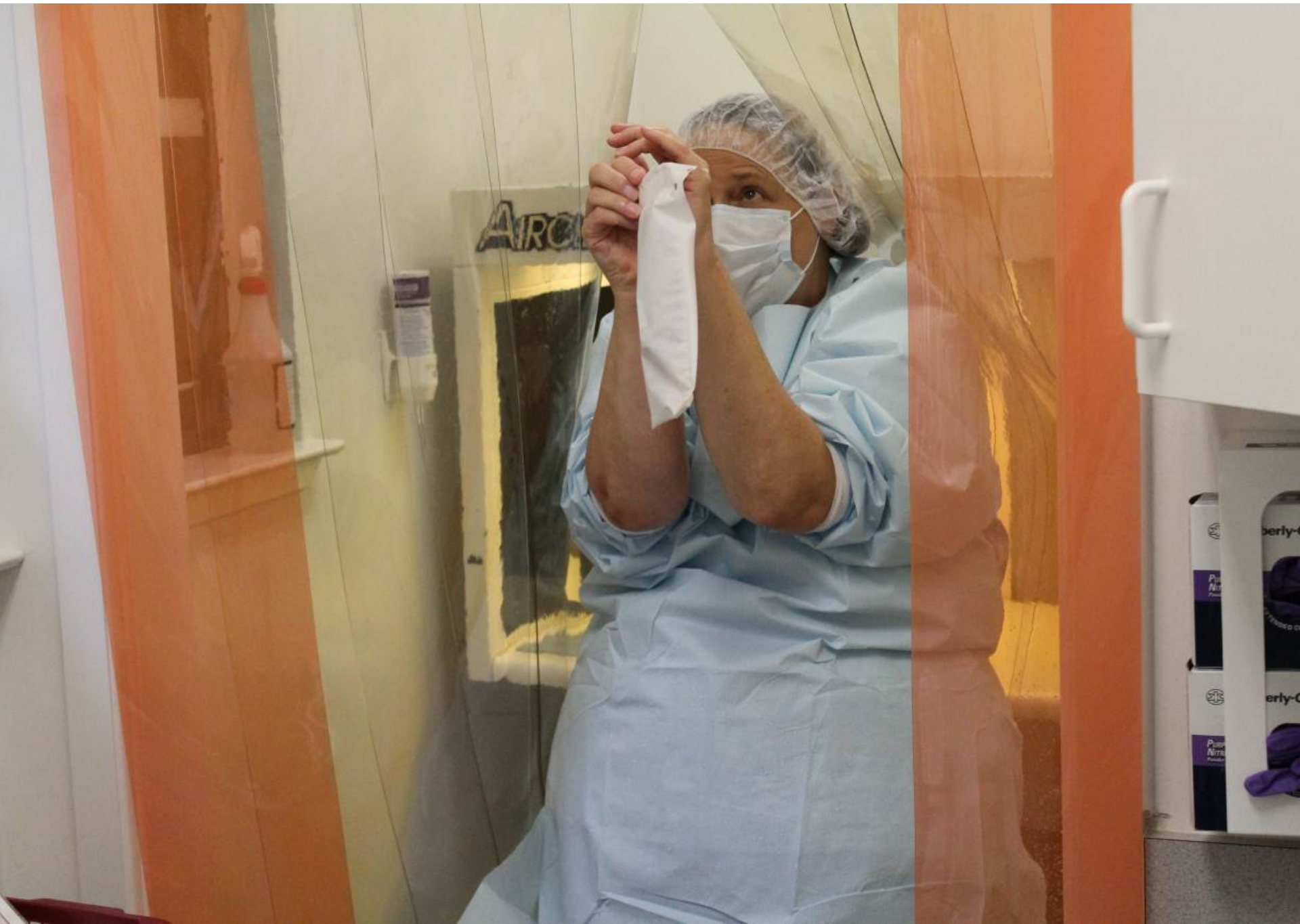








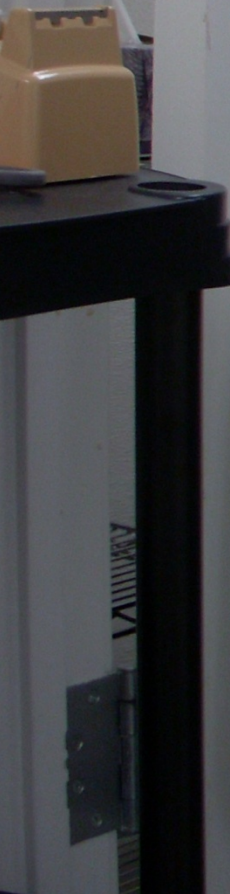








Caution:
Toilet flushes up
10 seconds





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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