



California State Board of Pharmacy

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

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www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

REQUIREMENTS FOR FILING AN APPLICATION FOR STERILE COMPOUNDING PHARMACY LICENSE

(Business & Professions Code Sections 4127 and 4127.1)

The following may compound sterile drug products in California: A pharmacy that is specially licensed with the board as a sterile compounding pharmacy; or a pharmacy that is operated by an entity that is licensed by the board or the California Department of Public Health and has a current accreditation from the Joint Commission on Accreditation of Healthcare Organizations or another accreditation agency approved by the board.

Important: Effective July 1, 2014, no accreditation (in lieu of licensure) is acceptable. All entities that compound sterile drug products shall be licensed by the board.

The following private accreditation agencies have been approved by the board **until July 1, 2014:**

- Accreditation Commission for Health Care, Inc. (ACHC)
 - Community Health Accreditation Program (CHAP)
 - Det Norske Veritas (DNV)
 - Pharmacy Compounding Accreditation Board (PCAB)
 - American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP)
- A license to compound sterile drug products may not be issued until the location is inspected by the board and found to be in compliance with Article 7.5 of Chapter 9, of Division 2 of 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. These regulations are found in Title 16 of the California Code of Regulations as Article 7, beginning with section 1751.

For a complete application, the following items must be submitted:

1. A completed and signed Application for Sterile Compounding Pharmacy License (17A-48).
2. Fee of \$780, 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 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 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 the pharmacy's proposed policies and procedures for sterile compounding on disk, CD or hard copy. If emailing the policies and procedures, please send to CompoundingPharmacy@dca.ca.gov.



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APPLICATION FOR A STERILE COMPOUNDING PHARMACY 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"/> Government owned

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

A license to compound sterile drug products may only be issued to the owner of a licensed pharmacy at the licensed location.

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

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PLEASE READ CAREFULLY

This application must be approved by the California State Board of Pharmacy before a Sterile Compounding License will be issued.

If changes are made during the application process, you may need to submit a new application with the appropriate fees. **Any application not completed within 60 days after you have been notified by the board of deficiencies in your file, may be deemed to have been abandoned, and you may be required to file a new application and meet all the requirements which are in effect at the time of application. Fees applied to this application are not transferable and are not refundable.**

Any material misrepresentation in the answer of any question is grounds for refusal or subsequent revocation of a license, and is a violation of the Penal Code of California. All items of information requested in this application are mandatory. Failure to provide any of the requested information will result in the application being rejected as incomplete.

The information will be used to determine qualifications for licensure under California Pharmacy Law. The officer responsible for information maintenance is the Executive Officer, (916) 445-5014, 400 R Street, Suite 4070, Sacramento, California 95814. The information may be transferred to another governmental agency (such as a law enforcement agency) if necessary for it to perform its duties. Each individual has the right to review the files or records maintained on him/her by the Board of Pharmacy, unless the records are identified as confidential information and exempted from disclosure by the California Information Practices Act. (Civil Code §1798, et seq.)

Signature Block

Under penalty of perjury, under the laws of the State of California, I certify and affirm that: (1) I am a person authorized to act for and bind the applicant and I am at least 18 years of age; (2) I have read the foregoing application and know the contents thereof and each and every statement made therein is true; (3) I understand that falsification of any information in this application may constitute grounds for denial or subsequent revocation of the license; (4) no person other than the applicant [or applicants] has any direct or indirect interest in the applicant's [or applicants'] business to be conducted under the license for which this application is made; and (5) all supplemental statements filed with this application are true, complete and accurate.

Signature of Person Authorized to Submit Application	Name (please print)	Title	Date
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Mail all correspondence to the following address below. If correspondence should be mailed to the pharmacy please insert "Same as Pharmacy."

Name and telephone number of contact person to clarify information provided on this application.	e-mail address
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**INSTRUCTIONS FOR COMPLETING A
"REQUEST FOR LIVE SCAN SERVICE" FORM
(California Residents)**

The following instructions are provided to assist you in completing this form accurately. Please follow all instructions carefully and print clearly; failure to do so may result in processing delays of your application.

