



California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
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www.pharmacy.ca.gov

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



APPLICATION INSTRUCTIONS
NONRESIDENT STERILE COMPOUNDING PHARMACY LICENSE
(Business & Professions Code Sections 4127 et. seq.)

A nonresident pharmacy shall not compound sterile drug products for shipment into California without a sterile compounding pharmacy license issued by the Board pursuant to Business and Professions Code Sections 4127.2. 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.

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 NONRESIDENT 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: \$8,500

Include a check or money order made payable to the California State Board of Pharmacy. This fee is nonrefundable.

Optional: Temporary License Fee: \$1,500

To request a temporary nonresident sterile compounding license, submit the temporary nonresident 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 nonresident 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 the nonresident sterile compounding pharmacy shall discontinue conducting business with California until a new license to compound sterile drug products is obtained.

- **NONRESIDENT STERILE COMPOUNDING PHARMACY APPLICATION** (form 17A-50 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 Sterile Compounding Pharmacy Application (17A-50)

1. Applicant Information:

- Name of Sterile Compounding Pharmacy:** List the name of the applicant, the name should match the name on the license issued by your home state and the primary nonresident pharmacy issued by California or the name on the primary nonresident pharmacy license application.
- Primary Nonresident Pharmacy Physical Location:** List the address of the primary nonresident pharmacy, this should match the licensed nonresident pharmacy or address listed on the primary nonresident pharmacy application.
- Nonresident 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 Nonresident Pharmacy and Nonresident Sterile Compounding Pharmacy Phone Number:** List the direct phone numbers to reach pharmacy staff in the primary and sterile compounding pharmacy locations.

- 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 Primary Nonresident Pharmacy:** Provide the FEIN# and Identify the type of ownership of the business entity that directly owns the primary nonresident pharmacy. This should match the ownership identified on primary nonresident pharmacy license or pending application.
- 4. Primary Nonresident Pharmacy:**
- A. Identify if the pharmacy is licensed in the home state.
 - B. Identify if the sterile compounding pharmacy is licensed in the home state. Identify if the home state issued the sterile compounding license independent of the pharmacy license.
 - C. Identify if the primary pharmacy is licensed in California as a nonresident pharmacy and if the Board should proceed with issuing the nonresident pharmacy license once approved prior to the issuance of the nonresident sterile compounding pharmacy. If answered no, the nonresident pharmacy will not be issued until the nonresident sterile compounding pharmacy is approved for issuance.
- 5. Pharmacist-in-Charge (PIC) of Nonresident Pharmacy:** The proposed PIC listed must match the reported PIC on the primary nonresident pharmacy license or pending application. The PIC must complete, sign, and date Section 5 of the license application.
- 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
- 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 license ownership of record with the Board or primary license applicant on identified in Section 13 and/or 14 of the application primary pharmacy license.
 - 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 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 nonresident pharmacy license record as having binding authority or an individual listed in Section 13 of the primary nonresident pharmacy license application.

ADDITIONAL DOCUMENTS TO SUBMIT IN ADDITION TO THE NONRESIDENT STERILE COMPOUNDING APPLICATION 17A-50.

- **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.
- **INSPECTION REPORT:** A copy of the inspection report issued by the pharmacy's resident state licensing agency within the prior 12 months, documenting the pharmacy's compliance with board regulations regarding the compounding of sterile drug products.
- **COPY OF LICENSE:** Submit either a copy of the home state sterile compounding pharmacy license if the home state issues a separate sterile compounding license from the primary pharmacy license OR a copy of the primary pharmacy license that identifies a sterile compounding pharmacy.

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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NONRESIDENT 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 Nonresident Pharmacy)
- B. _____
Primary Nonresident Pharmacy Physical Location: Street City State Zip Code
- C. _____
Nonresident Sterile Compounding Exact Physical Location: (Room Number or Name of Room)
- D. _____
Primary Pharmacy Telephone # Nonresident Sterile Compounding Pharmacy Telephone #

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

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

3. TYPE OF OWNERSHIP OF PRIMARY NONRESIDENT PHARMACY

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

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

For Board Use ONLY

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

4. PRIMARY NONRESIDENT PHARMACY

A. Is the Primary Nonresident Pharmacy licensed in the home state?

Yes No

If Yes, list the home state's Primary Pharmacy License # _____

B. Is the Sterile Compounding Pharmacy licensed in the home state?

Yes No

If Yes, list the home state's Sterile Compounding Pharmacy License # _____

If No, please explain: _____

C. Is the nonresident pharmacy licensed in California?

Yes No

If Yes, list the California nonresident pharmacy license # _____

If No, a nonresident pharmacy application must be submitted along with the nonresident sterile compounding application. Once the nonresident pharmacy application is approved for the issuance of a license, do you want the Board to issue the primary license while the nonresident sterile compounding pharmacy is in the inspection and review process?

Yes No

5. PHARMACIST-IN-CHARGE (PIC) OF NONRESIDENT PHARMACY: List the proposed PIC to serve as the supervisor or manager responsible for ensuring the pharmacy's compliance with all California and federal laws and regulations pertaining to the practice of pharmacy as well as the pharmacy's policy and practices. The proposed PIC must be approved by the Board.

Printed Name of Proposed PIC Pharmacist License Number

Email Address Telephone Number

I certify that the policies and procedures of the nonresident sterile compounding are consistent with California Code of Regulations Title 16, section 1735 et seq and 1751 et seq.

Signature of Proposed PIC Date

6. COMPOUNDING TO BE PERFORMED: (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: _____

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

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 Nonresident 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 nonresident 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
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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