California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

APPLICATION INSTRUCTIONS
HOSPITAL SATELLITE COMPOUNDING PHARMACY LICENSE

(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. The license shall be renewed annually and is not transferable.

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 with this article and regulations adopted by 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. The services provided shall be directly related to the services or treatment plan administered in the physical plant.

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 insufficient, please make copies. Please allow approximately 45 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.

A checklist is provided with these instructions. The Board encourages the submission of all required documentation with the application as well as the use of the checklist to assist with the application process. The Board may request additional documentation to confirm or substantiate information in the application. When submitting documents to the Board, please make a copy for your records.

CHECKLIST FOR FILING A HOSPITAL SATELLITE COMPOUNDING PHARMACY APPLICATION

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.

1. **THE APPLICATION PROCESSING FEE IS $2,305.**
   Include a check or money order made payable to the California State Board of Pharmacy. This fee is nonrefundable.

   - To apply for a temporary license, an additional fee of $715 must be submitted in addition to the application processing fee and the temporary application (17A-116). When a change of ownership occurs, a temporary license must be requested or **ALL** operations requiring a sterile compounding license must cease. If a temporary license is not requested, **OPERATIONS MUST STOP** until a new license to compound sterile drug products is obtained. This fee is nonrefundable.

2. **HOSPITAL SATELLITE COMPOUNDING PHARMACY APPLICATION** (form 17A-107 (rev.3/2020): Complete the entire application and submit with original signatures. Scanned or stamped signatures are not accepted.

3. **CHANGE OF OWNERSHIP / LOCATION**
   A hospital satellite compounding license is nontransferable. A license is issued to the owner(s) and for the location of the facility. All approved change of ownership and change of location applications will result in a new license number being issued. Operating the facility prior to a new license being issued is unlicensed activity and may result in denial or disciplinary action by the Board.

   Change of Ownership Documentation: In addition to these application requirements, a Hospital Pharmacy Application (17A-19) must be submitted along with all the required documentation identified in the instructions for the Hospital Pharmacy Application.

4. **POLICIES AND PROCEDURES -** A copy of the pharmacy's proposed policies and procedures for sterile compounding electronically (i.e. flashdrive, CD, email, etc.). If emailing the policies and procedures, please send to compounding.pharmacy@dca.ca.gov.

5. **SELF-ASSESSMENT FORM (17M-39):** A copy of the pharmacy's self-assessment may be submitted electronically (i.e. flashdrive, CD, email, etc.). If emailing the policies and procedures, please send to compounding.pharmacy@dca.ca.gov.

6. **GENERAL ACUTE CARE HOSPITAL LICENSE:** Submit a copy of the general acute care hospital license issued by the California Department of Public Health.

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HOSPITAL SATELLITE COMPOUNDING PHARMACY LICENSE APPLICATION

1. Applicant Information

_____
Name of Hospital Satellite Compounding Pharmacy (Cannot exceed 65 characters including spaces)

_____
Address of Hospital Satellite Compounding Pharmacy: Number and Street City State Zip Code

_____
Exact Location of Hospital Satellite Compounding Pharmacy (Room Number or Name of Room)

_____ _____
Name of Hospital Pharmacy License Number

_____
Address of Hospital Pharmacy: Street City State Zip Code

_____ _____
Hospital Telephone Number Hospital Satellite Compounding Pharmacy Telephone Number

Please provide the mailing address to receive correspondence while the hospital satellite compounding pharmacy application is pending, if different than the address listed above. When the license is issued, all correspondence will be sent to the address of the hospital satellite compounding pharmacy.

_____
Mailing Address, if different than above Street City State Zip Code

2. Type of Application

___ New License _____ Anticipated Opening Date
___ Change of Ownership _____ Anticipated Change of Ownership Date
___ Change of Location _____ Anticipated Move Date

3. Type of Ownership

___ Individual ___ Partnership ___ Limited Liability Company ___ Trust
___ Corporation ___ Nonprofit Corporation ___ Publicly Traded ___ Government

Provide the FEIN # (Federal Employer ID #) _____- _____

For Board Use ONLY Date Cashiered: _____
Date Processed: _____ Date Issued: _____ Cashiering #: _____
Processed by: _____ Issued by: _____ Amount Received: _____

4. **Contact Person:** The Board will ONLY discuss the status of this application with the person identified as the contact person and any person who has signed the application as an officer, partner, member, and/or owner of the applicant business. An authorized owner may designate additional individuals to receive information on this pending application by submitting the Authorization to Release Applicant Information form. The Board may communicate deficiencies and status of application to the contact person via email.

