

The slides provided are for informational purposes at this time and not the course to receive a certificate. Once the course is approved, an announcement will be sent out as a subscriber alert.

Pharmacist-in- Charge: Overview and Responsibility

CALIFORNIA STATE BOARD OF PHARMACY

DATE: JANUARY 2025

Disclaimer

- ▶ This presentation, including examples are provided for informational purposes only, the author makes no warranties, either expressed or implied.
- ▶ Information in this presentation is subject to change without notice.
- ▶ This presentation carries no authority and shall not be considered legal advice.
- ▶ Any opinions added in this presentation and on the following slides are solely those of the presenter and not necessarily those of the California State Board of Pharmacy.

Before We Begin

- ▶ To view closed captioning for this webinar, click on the CC button at the bottom of the viewer
- ▶ Abbreviations used in this presentation include:
 - ▶ PIC = Pharmacist-in-Charge
 - ▶ BPC = California Business and Professions Code
 - ▶ CCR = California Code of Regulations
 - ▶ HSC = California Health and Safety Code
 - ▶ CA = California
 - ▶ Board = California State Board of Pharmacy

Definition of a Pharmacist: CA BPC 4036

- ▶ "Pharmacist" means a natural person to whom a license has been issued by the board, under Section 4200, except as specifically provided otherwise in this chapter. The holder of an unexpired and active pharmacist license issued by the board is entitled to practice pharmacy as defined by this chapter, within or outside of a licensed pharmacy as authorized by this chapter.



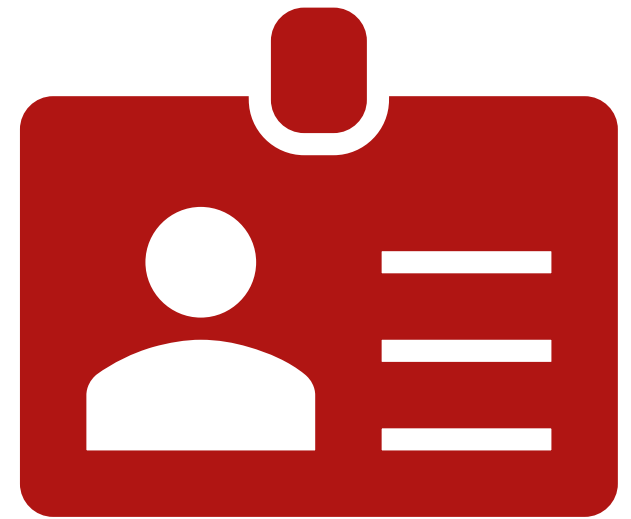
Definition of a Pharmacist-in-Charge: CA BPC 4036.5

- ▶ “Pharmacist-in-Charge” means a pharmacist proposed by a pharmacy and approved by the board as the supervisor or manager responsible for ensuring the pharmacy’s compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.



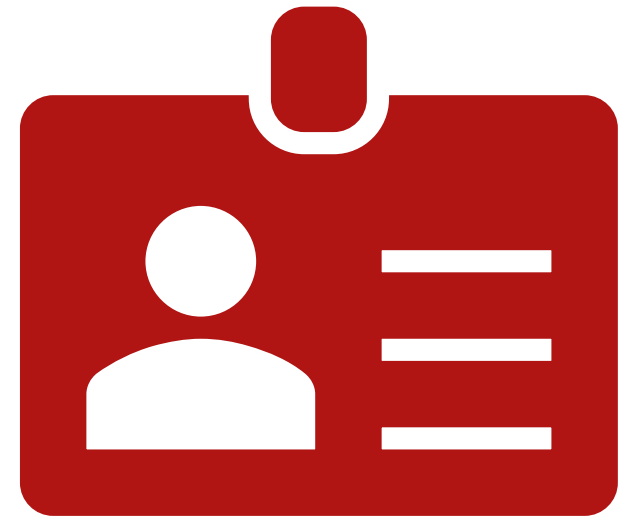
Association and Disassociation of PIC: CA BPC 4101

- ▶ (a) A pharmacist may take charge of and act as the Pharmacist-in-Charge of a pharmacy upon application by the pharmacy and approval by the board. A Pharmacist-in-Charge who ceases to act as the Pharmacist-in-Charge of the pharmacy shall notify the board in writing within 30 days of the date of that change in status.



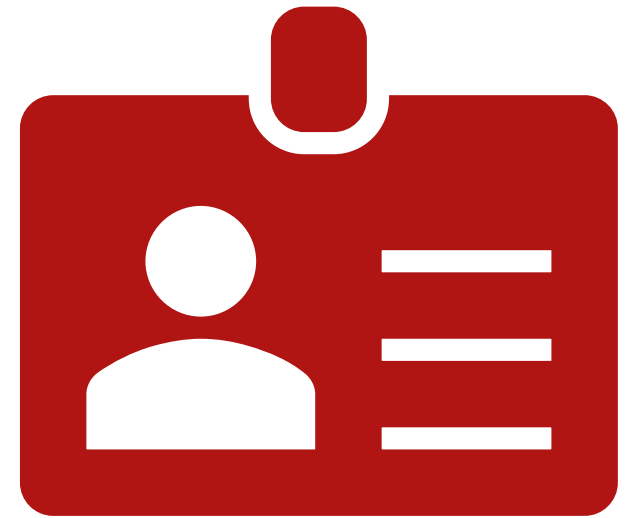
Pharmacist-in-Charge: Notifications to the Board; Responsibilities BPC 4113

- ▶ (a) Every pharmacy shall designate a Pharmacist-in-Charge and, within 30 days thereof, shall notify the board in writing of the identity and license number of that pharmacist and the date they were designated.
- ▶ (b) The proposed Pharmacist-in-Charge shall be subject to approval by the board. The board shall not issue or renew a pharmacy license without identification of an approved Pharmacist-in-Charge for the pharmacy.
- ▶ (c)(1) The Pharmacist-in-Charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.



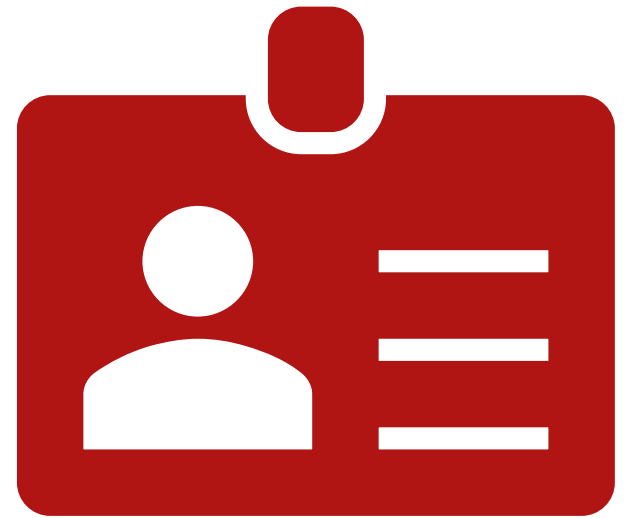
Pharmacist-in-Charge: Notifications to the Board; Responsibilities BPC 4113

- ▶ (e) Every pharmacy shall notify the board in writing, on a form designed by the board, within 30 days of the date when a Pharmacist-in-Charge ceases to act as the Pharmacist-in-Charge, and shall on the same form propose another pharmacist to take over as the Pharmacist-in-Charge. The proposed replacement Pharmacist-in-Charge shall be subject to approval by the board. If disapproved, the pharmacy shall propose another replacement within 15 days of the date of disapproval and shall continue to name proposed replacements until a Pharmacist-in-Charge is approved by the board.



