



HOSPITAL IN-PATIENT STERILE COMPOUNDING PHARMACY LICENSE INSTRUCTIONS

(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.

APPLICATION PROCESSING TIMEFRAME

- Allow the board 90 days to process the application. You will be notified in writing if your application is incomplete.
- Due to current workload the board is unable to respond to application status requests unless the application has been on file for over 90 days.
- You may confirm with your bank that your check has been processed. This will serve as verification that the board received your application.
- To verify if your license has been issued, visit the board's website at www.pharmacy.ca.gov. Select "Verify a License" and enter the pharmacy name. It will take from 4 to 6 weeks from the date a license is issued to receive the license document.

APPLICATION INSTRUCTIONS

Print the entire application and any required forms indicated in the **WHAT MAKES AN APPLICATION COMPLETE**. Review the **WHAT MAKES AN APPLICATION COMPLETE** section to ensure you have completed and included all the required forms prior to submitting the application. Failure to submit all necessary items will delay the processing the application.

NOTE: TEMPORARY PERMIT - Whenever a change of ownership occurs, a temporary permit must be requested or all operations requiring a sterile compounding license must cease. An additional fee of \$550.00 for the temporary permit must be submitted. If a temporary permit is not requested, **OPERATIONS MUST STOP** until a new license to compound sterile drug products is obtained.

WHAT MAKES AN APPLICATION COMPLETE

Use this checklist to ensure your application is complete prior to submitting. If the application is not complete, the board will notify you of any deficiencies. Failure to complete your application within 60 days after being notified of deficiencies will result in the application being deemed abandoned. You will then be required to file a new application and meet all of the requirements in effect at the time of reapplication.

- **APPLICATION FEE PRIOR TO JULY 1, 2017 \$780**: When you send your application, include a check or money order for \$780 made payable to the Board of Pharmacy for **EACH** compounding location identified on the application. The application fee is non-refundable and the application must be received in the office no later than June 30, 2017 in order to pay the processing fee of \$780. *Applications received after June 30, 2017, with the payment of \$780 may be returned for the new application fee of \$2,380. See Note above regarding Temporary Permit.*

APPLICATION FEE AS OF JULY 1, 2017 \$1,645: When you send your application, include a check or money order for \$1,645 made payable to the Board of Pharmacy for **EACH** compounding location identified on the application. The application fee is non-refundable. Applications received on or after July 1, 2017, must submit the processing fee of \$1,645. **See Note above regarding Temporary Permit.**

- **HOSPITAL IN-PATIENT STERILE COMPOUNDING PHARMACY APPLICATION** (form 17A-83): The application must be completed in its entirety. Failure to do so will result in an incomplete application and a deficiency letter will be mailed to you. All signatures must be original signatures. Scanned or stamped signatures are not accepted.

NOTE: If application is for a change of ownership, evidence that a change of ownership has been sought or obtained for the hospital pharmacy license must be submitted with this application

- **POLICIES AND PROCEDURES:** A copy of the pharmacy's proposed policies and procedures for sterile compounding submitted on disk, CD or hard copy. If emailing the policies and procedures, please send to CompoundingPharmacy@dca.ca.gov.
- **SELF-ASSESSMENT FORM:** A copy of the pharmacy's self-assessment may be submitted on disk, CD or hard copy. If emailing the policies and procedures, please send to CompoundingPharmacy@dca.ca.gov.



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GAVIN NEWSOM, GOVERNOR

**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"/> _____	Approved _____	Cashier # _____
<input type="checkbox"/> _____ <input type="checkbox"/> _____	Denied _____	Date _____
Referred for inspection: _____	Date _____	Amount of fee _____
Inspection Completed: _____		

Do you perform centralized packaging for unit dose packaging? If yes, provide the license number for the centralized hospital packaging location.	Yes <input type="checkbox"/> No <input type="checkbox"/>
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Indicate type of ownership:	<input type="checkbox"/> Individual	<input type="checkbox"/> Partnership	<input type="checkbox"/> Corporation
	<input type="checkbox"/> Not-for-profit Corporation	<input type="checkbox"/> Government Owned	<input type="checkbox"/> Limited Liability Company (LLC)

Indicate whether this application for a Sterile Compounding License is for:
<input type="checkbox"/> New License <input type="checkbox"/> Change of Location <input type="checkbox"/> Change of Ownership

If this is a **change of location**, or **change of ownership**, enter previous name, address and license number below.

Name:	Address:	License Number:
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Pharmacist in Charge

Name of pharmacist-in-charge of licensed pharmacy:		Pharmacist license number	
Residence address:	Street and Number	City	State Zip Code

I certify that the policies and procedures of the sterile compounding for this pharmacy are consistent with California Code of Regulations Title 16, section 1735 et seq and 1751 et seq. I further certify that the submitted self-assessment for sterile compounding is consistent with California Code of Regulations, Title 16, section 1735.5. Furthermore, the application to compound sterile drug products is being submitted by the owner of the license at this location.

(A copy of the pharmacy's proposed policies and procedures for sterile compounding and the sterile compounding self-assessment must accompany the application.)

Signature of Pharmacist-in-Charge

Name (please print)

Date

PLEASE READ CAREFULLY

This application must be approved by the California State Board of Pharmacy before a Sterile Compounding License will be issued.

If changes are made during the application process, you may need to submit a new application with the appropriate fees. **Any application not completed within 60 days after you have been notified by the board of deficiencies in your file, may be deemed to have been abandoned, and you may be required to file a new application and meet all the requirements which are in effect at the time of application. Fees applied to this application are not transferable and are not refundable.**

Any material misrepresentation in the answer of any question is grounds for refusal or subsequent revocation of a license, and is a violation of the Penal Code of California. All items of information requested in this application are mandatory. Failure to provide any of the requested information will result in the application being rejected as incomplete.

The information will be used to determine qualifications for licensure under California Pharmacy Law. The officer responsible for information maintenance is the Executive Officer, (916) 518-3100, 12720 Gateway Oaks Drive, Suite 100 Sacramento, CA 95833. The information may be transferred to another governmental agency (such as a law enforcement agency) if necessary for it to perform its duties. Each individual has the right to review the files or records maintained on him/her by the Board of Pharmacy, unless the records are identified as confidential information and exempted from disclosure by the California Information Practices Act. (Civil Code §1798, et seq.)

Required Signature

Under penalty of perjury, under the laws of the State of California, I certify and affirm that: (1) I am a person authorized to act for and bind the applicant and I am at least 18 years of age; (2) I have read the foregoing application and know the contents thereof and each and every statement made therein is true; (3) I understand that falsification of any information I this application may constitute grounds for denial or subsequent revocation of the license; (4) no person other than the applicant [or applicants] has any direct or indirect interest in the applicant's [or applicants'] business to be conducted under the license for which this application is made; and (5) all supplemental statements filed with this application are true, complete and accurate.

Signature of Person Authorized to Submit Application

Print Name of Authorized person	Title	Date Signed
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Provide the name and contact information for the person to contact should clarification be needed.

Please Print

Name of Contact Person	
Telephone number of contact person	Email address of contact person