



California State Board of Pharmacy
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www.pharmacy.ca.gov

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



APPLICATION INSTRUCTIONS
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 Title 16 of the California Code of Regulations beginning with section 1751.

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 sterile 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. Sterile 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 STERILE 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 may 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 sterile compounding license, submit the temporary sterile 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 sterile 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 sterile compounding license must cease. If a temporary license is not requested, **STERILE COMPOUNDING OPERATIONS MUST STOP** until a new license to compound sterile drug products is obtained.

- STERILE COMPOUNDING PHARMACY APPLICATION** (form 17A-48 rev 4/2025): 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 Sterile Compounding Pharmacy Application (17A-48)

1. Applicant Information:

- Name of Sterile 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.
- Primary Pharmacy Physical Location:** List the address of the primary pharmacy, this should match the licensed pharmacy or address listed on the primary pharmacy application.
- Sterile Compounding Exact Physical Location:** List the room number or room name of the specific area in which the sterile compounding functions will be conducted in the primary pharmacy location.
- Primary Pharmacy and Sterile Compounding Pharmacy Phone Number:** List the direct phone numbers to reach pharmacy staff in the primary and sterile 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.

Change of Location as A Result of a Natural Disaster or Declared Federal, State, or Local Emergency:

A pharmacy that is destroyed or severely damaged as a result of a natural disaster or due to events that led to a declared federal, state, or local emergency, may be relocated. The relocation shall not be considered a transfer of ownership or location under BPC section 4110 if no changes are made to the management and control, or ownership, of the pharmacy, and all applicable laws and regulations are followed. Severely damaged means damage that renders the premises unsafe or unfit for entry or occupation (see BPC section 4062(e)).

- Submit a copy of the signed lease agreement or a copy of the grant deed for the new location.
- Submit a letter from your primary wholesaler indicating the new delivery address.
- Submit documentation evidencing the pharmacy has been destroyed or damaged as a result of a natural disaster or declared federal, state, or local emergency.

- 3. Type of Ownership of Primary Pharmacy:** Provide the FEIN# and identify the type of ownership of the business entity that directly owns the primary pharmacy. This should match the ownership identified on the primary pharmacy license or pending application.
- 4. Primary Pharmacy:** Identify the status of the primary pharmacy license and provide the current license number if already licensed or the pending application file number of the primary pharmacy applicant.
- 5. Pharmacist-in-Charge (PIC):** The proposed PIC must match the reported PIC on the primary pharmacy license or pending application.
 - **EFFECTIVE APRIL 1, 2025**, pursuant to California Code of Regulations (CCR), title 16, section 1709.1, the proposed PIC is required to complete the [Board's Pharmacist-in-Charge Overview and Responsibility Training Course](#), available on the Board's website, within two years prior to the date of application to serve as a PIC.
 - The proposed PIC must complete, sign, and date Section 5 of the license application and complete the attestation of completing the PIC Overview and Responsibility Training Course.
- 6. 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.
- 7. 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 7A the individual who is the authorized contact person.
 - B. List in 7B an owner/officer of the primary pharmacy license on record with the Board or on the primary pharmacy application as an owner/officer.
 - C. Identify in 7C if the Board is authorized to communicate the status of the application to the proposed PIC.
 - D. **Change of Ownership Only:** Identify in 7D 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.

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

9. Applicant Advisements and Affidavit: Must be signed as instructed.

The application must be signed by a natural person listed on the primary license record or listed on the primary license application who has 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.

- FLOOR PLAN OF PRIMARY PHARMACY AND STERILE COMPOUNDING:** Provide a copy of the pharmacy's floor plan that clearly identifies the location of the primary pharmacy and the exact location of the sterile compounding pharmacy, including the room number or name of room.

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.

- 1. POLICIES AND PROCEDURES:** The pharmacy's proposed policies and procedures for sterile compounding.
- 2. SELF-ASSESSMENT FORM:** The pharmacy's self-assessment.



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STERILE COMPOUNDING PHARMACY LICENSE APPLICATION

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

- A. _____
Name of Sterile Compounding Pharmacy (Needs to mirror Primary Pharmacy)
- B. _____
Primary Pharmacy Physical Location: Street City State Zip Code
- C. _____
Sterile Compounding Exact Physical Location: (Room Number or Name of Room)
- D. _____
Primary Pharmacy Telephone Number **Sterile Compounding Pharmacy Telephone Number**

2. TYPE OF APPLICATION Request for a Temporary License

Note: Temporary Sterile Compounding License Fee Must Be Included.

