



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

**INSTRUCTIONS FOR FILING AN APPLICATION FOR
CENTRALIZED HOSPITAL PACKAGING PHARMACY LICENSE**

(Business & Professions Code sections 4128 et seq.)

A licensed centralized hospital packaging pharmacy may prepare medications as outlined in Article 7.6 (commencing with Section 4128) of the Business and Professions Code for administration only to inpatients within its own general acute care hospital and one or more general acute care hospitals if the hospitals are under common ownership and located within a 75-mile radius of each other. In order to be issued a centralized hospital packaging pharmacy license, the applicant must possess a current and valid hospital pharmacy license with the board.

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. 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 \$800:** When you send your application, include a check or money order for \$800 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 \$800. *Applications received after June 30, 2017, with the payment of \$800 may be returned for the new application fee of \$820.*

APPLICATION FEE AS OF JULY 1, 2017 \$820: When you send your application, include a check or money order for \$820 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 \$820.

- **CENTRALIZED HOSPITAL PACKAGING PHARMACY LICENSE APPLICATION** (form 17A-80 (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: For a change of ownership, evidence that a change of ownership has been sought or obtained for all hospital pharmacy licenses must be submitted along with this application.

- **HOSPITAL ACUTE CARE LICENSE** – Submit a copy of the hospital acute care license issued by the Department of Public Health.
- **ORGANIZATIONAL CHART** - Submit an organizational chart identifying the applicant Centralized Hospital Packaging Pharmacy and all receiving hospital pharmacies documenting common ownership.
- **COMMON OWNERSHIP STATEMENT** – Submit a statement on company letterhead signed by an authorized owner/officer certifying the applicant Centralized Hospital Packaging Pharmacy and all receiving hospital pharmacies are:
 - Under common ownership, and
 - Located within a 75-mile radius of each other.
- **STATEMENT THAT THE PHARMACY WILL IMPLEMENT REQUIREMENTS** - Submit a statement on company letterhead signed by an authorized owner/officer stating that the applicant pharmacy will implement the requirements of Article 7.6 (commencing with Section 4128) of the Business and Professions Code.

**Article 7.6 (commencing with Section 4128) of the Business and Professions Code
Centralized Hospital Packaging Pharmacies**

4128. (a) Notwithstanding Section 4029, a centralized hospital packaging pharmacy may prepare medications, by performing the following specialized functions, for administration only to inpatients within its own general acute care hospital and one or more general acute care hospitals if the hospitals are under common ownership and located within a 75-mile radius of each other:

(1) Preparing unit dose packages for single administration to inpatients from bulk containers, if each unit dose package is barcoded to contain at least the information required by Section 4128.4.

(2) Preparing compounded unit dose drugs for parenteral therapy for administration to inpatients, if each compounded unit dose drug is barcoded to contain at least the information required by Section 4128.4.

(3) Preparing compounded unit dose drugs for administration to inpatients, if each unit dose package is barcoded to contain at least the information required by Section 4128.4.

(b) For purposes of this article, "common ownership" means that the ownership information on file with the board pursuant to Section 4201 for the licensed pharmacy is consistent with the ownership information on file with the board for the other licensed pharmacy or pharmacies for purposes of preparing medications pursuant to this section.

4128.2. (a) In addition to the pharmacy license requirement described in Section 4110, a centralized hospital packaging pharmacy shall obtain a specialty license from the board prior to engaging in the functions described in Section 4128.

(b) An applicant seeking a specialty license pursuant to this article shall apply to the board on forms established by the board.

(c) Before issuing the specialty license, the board shall inspect the pharmacy and ensure that the pharmacy is in compliance with this article and regulations established by the board.

(d) A license to perform the functions described in Section 4128 may only be issued to a pharmacy that is licensed by the board as a hospital pharmacy.

(e) A license issued pursuant to this article shall be renewed annually and is not transferrable.

(f) An applicant seeking renewal of a specialty license shall apply to the board on forms established by the board.

(g) A license to perform the functions described in Section 4128 shall not be renewed until the pharmacy has been inspected by the board and found to be in compliance with this article and regulations established by the board.

(h) The fee for issuance or annual renewal of a centralized hospital packaging pharmacy license shall be six hundred dollars (\$600) and may be increased by the board to eight hundred dollars (\$800).

4128.3. A centralized hospital packaging pharmacy may prepare and store a limited quantity of the unit dose drugs authorized by Section 4128 in advance of receipt of a patient-specific prescription in a quantity as is necessary to ensure continuity of care for an identified population of inpatients of the general acute care hospital based on a documented history of prescriptions for that patient population.

4128.4. Any unit dose medication produced by a centralized hospital packaging pharmacy shall be barcoded to be readable at the inpatient's bedside. Upon reading the barcode, the following information shall be retrievable:

(a) The date the medication was prepared.

(b) The components used in the drug product.

(c) The lot number or control number.

(d) The expiration date.

(e) The National Drug Code Directory number.

(f) The name of the centralized hospital packaging pharmacy.

4128.5. The label for each unit dose medication produced by a centralized hospital packaging pharmacy shall contain all of the following:

(a) The expiration date.