NOTE TO APPLICANT and LIVE SCAN OPERATOR: The applicant's name, date of birth, and US social security number must be entered in at the time of the Live Scan transmission in order for the results to be accepted by the Board of Pharmacy. If any of the required information indicated below is not entered at the time of Live Scan transmission, the applicant may be required to have a new Live Scan transmission completed.

REQUIRED INFORMATION

- **Type of License/Certification/Permit OR Working Title:** It is important that you print out the Live Scan form that goes with your application, as this information is already entered on the form for you. It is important that the Live Scan operator types in this information exactly into their system or at least the numeric section.
- **Name:** Enter your name as it appears on your U.S. government photo identification. If you change your name, you are required to notify the board within 30 days of the change.
- **Other Name (AKA):** Enter all other names you have used, including your maiden name.
- **Date of Birth:** (month/day/year).
- **SEX:** Mark the appropriate gender box (male or female)
- **Driver's License Number:** California Driver's License Number.
- **Height:** Your height in feet and inches.
- **Weight:** Your weight in pounds.
- **Eye Color:** Color of your eyes
- **Hair Color:** Color of your hair
- **Place of Birth:** Enter your place of birth
- **Social Security Number (Mandatory):** Enter your US Social Security Number
- **Misc. Number:** Other identification number
- **Home Address:** Your residence address
- **Level of Service:** 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.

Take the completed form to your nearest Live Scan site for fingerprint scanning. There are more than 130 Live Scan sites throughout the state. An up-to-date Live Scan site list is on the Department of Justice's (DOJ) Internet web page at <http://ag.ca.gov/fingerprints/publications/contact.php> or call your local police or sheriff's department.

Contact the live scan service for hours of operation, an appointment (if necessary), acceptable forms of payment and identification requirements. Be prepared to pay **ALL applicable fees** (DOJ processing fee of \$32, FBI processing fee of \$17, and fingerprint scanning service fee) at the time your prints are taken. The live scan fingerprinting service fee varies from about \$5 to \$20. The cost to electronically submit your fingerprints is determined by the local Live Scan agency and the agency can charge a fee sufficient to recover its costs. The lower portion of the Request for Live Scan Service form must be completed by the live scan operator. Please print three copies of the Request for Live Scan Service form. The original of the form is retained by the scanning service; the second copy is to be attached to your application and submitted to the board; and the third copy is for your records.

FINGERPRINTING AUTHORITY

Section 144(b) of the Business and Professions Code authorizes the Board of Pharmacy to require an applicant for licensure to furnish a full set of fingerprints for purposes of conducting criminal history record checks. Fingerprints are required in order for the DOJ/FBI to conduct background checks for criminal convictions.



REQUEST FOR LIVE SCAN SERVICE

Applicant Submission

ORI (Code assigned by DOJ)

Authorized Applicant Type

Type of License/Certification/Permit OR Working Title (Maximum 30 characters - if assigned by DOJ, use exact title assigned)

Contributing Agency Information:

Agency Authorized to Receive Criminal Record Information

Mail Code (five-digit code assigned by DOJ)

Street Address or P.O. Box

Contact Name (mandatory for all school submissions)

City State ZIP Code

Contact Telephone Number

Applicant Information: **Live Scan Operator – The Board of Pharmacy requires you to enter the applicant's SSN.**

Last Name First Name Middle Initial Suffix

Other Name (AKA or Alias) Last First Suffix

Date of Birth Sex Male Female

Driver's License Number

Height Weight Eye Color Hair Color

Billing Number (Agency Billing Number)

Place of Birth (State or Country) Social Security Number - **MANDATORY**

Misc. Number (Other Identification Number)

Home Address Street Address or P.O. Box

City State ZIP Code

Your Number: OCA Number (Agency Identifying Number)

Level of Service: DOJ FBI

If re-submission, list original ATI number:
(Must provide proof of rejection)

Original ATI Number

Employer (Additional response for agencies specified by statute):

Employer Name

Mail Code (five digit code assigned by DOJ)

Street Address or P.O. Box

City State ZIP Code

Telephone Number (optional)

Live Scan Transaction Completed By:

Name of Operator

Date

Transmitting Agency LSID

ATI Number Amount Collected/Billed