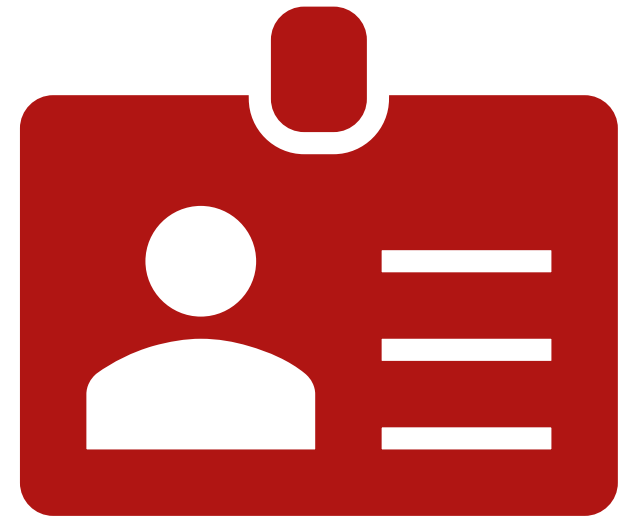
Pharmacist-in-Charge: Notifications to the Board; Responsibilities 4113

- ▶ Generally, if a pharmacy is unable to identify within 30 days a permanent replacement Pharmacist-in-Charge, the pharmacy may instead propose a pharmacist to act as the interim Pharmacist-in-Charge for a period not to exceed 120 days.



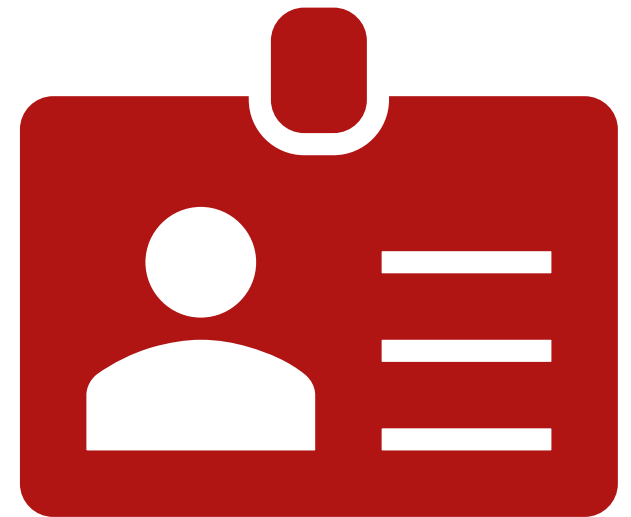
Names of Owners and Pharmacist-in-Charge: CCR 1709

- ▶ Each pharmacy shall, in its initial application and on the annual renewal form, report the name of the Pharmacist-in-Charge, the names of all owners and the names of the corporate officers (if a corporation). Any changes in the Pharmacist-in-Charge, or the owners, or corporate officers shall be reported to the Board within 30 days of the change.



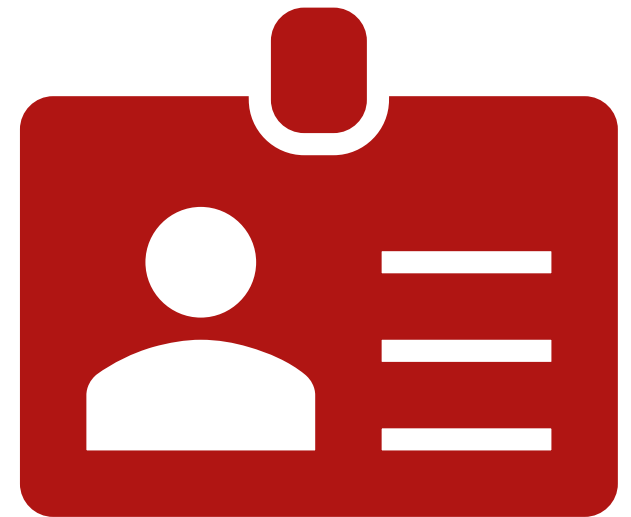
Designation of Pharmacist-in-Charge: CCR 1709.1

- ▶ The Pharmacist-in-Charge of a pharmacy shall be employed at that location and shall have responsibility for the daily operation of the pharmacy.
- ▶ The pharmacy owner shall vest the Pharmacist-in-Charge with adequate authority to assure compliance with the laws governing the operation of a pharmacy.
- ▶ No pharmacist shall be the Pharmacist-in-Charge of more than two pharmacies. If a pharmacist serves as Pharmacist-in-Charge at two pharmacies, those pharmacies shall not be separated by a driving distance of more than 50 miles.



Designation of Pharmacist-in-Charge: CCR 1709.1

- ▶ No pharmacist shall be the Pharmacist-in-Charge of a pharmacy while concurrently serving as the designated representative-in-charge for a wholesaler or a veterinary food-animal drug retailer.
- ▶ Temporary Pharmacist-in-Charge: a pharmacy can assign a temporary PIC for a period not to exceed 120 days while efforts are made to designate a permanent PIC.





MARCH 2022

THE SCRIPT

BE AWARE & TAKE CARE: Talk to your pharmacist!

Contents

- New pharmacy laws take effect in 2022.....1
- President's message.....2
- Staffing, consultation are key to a successful COVID-19 vaccination program.....5
- New vendor chosen for collecting CURES data7
- Alert regarding COVID-19 vaccine mix-ups related to age rules8
- New e-prescribing law took effect January 1, 2022 10
- Board issues compounding policy statement 11
- Mitigation strategies for preventing pharmacy drug diversion..... 12
- Licensee apologizes for neglecting PIC duties..... 13
- Resources for pharmacy inspections 15
- Board seeks input from pharmacy technicians..... 15
- Board welcomes 2 public members 16
- Board creates ad hoc panels to study medication errors and workforce issues, standard of care..... 16
- Registry helps patients find licensees offering health services 17
- Board salutes 40-year pharmacists..... 17
- Disciplinary terms and case summaries 18
- Calendar of 2022 Board, committee meetings 38

New year brings changes for pharmacy laws in 2022



Gov. Gavin Newsom has signed a variety of bills adding or amending laws that govern the practice of pharmacy in California. Unless specified otherwise, the new laws took effect January 1, 2022.

