



California State Board of Pharmacy

1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900 Fax: (916) 574-8618
www.pharmacy.ca.gov

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

HOSPITAL SATELLITE COMPOUNDING PHARMACY APPLICATION INSTRUCTIONS

(Business & Professions Code Sections 4127.15)

A California pharmacy shall not compound sterile drug products unless the pharmacy has obtained a sterile compounding pharmacy license from the board.

A hospital satellite compounding pharmacy shall compound sterile drug products for administration only to registered hospital patients who are on the premises of the same physical plant in which the hospital satellite compounding pharmacy is located.

A hospital satellite compounding pharmacy license shall not be issued or renewed until the location is inspected by the board and found to be in compliance.

IMPORTANT: Please follow these instructions completely. Failure to submit the necessary items will delay the processing of your application. If the number of forms included in this application is not sufficient, please make copies. Please allow approximately 60 days from the date your application is submitted before checking on the status. The contact person designated on the application will be advised if additional information is necessary. Any application not completed within 60 days after being notified by the board of deficiencies, may be deemed to have been abandoned, and 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.

A checklist is provided with the application to assist you. The board encourages the applicant to refer to the checklist to assist with the application process and to submit all supporting documentation along with the application. It is not uncommon for the board to request additional documentation to confirm or substantiate information contained in the application.

Note: A hospital satellite compounding pharmacy license is nontransferable. All approved change of ownership and change of location applications result in a new license number being issued. Operating the facility prior to being issued a new license due to a change of ownership or location is unlicensed activity.

- **Change of Ownership:** *A change of ownership requires board approval prior to the sale occurring.*
- **Change of Location:** *A change of physical location requires board approval prior to the change occurring.*

CHECKLIST FOR FILING A HOSPITAL SATELLITE COMPOUNDING PHARMACY APPLICATION

- Hospital Satellite Compounding Pharmacy Application (17A-107):** Complete the entire application and submit with original signatures.
 - **Do Not Leave Blanks:** If an item or question is not applicable, indicate N/A.
 - **Doing Business As (DBA):** If using a DBA, submit a Fictitious Business Name Statement.
- Application Processing Fee \$1,645:** Include a check or money order for \$1,645 made payable to the Board of Pharmacy. This fee is nonrefundable. (NOTE: A government owned pharmacy is fee exempt.)
 - To apply for a temporary license, an additional fee of \$550 must be submitted in addition to the application processing fee. If other than a change of ownership and/or location, include a written letter signed by the owner / partner / officer / member that clearly explains why it is in the best interest of the public for the board to issue the facility a temporary license.
- POLICIES AND PROCEDURES:** A copy of the pharmacy's proposed policies and procedures for sterile compounding that will be performed at the location, please submitted on disk, CD or hard copy. If emailing the policies and procedures, please send to Compounding.Pharmacy@dca.ca.gov.

- **SELF-ASSESSMENT FORM (17M-39):** A copy of the pharmacy's compounding self-assessment may be submitted on disk, CD or hard copy. If emailing the self-assessment form, please send to Compounding.Pharmacy@dca.ca.gov.
- **General Acute Care Hospital License:** Submit a copy of the general acute care hospital license issued by the California Department of Public Health.



HOSPITAL SATELLITE COMPOUNDING PHARMACY LICENSE APPLICATION

Applicant Business Information Please type or print

Name of Hospital Satellite Compounding Pharmacy: (Cannot exceed 65 characters including spaces)				
Address of Hospital Satellite Compounding Pharmacy Location:		Street and Number	City	State Zip Code
Name of Hospital Pharmacy:			Hospital Pharmacy License Number:	
Address of Hospital Pharmacy Location:		Street and Number	City	State Zip Code
Hospital Satellite Compounding Pharmacy Telephone Number: ()		Hospital Pharmacy Telephone Number: ()		

Application Check all that apply and attach appropriate fee(s). Additional fee is required for a temporary license request.

<input type="checkbox"/> New License Anticipated Opening Date: _____	<input type="checkbox"/> Temporary License Request
<input type="checkbox"/> Change of Ownership Anticipated Change of Ownership Date: _____	
<input type="checkbox"/> Change of Physical Location Anticipated Move Date: _____	

Change of Ownership or Location Provide the following

Name on Current License:		License Number and Expiration Date:		
Address:		City	State	Zip Code
Effective Date of Transaction/Move: Month/Day/Year				

Compounding Information Please indicate the type of compounding to be performed at the Hospital Satellite Compounding Pharmacy:
 (Check all that apply)

Type of compounding performed: <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: <input type="checkbox"/> Injectable <input type="checkbox"/> Inhalation <input type="checkbox"/> Ophthalmic	Number of Hoods/Barrier isolators List # _____
---	---	---

Do you perform centralized packaging for unit dose packaging? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, provide the license number for the centralized hospital packaging location. _____

Contact Person The board may only discuss the status of this application with the authorized person who is listed in this section.

Name:				
Address:		Number and Street	City	State Zip Code
Email Address for authorized person:			Telephone Number:	

For Office Use Only		
Date Processed: _____ By: _____	Date Issued: _____	Cashier #: _____ Date: _____ Amount: _____
Date Sent to 2LR: _____ By: _____	By: _____	
Date 2LR reviewed: _____ By: _____	Post Issuance: _____ By: _____	

Pharmacist-In-Charge

List the proposed Pharmacist-In-Charge (PIC) to serve as the supervisor or manager responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

Name of PIC:	License Type and No.
--------------	----------------------

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

Date

APPLICANT AFFIDAVIT - Read carefully and sign below

This application must be approved by the California State Board of Pharmacy before a hospital pharmacy license will be issued. The applicant hospital pharmacy shall not conduct business in California until a license is issued. If changes are made during the application process, the applicant may need to submit a new application with appropriate fees. **Any application not completed within 60 days after being notified by the board of deficiencies, may be deemed to have been abandoned, and be required to file a new application and meet all the requirements that are in effect at the time of application. Fees applied to this application are not transferable and are not refundable.**

Failure to provide any of the requested information may result in the application being considered incomplete. Any material misrepresentation in the answer of any question is grounds for denial or subsequent revocation of license, and is a violation of the California Penal Code.

The information will be used to determine qualifications for licensure under the California Pharmacy Law. The official responsible for information maintenance is the executive officer, (916) 574-7900, 1625 N. Market Blvd., Suite N219, Sacramento, CA 95834. The information may be transferred to another governmental agency, such as a law enforcement agency, if necessary, 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 by section 1798.38 of the Civil Code.

NOTICE: The State Board of Equalization and the Franchise Tax Board may share individual taxpayer information with the board. You are obligated to pay your state tax obligation. This application may be denied or your license may be suspended if the state tax obligation is not paid.

Under penalty of perjury, under the laws of the State of California, each person whose signature appears below, certifies and says that: (1) he/she is the owner or an officer of the applicant corporation named in the foregoing application, duly authorized to make this application on its behalf and is at least 18 years of age; (2) he/she has read the foregoing application and knows the contents thereof and that each and all statements therein made are true; (3) no person other than the applicant or applicants has any direct or indirect interest in the applicant(s) business to be conducted under the license(s) for which this application is made; (4) all supplemental statements are true and accurate; and (5) the change of ownership application may be withdrawn by either the applicant or the licensee with no resulting liability to the Board of Pharmacy.

Original Signature of executive officer, owner, member, or partner listed on the primary pharmacy license as a person authorized to bind the applicant business.

Print Name

Title

Date Signed