

California's Outsourcing Facility Licensure Program

CA State Board of Pharmacy

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Contact Information

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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.

CA Business and Professions Code 4001.1

California Law

Sterile Compounding Pharmacies

- Board licenses sterile compounding pharmacies and nonresident sterile compounding pharmacies.
- The board conducts inspections before license issuance and annual renewal both within and outside CA

Currently:

917 CA-located sterile compounding
pharmacies

92 nonresident sterile compounding pharmacies

Outsourcing Facilities

- Legislation currently on Governor's desk – has until the end of September to sign
- January 1, 2016 effective date
- Facility must be located within the USA
- Performs compounding of sterile and nonsterile drugs
- Registered with the FDA as outsourcing facility
- If doing business within CA, a board license is required

Additional Requirements

- Same facility cannot be concurrently licensed with the board as a compounding pharmacy
- Board is required to review any FDA requirements or guidance documents within 90 days to determine if revisions to law or regs are required
- Outsourcing facility shall not perform the duties of a pharmacy

General Requirements

- License is not transferrable to new owners or another location
- Must comply with federal current good manufacturing principles and board regulations
- Temporary permits may be issued for good cause

Before Renewal

An outsourcer must provide the board with:

- Policies and procedures for sterile and non-sterile compounding
- Copies of inspection reports conducted by other agencies, accreditation reports and certification reports of equipment and facilities conducted in the prior 12 months
- A list of all products compounded in the last 12 months (as reported to FDA)

Specific Reports to the Board

An outsourcer must report to the board:

- Any disciplinary or other action taken by another state or FDA within 10 days
- Notice within 24 hours of any recall initiated
- A copy of any clinically related complaint from a provider, pharmacy or patient in CA within 72 hours
- Notice within 24 hours of any adverse effects

Nonresident Outsourcers

- Licensed in CA before shipping into state
- Compliance with CA law involving outsourcing facilities
- Cost of inspection to be paid in advance

High-Risk Recalls

- When issued, outsourcer must notify the recipient pharmacy, prescriber or patient as soon as possible within 24 hours of recall IF:
 - Use of product may cause serious adverse health consequences or death
 - The product was dispensed in CA
 - Contact required of patients or prescribers

Citations and Fines

- Board can cite and fine violations of law or regulation \$5,000 per occurrence

Cease & Desist Authority

- Applies to CA resident an out-of-state located outsourcers, both sterile and nonsterile products, where compounded products pose a threat to public health or safety.
- Order issued by executive officer to cease production of product, duration 30 days.
- Written notice to outsourcer, appeal within 15 days; hearing within 5 days of request
- Failure to comply is unprofessional conduct

Thank You

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