Many of the key provisions are summarized below. Click on the bill number to read the full text for a more complete understanding of each new law.

AB 107 Licensure: Veterans and Military Spouses (Salas, Chapter 693, Statutes of 2021)

This law requires the Board to issue temporary licenses to practice within 30 days of receiving fingerprint background checks. In addition, the law requires pharmacist applicants to take and pass the CPJE before the temporary license is issued. This law becomes effective July 1, 2023. In the meantime, the Board will develop regulations to implement the law, possibly including requirements related to

See **New laws**, Page 3

PIC apologizes for dereliction of duties

Under California law, the pharmacist-in-charge (PIC) is responsible for a pharmacy's compliance with state and federal laws applicable to a pharmacy. (Business and Professions Code (BPC) sections 4036.5 & 4113(c); Title 16, California Code of Regulations (CCR), section 1709.1(a)). The scope of a PIC's potential responsibility can be broad. For example, the Board of Pharmacy has designated the [Sternberg decision](#) as a precedential decision, and in that case the PIC was disciplined for a pharmacy's violation of BPC section 4081 resulting from a pharmacy technician's theft of controlled substances without the pharmacist having actual knowledge of or authorizing the violations. Finally, the pharmacy owner must give the PIC adequate authority to assure compliance with the laws governing the operation of a pharmacy. (CCR section 1709.1(b)).

From some disciplinary cases, it appears some PICs are unaware of their role and responsibilities for a pharmacy's compliance with state and federal laws and the potential impact to their pharmacist license. To further the Board and the staff's goal to educate licensees, under the terms and conditions of probation in some disciplinary cases licensees may be required to submit to the Board a letter of apology regarding the incident that gave rise to disciplinary action. The letter is intended to educate and prepare other Board licensees, including those who have taken on the role of pharmacist-in-charge or other managerial positions at a pharmacy.

This article contains excerpts from a recent apology letter received by the Board. The letter was submitted by a pharmacist who served as a pharmacist-in-charge at a closed-door pharmacy. (The excerpts are printed verbatim in italics below.) The complaint included multiple causes for discipline against the pharmacy license, a sterile compounding license, three pharmacists' licenses and the license of one pharmacy technician.

The PIC has substantial responsibilities under California law to ensure a pharmacy's compliance with state and federal laws that help ensure drugs dispensed by the pharmacy are safe for California consumers.

I still vividly remember I was offered a pharmacist-in-charge role by [a chain] pharmacy right after graduating from pharmacy school. The [] district manager painted a rosy future: a higher hourly wage with a managerial title, and likelihood to climb higher and faster in the corporate hierarchy. It is not a secret that many pharmacists in charge are new graduates because more seasoned and experienced pharmacists know the responsibility and risk they are taking. According to American Association of College of Pharmacy, nearly 50% of students who were enrolled in a Pharm.D program is age 25 or younger. With

Inventory Reconciliation Report of Controlled Substances: CCR 1715.65

- ▶ (a) Every pharmacy, and every clinic licensed under sections 4180 or 4190 of the Business and Professions Code, shall perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances.
- ▶ (b) The Pharmacist-in-Charge of a pharmacy or consultant pharmacist for a clinic shall review all inventory and inventory reconciliation reports taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the inventory reconciliation reports required by this section.

Inventory Reconciliation Report of Controlled Substances: CCR 1715.65

- ▶ (e) The inventory reconciliation report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the Pharmacist-in-Charge or professional director (if a clinic) and be readily retrievable in the pharmacy or clinic for three years. A countersignature is not required if the Pharmacist-in-Charge or professional director personally completed the inventory reconciliation report.
- ▶ (f) A new Pharmacist-in-Charge of a pharmacy shall complete an inventory reconciliation report as identified in subdivision (c) within 30 days of becoming Pharmacist-in-Charge. Whenever possible an outgoing Pharmacist-in-Charge should also complete an inventory reconciliation report as required in subdivision (c).

Inventory Reconciliation Report of Controlled Substances: CCR 1715.65

- ▶ (h) The Pharmacist-in-Charge of an inpatient hospital pharmacy or of a pharmacy servicing onsite or offsite automated drug delivery systems shall ensure that:
 - ▶ (1) All controlled substances added to an automated drug delivery system are accounted for;
 - ▶ (2) Access to automated drug delivery systems is limited to authorized facility personnel;
 - ▶ (3) An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed; and
 - ▶ (4) Confirmed losses of controlled substances are reported to the board.

Assembly Bill 1286: Patient Safety Measure

17



This bill was sponsored by the Board



Established some first in the nation requirements aimed directly at reduction of medication errors



Stemmed from an evaluation of medication errors, working conditions and the intersection of the two

Assembly Bill 1286: Patient Safety Measure

18

- ▶ This bill authorized a Pharmacist-in-Charge to make staffing decisions to ensure sufficient personnel are present in the pharmacy to prevent fatigue, distraction, or other conditions that may interfere with a pharmacist's ability to practice competently and safely
- ▶ The bill authorized a pharmacist on duty, if the Pharmacist-in-Charge is not available, to adjust staffing according to workload if needed
- ▶ The bill would require the executive officer [of the Board], upon a reasonable belief that conditions within a pharmacy exist that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff, to issue a cease and desist order, as specified

Assembly Bill 1286: Patient Safety Measure

- ▶ CA BPC 4113(d)(1) - The Pharmacist-in-Charge or pharmacist on duty shall immediately notify store management of any conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff. Store management shall 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. If the conditions are not resolved within 24 hours, the Pharmacist-in-Charge or pharmacist on duty shall ensure the board is timely notified.

Assembly Bill 1286: Patient Safety Measure

20

- ▶ CA BPC 4113(d)(3) The conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff may include, but are not limited to, any of the following:
 - ▶ (A) Workplace safety and health hazards that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff.
 - ▶ (B) Sustained temperatures that could impact ambient temperature drug stability according to manufacturer data on acceptable drug storage conditions.
 - ▶ (C) Vermin infestation that poses a risk to the safety or efficacy of medicine.

Assembly Bill 1286: Patient Safety Measure

- ▶ Notifications to the Board if conditions are not resolved within 24 hours can be sent via email to:

PharmacyAlert@dca.ca.gov

Assembly Bill 1286: Patient Safety Measure

- ▶ CA BPC 4113.6 (a) - A chain community pharmacy subject to Section 4113.5 shall be staffed at all times with at least one clerk or pharmacy technician fully dedicated to performing pharmacy-related services. The board shall not take action against a pharmacy for a violation of this subdivision if any of the following conditions apply:
 - ▶ (1) The pharmacist on duty waives the requirement in writing during specified hours based on workload need.
 - ▶ (2) The pharmacy is open beyond normal business hours, which is before 8:00 am and after 7:00 pm. During the hours before 8:00 am and after 7:00 pm, the requirement shall not apply.
 - ▶ (3) The pharmacy's prescription volume per day on average is less than 75 prescriptions per day based on the average daily prescription volume for the past calendar year. However, if the pharmacist is also expected to provide additional pharmacy services such as immunizations, tests classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a), or any other ancillary services provided by law, this paragraph does not apply.
- ▶ (b) Where staffing of pharmacist hours within a chain community pharmacy does not overlap sufficiently, scheduled closures for lunch time for all pharmacy staff shall be established and publicly posted and included on the outgoing telephone message.

