

California State Board of Pharmacy

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Enforcement and Compounding Committee Report October 16, 2025

Maria Serpa, PharmD, Licensee Member, Chair Renee Barker, PharmD, Licensee Member, Vice Chair Jeff Hughes, Public Member Seung Oh, PharmD, Licensee Member, President Ricardo Sanchez, Public Member Nicole Thibeau, PharmD, Licensee Member

- I. Call to Order, Establishment of Quorum, and General Announcements
- II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

 Note: The Committee may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide whether to place the matter on the agenda of a future meeting. [Government Code sections 11125, 11125.7(a)]
- III. <u>Discussion and Possible Action to Approve Minutes of the June 11, 2025, Enforcement and Compounding Committee Meeting</u>

Attachment 1 includes a copy of the draft minutes.

IV. <u>Presentation by JK Fujimoto, Supervising Inspector and Discussion Related to the</u> Board's Outsourcing Program

Relevant Law

Business and Professions Code (BPC) section 4034 provides the definition of an outsourcing facility. BPC sections 4129.1 and 4129.2 outline requirements governing resident and nonresident outsourcing facilities.

Background

The Drug Quality and Security Act (DQSA) was signed into law in 2013 and added section 503B to the Federal Food, Drug, and Cosmetic Act (FD&C Act). Section 503B created a new regulatory category of compounders called outsourcing facilities. A 503B facility or outsourcer produces sterile drugs in bulk without the need of a patient specific prescription. While an entity must be engaged in the compounding of sterile drugs to qualify as an outsourcing facility, outsourcing facilities are also permitted to compound nonsterile drugs. Because drugs compounded by outsourcing facilities are

not exempt from section 501(a)(2)(B) of the FD&C Act, outsourcing facilities are subject to current good manufacturing practice (cGMP) requirements.

The creation of outsourcers was a direct response to a fungal meningitis outbreak in 2012 linked to contaminated drug products. The DQSA aimed to improve oversight of large scale compounding and enhance drug safety for patients.

Senate Bill 1193 (Hill, Chapter 484, Statutes of 2016) added Article 7.7 (BPC sections 4129 to 4129.9) regarding outsourcing facilities to Chapter 9 of Division 2 of the BPC. Article 7.7 requires an outsourcing facility to be licensed by the Board before doing business in the state of California. It further requires that the Board inspect the outsourcing facility for compliance with all laws and regulations prior to issuance or annual renewal of the license.

For Committee Consideration and Discussion

During the meeting, the Committee will receive a presentation on outsourcing facilities from Supervising Inspector JK Fujimoto.

Attachment 2 includes a copy of the presentation.

V. <u>Presentation by Julie Ansel, Deputy Executive Officer and Discussion Related to Duty to Consult Including Possible Discussion of California Code of Regulations, Title 16, Section 1707.2</u>

Relevant Law:

California Code of Regulations (CCR), title 16, section 1707.2 outlines the Board's requirements governing the duty to consult. This section establishes requirements for a pharmacist to provide consultation to a patient or the patient's agent.

Background

The Board's Strategic Plan 2022-2026 includes strategic goals to guide the work of the Enforcement and Compounding Committee. At the July 2024 Enforcement and Compounding Committee meeting, members recommended adding strategic goal 2.11, "Enhance patient consultation compliance by evaluating barriers to consultation to provide patient education and reduce medication errors." At the November 2024 Board meeting, members approved the addition of strategic objective 2.11.

Provided below is the number of investigations conducted by the Board over the past three fiscal years where violations of the duty to consult (16 CCR 1707.2) were substantiated:

Fiscal Year 2022.23: 43
Fiscal Year 2023.24: 47
Fiscal Year 2024.25: 46

For Committee Consideration and Discussion

During the meeting, the Committee will receive a presentation from Board staff on patient consultation. After the presentation, the Committee will have the opportunity to discuss if the Board's current consultation requirements remain appropriate and to consider if barriers currently exist to pharmacist-provided consultation. As part of its consideration, it may be appropriate for the Committee to evaluate opportunities to improve patient understanding of medications, reduce medication errors and best practices on educating patients on their medications, so they are taken safely and effectively. In seeking to better understand current barriers to consultation, it may be particularly helpful to the Committee to receive feedback from the public and the Board's licensee population.

Attachment 3 includes a copy of the presentation.

VI. <u>Discussion of Hospital Pharmacy and Business and Professions Code Section 4113.1</u> <u>Medication Error Reporting Including Possible Action to Make a Recommendation to the Board Regarding Proposed Amendment to California Code of Regulations, Title 16, Section 1710</u>

Relevant Law:

BPC section 4113.1 establishes requirements for a community pharmacy to report, either directly or through a designated third party, all medication errors to an entity approved by the Board, as specified. Subdivision (c) of section 4113.1 defines "community pharmacy" as follows: "For purposes of this section, 'community pharmacy' includes any pharmacy that dispenses medication to an outpatient, but does not include facilities of the Department of Corrections and Rehabilitation."