_____

Name of Contact Person

_____

Address: Street City State Zip Code

_____ _____

Telephone Number Email Address

5. **Change of Ownership or Location** Provide the exact name, address, location, and license number as listed on the current hospital satellite compounding pharmacy license.

_____ _____

Name listed on the Current Hospital Satellite Compounding Pharmacy License License Number

_____

Address: Street City State Zip Code

_____ _____

Expiration Date of License Effective Date of Change of Ownership/Location

6. **Pharmacist-in-Charge (PIC) of Licensed Pharmacy** List the 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. The PIC must be approved by the board.

_____ _____

Name of PIC Pharmacist License Number

_____ _____

Telephone Number of PIC Email Address

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.)

_____ _____

Original Signature of PIC Date

7. Compounding to be Performed at the Satellite Location: (Check all that apply)

Type of compounding performed:

____ Non-sterile to sterile
____ Chemotherapy
____ Sterile to Sterile
____ Radiopharmacy

Type of Products to be compounded:

____ Injectable
____ Inhalation
____ Ophthalmic

Number of Hoods/Barrier Isolators: _____

Do you perform centralized packaging for unit dose packaging? ____ Yes ____ No

If yes, provide the license number for the centralized hospital packaging location. _____

PLEASE READ CAREFULLY

This application must be approved by the California State Board of Pharmacy before a hospital satellite compounding pharmacy license will be 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 the applicant will 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 instant application are not transferable or 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 the 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) 518-3100, located at the Board's address. 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 and exempted by Civil Code section 1798.38.

*Disclosure of your social security number if you are a sole proprietor or federal employer identification number ("FEIN") if you are a partnership is mandatory. Section 30 of the Business and Professions Code and Public Law 94-455 (42 USCA 405(c)(2)(C)) authorize collection of your social security number. Your social security number or FEIN will be used exclusively for tax enforcement purposes or compliance with any judgment or order for family support in accordance with section 17520 of the Family Code. If you fail to disclose your social security number or your FEIN, your application for initial or renewal license will not be processed AND you may be reported to the Franchise Tax Board, which may assess a $100 penalty against you.

**Residence address will not be made available to the public.

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, the person whose signature appears below, certifies the hospital pharmacy and hospital satellite compounding pharmacy is under common ownership, is listed on the hospital pharmacy application/license and is:

1. The **owner, partner, member, officer, director, manager, trustee, or the administrator (government owned),** of the hospital pharmacy named in the foregoing application, is duly authorized to make this application on its behalf and is at least 18 years of age.
2. 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 or management and control in the applicant business to be conducted under the license for which this application is made.
4. Understands that falsification of any information in this application may constitute grounds for denial or subsequent revocation of the license.
5. All supplemental statements are true and accurate.
6. A change of ownership application may be withdrawn by either the applicant or the licensee with no resulting liability to the California State Board of Pharmacy.

Provide original signature. Scanned, stamped or electronic signature may not be accepted.

_____	_____	_____	_____
Signature	Print Name	Title	Date

AUTHORIZATION TO RELEASE APPLICANT INFORMATION

(Optional)

Applicant Business Information – Please print or type File Number, if applicable _____

_____ _____
Name of Business Telephone Number of Business

_____
Name of Business DBA if different than above

_____
Address of Business – Street City State Zip Code

The Board will ONLY discuss the status of this application with the authorized person identified on the application and any person who has signed the application as an officer, partner, member, and/or owner of the applicant business. In order for the Board to discuss the status of this application with another individual, the authorized person identified on the application must authorize in writing the Board to discuss the application status with a his or her authorized representative.

Giving consent for the Board to disclose application and business information will authorize the Board to disclose all personal and business information pertaining to this application. This includes but is not limited to social security number, date of birth, address information, all application requirement information, application approval or denial status, and any criminal conviction information the Board may have on record for your application.

Applicant Consent – Must be signed and dated by the applicant for optional authorization to be valid.
As a person identified on the application that is authorized to act for and bind the applicant business, I hereby give the Board consent to communicate to the individual listed below.

I, _____, hereby give consent to
Print Name of Person Authorized to Bind the Applicant Business

the California State Board of Pharmacy to disclose information about this application as specified above to the following individual:

_____ _____ _____
Name Telephone Number Email Address

_____
Mailing Address – Street City State Zip Code

This consent will expire on _____ , within one year, or upon licensure, whichever comes first. (Date)

_____ _____
Original Signature of Person Authorized to Bind the Applicant Business Date