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: Follow these instructions completely. A checklist is provided with these instructions. The Board encourages the use of the checklist to assist with the application process. If the number of forms included in this application is insufficient, print additional copies. Allow approximately 45 days from the date your application is received by the Board before checking on the status. The contact person(s) designated on the application will be advised if additional information is necessary. Incomplete or redacted copies of supporting documents will not be accepted.

CHANGE OF OWNERSHIP / LOCATION

A hospital satellite compounding pharmacy 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 / LOCATION DOCUMENTATION: In addition to these application requirements, an application for the primary pharmacy must be submitted along with all the required documentation identified in the instructions for the appropriate primary application.

SIGNATURES: Any time a signature is required, it must be an original dated signature or a digital signature that complies with the Board's Digital Signatures Policy Statement located on the Board's website. Hospital Satellite Compounding applications with digital signatures shall be emailed to Compounding.Pharmacy@dca.ca.gov.

WHEN SUBMITTING DOCUMENTS TO THE BOARD, KEEP 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.

☐ **APPLICATION FEE: $3,875**
Include a check or money order made payable to the California State Board of Pharmacy. This fee is nonrefundable.

Optional: Temporary License Fee: $1,065
To request a temporary hospital satellite compounding license, submit the temporary hospital satellite compounding pharmacy license fee in addition to the application fee. **NOTE:** Temporary licenses may be issued by the Board in its discretion, upon such conditions and for such periods of time, not to exceed 180 days, as the Board determines to be in the public interest. The temporary hospital satellite compounding pharmacy license fee is nonrefundable once the application has been reviewed.

- If other than a change of ownership and/or location, **include a written letter signed by the owner, partner, officer, member, etc., that clearly explains why a temporary license is needed to protect public safety.**
- When a change of ownership/location occurs, a temporary license must be requested or **ALL** operations requiring a hospital satellite compounding license must cease. If a temporary license is not requested, **HOSPITAL SATELLITE COMPOUNDING OPERATIONS MUST STOP** until a new license to compound sterile drug products is obtained.

☐ **HOSPITAL SATELLITE COMPOUNDING PHARMACY APPLICATION** (form 17A-107 rev.1/2025): Complete the entire application and submit with an original dated signature or a digital signature that complies with the Board's Digital Signatures Policy Statement. Scanned or stamped signatures are not accepted.

The following items numbered below correspond to the numbered sections on the Hospital Satellite Compounding Pharmacy Application (17A-107)

1. **Applicant Information:**
   A. **Name of Hospital Satellite Compounding Pharmacy:** List the name of the applicant, the name should match the name on the license issued to the primary pharmacy or the name on the primary pharmacy license application.
   B. **Hospital Satellite Compounding:** List the address of the hospital satellite compounding pharmacy.
   C. **Hospital Satellite Compounding Exact Physical Location:** List the room number or room name of the specific area in which the hospital satellite compounding functions will be conducted in the primary pharmacy location.
   D. **Name of Primary Hospital Pharmacy:** List the name and license number for the hospital pharmacy.
   E. **Hospital Pharmacy Address:** List the address of the primary hospital pharmacy, this should match the licensed hospital pharmacy or address listed on the primary hospital pharmacy application.

F. **Hospital Pharmacy and Hospital Satellite Compounding Pharmacy Phone Numbers:** List the direct phone numbers to reach the hospital pharmacy staff and hospital satellite compounding pharmacy locations.

2. **Type of Application:** Identify the type of application and include the anticipated opening, change of ownership, or move date, as applicable. If requesting a temporary license, submit the required fee.

3. **Type of Ownership of Hospital Pharmacy:** Provide the FEIN# and identify the type of ownership of the business entity that directly owns the primary hospital pharmacy. This should match the ownership identified on the primary hospital pharmacy license or pending application.

4. **Pharmacist-in-Charge (PIC):** The proposed PIC must match the reported PIC on the primary pharmacy license or pending application. The PIC must complete, sign, and date Section 5 of the license application.

5. **Compounding to be Performed:**
   - Indicate the type of sterile compounding to be performed.
   - Indicate the type of products to be compounded.
   - Identify the number of hoods/barrier isolators.
   - Indicate if the sterile compounded medications will be packaged as unit doses for centralized hospital packaging and provide the license number if applicable.

6. **Contact Person:** The individuals listed in this section will be authorized for the Board to correspond and communicate with regarding the application.
   A. List in 6A the individual who is the authorized contact person.
   B. List in 6B an owner/officer of the primary hospital pharmacy license on record with the Board or on the primary hospital pharmacy application as an owner/officer.
   C. Identify in 6C if the Board is authorized to communicate the status of the application to the proposed PIC.
   D. **Change of Ownership Only:** Identify in 6D if the Board is authorized to communicate the status of the application with the current owner on record.
   Note: If additional individuals need to be included in the Board's correspondence, submit a completed Authorization to Release Applicant Information form (see page 5 of the application) signed by an owner/officer of the applicant.

7. **Change of Ownership or Location:** If applicable, list the current licensee information that will be changing ownership or location.