(b) The established name of the drug.

(c) The quantity of the active ingredient.

(d) Special storage or handling requirements.

4128.6. All compounding and packaging functions specified in Section 4128 shall be performed only in the licensed centralized hospital packaging pharmacy and that pharmacy shall comply with all applicable federal and state statutes and regulations, including, but not limited to, regulations regarding compounding and, when appropriate, sterile injectable compounding.

4128.7. A centralized hospital packaging pharmacy and the pharmacists working in the pharmacy shall be responsible for the integrity, potency, quality, and labeled strength of any unit dose drug product prepared by the centralized hospital packaging pharmacy.



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CENTRALIZED HOSPITAL PACKAGING PHARMACY LICENSE APPLICATION

Please print or type ALL BLANKS MUST BE COMPLETED; IF NOT APPLICABLE, ENTER N/A

Name of Hospital Pharmacy:		Hospital Pharmacy License Number	
Hospital Pharmacy Telephone Number:	Centralized Hospital Packaging Pharmacy Telephone Number: (if different)		
Physical Address and Location of Hospital Pharmacy (street and number)		City	State Zip Code

Name of pharmacist-in-charge of Hospital Pharmacy:	Pharmacist license number:
Pharmacist-in-charge email address:	Pharmacist-in-charge phone number:

Indicate whether this application is for:

New Licensed Centralized Hospital Packaging Pharmacy
 Change of Location of Licensed Centralized Hospital Packaging Pharmacy
 Change of Ownership of Licensed Centralized Hospital Packaging Pharmacy (submit evidence of change of ownership for all hospitals)

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

Name:	Address:	License Number:
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Please indicate type of ownership:

Sole Proprietor
 Partnership
 Corporation
 Limited Liability Company
 Government owned

I have read the attached statutes pertaining to licensure of centralized hospital packaging pharmacies at Article 7.6 (commencing with section 4128) of the Business and Professions Code.

_____	_____	_____
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 for the Centralized Hospital Packaging Pharmacy

A license for centralized hospital packaging pharmacy may only be issued to the owner of a licensed hospital pharmacy at the licensed location.

If a Sole Proprietor:				
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 (for partnership)	Telephone Number	
Address	number and street	City	State	Zip Code
Name of Partner		*FEIN Number (for partnership)	Telephone Number	
Address	number and street	City	State	Zip Code
If a Corporation/Limited Liability Company: (attach additional sheet if needed)				
Name of Corporation/Limited Liability Company (if applicable)			Telephone Number	
Address	number and street	City	State	Zip Code
<p>Print below the name, title, address and license number of all the limited liability members/managers, corporate officers/directors, and hospital 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.</p>				
Title	Name	Residence Address**	License Type Held	License Number

*Disclosure of your social security number if you are a sole proprietor 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.

**Residence address will not be made available to the public.

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.

Complete this section for EACH hospital pharmacy under common ownership that will be RECEIVING from the Centralized Hospital Packaging Pharmacy. (Use additional pages if necessary.)

Name of RECEIVING Hospital Pharmacy:	RECEIVING Hospital Pharmacy License Number
Physical Address and Location of RECEIVING Hospital Pharmacy (Include Street, Number, City, State and Zip Code)	
Name of pharmacist-in-charge of licensed RECEIVING hospital pharmacy:	Pharmacist license number:
Pharmacist-in-charge email address (optional)	RECEIVING Hospital Pharmacy Telephone Number:

Print below the name of all sole owners, partners, corporations, or limited liability companies for all levels of the pharmacy ownership for the RECEIVING PHARMACY. Attach additional sheets if necessary.

Type of ownership/corporate structure (sole proprietor, partnership, corporation, or LLC)	Name of Owner

Print below the name, title, and license number of all the limited liability members/managers, corporate officers/directors, and 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	License type held	License number

PLEASE READ CAREFULLY

This application must be approved by the California State Board of Pharmacy before a Centralized Hospital Packaging Pharmacy license will be issued. Falsification of any information on this application may constitute grounds for denial or subsequent revocation of the license.

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 as authorized by Business and Professions Code section 4128 and following. 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) 574-7900, 1625 North Market Blvd., Suite N219, Sacramento, CA 95834. The information may be transferred to or provided pursuant to court order or subpoena 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 Section 1798.40 of 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) 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 (4) all supplemental statements filed with this application are true, complete and accurate.

USE ADDITIONAL SHEETS IF NECESSARY. ALL MEMBERS OF AN LLC SHOULD SIGN THE APPLICATION.

Signature of Corporate officer, owner, member, or partner	Name (please print)	Title	Date
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Signature of Corporate officer, owner, member, or partner	Name (please print)	Title	Date
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Signature of Corporate officer, owner, member, or partner	Name (please print)	Title	Date
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Signature of Corporate officer, owner, member, or partner	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 (optional)



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PARTNERSHIP OR INDIVIDUAL OWNERSHIP INFORMATION

Please print or type

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

Name of premises:				Telephone number ()	
Address of premises:		Number and Street	City	State	Zip Code

A. Partnership

If any of the partners listed below is a corporation or limited liability company, form 17A-33 must also be completed for each such entity. Under the heading "Licensed as" list any state professional or vocational licenses held; e.g., pharmacist, physician, podiatrist, dentist, veterinarian, etc., and the license number.

