



Alerts

Don't Jeopardize Your License: Ensure Compliance With California State Board of Pharmacy Notification and Reporting Obligations

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Health Care Alert

Pharmacies, wholesalers, third-party logistics providers, outsourcing facilities, clinics, and pharmacists must obtain the California State Board of Pharmacy's (the "Board") approval or otherwise notify the Board about changes in ownership, corporate structure, staffing, and the scope of services provided. Reportable changes can be grouped into the following three areas:

A review of recent California State Board of Pharmacy inspection report summaries and enforcement actions demonstrates that the noncompliance most frequently reported is failure to timely obtain approval for or licensee changes related to Change of Ownership, Change of Corporate Structure, Change of Permit, Change of Corporate Officers, and Change of the Pharmacist-In-Charge.

Failure to timely obtain California State Board of Pharmacy approval or otherwise provide timely notification of such changes may result in a citation, fine, or other disciplinary action, including but not limited to licensee probation, suspension, or revocation.

1. Facility Changes

Change of Ownership, Corporate Structure, or Location

Before any change of ownership, corporate structure, or location, a Facility Licensee must obtain California State Board of Pharmacy approval of such change by completing and submitting a [new license application](#).

A change of ownership is defined as any transfer of a beneficial interest in a business entity licensed by the Board, in a single transaction or a series of transactions, to any person or entity, which transfer results in the transferee's holding 50 percent or more of the beneficial interest in that license.

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A change of corporate structure means a change in the type of legal entity (e.g., corporation, LLC, partnership), the creation of a new parent entity, or a change in any of the parent entities within the licensee's ownership tier. A change of location is defined as a change in the physical location and address of a facility.

All approved changes of ownership, corporate structure, or change of location applications will result in a new license number being issued. Change of ownership or location applications should be submitted at least 30 days before the changes occur. However, it could take six months or longer to obtain the new license.

Operating the facility prior to a new license being issued constitutes unlicensed activity and may result in denial of approval of the Change of Ownership, Corporate Structure, Location, or disciplinary action by the Board. California Business and Professions Code Section 4035, 4201, and [Cal. Code Regs. Tit. 16 § 1709](#)

Closure of Facility or Discontinuance of Business

A license holder must contact the Board prior to transferring or selling any dangerous drugs, devices, or hypodermics inventory because of termination of business or bankruptcy proceedings. [Discontinuance of Business Application \(17M-8\)](#); [Cal. Code Regs. tit. 16 § 1709](#)

Changes to a Permit (Facility License)

The California State Board of Pharmacy requires pharmacies to submit a Change of Permit application to the Board within 30 days when one of the following changes occurs:

1. Change of Trade Style Name or Corporate Name (not a change of ownership);
2. Change of Administrator;
3. Change of Consulting Pharmacist (Drug Room);
4. Change of Warden (Licensed Correctional Facility);
5. Change of Corporate Officers;
6. Transfer of 10 percent to 49 percent of Ownership;
7. Address Correction Change;
8. Notification of Discontinuance or Replacement of an Automated Drug Delivery License; and
9. Notification of Installation or Discontinuance of a Drug Take-Back

Pharmacies should allow four to six weeks for processing the Change of Facility License (Change of Permit) application.

Transfer or Assignment of a Beneficial Interest

A transfer of beneficial interest in a facility licensed by the board, in a single transaction or a series of transactions, to any person or entity, which transfer results in the transferee's holding 10-49 percent of the beneficial interest in the licensed facility must submit a Change of Permit application to the Board within 30 days. A transfer of assignment of a beneficial interest in the amount of 50 percent or more will require a Change of Ownership application.

Notification to Operate or Discontinue Operating a Mobile Unit

Pharmacies must provide notification to operate or discontinue the operation of a mobile unit to provide prescription medication within its jurisdiction to those individuals without fixed addresses, individuals living in county-owned or city-and-county-owned housing facilities, and those enrolled in Medi-Cal plans operated by the county or a city and county, a health district, or a joint powers authority. [Form For Notification to Operate or Discontinue Operating a Mobile Unit](#), California Business and Professions Code Section 4110.5.



Notification of Temporary Closure Exceeds Three Days

Except for Correctional Pharmacies, a permit holder shall notify the Board of any temporary closure of a facility as soon as any closure exceeds three consecutive calendar days. A temporary closure shall not include a routine closure (including weekends or state and federal holidays) unless that closure exceeds four consecutive calendar days.

