



## **INSTRUCTIONS FOR FILING AN APPLICATION FOR NONRESIDENT PHARMACY STERILE COMPOUNDING LICENSE**

(Business & Professions Code Sections 4127 et. seq.)

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 the California Code of Regulations beginning with section 1751.

### **APPLICATION PROCESSING TIMEFRAME**

- Allow the board 90 days to process the application. You will be notified in writing if your application is incomplete.
- Due to current workload the board is unable to respond to application status requests unless the application has been on file for over 90 days.
- You may confirm with your bank that your check has been processed. This will serve as verification that the board received your application.
- To verify if your license has been issued, visit the board's website at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov). Select "Verify a License" and enter the pharmacy name. It will take from 4 to 6 weeks from the date a license is issued to receive the license document.

## **APPLICATION INSTRUCTIONS**

Print the entire application and any required forms indicated in the **WHAT MAKES AN APPLICATION COMPLETE**. Review the **WHAT MAKES AN APPLICATION COMPLETE** section to ensure you have completed and included all the required forms prior to submitting the application. Failure to submit all necessary items will delay the processing the application.

**NOTE: TEMPORARY PERMIT** - Whenever a change of ownership occurs, a temporary permit must be requested or all operations requiring a sterile compounding license must stop. An additional fee of \$550.00 for the temporary permit must be submitted. If a temporary permit is not requested, **OPERATIONS MUST STOP** until a new license to compound sterile drug products is obtained.

## **WHAT MAKES AN APPLICATION COMPLETE**

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 PRIOR TO JULY 1, 2017 \$780 (EXCEPTION:** Government owned pharmacies are fee exempt): When you send your application, include a check or money order for \$780 made payable to the Board of Pharmacy. The application fee is non-refundable and the application must be received in the office no later than June 30, 2017 in order to pay the processing fee of \$780. *Applications received after June 30, 2017, with the payment of \$780 may be returned for the new application fee of \$2,380.* **See Note above regarding Temporary Permit.**

**APPLICATION FEE AS OF JULY 1, 2017 \$2,380 (EXCEPTION:** Government owned pharmacies are fee exempt): When you send your application, include a check or money order for \$2,380 made payable to the Board of Pharmacy. The application fee is non-refundable. Applications received on or after July 1, 2017, must submit the processing fee of \$2,380. **See Note above regarding Temporary Permit.**

- **NONRESIDENT PHARMACY STERILE COMPOUNDING APPLICATION:** (form 17A-50 (rev. 4.14): The application must be completed in its entirety. Failure to do so will result in an incomplete application and a deficiency letter will be mailed to you. All signatures must be original signatures. Scanned or stamped signatures are not accepted.

**NOTE: If application is for a change of ownership, evidence that a change of ownership has been sought or obtained for the pharmacy license must be submitted with this application**

- **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.
- **POLICIES AND PROCEDURES:** A copy of the nonresident pharmacy's proposed policies and procedures for sterile compounding on disk, CD, or via email. If emailing the policies and procedures, please send to [Compounding.Pharmacy@dca.ca.gov](mailto:Compounding.Pharmacy@dca.ca.gov).

Failure to submit all of the information requested or required by the board may result in the board considering your application incomplete.



**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 FOR NONRESIDENT PHARMACY  
STERILE COMPOUNDING LICENSE**

*Please print or type*

**ALL BLANKS MUST BE COMPLETED; IF NOT APPLICABLE, ENTER N/A**

Name of Pharmacy:		Pharmacy License Number		
Pharmacy Telephone Number:		Sterile Compounding Telephone Number: (if different)		
Address of Pharmacy:	Street and Number	City	State	Zip Code

Name of pharmacist-in-charge of licensed pharmacy:		Pharmacist license number		
Residence address:	Street and Number	City	State	Zip Code

Indicate whether this application is for:

New Licensed Sterile Compounding License     
 Change of Location of Licensed Sterile Compounding pharmacy     
 Change of Ownership of Licensed Sterile Compounding pharmacy

If this is a **change of ownership** or **change of location**, indicate previous name, address and license number of compounding pharmacy.

Name:	Address:	License Number:
-------	----------	-----------------

Please indicate type of ownership:

Individual     
 Partnership     
 Corporation     
 Not-for-profit corporation     
 Limited Liability

***I certify that the policies and procedures of the sterile compounding are consistent with California Code of Regulations Title 16, section 1735 et seq and 1751 et seq (A copy of the pharmacy's proposed policies and procedures for sterile compounding must accompany the application.)***

\_\_\_\_\_  
Signature of Pharmacist-in-Charge

\_\_\_\_\_  
Name (please print)

\_\_\_\_\_  
Date

CONTINUE ON REVERSE		
FOR OFFICE USE ONLY		
STAFF REVIEW	CASHIER LOG	
<input type="checkbox"/> _____ <input type="checkbox"/> _____ <input type="checkbox"/> _____ <input type="checkbox"/> _____ Referred for inspection: _____ Inspection Completed: _____	Approved _____ Denied _____ Date _____	Cashier # _____ Date _____ Amount of fee _____

## Ownership Information

<b>If a Sole Ownership:</b>			
Name of Sole Owner	*Social Security Number	Telephone Number	
Address	number and street	City	State Zip Code

<b>If a Partnership: (attach additional sheet if needed)</b>			
Name of Partner	*FEIN Number	Telephone Number	
Address	number and street	City	State Zip Code

Name of Partner	*FEIN Number	Telephone Number	
Address	number and street	City	State Zip Code

<b>If a Corporation: (attach additional sheet if needed)</b>			
Name of Corporation (If applicable)			Telephone Number
Address	number and street	City	State Zip Code

Print below the name, title, address and license number of all the pharmacy owners. This includes the individual owner, all partners, corporate officers. Under the heading "Licensed as" list any state professional or vocational licenses held; e.g., pharmacist, physician, podiatrist, dentist or veterinarian etc., and license number. Non-profit organizations must list the names and titles of persons holding corporate positions. Attach additional sheets if necessary.

Title	Name	Residence Address	Social Security Number	Licensed as and license number

\*Disclosure of your social security number (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.

NOTICE: Effective July 1, 2012, 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.

Federal Employer Identification Number\* □ □ □ □ □ □ □ □ □ □