Assembly Bill 1286: Patient Safety Measure

23

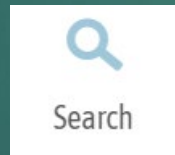
▶ CA BPC 4301- Unprofessional Conduct

(w) Actions or conduct that would subvert the efforts of a Pharmacist-in-Charge to comply with laws and regulations, exercise professional judgment, or make determinations about adequate staffing levels to safely fill prescriptions of the pharmacy or provide other patient care services in a safe and competent manner. This subdivision does not apply to facilities of the Department of Corrections and Rehabilitation.

(y) Establishing policies and procedures related to time guarantees to fill prescriptions within a specified time unless those guarantees are required by law or to meet contractual requirements. This subdivision does not apply to facilities of the Department of Corrections and Rehabilitation.

The Board published a special edition Script Newsletter for AB 1286 (March 2024)

- ▶ Home page > Licensees > Important Information for Licensees > Publications > The Script Newsletter
- ▶ Search for “The Script Newsletter”
- ▶ <https://www.pharmacy.ca.gov/publications/script.shtml>



March 2024

THE SCRIPT

24

BE AWARE & TAKE CARE: Talk to your pharmacist!

SPECIAL EDITION!

AB 1286 Patient Safety Measure

California Becomes National Leader in Pharmacy Safety



[Assembly Bill 1286](#) is a first in the nation patient safety measure that among its requirements includes mandatory reporting of outpatient medication errors. This patient safety measure went into effect January 1, 2024, and it's designed to provide pharmacists and other pharmacy personnel with additional support in their working environment to decrease medication errors. AB 1286 allows the Board of Pharmacy (BOP) access to reports of medication errors, which allows the Board to understand and evaluate where and why medication errors are happening.

Contents

President's Message.....	2
Summary of Changes.....	3
Implementation Statement.....	6
Collecting and Reporting Medication Errors	7
AB 1286 FAQs.....	8

The California State Board of Pharmacy is engaging in the state contracting process to approve a third party vendor for purposes of medication error reporting. Medication error reporting will not begin until the Board approves such an

See **AB 1286 Patient Safety**, Page 3

Pharmacist-in-Charge Responsibilities in Compounding

25



CCR 1735 and
CCR 1751



Identifying drugs,
compounds or
materials as
hazardous
(1735.1 (r))



Completing the
Compounding
Self-Assessment
(1735.2(k))



Reviewing
compounding
policy and
procedures
(1735.5)



Training of
pharmacy
personnel engaged
in compounding
sterile drug
preparations and
continued
competence
(1751.6)



Maintaining quality
assurance plans
where sterile
compounded end
products are
periodically
sampled (1751.7)

Strict Liability

- ▶ The California State Board of Pharmacy prevailed in a state court of appeal case against a pharmacist who appealed the board's disciplinary decision affecting his license in *Sternberg v. California State Board of Pharmacy* (239 Cal. App. 4th 1159 (2015)).
- ▶ The case involved substantial controlled substance losses over a substantial period of time under the pharmacist's supervision. Most significantly, the court held that a Pharmacist-in-Charge could be held "strictly liable" for violations of Pharmacy Law by a subordinate even without actual knowledge of the wrongdoing.

Strict Liability

- ▶ The outcome of this case was designated as a precedential decision effective 12/11/2019.
- ▶ A precedential decision is a decision that contains a significant legal or policy determination of general application that is likely to recur (see Government Code section 11425.60). Once a decision is designated as precedential, the Board may rely on it, and parties may cite to such decision in their argument to the Board and courts.



OCTOBER 2017

THE SCRIPT

BE AWARE & TAKE CARE: Talk to your pharmacist!

Contents

- New Drug Take-Back Regs.....1
- Board Adopts Travel Meds Rule1
- President's Message2
- PHY v. Outsourcing Licenses3
- FDA Offers Free CE Online.....4
- Upcoming Meetings5
- Pharmacist Held "Strictly Liable" ...7
- New Reg Delegates Authority8
- Samples of Changes to Rx Labels.8
- AB 602 Targets Diabetes Devices..9
- Self-Assessment Forms Required. 9
- Did You Know?9
- Drug Supply Chain Security Act..10
- Unfilled Electronic CS Scripts.....12
- Board, DEA Co-Sponsor CE12
- Questions? Ask an Inspector!.....13
- Butler, Veale Reappointed13
- Handling Chemotherapy Drugs .14
- Fifty-Year Pharmacists Honored..16
- Disciplinary Terms17
- Disciplinary Actions.....17

New Regulation Sets Standards for Furnishing Travel Medications

The [California State Board of Pharmacy](#) announces the formal adoption of a [new regulation](#) setting out standards for pharmacists to follow in order to furnish travel medications without a doctor's prescription. The regulation took effect June 8, 2017.

The regulation will make it easier for people traveling to destinations outside the United States to obtain prescription medications for conditions that are recognized as both self-

See [Travel Medications](#), Page 5

New Drug Take-Back Rules Include Key Requirements

[New regulations](#) adopted by the Board of Pharmacy create a comprehensive framework for pharmacies that choose to provide drug take-back services for the public to safely dispose of unwanted, unused or outdated prescription medications, including controlled substances.

The board added Article 9.1, Prescription Drug Take-Back Services, to Division 17 of Title 16 of the California Code of Regulations (CCR). The new regulations, which took effect June 6, 2017, authorize pharmacies to provide take-back services in the form of on-site collection receptacles and/or mail-back envelopes or packages. Pharmacies that choose to provide collection receptacles must be registered as collectors with the U.S. Drug Enforcement Administration (DEA) and be licensed in good standing with the Board of Pharmacy.

Natomas Pharmacy in Sacramento has established a collection receptacle registered with the DEA for more than a year. The locked bin includes posted information about what items may and may not be placed in the collection receptacle.

"It fills up pretty quickly," pharmacist Parmjit Bains said. "We try to talk to people and go through their items and



guide them before they put them in. It's an opportunity for us to present ourselves and our business."

