



California State Board of Pharmacy

1625 N. Market Blvd, N219, Sacramento, CA 95834

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www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

APPLICATION REQUIREMENTS FOR HOSPITAL IN-PATIENT STERILE COMPOUNDING PHARMACY LICENSE

(Business & Professions Code Sections 4127 and 4127.1)

A California pharmacy shall not compound sterile drug products unless the pharmacy has obtained a sterile compounding pharmacy license from the board pursuant to Business and Professions Code Sections 4127 and 4127.1. The license shall be renewed annually and is not transferable.

A license to compound sterile drug products may not be issued or renewed until the location is inspected by the board and found to be in compliance with the Business and Professions Code and regulations adopted by the board.

All pharmacies that compound sterile drug products must follow board regulations for sterile compounding found in the California Code of Regulations beginning with section 1751.

For an application to be considered complete, the following items must be submitted:

1. A completed and signed Application for Hospital In-Patient Sterile Compounding Pharmacy License (form LSC inpatient app (2/14))
2. Fee of \$780 for each compounding location identified on the application. Payment shall be made to "Board of Pharmacy."

NOTE: FOR TEMPORARY LICENSE (when a change of ownership occurs):

This application form may be used to apply for a temporary permit when the ownership of a pharmacy that is licensed to compound sterile drug products is transferred from one entity to another. Before a change of ownership occurs, the prospective new owners must:

- Submit an application requesting a temporary permit along with all required documents for a new license. (form LSC inpatient app (2/14))
 - Submit the \$550 temporary permit fee for each location listed, in addition to the \$780 application fee for each compounding location.
 - If a temporary permit is not requested, **OPERATIONS MUST STOP** until a new license to compound sterile drug products is obtained.
3. All requested supporting documents (including the pharmacy's policies and procedures for sterile compounding and the completed self-assessment form) may be submitted on disk, CD or hard copy. If emailing the required documents, please send to CompoundingPharmacy@dca.ca.gov.
 4. Provide copies of all inspection reports conducted of the pharmacy's premises done by agencies other than the Board of Pharmacy and any reports from a private accrediting agency that have been conducted in the prior 12 months documenting the pharmacy's operations.



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APPLICATION FOR HOSPITAL IN-PATIENT STERILE COMPOUNDING PHARMACY LICENSE

Please print or type ALL BLANKS MUST BE COMPLETED; IF NOT APPLICABLE, ENTER N/A

Name of Pharmacy:				
Pharmacy Telephone Number:			Pharmacy License Number	
Address of Pharmacy:	Street and Number	City	State	Zip Code

List below all locations where sterile compounding will be performed. Attach additional sheets, if needed.			
Location (e.g., floor, room number)	Type of compounding performed: (Check all that apply) <input type="checkbox"/> Non-sterile to sterile <input type="checkbox"/> Sterile to sterile <input type="checkbox"/> Chemotherapy <input type="checkbox"/> Radiopharmacy	Type of Products to be compounded: (Check all that apply) <input type="checkbox"/> Injectable <input type="checkbox"/> Inhalation <input type="checkbox"/> Ophthalmic	Number of Hoods/Barrier isolators _____
Location (e.g., floor, room number)	Type of compounding performed: (Check all that apply) <input type="checkbox"/> Non-sterile to sterile <input type="checkbox"/> Sterile to sterile <input type="checkbox"/> Chemotherapy <input type="checkbox"/> Radiopharmacy	Type of Products to be compounded: (Check all that apply) <input type="checkbox"/> Injectable <input type="checkbox"/> Inhalation <input type="checkbox"/> Ophthalmic	Number of Hoods/Barrier isolators _____
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FOR OFFICE USE ONLY		
STAFF REVIEW	CASHIER LOG	
<input type="checkbox"/> _____ <input type="checkbox"/> _____ Referred for inspection: _____ Inspection Completed: _____	Approved _____ Denied _____ Date _____	Cashier # _____ Date _____ Amount of fee _____