The licensee must complete the renewal application and submit the renewal fees per Pharmacy Law while the facility is temporarily closed. [Title 16, California Code of Regulations section 1708.1](#). The Board may cancel the license of a facility licensed by the Board if the licensed premises remain closed. "Closed" means not engaged in the ordinary activity for which a license has been issued for at least one day each calendar week during any 120-day period. [California Business and Professions Code Section 4312](#).

Change of Facility Name

A change of permit must be submitted to the Board within 30 days of a change in facility name. Reporting a corporate name change is required for any of the parent entities within the licensee's ownership tier.

Facility Address Correction

A change of permit must be submitted to the Board within 30 days of an address correction. An address correction includes change of street name or number made by the United States Postal Service, government entity, suite number, etc., but does not include a change of location.

Installation or Discontinuance of Drug Take-Back Collection Receptacle

Pharmacies and hospitals/clinics with onsite pharmacies licensed by the Board may, under the requirements in California pharmacy regulations, offer specified prescription drug take-back services through collection receptacles and/or mail back envelopes/packages to provide options for the public to discard unwanted, unused or outdated prescription drugs. Entities must notify the board within 30 days of installing or discontinuing a drug take-back receptacle. CCR, Title 16, Article 9.1 of Division 17

Discontinuance or Replacement of an Automated Drug Delivery License

Pharmacy law requires notification within 30 days when the responsible primary license discontinues operation or replaces the existing Automated Drug Delivery System device with a different Automated Drug Delivery System.

2. Staffing Changes

The California State Board of Pharmacy requires several types of notifications for staff changes, including: Change of Corporate Officers, [Change of Pharmacist-in-Charge](#), [Designated Representative-in-Charge](#), [Responsible Manager](#), [Professional Director](#), Consulting Pharmacist, or Correctional Clinic Chief Executive Officer.

Change of Corporate Officers

Each pharmacy wholesaler, third-party logistic provider, licensed clinic, or correctional facility clinic must notify the Board in writing within 30 days of any changes in corporate officers. "Corporate officers" are defined to include Officer(s), Director (s), Manager(s), Member(s), Partner(s), and Owner(s).



Change of Pharmacist-in-Charge (PIC)

During recent inspections, the Board has cited a significant number of pharmacies and pharmacists for failing to notify the Board when a PIC ceased acting as PIC. Pharmacies and PICs who fail to notify the Board when a PIC ceases acting as a PIC are in violation of pharmacy law and, therefore, potentially subject to significant fines, penalties, or other disciplinary action.

Pharmacists-in-Charge must notify the Board in writing within 30 days of any status changes, such as termination or a change in PIC. The notification must be on a form provided by the Board and include the proposed replacement PIC and the Board's approval.

If the Board disapproves the proposed replacement, the pharmacy must propose another within 15 days and continue until the Board approves. Failure to notify the Board may result in a citation, fine, or other disciplinary action. Pursuant to California Business and Professions Code Section 4101(a), 4113(d). [Change of Pharmacist-in-Charge Application](#)

Change of Designated Representative-in-Charge (DRIC)

Each wholesale pharmacy that makes an application for a pharmacy license is required to show evidence that they have retained the services of a Designated Representative-in-Charge who is responsible for the safe, orderly, and lawful provision of pharmacy services.

Wholesalers must notify the Board in writing within 30 days of any status changes, such as termination or a change in DRIC. The notification must be on a form provided by the Board and include the proposed replacement DRIC and the Board's approval. If the Board disapproves the proposed replacement, the pharmacy must propose another within 15 days and continue until the Board approves. Failure to notify the Board may result in a citation, fine, or other disciplinary action. [California Business and Professions Code Sections 4160 Change of Designated Representative-in-Charge Application](#)

Change of Responsible Manager (RMG)

Each third-party logistics provider that makes an application for a pharmacy license is required to show evidence that they have retained the services of a Responsible Manager responsible for the safe, orderly, and lawful provision of pharmacy services. A third-party logistics provider must notify the Board in writing within 30 days of a termination or a change in RMG.

The notification must be on a form provided by the Board and include the proposed replacement RMG and the Board's approval. If the Board disapproves the proposed replacement, the pharmacy must propose another within 15 days and continue until the Board approves. Failure to notify the Board may result in a citation, fine, or other disciplinary action. [California Business and Professions Code Sections 4160\(g\). Change of Responsible Manager Application](#)

Change of Professional Director, Consulting Pharmacist, or Administrator in a Licensed Clinic

Each licensed clinic that makes an application for a pharmacy license is required to show evidence that they have retained the services of a professional director who is responsible for the safe, orderly, and lawful provision of pharmacy services; and an administrator and consulting pharmacist to approve the policies and procedures in conjunction with the Professional Director. Licensed Clinics must notify the Board in writing within 30 days of a termination or a change in the Professional Director, Consulting Pharmacist, or Administrator.