Regulations for take-back services are established in CCR sections 1776 through 1776.6. CCR section 1776.1(i) requires pharmacies to notify the board in writing within 30 days of establishing a collection receptacle or ceasing to maintain a receptacle. Pharmacies also must notify the board of collection

See [Drug Take-Back](#), Page 4

State Court Holds Pharmacist "Strictly Liable"

Board Wins Key Ruling in Disciplinary Case

The California State Board of Pharmacy prevailed in a state court of appeal case against a pharmacist who appealed the board's disciplinary decision affecting his license in *Sternberg v. California State Board of Pharmacy* (239 Cal. App. 4th 1159 (2015)). The case involved substantial controlled substance losses over a substantial period of time under the pharmacist's supervision. Most significantly, the court held that a pharmacist-in-charge could be held "strictly liable" for violations of Pharmacy Law by a subordinate even without actual knowledge of the wrongdoing.

Summary of Case

The case involved a pharmacist-in-charge (PIC) of a West Hills, California, community pharmacy of a chain store. An employee of the pharmacy, a pharmacy technician, ordered and then stole, over 216,000 Norco tablets with an estimated retail value of \$325,000 and a street value of nearly \$1.1 million. The theft took place over a two-year period, from Sept. 1, 2006, through Aug. 31, 2008. The pharmacy's ordering system allowed anyone with an access code to order from anywhere. The technician was authorized to place orders with the manufacturer and even did so from her home. She had a pattern of ordering six bottles of 500 tablets of Norco at a time; she did this about 85 times over approximately two years.

Although in most cases a pharmacist signed for the delivery, the technician signed for three deliveries herself. Even when the PIC did sign for the delivery, he acknowledged he did not review the contents, counting only the number of bottles received and matching that to the delivery log that was provided, which did not contain the names of the drugs. The PIC's practice was to then hand the delivery to a technician for further handling. In this case, one particular technician would collect the delivery, go to a far corner of the pharmacy, hide the bottles in the store room, and destroy the invoices. When no pharmacist was on duty (for the pharmacist's lunch or break), the technician would then take three bottles at a time, place them in her purse and take them out to her car.

The PIC acknowledged that he "never" looked at the invoices as they arrived and did not check them against the drugs received. Invoices were not reviewed regularly by a pharmacist, nor were they audited. Only "occasionally" were the invoices reviewed, typically to look for a specific drug to see if it came in for a particular patient. Review or audit information would have been particularly insightful because the pharmacy did not usually dispense Norco. The pharmacy's corporate office also failed to notice that it was paying for drugs for which it did not have related sales or income. Eventually, the PIC found a bottle of Norco while looking through the store room, became suspicious and alerted corporate management. The corporate office initiated a loss prevention investigation. The employee was eventually caught on surveillance and arrested with 3,000 stolen Norco tablets.

Disciplinary Action by the Board

Based on these incidents, the board filed an accusation against both the pharmacy and PIC. After considering the record of the case, the board described the scope of the theft as "staggering." The board found violations of law and cause to discipline the pharmacist on several grounds. Specifically, the board found:

1. The pharmacist violated the law in that, as PIC, his failure to adequately supervise the technician contributed to the pharmacy's resulting failure to maintain accurate records, even if the drugs were stolen out of his presence and without his knowledge or approval (Bus. & Prof. Code §§ 4300, 4301, subds. (j) and (o), in conjunction with §§ 4005, 4081, & 4105 and Cal. Code Regs., tit. 16, § 1718).
2. The pharmacist violated the law in that, as PIC, he failed to maintain the records described above or a current inventory for three years, even if the drugs were stolen out of his presence and without his knowledge or approval (Bus. & Prof. Code § 4081(a)).
3. The pharmacist violated the law in that, as PIC, he allowed, through the absence of effective supervision, the technician to sign for and accept delivery of dangerous drugs, even if he was not on duty when the technician did so (Bus. & Prof. Code § 4095.5(a)).
4. The pharmacist violated the law in that, because he was directly responsible for the acts of the technician, and when she violated the law, so did he (Bus. & Prof. Code § 4115(h)).
5. The pharmacist violated the law in that, as PIC, he failed to maintain the pharmacy facility, space, fixtures and equipment so that drugs were "safely and properly prepared maintained and secured," in this case from diversion or theft (Cal. Code Regs., tit. 16, § 1714(b)).
6. The pharmacist violated the law in that he failed to secure the prescription department and provide effective controls to prevent the technician's theft, because he failed to provide easily available and effective controls to prevent the theft, such as: a) limiting an employee's access to the pharmacy's account code numbers and the location from which orders could be placed, and auditing the orders by checking the invoices against the orders that were placed; b) looking at the invoices being taken out of the delivery container or checking the invoices against the drugs received; c) closing the pharmacy when no pharmacist was present or instituting security measures to ensure adequate supervision;

See [Strict Liability](#), Page 11



sternberg case summary



About 45 results (0.21 seconds)

[California State Board of Pharmacy - Sternberg Case ... - CA.gov](#)[www.pharmacy.ca.gov](#) > [enforcement](#) > [sternberg_lexis](#)

File Format: PDF/Adobe Acrobat

Aug 6, 2015 ... **STERNBERG CASE SUMMARY**. Sternberg v. California State Board of Pharmacy (2015) 239 Cal.App.4th 1159. California Court of Appeal, Second ...

Precedential Decisions

Under the Administrative Procedure Act (APA) a decision that contains a significant legal or policy determination of general application that is likely to recur may be designated as precedential (see Government Code section 11425.60). Once a decision is designated as precedential, the California State Board of Pharmacy (hereinafter "Board") may rely on it, and parties may cite to such decision in their argument to the Board and courts.

Index By Precedential Decision Number

Precedential Decision Number	Respondent	Case Numbers
No. 2013-01	Pacifica Pharmacy Corp.; Thang Tran	Case No. 3802 OAH No. 2011010644
No. 2019-01	ESI Mail Pharmacy Inc., dba Express Scripts	Case No. CI 2009 44657 OAH No. 2011060384
No. 2019-02	Andrew Mark Sternberg	Case No. AC 2008 3377 OAH No. 2010080067
No. 2020-01	IV Solutions, Inc.; Alireza Varatehpour, President; Renee Sadow, PIC	Case No. 3606 OAH No. 2011050988

Self-Assessment of a Pharmacy: CCR 1715

30

- ▶ (a) The Pharmacist-in-Charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
- ▶ (b) In addition to the self-assessment required in subdivision (a) of this section, the Pharmacist-in-Charge shall complete a self-assessment within 30 days whenever:
 - ▶ (1) A new pharmacy permit has been issued, or
 - ▶ (2) There is a change in the Pharmacist-in-Charge, and he or she becomes the new Pharmacist-in-Charge of a pharmacy.