Federal Employer ID Number:*

Name or corporate name		Percentage owned %
Residence or corporate address		*Social security number
Licensed as	License number	States licensed in

Name or corporate name		Percentage owned %
Residence or corporate address		*Social security number
Licensed as	License number	States licensed in

Name or corporate name		Percentage owned %
Residence or corporate address		*Social security number
Licensed as	License number	States licensed in

B. Individual owner

Under the heading "Licensed as" list any state professional or vocational licenses held; e.g., pharmacist, physician, podiatrist, dentist or veterinarian; and the license number.

Name		Do you own 100% of business?	
		Yes <input type="checkbox"/>	No <input type="checkbox"/>
Residence address		*Social security number	
Licensed as	Lic	ense number	States licensed in

PLEASE READ CAREFULLY. ALL PARTNERS/OWNERS MUST SIGN BELOW.

This application must be approved by the California State Board of Pharmacy before a pharmacy permit can be issued. If changes are made during the application process, you may need to submit a new application with the appropriate fees. **Fees applied to this application are not transferable and are not refundable.**

Any material misrepresentation in a response to any question is grounds for refusal or subsequent revocation of license, and is a violation of the Penal Code. 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 the California Pharmacy Law. The officer responsible for information maintenance is the executive officer, (916) 574-7900, 1625 N. Market Blvd., Suite N219, Sacramento, CA 95834. 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 by section 1798.3 of the Civil Code.

Under penalty of perjury, under the laws of the State of California, each person whose signature appears below, certifies and says that: (1) he/she is the owner or an officer of the applicant corporation named in the foregoing application, duly authorized to make this application on its behalf and is at least 18 years of age; (2) he/she has read the foregoing application and knows the contents thereof and that each and all statements therein made are true; (3) 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(s) for which this application is made; (4) all supplemental statements are true and accurate; and (5) the transfer application may be withdrawn by either the applicant or the licensee with no resulting liability to the Board of Pharmacy.

Signature of partner or individual owner	Name (please print)	Date
Signature of partner or individual owner	Name (please print)	Date
Signature of partner or individual owner	Name (please print)	Date

*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, for purposes of compliance with any judgement or order for family support in accordance with section 11350.6 of the Welfare and Institutions Code, or for verification of licensure or examination status by a licensing or examination entity which utilizes a national examination and where licensure is reciprocal with the requesting state. 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 will 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.



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Parent Corporation or Limited Liability Company Ownership Information

Please print or type **All blanks must be completed; if not applicable, enter N/A**

Name of parent corporation or limited liability company			Telephone number	
			()	
Address	Number and Street	City	State	Zip Code
Name & address of premises	Number and Street	City	State	Zip Code

Is the parent corporation a subsidiary? Yes No
If yes, name of parent corporation _____ . This parent corporation must also complete a Parent Corporation or Limited Liability Company Ownership information form. Please attach an organization chart.

A. Limited Liability Members or Manager(s) (Use additional sheets if necessary)

Under the heading "Licensed as" list any state professional or vocational licenses held; e.g., pharmacist, physician, podiatrist, dentist or veterinarian, etc., and the license number (if applicable). Non-profit organizations must list the names and titles of persons holding corporate positions.

Title	Name	Residence address & telephone number	Licensed as, license no. and state(s)

For Limited Liability Companies Only: We, the undersigned members, authorize _____
(Name of member)
 to sign all Board of Pharmacy forms, documents and operating conditions on our behalf.

B. Corporate Officers/Directors (Top 5 of each. Use additional sheets if necessary.)

Under the heading "Licensed as" list any state professional or vocational licenses held; e.g., pharmacist, physician, podiatrist, dentist or veterinarian, etc., and the license number (if applicable). Non-profit organizations must list the names and titles of persons holding corporate positions.

Title	Name	Residence address & telephone number	Licensed as, license no. and state(s)

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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.

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ALL OWNERS AND OFFICERS DESIGNATED ON THIS FORM MUST SIGN BELOW.

Under penalty of perjury, under the laws of the State of California, each person whose signature appears below, certifies and says that: (1) he/she is the owner or an officer of the corporation or limited liability company named on this application form, duly authorized to make this application on its behalf and is at least 18 years of age; (2) he/she has read the foregoing application and knows the contents thereof and that each and all statements therein made are true; (3) 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 (4) all supplemental statements are true and accurate.

Print Name _____ Signature _____ Date _____

Print Name _____ Signature _____ Date _____

Print Name _____ Signature _____ Date _____

Print Name _____ Signature _____ Date _____

Print Name _____ Signature _____ Date _____

Print Name _____ Signature _____ Date _____

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Print Name _____ Signature _____ Date _____

Print Name _____ Signature _____ Date _____

Print Name _____ Signature _____ Date _____

Print Name _____ Signature _____ Date _____

Print Name _____ Signature _____ Date _____

Print Name _____ Signature _____ Date _____