California Code of Regulations, title 16, section 1710 establishes the limited conditions under which a hospital pharmacy may furnish drugs to outpatients or employees of the hospital or to walk-in customers.

Background:

The Institute for Safe Medication Practices was approved by the Board as the entity to receive and review medication error reports under BPC section 4113.1. The Board refers to medication error reporting under section 4113.1 as the California Medication Error Reporting (CAMER) program.

The Board has received comments including during previous committee and Board meetings asking for clarity on whether hospital pharmacies are required to register and report to CAMER. Staff believes that it is the policy and intent of the Board that if the hospital pharmacy dispensing volume to outpatients is within the limits set forth in 16 CCR section 1710, the hospital pharmacy is not required to report medication errors through the CAMER program, but seeks clarity from the Committee and the Board.

For Committee Discussion and Consideration:

During the meeting, the Committee will have the opportunity to discuss this issue. Should the Committee agree that clarity is needed, it is recommended that the Committee confirm the Board's policy and, if appropriate, consider a change to the regulatory text of 16 CCR section 1710 to provide further clarity to the Board's regulated public that the term "community pharmacy," as defined in BPC section 4113.1, does not include a hospital pharmacy operating consistent with subdivision (a) of section 1710.

Staff have drafted proposed amendments to section 1710 for the Committee's review and consideration.

Should the Committee believe the draft regulatory language is ready for consideration and approval by the Board, the Committee will refer the draft language to the full Board.

Attachment 4 includes draft amendments to 16 CCR section 1710.

VII. <u>Discussion and Possible Action to Make a Recommendation to the Board Regarding Updates to Frequently Asked Questions (FAQs) Related to Assembly Bill 1286 (Haney, Chapter 470, Statutes of 2023)</u>

Background

Assembly Bill 1286 (Haney, Chapter 470, Statutes of 2023) included several significant patient safety measures. As part of the Committee's prior discussions on implementation of Assembly Bill 1286, staff prepared a list of Frequently Asked Questions (FAQs) to assist stakeholders in gaining an understanding of the bill's requirements. The most recent version of the FAQs was approved by the Board during its June 2025 meeting. More recently, new questions and edits were submitted for inclusion by Board staff.

For Committee Consideration and Discussion

During the meeting, members will have the opportunity to review the edits to the FAQs and provide feedback to staff. The updates to the FAQs pertain to the topics of California Medication Error Reporting (CAMER), Pharmacy Technician Expanded Duties, Unprofessional Conduct, and Surgical Clinic Provisions. Some of the proposed changes are suggested due to changes enacted by the Board's sunset bill, AB 1503 (Berman, 2025). After discussion of the updates, should the Committee believe the FAQs are ready for consideration and approval by the Board, the following motion may be appropriate.

Suggested Motion: Recommend approval of the updated FAQs related to Assembly Bill 1286 [either as presented or consistent with the Committee's discussion].

Attachment 5 includes a copy of the updated FAQs.

VIII. <u>Discussion of Enrolled or Recently Signed Legislation Impacting the Practice of Pharmacy</u>

- a. Assembly Bill 82 (Ward, 2024) Health Care: Legally Protected Health Care Activity Summary: This bill expands the address confidentiality program to a gender-affirming health care provider, employee, or volunteer, as defined, who faces threats of violence or harassment from the public because of their affiliation with a gender-affirming health care services facility. Additionally, this bill prohibits a prescription for or the dispensing of testosterone or mifepristone from being reported to the Department of Justice, CURES, or a contractor, as specified. Implementation: Staff recommend that implementation activities focus on education on the provisions, including highlighting the provisions in the Board's Annual Changes in Pharmacy Law webinar, and information in the upcoming issue of The Script. Additionally, staff recommend collaboration with the Department of Justice regarding CURES reporting and the dissemination of information to licensees.
- b. Assembly Bill 144 (Committee on Budget, Chapter 105, Statutes of 2025) Health Summary: The bill provides authority for pharmacists to independently initiate and administer an immunization that, as of January 1, 2025, had a federal Advisory Committee on Immunization Practices (ACIP) recommendation in effect or is recommended by the California Department of Public Health, Additionally, the bill includes provisions requiring Medi-Cal coverage of vaccines and immunizations in accordance with the recommendations above. Finally, this bill exempts health care practitioners licensed in another state, territory, or country from specific healing arts licensure, certification, or registration requirements, while providing professional services at Olympic and Paralympic activities, as defined, if the Los Angeles Organizing Committee has invited the health care practitioner for the 2028 Olympic and Paralympic Games to provide those services and the committee provides specified information to the Director of Consumer Affairs. **Implementation:** Staff recommend that implementation activities focus on education on the provisions, including highlighting the provisions in the Change in Pharmacy Law webinar, and information in the upcoming issue of The Script. A pharmacy alert was sent to licensees on September 18, 2025.
- c. <u>Assembly Bill 260 (Aguiar-Curry, Chapter 136, Statutes of 2025) Sexual and</u> Reproductive Health Care

<u>Summary:</u> This bill authorizes pharmacists to dispense medication abortion drugs—such as mifepristone—without including the patient's name, the prescriber's name, or the pharmacy's identifying information on the label. Pharmacists must maintain a confidential log of these transactions, which is shielded from law enforcement access unless a subpoena is issued, and cannot be disclosed to out-of-state entities. The bill also provides legal protections for pharmacists, protecting them

from criminal or civil liability and professional discipline when dispensing these medications in compliance with California law. Additionally, the California Department of Public Health is granted the authority to regulate the inclusion or exclusion of these drugs from specific labeling laws, particularly in the event of changes in federal approval.