8. **Applicant Advisements and Affidavit:** Must be signed as instructed in A or B.
   A. If the applicant is a natural person, that individual must sign.
   B. If the applicant is other than a natural person, the application must be signed by an individual listed on the primary license record as and owner/officer or an owner/officer listed on the primary license application.

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

DOCUMENTS REQUIRED TO BE PROVIDED TO THE INSPECTOR

The Board's inspector will request these items either prior to or at the time of inspection.

2. **POLICIES AND PROCEDURES:** The pharmacy's proposed policies and procedures for hospital satellite compounding.

3. **SELF-ASSESSMENT FORM**: The pharmacy's self-assessment.

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HOSPITAL SATELLITE COMPOUNDING PHARMACY LICENSE APPLICATION

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1. APPLICANT INFORMATION (License will print only the first 65 characters, including spaces.)

A. ____
Name of Hospital Satellite Compounding Pharmacy (Needs to mirror Primary Hospital Pharmacy)

B. ____
Hospital Satellite Compounding Pharmacy Address: Street City State Zip Code

C. ____
Exact Location of Hospital Satellite Compounding Pharmacy (Room Number or Name of Room)

D. ______________________________ ______________
Name of Hospital Pharmacy **License Number**

E. ____
Hospital Pharmacy Address: Street City State Zip Code

F. ______________ ______________________________
Hospital Telephone Number **Hospital Satellite Compounding Pharmacy Telephone Number**

2. TYPE OF APPLICATION ___ Request for a Temporary License
Note: Temporary Hospital Sterile Compounding License Fee Must Be Included.

___ New Sterile Compounding Pharmacy _______________ Anticipated Opening Date
___ Change of Ownership _______________ Anticipated Change of Ownership Date
___ Change of Location _______________ Anticipated Move Date

3. TYPE OF OWNERSHIP OF HOSPITAL PHARMACY

Provide the FEIN # (Federal Employer ID #) ________- ___________________________

___ Individual
___ Partnership
___ Limited Liability Company
___ Trust
___ Corporation
___ Professional Corporation
___ Nonprofit Corporation
___ Publicly Traded Corporation
___ Government Owned
___ Native American Tribe
___ Non-Native American Operating on Tribal Land

For Board Use ONLY
Date Processed: _______________ Date Issued: __________________ Date Cashiered: ____________________
Processed by: _______________ Issued by: __________________ Cashiering #: ____________________
Amount Received: __________________

4. **PHARMACIST-IN-CHARGE (PIC) OF HOSPITAL 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.

____ ________________

Original Signature of PIC | Date

5. **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. ______________________

6. **CONTACT PERSON:** The Board will discuss the status of this application ONLY with the authorized individual listed below. An owner/officer listed on the primary license must also be identified below to be included in **all** communications regarding the application. An owner/officer listed on the primary license may designate additional individuals to receive information on this application by submitting an Authorization to Release Applicant Information form (see page 5 of this application).

A. ____

Name of Authorized Contact Person | Telephone Number | Email Address

B. ____

Owner/Officer Listed on Primary License | Telephone Number | Email Address

C. Is the proposed PIC listed in Section 4 of this application authorized as a contact person with this application?

___ Yes ___No **If Yes,** be advised the PIC will be authorized to receive all status communication.

D. **Change of Ownership ONLY:** The Board will discuss the status of this change of ownership application ONLY with the individual(s) listed in Section 6 A and B above. Check “yes” or “no” below to indicate whether the Board is also authorized to communicate the status of this change of ownership application with the current owner on record for the primary pharmacy (*i.e.*, the seller/transferor in the change of ownership transaction).

___ Yes ___No **If Yes,** list the name of the individual the Board is authorized to communicate with and submit a completed Authorization to Release Applicant Information (see page 5 of this application) signed by an individual listed on the primary pharmacy license.
NOTE: The person named below must be listed on the current license.

____
Name

7. CHANGE OF OWNERSHIP OR LOCATION: Provide the exact name, address, and license number as listed on the current pharmacy license.

____
Name Listed on the Current Hospital Sterile Compounding License

____
Physical Location Street City State Zip Code

____
Current Hospital Sterile Compounding License Number Expiration Date of License

8. APPLICANT ADVISEMENTS AND AFFIDAVIT This application must be approved by the California State Board of Pharmacy before a hospital sterile compounding pharmacy license will be issued.

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 may be 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 them by the Board of Pharmacy, unless the records are identified as confidential and exempted by Civil Code section 1798.38.

REQUIRED SIGNATURE: Provide an original dated signature or a digital signature that complies with the Board's Digital Signatures Policy Statement. A Sterile Compounding Pharmacy Application with digital signatures shall be emailed to Compounding.Pharmacy@dca.ca.gov.

Under the laws of the State of California, the natural person whose signature appears below certifies that:

1) They are at least 18 years of age.
2) They are listed as an owner or officer on the primary pharmacy application or license.
3) They have the authority to make this application to apply for a license with the California State Board of Pharmacy on behalf of the applicant named in the foregoing application.
4) They have read or have knowledge of the foregoing application for licensure, are familiar with the contents thereof, and attest to the truth and accuracy of all statements, answers, and representations made in this application, including any and all supplementary statements.
5) They understand that falsification of any information in this application may constitute grounds for denial or subsequent revocation of the license.

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