



California State Board of Pharmacy

1625 N. Market Blvd, N219, Sacramento, CA 95834

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www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

REQUIREMENTS FOR FILING AN APPLICATION FOR NONRESIDENT PHARMACY STERILE COMPOUNDING LICENSE

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

Effective July 1, 2003, a nonresident pharmacy may not compound injectable sterile drug products for shipment into California unless:

1. The nonresident pharmacy is licensed with the board as an injectable sterile drug compounding nonresident pharmacy, OR:
2. The nonresident pharmacy is operated by an entity that is licensed as a hospital, home health agency, or a skilled nursing facility, and has a current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or another accreditation agency approved by the board. The following private accreditation agencies have been approved by the board:
 - Accreditation Commission for Health Care, Inc. (ACHC) through February 2014,
 - Community Health Accreditation Program (CHAP) through February 2014,
 - Det Norske Veritas (DNV) through July 2013,
 - Pharmacy Compounding Accreditation Board (PCAB) through February 2014, or
 - American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP) through February 2014.

Nevertheless all nonresident pharmacies that compound injectable sterile drug products and ship these products into California must follow board regulations for injectable sterile drug compounding. These regulations are found in Title 16 California Code of Regulations at Article 7, beginning with section 1751.

A license for a nonresident pharmacy to compound injectable sterile drug products may only be issued for a location that is separately licensed as a nonresident pharmacy, and may only be issued to the owner of the nonresident pharmacy license at that location.

To begin the application process, the following items must be submitted:

1. A completed and signed Application for Nonresident Sterile Compounding Pharmacy License (Form 17A-50).
2. Fee of \$600, made payable to "Board of Pharmacy". Note: This application may be used to apply for a temporary permit when the ownership of a pharmacy that is licensed to compound injectable sterile drug products is transferred from one person to another. Whenever a change of ownership occurs, either a temporary permit must be sought and obtained by the new owners or operation must stop until a license to compound injectable sterile drug products is obtained. In addition to the regular items required for this application, a \$550 temporary permit fee must also be submitted.
3. A copy of an inspection report issued by the pharmacy's licensing agency within the prior 12 months, documenting the pharmacy's compliance with board regulations regarding the compounding of injectable sterile drug products.
4. 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 CompoundingPharmacy@dca.ca.gov.
5. Corporate officer, owner, or partner who signed the application will need to complete the enclosed fingerprint cards.

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

**** Effective January 1, 2001, the Board of Pharmacy requires all applicants for a new license to have not only a California Department of Justice (DOJ) criminal record check but also a federal background check through the Federal Bureau of Investigation (FBI). No license will be issued without background clearances from both agencies.**

Note to Applicants Submitting Fingerprints Via Live Scan: While the Live Scan forms contained in the board's application package are pre-slugged to indicate level of service at the DOJ and FBI level, please ensure at the time of Live Scan transmission that the Live Scan operator selects both the DOJ and FBI levels of service. If FBI is not selected at the time of original transmission, you may be required to have your Live Scan redone at another time and have to repay for the DOJ and FBI levels of services again. The board has been notified by the DOJ that effective 9/1/07, if the FBI level of service is not requested at the time of original transmission both DOJ and FBI levels of service will have to be redone. Any issue of cost for resubmission should be handled at the Live Scan Site level.

Fingerprint Requirements

California Residents

The board will only accept Live Scan Service Forms from California residents.

Complete a Live Scan Request form and take all 3 copies to a Live Scan site for fingerprint scanning. Please refer to the Instructions for completing a "Request for Live Scan Service" form. Live Scan sites are located throughout California. For more information about locating a Live Scan site near you, visit the Department of Justice website at <http://ag.ca.gov/fingerprints/publications/contact.php> or the sources listed on the bottom of the instructions for completing a "Request for Live Scan Service" form.

The lower portion of the Live Scan Request form must be completed by the Live Scan operator verifying that your prints have been scanned and all applicable fees have been paid. Attach the second copy of the form to your application and submit it to the board.

Non California Residents

If an owner, partner, corporate officer, major shareholder or director reside out of state they must submit rolled fingerprints on cards provided by the board and include a separate fee of \$49 (\$32 California Department of Justice (DOJ) fee, \$17 FBI fingerprint processing fee). (Live Scan processing fees are paid directly at the Live Scan site.) You may contact the board to request fingerprint cards at (916) 574-7900. You may also request cards on our website at www.pharmacy.ca.gov.

Fingerprints submitted on cards should be taken by a person professionally trained in the rolling of prints. Fingerprint clearances from cards take approximately six weeks (live scan is faster). Poor quality prints may result in rejection and will substantially delay licensing as additional fingerprint cards will be required from you for processing.

The board will only accept fingerprint cards from residents outside of California.



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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:			
<input type="checkbox"/> New Licensed Sterile Compounding License	<input type="checkbox"/> Change of Location of Licensed Sterile Compounding pharmacy	<input type="checkbox"/> 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:			
<input type="checkbox"/> Individual	<input type="checkbox"/> Partnership	<input type="checkbox"/> Corporation	<input type="checkbox"/> Not-for-profit corporation <input type="checkbox"/> 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

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

If a Partnership: (attach additional sheet if needed)			
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

If a Corporation: (attach additional sheet if needed)			
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* □ □ □ □ □ □ □ □ □ □