<u>Implementation:</u> Staff recommend that implementation activities focus on education on the provisions, including highlighting the provisions in the Change in Pharmacy Law webinar, and information in the upcoming issue of *The Script*.

d. Assembly Bill 309 (Zbur, 2025) Hypodermic Needles and Syringes

Summary: This bill makes permanent the requirement for pharmacies that furnish nonprescription syringes to provide written information or verbal counseling to consumers, as specified, at the time of furnishing or selling nonprescription hypodermic needles or syringes.

<u>Implementation:</u> Staff recommend that implementation activities focus on education on the provisions, including highlighting the provisions in the Change in Pharmacy Law webinar, and information in the upcoming issue of *The Script*.

e. <u>Assembly Bill 447 (González, 2025) Emergency Room Patient Prescriptions</u>

Summary: The bill allows prescribers to dispense the unused partial of a dispense the u

Summary: The bill allows prescribers to dispense the unused portion of a dangerous drug as defined—excluding controlled substances—that the hospital pharmacy acquired, to emergency room patients upon discharge, provided it is necessary to continue treatment. Such drugs must have been administered from single patient use multidose packaging and can be self-administered by the patient, including, but not limited to, an inhaler, eye drop, ear drop, nose drop or spray, topical product, or liquid product and must have a label on the drug containing all of the information required by BPC section 4076. Additionally, the bill exempts certain automated unit dose systems (AUDS) from licensure requirements when used to dispense drugs to emergency room patients, provided specific conditions are met. **Implementation:** Staff recommend that implementation activities focus on education on the provisions, including updating the ADDS FAQs, highlighting the provisions in the Change in Pharmacy Law webinar, and information in the upcoming issue of *The Script*.

f. <u>Assembly Bill 742 (Elhawary, 2025) Department of Consumer Affairs: Licensing: Applicants Who Are Descendants of Slaves</u>

Summary: This bill requires boards within the Department of Consumer Affairs to expedite applications for applicants who are descendants of American slaves once a process to certify descendants of American slaves is implemented, as specified. The bill repeals these provisions four years from the date on which the certification process is implemented or on January 1, 2032, whichever is earlier. **Implementation:** Staff recommend that implementation activities focus on education on the provisions, including highlighting the provisions in the Change in Pharmacy Law webinar, and information in the upcoming issue of *The Script*. The Board's licensing systems will also require programming changes and application

forms will require updates.

g. Senate Bill 40 (Wiener, 2024) Health Care Coverage: Insulin

Summary: This bill will, effective January 1, 2026, prohibit a health care service plan or health insurer from imposing step therapy as a prerequisite to authorizing coverage of insulin and, generally, prohibits a health care service plan contract or health insurance policy issued, amended, delivered, or renewed on or after January 1, 2026, from imposing a copayment, coinsurance, deductible, or other cost sharing of more than \$35 for a 30-day supply of an insulin prescription drug, except as specified.

<u>Implementation:</u> Staff recommend that implementation activities focus on education on the provisions, including highlighting the provisions in the Change in Pharmacy Law webinar, and information in the upcoming issue of *The Script*. Additionally, staff recommend consumer-facing education activities.

h. Senate Bill 41 (Wiener, 2024) Pharmacy Benefits

<u>Summary:</u> This bill prohibits Pharmacy Benefit Mangers (PBMs) from requiring patients to use only affiliated pharmacies or from discriminating against nonaffiliated pharmacies in dispensing drugs. It mandates that PBMs operate under a passthrough pricing model and limits their income to pharmacy benefit management fees. Beginning January 1, 2027—or once the Department of Managed Health Care establishes a licensure process—PBMs must be licensed and in good standing to contract with health insurers or health care service plans. The bill also empowers the Attorney General to enforce these provisions through civil penalties and equitable relief.

<u>Implementation:</u> Staff recommend that implementation activities focus on education on the provisions, including highlighting the provisions in the Board's Annual Changes in Pharmacy Law webinar, and information in the upcoming issue of *The Script*. Additionally, staff recommend consumer-facing education activities and collaboration with the Department of Managed Health Care regarding complaints and investigations.

i. Senate Bill 306 (Becker, 2025) Health Care Coverage: Prior Authorizations

<u>Summary:</u> This bill requires health plans and insurers to temporarily exempt certain services from prior authorization if 90% or more of requests for those services were approved in the previous calendar year. Starting April 1, 2025, these exemptions will last for one year and must be publicly disclosed by March 15 annually. The bill also directs the Department of Managed Health Care and the California Department of Insurance to evaluate long-term data and, by January 1, 2028, establish a permanent list of services that must be exempt from prior authorization. Certain exceptions remain, such as for high-tier prescription drugs and off-label uses not approved by the FDA. Additionally, health plans may petition to reinstate prior authorization for specific services if there is clear evidence of fraud or misuse. A comprehensive impact report is required within four years to assess the effectiveness of these reforms.

