

Sterile Compounding Pharmacy License Mandatory for California Pharmacies

Background

Joint Commission accreditation is no longer sufficient to avoid having to register as a compounding pharmacy in California. On October 04, 2013, SB 294 was signed into law and it specifically prohibits a pharmacy from compounding or dispensing, and a nonresident pharmacy from compounding for shipment into California, sterile drug products for injection, administration into the eye, or inhalation, unless the pharmacy has obtained a Sterile Compounding Pharmacy License from the California Board of Pharmacy.

What Pharmacies Are Affected by the New Law?

All pharmacies (including a nonresident pharmacy that ships to California) that compound sterile drug products for injection, administration into the eye, or inhalation.

Effective Date of the Law

Affected pharmacies must have a Sterile Compounding Pharmacy License by July 1, 2014.

License Application:

The application for a Sterile Compounding Pharmacy License may be accessed at http://www.pharmacy.ca.gov/forms/app_forms.shtml.

- Review Board of Pharmacy form 17A-47, which lists the Requirements For Filing An Application For Sterile Compounding License.
- Complete form 17A-48 – Application For A Sterile Compounding Pharmacy License.
- Insert licensee ownership information as solicited on page 2 of form 17A-48. Note the following for corporation owners:
 - If the pharmacy is owned by a nonprofit Corporation, provide information for only corporate officers (CEO, CFO, and Secretary) as filed on the Statement of Information with the California Secretary of State. Information about the Board of Directors is not required.
 - If the pharmacy is owned by a for-profit Corporation,



by Janet C. Eisenbeis & Deidré A. Schönfeldt



provide information about individual owners and corporate officers (CEO, CFO, and Secretary) as filed on the Statement of Information with the California Secretary of State. Information about the Board of Directors is not required.

- Attach a list of current corporate officers and board of directors (names only) and a current Statement of Information filed with the California Secretary of State.
- Attach an ownership organization chart.
- Attach a copy of the pharmacy's policies and procedures for sterile compounding.
- A corporate officer, owner, or partner, as applicable, must sign form 17A-48 as the "Authorized Representative" of the pharmacy licensee.
- The signatory (Authorized Representative) must also complete the "Request for Live Scan Service" form 17M-15 (811) located at http://www.pharmacy.ca.gov/forms/app_forms.shtml. Note the signatory (Authorized Representative) of a nonprofit corporation pharmacy owner is exempt from the Live Scan Requirements.
- Attach a check for the application fee made out to the California Board of Pharmacy for \$600 for resident pharmacies and \$780 for a nonresident pharmacies.
- Be prepared to provide the following additional information if requested by the Board of Pharmacy after its initial review of the Application:
 - Copies of inspection reports conducted on the pharmacy premises;
 - Accrediting agency reports;
 - A list of all sterile medications compounded by the pharmacy;
 - A Compounding Self-Assessment form (17M-39).

Inspection by the California Board of Pharmacy

Prior to the issuance of the new license, the California Board of Pharmacy will conduct an initial licensure inspection of the pharmacy.

Timing

The Board of Pharmacy is encouraging affected pharmacies to file the Sterile Compounding Pharmacy License Application as soon as possible to allow time required for application processing and inspection to occur before July 1, 2014. Failure to obtain the new license by July 1, 2014 may have significant effects on the pharmacy's ability to operate after that date. Hence the timing for submission of the Application is critical.

New Regulations

Changes to Title 16 are in the works. You can review the proposed regulations by going to the California Board of Pharmacy's website at http://www.pharmacy.ca.gov/laws_regs/index.shtml

For more information, please contact:

Janet C. Eisenbeis, Partner
916-491-3039
jeisenbeis@hansonbridgett.com

Deidré A. Schönfeldt, Partner

415-995-5050
dschonfeldt@hansonbridgett.com