- | | |
|---|--|
| <input type="checkbox"/> New Sterile Compounding Pharmacy | _____ Anticipated Opening Date |
| <input type="checkbox"/> Change of Ownership | _____ Anticipated Change of Ownership Date |
| <input type="checkbox"/> Change of Location | _____ Anticipated Move Date |
- Is this change of location a result of a declared federal, state, or local emergency? Yes No

3. TYPE OF OWNERSHIP OF PRIMARY PHARMACY

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

- | | | |
|--|--|---|
| <input type="checkbox"/> Individual | <input type="checkbox"/> Corporation | <input type="checkbox"/> Government Owned |
| <input type="checkbox"/> Partnership | <input type="checkbox"/> Professional Corporation | <input type="checkbox"/> Native American Tribe |
| <input type="checkbox"/> Limited Liability Company | <input type="checkbox"/> Nonprofit Corporation | <input type="checkbox"/> Non-Native American Operating on Tribal Land |
| <input type="checkbox"/> Trust | <input type="checkbox"/> Publicly Traded Corporation | |

For Board Use ONLY

Date Processed: _____	Date Issued: _____	Date Cashiered: _____
Processed by: _____	Issued by: _____	Cashiering #: _____
		Amount Received: _____

4. PRIMARY PHARMACY

Does the Primary Pharmacy have a license?

___ Yes ___ No

If Yes, list the Primary Pharmacy License # _____

If No, if available, list the Primary Pharmacy pending application file # (if known) _____

Once the primary pharmacy application is complete and ready to operate, do you authorize the Board to issue the primary pharmacy a license while the sterile compounding pharmacy license is still under review for issuance of a license?

___ Yes ___ No

5. PHARMACIST-IN-CHARGE (PIC): The proposed PIC must match the reported PIC on the primary license or pending application. List the proposed 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 as well as the pharmacy’s policy and practices. The pharmacist-in-charge (PIC) of a pharmacy shall be employed at that location and shall have responsibility for the daily operation of the pharmacy. Prior to approval of the board, and as part of the application and notice process set forth in Section 1709 of this Division (“application”), a pharmacy shall submit its proposed PIC. The PIC shall have completed the board-provided Pharmacist-in-Charge Overview and Responsibility training course, available on the board’s website, within two years prior to the date of application. The proposed PIC must be approved by the Board.

Pursuant to BPC section 4101(a), any pharmacist-in-charge who ceases to act as the pharmacist-in-charge of a pharmacy shall notify the Board in writing within 30 days of the date of that change in status. The pharmacist may complete this required notification by sending the Board a [Notification of Disassociation as Pharmacist-in-Charge \(PIC\) \(17A-121\)](#) via email to PICstatus@dca.ca.gov.

ATTESTATION STATEMENT OF PROPOSED PIC:

My name and license number are correctly set forth below. I have read sections 4036.5, 4081, 4113, and 4330 of the Business and Professions Code and California Code of Regulations, title 16, section 1709.1. I completed the [Board’s Pharmacist-in-Charge Overview and Responsibility training course](#) on the date set forth in this section below. I declare under penalty of perjury of the laws of the State of California that all statements and information provided in this attestation statement are true and correct.

List the date the proposed PIC completed the Board’s Pharmacist-in-Charge Overview and Responsibility training course (Month/Day/Year) __________ _____

Printed Name of Proposed PIC Pharmacist License Number

Email Address Telephone Number

Original Signature of Proposed PIC Date

6. COMPOUNDING TO BE PERFORMED: (Check all that apply)

Type of compounding performed:

Type of Products to be compounded:

Non-sterile to sterile

Injectable

Chemotherapy

Inhalation

Sterile to Sterile

Ophthalmic

Radiopharmacy

Number of Hoods/Barrier Isolators: _____

Do you perform centralized packaging for unit dose packaging?

Yes **No**

If Yes, provide the Centralized Hospital Packaging location Hospital Pharmacy license # _____

7. 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 5 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 7 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

8. 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 Sterile Compounding License

Physical Location	Street	City	State	Zip Code
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Current Sterile Compounding License Number

Expiration Date of License

9. APPLICANT ADVISEMENTS AND AFFIDAVIT This application must be approved by the California State Board of Pharmacy before a 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