<u>Implementation:</u> Staff recommend that implementation activities focus on education on the provisions, including highlighting the provisions in the Boards Annual Changes in Pharmacy Law webinar, and information in the upcoming issue of *The Script*. Additionally, staff recommend consumer-facing education activities.

j. <u>Senate Bill 418 (Menjivar, 2025) Health Care Coverage: Prescription Hormone Therapy and Nondiscrimination</u>

<u>Summary:</u> This bill requires health care service plans and insurers to cover up to a 12-month supply of FDA-approved prescription hormone therapy and related supplies for self-administration. It also establishes protections against discrimination in health programs that receive federal or state funding, explicitly including safeguards for individuals based on sex characteristics, gender identity, sexual orientation, pregnancy, and other factors.

<u>Implementation:</u> Staff recommend that implementation activities focus on education on the provisions, including highlighting the provisions in the Board's Annual Changes in Pharmacy Law webinar, and information in the upcoming issue of *The Script*. Additionally, staff recommend consumer-facing education activities.

k. <u>Senate Bill 470 (Laird, 2025) Healing Arts: Bagley-Keene Open Meeting Act: Teleconferencing</u>

<u>Summary:</u> This bill authorizes state bodies and advisory boards to conduct public meetings via teleconference through January 1, 2030, under specific conditions, including requiring a majority of members to be physically present at a designated location and ensuring that members appear visibly on camera during publicly accessible portions of the meetings. It also permits remote participation from private locations under certain circumstances, while maintaining transparency and public access by requiring clear notice and opportunities for public comment. <u>Implementation:</u> Staff recommend that implementation activities focus on education on the provisions, including highlighting the provisions in the Board's Annual Changes in Pharmacy Law webinar, and information in the upcoming issue of *The Script*.

I. Senate Bill 497 (Wiener, 2025) Legally Protected Health Care Activity

<u>Summary:</u> This bill prohibits health care providers, insurers, contractors, and employers from disclosing medical information in response to civil or criminal actions—including foreign subpoenas—based on laws from other states that penalize such care. It also bars cooperation with out-of-state or, where permitted, federal law enforcement agencies attempting to identify individuals involved in legally protected health care activities. The bill has an urgency clause and will take effect immediately upon being signed by the governor and chaptered by the Secretary of State.

<u>Implementation:</u> Staff recommend that implementation activities focus on education on the provisions, including highlighting the provisions in the Board's Annual Changes in Pharmacy Law webinar, and information in the upcoming issue of *The Script*.

m. <u>Senate Bill 568 (Niello, 2025) Pupil Health: Epinephrine Delivery Systems: School Sites</u> and Childcare Programs

Summary: This bill expands the authority of pharmacies to provide a broader range of epinephrine delivery devices, including those other than auto-injectors, to local educational agencies—including school districts, county offices of education, and charter schools—under existing safety and training requirements.

<u>Implementation:</u> Staff recommend that implementation activities focus on education on the provisions, including highlighting the provisions in the Change in Pharmacy Law webinar, and information in the upcoming issue of *The Script*.

n. <u>Senate Bill 641 (Ashby, 2025) Department of Consumer Affairs and Department of Real Estate: States of Emergency: Waivers and Exemptions</u>

<u>Summary:</u> This bill authorizes licensing boards under the Department of Consumer Affairs to waive specific statutory requirements for licensees and applicants affected by declared federal, state, or local emergencies. This includes individuals whose homes or businesses are in areas affected by disasters. The bill also requires licensees and applicants to provide email addresses to their licensing agencies for timely communication during emergencies. The bill has an urgency clause and will take effect immediately upon being signed by the governor and chaptered by the Secretary of State.

<u>Implementation:</u> Staff recommend that implementation activities focus on education about the provisions, including highlighting them in the Board's Annual Changes in Pharmacy Law webinar and providing information in the upcoming issue of *The Script*. Additionally, staff note that a regulatory update may be needed related to the requirement to provide email addresses to the Board, which is currently specified in 16 CCR section 1704.

IX. Discussion of Enforcement Statistics

During the first quarter of the new fiscal year, July 1, 2025, through September 30, 2025, the Board initiated 914 complaints and closed 747 investigations. The Board has issued 12 letters of admonishment and 95 citations and referred 75 cases to the Office of the Attorney General. The Board has revoked 19 licenses, accepted the disciplinary surrender of 6 licenses, formally denied 1 application, and imposed other levels of discipline against 19 licensees and/or applicants.