Self-Assessment of a Pharmacy: CCR 1715

- ▶ (3) There is a change in the licensed location of a pharmacy to a new address.
- ▶ (c) A pharmacist-in-charge of a community pharmacy shall assess the pharmacy's compliance with current laws and regulations by using the components of Form 17M-13 (Rev. 1/22) entitled "Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment." As used in this section, a community pharmacy means a pharmacy serving retail or outpatient consumers. A pharmacist-in-charge of a hospital pharmacy serving inpatient consumers shall assess compliance with current laws and regulations using the components of Form 17M-14 (Rev. 01/22) entitled "Hospital Pharmacy Self-Assessment."
- ▶ (d) Each self-assessment shall be completed in its entirety and kept on file in the pharmacy for three years after it is performed. The completed, initialed, and signed original must be readily available for review during any inspection by the board



Facility License Information/Renewal

Please review the [Fee Schedule](#) to ensure you submit the correct renewal fee to renew the facility license. Incorrect fees may impact the renewal of the license.

Pursuant to Business and Professions Code (B&P) section 4013, California law requires any facility licensed by the board to join the board's e-mail notification list within 60 days of obtaining a license or at the time of license renewal.

An owner/company may use the [E-Mail Notification from Centralized Owner/Company form](#) to comply with this law by subscribing a single e-mail address to the board's e-mail notification list, where the owner/company receives an electronic notification from the board, then immediately transmits electronic notice of the same notification to all of its licensed facilities (this is also authorized by B&P section 4013).

Renewal/License Applications

- ▶ [Renewal of License](#)
- ▶ [Self-Assessment Forms](#)
- ▶ [Duplicate/Replacement License](#)
- ▶ [Offsite Storage Waiver \(PDF\)](#)

How to Prepare for a Board Inspection

AS THE PHARMACIST-IN-CHARGE

What Prompts a Board Inspection?

34

- ▶ Complaint Investigations (external and internal)
- ▶ Routine Inspections
- ▶ New Sterile Compounding License
- ▶ Annual Sterile Compounding License Renewal
- ▶ Change of Location
- ▶ Probation Inspection
- ▶ Assisting other law enforcement agency
- ▶ By request

The Inspector Arrives

35

- ▶ Check for State issued identification
- ▶ Allow entry (BPC 4008)



What the Inspector Has Already Observed

- ▶ Notice to Consumer Poster
- ▶ Point to Your Language Sign
- ▶ Pharmacy permit
- ▶ Security Features
- ▶ Name Tags
- ▶ Staffing Ratio and duties being performed
- ▶ Privacy (audio and visual)
- ▶ And more

AFTER THE INSPECTION

If the inspector orders a correction, you will be instructed how to submit a plan or proof of correction to the board within a specified period. Keep all documentation related to completing the correction order with the inspection report.

If the inspector suspects a violation of pharmacy law has occurred, you may receive a written notice. Depending on the type of violation, the board may:

- Issue a letter of admonishment.
- Issue a citation (with or without a fine).
- Refer the case for disciplinary action against the pharmacy and/or individual licensee(s).

Letters of admonishment and citations are not considered to be discipline or disciplinary actions. You may contest a letter of admonishment or citation by requesting an informal office conference. In the case of a citation, you also may request a formal hearing before an administrative law judge. You will receive a letter from the board about the administrative action process, and you must reply by the specified due date.

LET US KNOW HOW WE PERFORMED

The board welcomes your feedback about the inspection experience. Contact any executive staff member listed on the back of this brochure with questions, comments or complaints.

You also may file an anonymous comment or complaint with the board's parent agency, the Department of Consumer Affairs (DCA). Visit the DCA website at www.dca.ca.gov, go to the Consumer tab, and click on "File a Complaint."

BOARD OF PHARMACY EXECUTIVE STAFF

Anne Sodergren, Executive Officer
(916) 518-3110
Anne.Sodergren@dca.ca.gov

Julia Ansel, Chief of Enforcement
(916) 518-3108
Julia.Ansel@dca.ca.gov

Lyle Matthews, Assistant Executive Officer
(916) 518-3111
Lyle.Matthews@dca.ca.gov



BE AWARE AND TAKE CARE:
Talk to your pharmacist!
CALIFORNIA STATE BOARD OF PHARMACY

P: (916) 518-3100
F: (916) 574-8618
A: 2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

www.pharmacy.ca.gov



PHARMACY INSPECTIONS

BY THE CALIFORNIA STATE BOARD OF PHARMACY



WHAT YOU CAN EXPECT FROM AN INSPECTION—WHAT THE BOARD EXPECTS FROM YOU

The Board of Pharmacy appreciates your cooperation during this inspection. The goal of an inspection is to safeguard the health and safety of consumers. This is also an important educational opportunity for inspectors to provide guidance and answer your questions about pharmacy laws and regulations. After the inspection is complete, we welcome feedback about your experience and any comments about the inspector and the inspection process.

Pharmacy Inspections Brochure

Pharmacy Inspection Brochure



DOCUMENTS FOR INSPECTION

Pharmacies are required to have certain documents readily available for inspectors to review. Hard and electronic copies of records must be available during business hours.

DOCUMENTS TO HAVE AVAILABLE INCLUDE:

- Past inspection reports.
- Pharmacy self-assessments.
- Copies of staff licenses.
- Master list of pharmacist and technician initials.
- DEA 222 forms.
- Power of attorney to execute DEA 222 forms.
- DEA biennial inventory.
- Drug take-back records.
- Wholesaler invoices.
- Records of drug returns.
- Records of destruction.
- Off-site records waiver.
- Pedigrees for drugs purchased.
- Inventory reconciliation reports.
- Controlled substances refill reports.
- Policies:
 - Quality assurance reports.
 - QA for medication errors.
 - Theft and impaired licensees.
 - Pharmacy technician job description.
 - Pharmacist absence for meals.
 - After hours deliveries.
 - Interpretive services.
 - Repackaging previously dispensed drugs.
 - Automated Drug Delivery Systems.
 - Common electronic files to prevent unauthorized release of patient information.
- Protocols:
 - Refusing to dispense on ethical, moral, religious grounds.
 - Immunizations.
 - Emergency contraception.
 - Nicotine replacement.
 - Advanced practice pharmacist.
 - Procedures performed pursuant to BPC section 4052.2.

ADDITIONAL ITEMS

THE INSPECTOR ALSO WILL CHECK:

- DEA registration.
- Drug expiration dates.
- Drug take-back receptacles.
- Hot/cold running water (separate from restroom).
- Confidential waste disposal.
- Interpretive services poster.
- Notice to consumers poster.
- Restroom location.
- Patient consultation.
- Posted pharmacy license and renewal.
- Out-of-state licenses.
- Prescription labeling.
- Prescription records.
- Quarantine area for expired and recalled drugs.
- Refrigerator/freezer temperature.
- Security features.
- Staffing ratio.
- Transmission of CURES data.
- Wearing identification or name tag printed in at least 18-point type.
- Possession of keys to the pharmacy.