The notification must be on a form provided by the Board and include the proposed replacement Professional Director, Consulting Pharmacist, or Administrators and obtain the Board's approval. If the Board disapproves the proposed replacement, the pharmacy must propose another within 15 days and continue until the Board approves. Failure to notify the Board may result in a citation, fine, or other disciplinary action Business and Professions Code sections 4180, 4182, and 4192. [Clinic Change of Permit Application](#); [Change of Professional Director Application](#); [Business and Professions](#)



Code section 4180, 4182 and 4192. Change of Consulting Pharmacist Application

Change of Chief Executive Officer/Warden for Correctional Facility Clinic

Each Correctional Facility Clinic that makes an application for a pharmacy license is required to show evidence that it has retained the services of a Chief Executive Officer/Warden who is responsible for the safe, orderly, and lawful provision of pharmacy services.

Correctional Facility Clinics must notify the Board in writing within 30 days of a termination or a change in the Chief Executive Officer/Warden. The notification must be on a form provided by the Board and include the proposed replacement Chief Executive Officer/Warden and the Board's approval.

If the Board disapproves the proposed replacement, the pharmacy must propose another within 15 days and continue until the Board approves. Failure to notify the Board may result in a citation, fine, or other disciplinary action. California Business and Professions Code section 4187.2

3. Reporting Obligations

The California State Board of Pharmacy requires pharmacies to report certain events, including medication errors, controlled substance loss, unsafe conditions, counterfeit or dangerous drugs, suspicious orders, sterile compounding qualifications, Change of Address or Name and Email Notification List, Change of Address or Name and Email Notification List, and Notification of Bankruptcy.

Reporting a Drug Theft, Drug Loss, or Impaired Licensee

Any controlled substance loss (significant or not) must be reported to the California State Board of Pharmacy within 14 calendar days from the date of loss for losses due to licensed employee theft (pursuant to Business and Professions Code, §4104) or 30 calendar days (pursuant to California Code of Regulations, Title 16, §1715.6) for any other type of loss.

To report an impaired licensee, the PIC must [file a complaint](#) with the California State Board of Pharmacy within 14 days of discovery. If a DEA-106 form was completed and submitted to the DEA, a copy can be sent to the Board of Pharmacy.

Medication Errors

Community pharmacies must report all medication errors to the Board, or a third party approved by the Board within 14 days of discovering the error. Medication Errors include any variation from a prescription drug order not authorized by the prescriber, including, but not limited to, errors involving the wrong drug, the wrong dose, the wrong patient, the wrong directions, the wrong preparation, or the wrong route of administration.

Reports are considered confidential and are not subject to disclosure under the California Public Records Act. [California Business and Professions Code Section 4113.1](#).

Unsafe Conditions

Pharmacists must immediately notify store management of any conditions that could pose an immediate risk to patients, staff, or personnel. The law requires the PIC or pharmacist on duty to immediately notify store management of any conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff.

Pharmacy store management must take immediate and reasonable steps to address and resolve the conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff. [California Business and Professions Code 4113\(d\)\(1\)](#).



Counterfeit or Dangerous Drugs

Licensees must notify the Board if a manufacturer, wholesaler, third-party logistics provider, or pharmacy has reasonable cause to believe that a dangerous drug or dangerous device in, or having been in, its possession is counterfeit or the subject of a fraudulent transaction, the manufacturer, wholesaler, third-party logistics provider, or pharmacy shall notify the Board within 72 hours of obtaining that knowledge. [California Business and Professions Code 4107.5](#).

Suspicious Orders

Wholesalers must report suspicious orders to the Board in writing about all suspicious orders of controlled substances placed by a California-licensed pharmacy or wholesaler. Suspicious orders include—but are not limited to—orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. Wholesalers should provide the Board with a copy of the information that the wholesaler provides to the United States Drug Enforcement Administration.

Sterile Drug Compounding Compliance

Sterile compounding pharmacies must provide the Board with:

1. a copy of any disciplinary or other action taken by another state within 10 days of the action;
2. a notification to the Board within 10 days of the suspension of any accreditation held by the pharmacy; and
3. within 12 hours, a copy of any recall notice issued by the pharmacy for sterile drug products it has compounded.
[California Business and Professions Code 4127.1](#)

Change of Name or Address

All licensees (including but not limited to a pharmacist, intern pharmacist, technician, designated representative, designated representative-3PL, or designated representative-reverse distributor) who change their name or address are required to notify the California State Board of Pharmacy within 30 days after changing their name.