As of September 30, 2025, the Board had 1,736 field investigations pending. Following is a breakdown providing more detail in the various investigation processes:

	Oct. 1, 2024		Jan. 1, 2025		Apr. 1, 2025		Jul. 1, 2025		Oct.	1, 2025
	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days
Awaiting Assignment	63	14	31	10	71	14	107	10	125	7
Cases Under Investigation	908	146	978	141	1,021	143	957	137	987	110
Pending Supervisor Review	147	74	173	62	295	70	322	65	401	76
Pending Second Level Review	229	26	116	64	93	68	161	41	165	50
Awaiting Final Closure	34	14	49	34	29	52	35	42	58	29

Attachment 6 includes the enforcement statistics.

X. <u>Advisement of Future Committee Meeting Dates</u>

- January 7, 2026
- April 16, 2026
- June 10, 2026
- October 8, 2026

XI. Adjournment

Attachment 1



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California State Board of Pharmacy Department of Consumer Affairs DRAFT Enforcement and Compounding Committee Meeting Minutes

Date: June 11, 2025

Location: OBSERVATION AND PUBLIC COMMENT IN PERSON:

California State Board of Pharmacy

2720 Gateway Oaks Drive, First Floor Hearing Room

Sacramento, CA 95833

Board of Pharmacy staff members were present at the observation and public comment location.

PUBLIC PARTICIPATION AND COMMENT FROM

REMOTE LOCATIONS VIA WEBEX

Board Members

Present: Maria Serpa, PharmD, Licensee Member, Chair

Renee Barker, PharmD, Licensee Member, Vice Chair

Seung Oh, PharmD, Licensee Member Nicole Thibeau, PharmD, Licensee Member

Board Members Not

Present: Jeff Hughes, Public Member

Ricardo Sanchez, Public Member

Staff Present: Anne Sodergren, Executive Officer (Webex)

Julie Ansel, Deputy Executive Officer

Lori Martinez, Chief of Legislation, Policy and Public Affairs

Corinne Gartner, DCA Counsel

Jennifer Robbins, DCA Regulations Counsel Debbie Damoth, Senior Administration Manager

I. Call to Order, Establishment of Quorum, and General Announcements

Chairperson Serpa called the meeting to order at approximately 9:08 a.m. Dr. Serpa reminded everyone that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. Department of Consumer Affairs' staff provided instructions for participating in the meeting.

Roll call was taken. The following members were present via Webex: Renee Barker, Licensee Member; Seung Oh, Licensee Member; Nicole Thibeau, Licensee Member; and Maria Serpa, Licensee Member. A quorum was established.

Dr. Serpa reminded Committee members to remain visible with cameras on throughout the open session of the meeting. Dr. Serpa advised if members needed to temporarily turn off their camera due to challenges with internet connectivity, they must announce the reason for their non-appearance when the camera was turned off.

II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

Members of the public in Sacramento were provided the opportunity to comment; however, no comments were made.

Members of the public participating via Webex were provided the opportunity to comment.

A member of the public requested the Board become more transparent regarding how settlements are reached for community pharmacies. DCA Counsel noted the Committee could not discuss open citations.

Members were provided the opportunity to comment; however, no comments were made.

III. Approval of Draft Minutes from the March 27, 2025 Enforcement and Compounding Committee Meeting

The draft minutes of the March 27, 2025 Enforcement and Compounding Committee meeting were presented for review and approval. Members were provided the opportunity to comment; however, no comments were made.

Motion: Approve March 27, 2025 Enforcement and Compounding

Committee meeting minutes as presented.

M/S: Oh/Barker

Members of the public participating in Sacramento and via Webex were provided the opportunity to comment; however, no comments were made.

Support: 4 Oppose: 0 Abstain: 0 Not Present: 2

Board Member	Vote
Barker	Support
Hughes	Not Present
Oh	Support
Sanchez	Not Present
Serpa	Support
Thibeau	Support

IV. Annual Presentation on the Board's Inspection Program

Chairperson Serpa advised strategic objective 2.3 of the Board's strategic plan calls for completion of routine inspections of all licensed pharmacies at least every four years to proactively assess pharmacy operations and educate licensees. Annually, the Committee receives a presentation providing summary information detailing accomplishments towards this objective. Dr. Serpa commended Board staff on their significant efforts to meet the Board's strategic goal.

Dr. Serpa welcomed Deputy Executive Officer Julie Ansel to provide the annual inspection presentation. Ms. Ansel provided an overview of the Board's inspection process including observations, items reviewed, what's inspected, and education of licensees. Ms. Ansel reviewed historical trends of inspections completed, types of inspections, routine inspections including outcomes, top violations, and top corrections.

Dr. Serpa recalled comments from members of the public at previous Board meetings regarding hospital pharmacies' request to provide inspection data divided by pharmacy license type. Dr. Serpa requested next year's inspection data be broken down by license type as it may be more informative to licensees.