AN INSPECTOR WILL:

- Identify himself/herself with a board-issued badge and provide a business card.
- Be professional and courteous.
- Provide a receipt for any records taken into possession.
- Review and leave a copy of the inspection report with the pharmacist on duty and/or pharmacist-in-charge.
- Provide information and answer questions about pharmacy laws and regulations.

WHAT YOU CAN EXPECT

PHARMACY STAFF WILL:

- Provide access to the inspector during regular business hours.
- Provide access to review all stocks of dangerous drugs and devices.
- Provide access to review all records of manufacture, sale, acquisition, receipt, shipment and disposition.
- Allow the inspector to secure samples or specimens.

WHAT IS EXPECTED OF YOU



AFTER THE INSPECTION

If the inspector orders a correction, you will be instructed how to submit a plan or proof of correction to the board within a specified period. Keep all documentation related to completing the correction order with the inspection report.

If the inspector suspects a violation of pharmacy law has occurred, you may receive a written notice. Depending on the type of violation, the board may:

- Issue a letter of admonishment.
- Issue a citation (with or without a fine).
- Refer the case for disciplinary action against the pharmacy and/or individual licensee(s).

Letters of admonishment and citations are not considered to be discipline or disciplinary actions. You may contest a letter of admonishment or citation by requesting an informal office conference. In the case of a citation, you also may request a formal hearing before an administrative law judge. You will receive a letter from the board about the administrative action process, and you must reply by the specified due date.

LET US KNOW HOW WE PERFORMED

The board welcomes your feedback about the inspection experience. Contact any executive staff member listed on the back of this brochure with questions, comments or complaints.

You also may file an anonymous comment or complaint with the board's parent agency, the Department of Consumer Affairs (DCA). Visit the DCA website at www.dca.ca.gov, go to the Consumer tab, and click on "File a Complaint."

BOARD OF PHARMACY EXECUTIVE STAFF

Anne Sodergren, Executive Officer
(916) 518-3110
Anne.Sodergren@dca.ca.gov

Julia Ansel, Chief of Enforcement
(916) 518-3108
Julia.Ansel@dca.ca.gov

Lyle Matthews, Assistant Executive Officer
(916) 518-3111
Lyle.Matthews@dca.ca.gov



BE AWARE AND TAKE CARE:
Talk to your pharmacist!
CALIFORNIA STATE BOARD OF PHARMACY

P: (916) 518-3100
F: (916) 574-8618
A: 2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

www.pharmacy.ca.gov



PHARMACY INSPECTIONS

BY THE CALIFORNIA STATE
BOARD OF PHARMACY



**WHAT YOU CAN EXPECT
FROM AN INSPECTION—
WHAT THE BOARD
EXPECTS FROM YOU**

The Board of Pharmacy appreciates your cooperation during this inspection. The goal of an inspection is to safeguard the health and safety of consumers. This is also an important educational opportunity for inspectors to provide guidance and answer your questions about pharmacy laws and regulations. After the inspection is complete, we welcome feedback about your experience and any comments about the inspector and the inspection process.

Pharmacy Inspections Brochure

Top Ten Pharmacy (PHY) Violations

40

Violation Code	Description	Number of Violations
BPC 4113	Notify Board Regarding PIC	116
CCR 1716	Medication Error	101
CCR 1714	Operational Standards and Security	53
BPC 4301	Unprofessional Conduct	52
BPC 4305	Operate for More than 30 Days without PIC	36
CCR 1764/CCC 56.10	Disclosure of Medical Information	35
CCR 1707.2	Duty to Consult	33
BPC 733	Obstruction/Delay in Therapy	27
BPC 4115	Pharmacy Technician; Tasks, Ratios, Supervision	23
CCR 1715	Self-Assessment by PIC	23

Top Ten Pharmacist (RPH) Violations

41

Violation Code	Description	Number of Violations
CCR 1716	Medication Error	58
BPC 4301	Unprofessional Conduct	76
CCR 1714	Operational Standards and Security	42
BPC 4306.5	Misuse of Education	27
BPC 4081	Record Maintenance and Inventory	20
CCR 1715	PIC Self-Assessment	17
CCR 1711	Quality Assurance; No QA; Not Immediately Retrievable, QA Program Lacking	16
CCR 1761	Erroneous/ Uncertain Prescription	16
CCR 1715.65	Controlled Substance Inventory Reconciliation	16
CCR 1718	Controlled Substance Inventory Accessible for 3 Years	16

