



California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



INSTRUCTIONS FOR FILING AN APPLICATION FOR CENTRALIZED HOSPITAL PACKAGING PHARMACY LICENSE

Chapter 9, Division 2, Article 7.6 (section 4128, et seq.) of the Business and Professions Code.

A licensed centralized hospital packaging pharmacy (CHP) 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.

IMPORTANT: Please follow these instructions completely. Failure to submit the necessary items will delay the processing of your application. If the number of forms included in this application is insufficient, please make copies. Please allow approximately 45 days from the date your application is submitted before checking on the status. The contact person designated on the application will be advised if additional information is necessary.

A checklist is provided with these instructions. The Board encourages the submission of all required documentation with the application as well as the use of the checklist to assist with the application process. The Board may request additional documentation to confirm or substantiate information in the application. When submitting documents to the Board, please make a copy for your records.

CHECKLIST FOR FILING A CHP 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 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.

- 1. CENTRALIZED HOSPITAL PACKAGING PHARMACY LICENSE APPLICATION (form 17A-80 (rev. 2/2020):**
Complete the entire application and submit with original signatures. Scanned or stamped signatures are not accepted.

PLEASE 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.

A CHP 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.

2. APPLICATION PROCESSING FEE IS \$3,815.

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

3. HOSPITAL ACUTE CARE LICENSE: Submit a copy of the hospital acute care license issued by the Department of Public Health.

4. ORGANIZATIONAL CHART: Submit an organizational chart identifying the applicant CHP and all receiving hospital pharmacies documenting common ownership.

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

Chapter 9, Division 2, Article 7.6 (section 4128, et seq.) of the Business and Professions Code.

1. Applicant Information (Name of Hospital Pharmacy cannot exceed 65 characters including spaces)

 Name of Hospital Pharmacy License Number

 Address of Centralized Hospital Packaging Pharmacy: Street City State Zip Code

 Exact Location of Centralized Hospital Packaging Pharmacy (Room Number or Name of Room)

 Hospital Pharmacy Telephone Number Centralized Hospital Packaging Pharmacy Telephone Number

Please provide the mailing address to receive correspondence while the centralized hospital packaging pharmacy (CHP) application is pending, if different than the address listed above. When the license is issued, all correspondence will be sent to the CHP address.

 Mailing Address, if different than above Street City State Zip Code

2. Type of Application

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

3. Type of Ownership

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

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

4. Contact Person: The Board will ONLY discuss the status of this application with the person identified as the contact person and any person who has signed the application as an officer, partner, member, and/or owner of the applicant business. An authorized owner may designate additional individuals to receive information on this pending application by submitting the Authorization to Release Applicant Information form. The Board may communicate deficiencies and status of application to the contact person via email.

 Name of Contact Person Telephone Number Email Address

For Board Use ONLY

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

5. Change of Ownership or Location Provide the exact name, address, location, and license number as listed on the current CHP license.

Name listed on the Current CHP License

CHP License Number

Address: Street

City

State

Zip Code

Expiration Date of License

Effective Date of Change of Ownership/Location

6. Pharmacist-in-Charge (PIC) of Hospital Pharmacy List the proposed Pharmacist-In-Charge (PIC) to serve as the supervisor or manager responsible for ensuring the hospital pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy as well as the hospital pharmacy's policy and practices. The PIC must be approved by the board.

Name of PIC

Pharmacist License Number

Telephone Number of PIC

Email Address

I have read the statutes included in the CHP instructions pertaining to licensure of a CHP in Chapter 9, Division 2, Article 7.6 (section 4128, et seq.) of the Business and Professions Code.

Original Signature of PIC

Date

7. Requirements for a CHP Pharmacy License Prior to issuance of the license, the Board shall conduct a prelicensure inspection.

A. Is the CHP in compliance with the statutes in Chapter 9, Division 2, Article 7.6 (section 4128, et seq.) of the Business and Professions Code?

Yes ____ No ____ If No, provide the date when the applicant pharmacy be in compliance? _____

B. Is the CHP and each Receiving Hospital Pharmacy under common ownership?

Yes ____ No ____

C. Is the CPH and each Receiving Hospital Pharmacy located within a 75-mile radius of each other?

Yes ____ No ____

8. Ownership Information for the Centralized Hospital Packaging Pharmacy A CHP license may only be issued to the owner of a licensed hospital pharmacy at the licensed location. List the name(s) of all owner(s), partners, corporation(s), limited liability company(ies), or trust(s) **for all levels** of ownership for the **hospital pharmacy**.

Type of Ownership Structure (Individual, Corporation, Partnership, LLC, Trust, or Government)	Name

Provide the name(s) of the top five officer(s), director(s), trustee(s), managers, and the Administrator (government owned). Under the heading "License" list any state professional or vocational license(s) (current or expired) - e.g., pharmacist, physician, podiatrist, dentist or veterinarian, etc. Nonprofit organizations must list the names and titles of persons holding corporate positions. If licensed, include the license type, license number, and the state(s) licensed in below. **LIST ALL TITLES, IF SERVING IN MORE THAN ONE CAPACITY.**

Position Title(s)	Full Legal Name	License Type Held	License Number

9. List EACH hospital pharmacy under common ownership that will be RECEIVING from the CHP. (If more than one receiving hospital pharmacy, use additional pages.)

Receiving Hospital Pharmacy Information

 Name Hospital Pharmacy Hospital License Number

 Receiving Hospital Pharmacy Location: Street City State Zip Code

 Name of PIC at Receiving Hospital Pharmacy Pharmacist License Number

 Receiving Hospital Pharmacy Telephone Number PIC Email Address

List the name(s) of all owner(s), partners, corporation(s), limited liability company(ies), or trust(s) for all levels of the pharmacy ownership for the **RECEIVING HOSPITAL PHARMACY**.

Type of Ownership Structure (Individual, Corporation, Partnership, LLC, Trust, or Government)	Name

Provide the name(s) of the top five officer(s), director(s), trustee(s), managers, and the Administrator (government owned). Under the heading "License" list any state professional or vocational license(s) (current or expired) - e.g., pharmacist, physician, podiatrist, dentist or veterinarian, etc. Nonprofit organizations must list the names and titles of persons holding corporate positions. If licensed, include the license type, license number, and the state(s) licensed in below. **LIST ALL TITLES, IF SERVING IN MORE THAN ONE CAPACITY.**

Position Title(s)	Full Legal 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 license will be issued.

If changes are made during the application process, the applicant may need to submit a new application with appropriate fees. **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 is 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 him/her by the Board of Pharmacy, unless the records are identified as confidential and exempted by Civil Code section 1798.38.

*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: 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.

REQUIRED SIGNATURES: All natural persons authorized to bind the applicant business are required to sign the application. Provide original signatures.

Under penalty of perjury under the laws of the State of California, each person whose signature appears below, certifies and says:

1. The **owner, partner, member, officer, director, manager, trustee, or the administrator (government owned)**, of the CHP pharmacy named in the foregoing application, is duly authorized to make this application on its behalf and is at least 18 years of age.
2. 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 or management and control in the applicant CHP business to be conducted under the license for which this application is made.
4. Understands that falsification of any information in this application may constitute grounds for denial or subsequent revocation of the license.
5. All supplemental statements are true and accurate.
6. A change of ownership application may be withdrawn by either the applicant or the licensee with no resulting liability to the California State Board of Pharmacy.

Signature	Name (please print)	Title	Date
Signature	Name (please print)	Title	Date
Signature	Name (please print)	Title	Date
Signature	Name (please print)	Title	Date
Signature	Name (please print)	Title	Date
Signature	Name (please print)	Title	Date

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