Following the presentation, members were provided the opportunity to comment. Members thanked Board staff for their efforts in this accomplishment. Members discussed creating a fact sheet or *Script* article on orders of corrections, notice of violations, and possible outcomes.

Members of the public participating in Sacramento and via Webex were provided the opportunity to comment; however, no comments were made.

V. Annual Presentation on the Board's Citation Program – Anne Sodergren, Executive Officer

Chairperson Serpa advised consistent with strategic objective 2.2, on an annual basis the Committee receives a presentation on the citation and fine program that includes information on common violations. The information shared during the annual presentation generally is also provided in the Board's newsletter, providing education to licensees about the most common violations for which citations are issued.

Dr. Serpa welcomed Executive Officer Anne Sodergren to provide the annual citation program. Ms. Sodergren reminded members and participants depending on the nature and severity of the violations, the Board has various tools to use ranging from education, issuance of a letter of admonishment, or issuance of a citation (with or without a fine). Ms. Sodergren reviewed the complaint and citation process; and relevant law including fine authority. Ms. Sodergren provided an overview of factors considered in assessing administrative fines and reviewed citation statistics. Ms. Sodergren reviewed top violations by license type as well as related to duty to consult. Ms. Sodergren provided an overview of orders of abatement and abatement statistics. Ms. Sodergren highlighted the appeal process and appeal outcomes.

Following the presentation, members were provided the opportunity to comment. A member requested additional information on what qualifies as "unlicensed activity." Ms. Sodergren explained it encompasses a wide range of factors and provided an example. A member requested clarification on the average days to complete a citation. Ms. Sodergren explained the data reflected the entire timelines from the receipt of the complaint and the initiation of the investigation, through the norming and review stages, culminating in the issuance of the citation.

Members of the public participating in Sacramento and via Webex were provided the opportunity to comment; however, no comments were made.

VI. Presentation on Quality Assurance Reports Received Pursuant to California Code of Regulations, Title 16, Section 1711(f) Related to the Use of Automated Drug Delivery Systems

Chairperson Serpa advised that Business and Professions Code (BPC) section 4427.8 required the Board, on or before January 1, 2025, to report to the Legislature on the regulation of automated drug delivery system (ADDS) units as part of the sunset evaluation process. This report was submitted to the Legislature in January of 2025. In addition, Title 16 CCR Section 1711(f) established an ongoing reporting requirement for any quality assurance record related to the use of an ADDS.

Dr. Serpa noted the Committee received presentations related to the findings of the Quality Assurance (QA) reports which revealed what appeared to be a lack of compliance with reporting requirements. Staff continues to educate licensees on the reporting requirements. Dr. Serpa thanked everyone for submitting reports and the staff for performing additional education about the mandatory reporting.

Dr. Serpa welcomed Supervising Inspector Janice Dang, PharmD, to provide the presentation on the data received through these reports. Dr. Dang provided an overview of the ADDS system and provided ADDS licensing statics from July 2024 to April 2025. Dr. Dang provided information about the ADDS medication error reporting requirements and ADDS Quality Assurance reporting requirements.

Dr. Dang provided an overview of the data collected. She reviewed the types of ADDS related medication errors by ADDS location including correctional clinics, skilled nursing facilities, inside a pharmacy, and a few hospitals.

Dr. Serpa noted it appeared there may still be an underreporting of QA records for ADDS and confusion on the reporting requirements. She further noted that over the next year, the Board will continue outreach and education efforts.

Dr. Serpa emphasized that 16 CCR section 1711(d) requires all medication errors discovered are subject to a quality assurance review and for errors related to an ADDS there are two separate reporting requirements. Dr. Serpa reviewed each reporting requirement. Dr. Oh added that for unlicensed

ADDS used in a pharmacy, for purposes of counting and pouring, those medication errors need to be reported at the time of renewal.

Dr. Oh requested inspectors make it priority to remind pharmacies that they must report ADDS medication errors.

Members discussed developing a standardized template for ADDS quality assurance reporting.

Members of the public in Sacramento were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment via Webex. A hospital pharmacy director commented that clarification is needed on what needs to be reported. Dr. Dang reminded members that there are ADDS FAQs on the website to help clarify. A representative from Scripps Health expressed concern that QA reports were peer reviewed and therefore protected. The representative further expressed concern that licensees may refrain from reporting errors due to fear that doing so may lead to disciplinary action.

Dr. Serpa suggested staff review the FAQs to provide more clarity.

The Committee took a break from 10:56 a.m. to 11:15 a.m. Roll call was taken. The following members were present via Webex: Renee Barker, Licensee Member; Seung Oh, Licensee Member; Nicole Thibeau, Licensee Member; and Maria Serpa, Licensee Member.

VII. Discussion and Consideration of Updates to Frequently Asked Questions Related to the Board's Ask An Inspector Program

Dr. Serpa noted the Board provides a service where inspectors and staff respond to verbal and written inquiries from licensees. The Board has compiled a list of FAQs that it has received through this program. Recommended updates to the FAQs were included in the meeting materials. Dr. Serpa provided a summary of the updates.