The Board will not automatically issue a new license. To obtain an updated license with a changed name, submit an Application for Reissue of License with the appropriate fee. A change of address can be submitted online or by mailing a change of address form to the Board. [California Business and Professions Code section 4100](#) and [Title 16, California Code of Regulations, section 1704](#).

Email Notification List and Subscriber Alerts

All licensees must join the Board's email notification list within 60 days of receiving their license or when renewing their license. They must also update their email address within 30 days of any changes. Individuals can sign up for the list on the Board's website.

All facilities, pharmacists, intern pharmacists, pharmacy technicians, and designated representatives must sign up for subscriber alerts for their license type within 60 days of obtaining a license or at the time of license renewal. [California Business and Professions Code section 4100](#) and [Title 16, California Code of Regulations, section 1704](#).

Name and Gender Change

Licensees may notify the Board of a name and/or gender change and request confidentiality of the previous name or gender information when meeting certain specific requirements. Upon request by a licensee or registrant whose name or gender, the Board shall replace references to the licensee's or registrant's former name or gender with the individual's current name or gender, as applicable, on the publicly viewable information displayed on the internet about the licensee or registrant.



The licensee's or registrant's former name or gender, as applicable, shall not be published online. If the licensee changed their name or gender and was previously the subject of an enforcement action, those records will not be publicly posted on the Board's website. [California Business and Professions Code section 27.5](#)

Offsite Storage Waiver

California law requires pharmacies and other licensed facilities to maintain records and other documentation of the acquisition and distribution of dangerous drugs and devices for three years and to retain these records in readily retrievable form.

Any pharmacy that wishes to store records offsite must submit an application for a waiver to allow offsite storage of records by completing the applicable waiver application and obtaining approval prior to the offsite record storage. Business and Professions Code sections 4081, 4105, 4333; Code of Regulations, Division 17, Title 16, sections 1707.

Notification of Bankruptcy

Any pharmacy, wholesaler, or manufacturer who makes any assignment for the benefit of creditors or enters into any creditor compromise arrangement, or who files a petition in bankruptcy, or who has a receiver appointed, or who enters into any liquidation or other arrangement which may result in the sale or transfer of drugs, devices or appliances which are required to be sold by a registered pharmacist or other licensee, shall notify the Board immediately in writing of such fact. [Title 16, California Code of Regulations, section 1705](#), and California Business and Professions Code. Reference: Sections [4005](#), [4024](#), [4080](#), [4081](#) and [4332](#).

Conclusion

Failure to notify the California State Board of Pharmacy of significant changes, such as a change of ownership, staffing, or operations, is a very serious matter. Licensees who fail to comply may face disciplinary action such as fines and licensure probation, suspension, or revocation, which are likely to result in a negative impact on pharmacy revenues due to loss of accreditation or the termination of pharmacy benefit management contracts due to the imposition of disciplinary action.

Disciplinary actions are a large issue for multi-state pharmacies, as pharmacies with licenses in multiple states are subject to disciplinary action in each licensed state, and disciplinary actions in one licensed state can lead to additional disciplinary actions in other licensed states. Due to the significant risks, it is important that all pharmacies incorporate compliance with California State Board of Pharmacy notification and disclosure requirements into their corporate compliance programs, which include requisite policies and procedures to ensure compliance.

If you discover the failure to comply with a California State Board of Pharmacy deadline for approval or disclosure of changes in ownership, staff, or operations, it is important to obtain the services of a qualified pharmacy law counsel with significant experience in pharmacy license defense and California State Board of Pharmacy requirements.

Many pharmacy owners and/or pharmacists-in-charge attempt to resolve pharmacy law compliance issues on their own, notwithstanding the fact that the risk of potential disciplinary action could result in a significant loss of revenues due to loss of accreditation or PBM contracts, an outcome greatly outweighing the cost of retaining legal counsel. Experienced pharmacy law counsel may be able to achieve a settlement and implementation of a corrective action plan with no disciplinary action being reported against the licensee or otherwise greatly reduce potential sanctions.

Hinshaw has a pharmacy law team that assists clients with [pharmacy compliance and regulatory issues](#), including State Board of Pharmacy license applications, California Department of Public Health Clinical Laboratory license applications, regulatory compliance, and notification and reporting requirements. Please contact your [Hinshaw attorney](#) with any questions and for additional guidance on pharmacy regulatory and compliance matters.