Additional Resources to Aid in Compliant Pharmacy Practice



Contact Us

Settings



California State Board of Pharmacy



Consumers



Applicants



Licensees



About Us



Enforcement

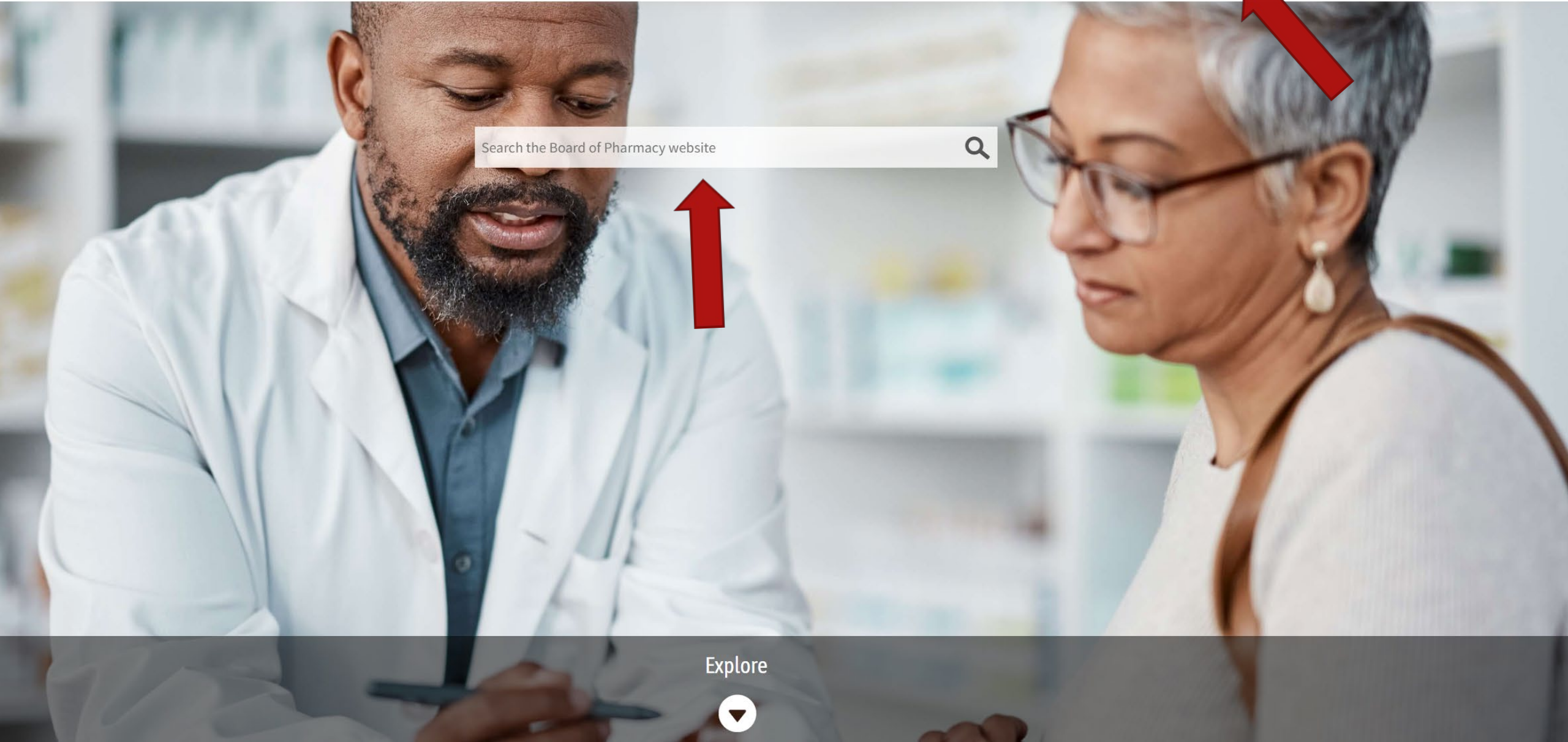


Verify a License



Search

Select Language



Search the Board of Pharmacy website



Explore





Welcome to the California State Board of Pharmacy

The Board of Pharmacy protects and promotes the health and safety of Californians by pursuing the highest quality of pharmacist's care and the appropriate use of pharmaceuticals through education, communication, licensing, legislation, regulation, and enforcement.

[Learn More](#)

Upcoming Meetings

Watch Meetings Live

JUL-AUG	Full Board
31-1	Meeting details/information
SEP	Full Board
12	Meeting details/information
OCT	Enforcement Committee
16	Meeting details/information
OCT	Licensing Committee
17	Meeting details/information

[More Meetings](#)

★ Popular Pages

- ▶ [Verify a License](#)
- ▶ [Licensees](#)
- ▶ [Applicants](#)
- ▶ [Continuing Education Information](#)
- ▶ [Contact Us](#)
- ▶ [Where to Dispose of Unused Medications](#)
- ▶ [40 Year Pharmacists](#)
- ▶ [Change of Address/Email/Name](#)
- ▶ [CPJE Test Dates](#)
- ▶ [Laws and Regulations](#)
- ▶ [Electronic Data Transmission Prescriptions - FAQs](#)
- ▶ [Self-Assessment Forms](#)
- ▶ [Lawbook](#)
- ▶ [Consumers](#)



Contact Us

Settings



California State
Board of Pharmacy

Consumers

Applicants

Licenses

About Us

Enforcement

Verify a License

Search

Select Language

Important Information for Licensees

- ▶ [Advanced Practice Pharmacist](#)
- ▶ [Ask an Inspector](#) ←
- ▶ [Biological Products](#)
- ▶ [Board Inspections](#)
- ▶ [Cannabidiol – Legal Status of Products \(PDF\); Accessible Version \(PDF\) 1/24/19](#)
- ▶ [Collaborative Practice Agreement – Sample](#)
- ▶ [Complaints about Pharmacy Performance Quotas](#)
- ▶ [Compounding](#)
- ▶ [Continuing Education](#)
- ▶ [Contraception](#)
- ▶ [Controlled Substances](#)
- ▶ [Corresponding Responsibility](#)
- ▶ [CURES](#)
- ▶ [Declared States of Emergency](#)
- ▶ [Diabetes Test Devices](#)
- ▶ [Drug Abuse](#)
- ▶ [Drug Loss Reporting](#)
- ▶ [Drug Take-Back](#)
- ▶ [Fee Schedule](#)
- ▶ [Frequently Asked Questions](#) ←
- ▶ [Health Services Registry](#)
- ▶ [HIV PrEP/PEP](#)
- ▶ [Institute for Safe Medication Practices – ISMP](#)
- ▶ [Law and Ethics Webinars](#)
- ▶ [Licensing](#)
- ▶ [Links](#)
- ▶ [Naloxone](#)
- ▶ [Nicotine Replacement Therapy \(NRT\)](#)
- ▶ [Pharmacist Recovery Program](#)
- ▶ [Prescribers with Restricted Authority to Prescribe Controlled Substances](#)
- ▶ [Prescriptions](#)
- ▶ [Security Prescription Forms Reported Stolen or Fraudulent](#)
- ▶ [Publications](#)
- ▶ [Travel Medications](#)
- ▶ [Vaccinations](#)



Contact Us

Settings

California State
Board of Pharmacy

Consumers ▾



Applicants ▾



Licensees ▾



About Us ▾



Enforcement ▾



Verify a License



Search

Select Language ▾

[Home](#) | [Licensees](#) | [Important Information for Licensees](#) | [Got a question? Ask an Inspector](#)

Got a question? Ask an Inspector

Contact a board inspector if you have questions about pharmacy law or regulations. An inspector is available to answer telephone inquiries Monday through Thursday from 9 a.m. to 1 p.m.

- ▶ Phone: (916) 518-3100
- ▶ Fax: (916) 574-8618
- ▶ [Send us a message](#). Please include your name, organization, phone number, and the best time to reach you.

Note: The board's inspectors and staff cannot provide legal advice, but they will assist you by identifying statutory and regulatory sections that pertain to your questions. If you need legal advice, please contact a lawyer.

Frequently Asked Questions

- ▶ [Ask an Inspector FAQs](#)

Resources

- ▶ California State Board of Pharmacy: www.pharmacy.ca.gov
- ▶ California Code of Regulations: <https://oal.ca.gov/>
- ▶ California Business and Professions Code:
<https://leginfo.legislature.ca.gov>
- ▶ California Health and Safety Code:
<https://leginfo.legislature.ca.gov>
- ▶ Code of Federal Regulations, Title 21, Part 1300-1399:
<https://www.deadiversion.usdoj.gov/21cfr/cfr/index.html>
- ▶ United States Code, Title 21, Controlled Substances Act:
<https://www.deadiversion.usdoj.gov/21cfr/21usc/>
- ▶ Drug Enforcement Administration:
<https://www.deadiversion.usdoj.gov/>

Certificate of Completion

- ▶ This concludes the Board's Pharmacist-in-Charge overview and responsibility training. The Board will receive electronic notification that you have completed the training.
- ▶ To obtain a certification of completion, select the "View Certificate" button below. When the certificate appears, save it to your computer to fill out, print and keep for your records.
- ▶ You are required to keep the certificate for at least four years in case you are asked for evidence of completing this training. Do not mail the certificate to the Board of Pharmacy