Members were provided the opportunity to comment. Dr. Thibeau spoke in support of the updates and suggested a disclaimer be added that the Ask An Inspector Program will not result in an investigation or inspection from the

Board. Dr. Oh recommended adding in a response to question 1 to clarify that an electronic signature is acceptable. Dr. Oh further recommended adding additional language to the Health and Safety code with the caveat that pharmacies can dispense the remaining portion of a controlled substance prescription if it's not dispensed originally within 30 days from the written date. Dr. Oh noted that the response to question 17 may change if the Sunset Bill is approved.

Members discussed various viewpoints related to question 18 and deferred further consideration to a future committee meeting.

Motion: Recommend approval of the updated FAQs related to the

Board's Ask An Inspector Program consistent with the

Committee's discussion.

M/S: Thibeau/Oh

Members of the public participating in Sacramento and via Webex were provided the opportunity to comment. A member of the public noted that the nametag requirement was not in the pharmacy law book and felt that question 18 adds confusion as healthcare practitioners seems specific to pharmacists and not clear about technicians.

Support: 4 Oppose: 0 Abstain: 0 Not Present: 2

Board Member	Vote
Barker	Support
Hughes	Not Present
Oh	Support
Sanchez	Not Present
Serpa	Support
Thibeau	Support

VIII. Discussion and Consideration of Updates to Frequently Asked Questions Related to Assembly Bill 1286 (Haney, Chapter 470, Statutes of 2023)

Dr. Serpa advised FAQs were developed due to the comprehensive nature of Assembly Bill 1286. Last year, the Board approved the Institute for Safe Medication Practices (ISMP) as the entity to receive medication error reports from community pharmacies under BPC 4113.1. Board staff updated the FAQs to include this information as well as information about the California Medication Reporting (CAMER). Meeting materials included the updated FAQs.

Members were provided the opportunity to comment; however, no comments were made.

Motion: Approve FAQs as presented

M/S: Oh/Thibeau

Members of the public participating from Sacramento and via Webex were provided the opportunity to comment. A representative of Scripps Health felt it was not clear whether they should be licensing hospital pharmacies and requested clarification. Legal counsel directed members to FAQ number one which defined community pharmacy in the statute.

Members were provided the opportunity to comment. Members discussed criteria for hospital (HSP license type) versus out-patient hospital pharmacies (PHY license type).

Support: 4 Oppose: 0 Abstain: 0 Not Present: 2

Board Member	Vote
Barker	Support
Hughes	Not Present
Oh	Support
Sanchez	Not Present
Serpa	Support
Thibeau	Support

The Committee took a break from 11:50 a.m. to 11:55 a.m. Roll call was taken. The following members were present via Webex: Renee Barker, Licensee Member;

Seung Oh, Licensee Member; Nicole Thibeau, Licensee Member; and Maria Serpa, Licensee Member.

IX. Discussion and Consideration of the Committee's Strategic Objectives

Dr. Serpa provided an overview of the Committee's strategic objectives. Dr. Serpa was proud of the Committee's accomplishments and looked forward to continued efforts.

Dr. Serpa acknowledged the progress staff made in strategic objective in 2.1, noting the Institute for Safe Medication Practices (ISMP) had been approved by the Board as the entity to receive medication error reports from community pharmacies under BPC 4113.1. Medication errors that occur on or after September 1, 2025, must be reported to the California Medication Error Reporting (CAMER).

Dr. Serpa acknowledged the progress staff made in meeting the strategic objective in 2.3, noting additional assigned routine inspections were made to reach the four-year inspection goal.

Dr. Serpa also acknowledged the progress made in meeting strategic objective 2.4. Proposed amendments to BPC sections 4081 and 4105 were included in the Board's sunset measure, AB 1503. In addition, the Board implemented a new digital process to streamline the investigative process and reduce investigation time frames.

Dr. Serpa next highlighted that the Committee had been working on strategic goal 2.5 for several years, and provisions to transition pharmacist practice to a more robust standard of care practice model were included in AB 1503.

Related to strategic objective 2.8, Dr. Serpa noted that the Board implemented a new learning management system for licensees to complete Board-provided continuing education (CE), including the newly required PIC training course. She further noted that strategic objective 2.10, regarding the Board's compounding regulations, resulted in five formal comment periods, a regulatory hearing, and extensive review and discussion over the course of multiple public meetings. The Board approved final regulatory text in March 2025 and thereafter submitted the final rulemaking file to the Office of Administrative Law.

Finally, Dr. Serpa highlighted that the Committee added strategic objective 2.11, regarding evaluating barriers to consultation, in November of 2024. The Committee will continue to discuss this issue at a future meeting. Members were provided the opportunity to comment. Members discussed strategic objective 2.5 in relation to the Committee's completed work, noting that further action remains for the Board. Member Barker expressed gratitude for the work being done in meeting strategic objective 2.6.

Members of the public participating from Sacramento and via Webex were provided the opportunity to comment; however, no comments were made.

X. Discussion, Consideration, and Possible Action on Proposal to Add New Section 1707.51 Related to Accessible Prescription Drug Labels to Article 2 of Division 17 of Title 16 of the California Code of Regulations

Dr. Serpa recalled during the October 2024 meeting the Committee discussed implementation activities for measures signed by the governor, including Assembly Bill 1902, a measure related to prescription drug label accessibility. During the Committee's March 2025 meeting, the Committee agreed that the Board's regulations should focus on ensuring pharmacies developed policies and procedures to define how compliance with the legislation would be achieved. During the April 2025 Board meeting, Board members spoke in support of the recommended approach. Meeting materials included draft regulation text.

Members were provided the opportunity to comment. Dr. Oh spoke in support of the text agreeing clarification was requested on whether a spoken or verbal label would meet the requirements, given that some individuals do not read Braille. Members were referred to (3) which noted pharmacies should describe the process and the inclusion of any deviations from the law. Members further discussed the possibility of adding FAQs in the future.

Motion: Recommend initiation of a rulemaking to add California Code of

Regulations, title 16, section 1707.51 consistent with the Committee's discussion. Authorize the executive officer to further

refine the language consistent with the Committee's discussion and make any nonsubstantive changes prior to presenting the

proposed rulemaking to the Board.

M/S: Oh/Thibeau

Members of the public participating via Webex were provided the opportunity to comment. A member of the public asked the Committee to consider the administrative burden placed on licensees and consider the removal of subsection (b), which says the pharmacy personnel must read and sign a copy and maintain a copy in the pharmacy.

Members were provided the opportunity to comment. Members discussed whether (b) should be removed. No consensus was reached on the removal of (b); therefore, the text will be sent to the Board as written.

Support: 4 Oppose: 0 Abstain: 0 Not Present: 2

Board Member	Vote
Barker	Support
Hughes	Not Present
Oh	Support
Sanchez	Not Present
Serpa	Support
Thibeau	Support

XI. Discussion and Consideration of Enforcement Statistics

Dr. Serpa advised the meeting materials included a summary of the enforcement statistics for the first eight months of fiscal year 2024/25. The Board initiated 2,850 complaints and closed 2,597 investigations. As of May 31, 2025, the Board had 1,582 field investigations pending. The meeting materials provided a breakdown of the average timeframe for the various stages of the field investigation process.

Members were provided the opportunity to comment; however, no comments were made.

Members of the public participating from Sacramento and via Webex were provided the opportunity to comment; however, no comments were made.

XII. Future Committee Meeting Dates

Dr. Serpa advised the next meeting was scheduled for October 16, 2025.

The meeting	adjourned a	t 12:30 p.m		

Attachment 2

What is a 503B Outsourcing Facility?

The Drug Quality and Security Act defines an outsourcing facility as a facility at one geographic location or address that is engaged in the compounding of sterile drugs; has elected to register as an outsourcing facility; and complies with all of the requirements of section 503B.

Drugs compounded by an outsourcing facility can qualify for exemptions from FDA approval requirements and the requirement to label products with adequate directions for use, but not from current good manufacturing practice (CGMP) requirements.

What is a 503B Outsourcing Facility?

Outsourcing facilities:

- must comply with CGMP requirements;
- are inspected by FDA according to a risk-based schedule; and
- must meet certain other conditions, such as reporting adverse events and providing FDA with certain information about the products they compound.

503A Compounding Pharmacy Versus 503B Outsourcing Facility

503A Compounding Pharmacy

- Requires patient specific prescription
 - Batching is less common
- Primarily regulated by State Boards of Pharmacies
- Smaller Scale, batching is uncommon
- Regulation expectations USP <797> and applicable California Code of Regulations

503B Outsourcing Facility

- No prescription required
 - Batching is the norm
- Regulated by the FDA and State Boards of Pharmacies
- Large Scale, batching is the norm
- Regulation expectations Current Good Manufacturing Practices (CGMP) 21 CFR Part 210 and 211.

What do they Compound?

Sterile Preparations

- Vials
- Pre-filled Syringes
- IV Bags
- Ophthalmic Drops
- Implantable Pellets

Non-Sterile Preparations

- Topical Agents Solution / Creams / Gel
- Oral Tablet / Capsule / Lozenge
- Suppository

What does a typical 503B Outsourcing Facility "look" like?

- Not open to the public
- Size 10,000's sq. ft. to greater than 750,000 sq. ft.
 - Can include multiple structures or areas i.e., warehousing, laboratory, distribution.
- Utilities Robust capabilities such as:
 - HVAC with humidification / de-humidification
 - Process gases compressed air, nitrogen, helium, argon.
 - Purified water systems Purified Water, USP and Water for Injection (WFI), USP
- Production Capabilities
 - Manual to fully automated processes
 - Batch sizes ranging from 100's to 100,000's of units. Batch sizes of <250 are atypical
- Distribution
 - All locations currently licensed are multi-state licensed which do business throughout the country
 - While some products are sold in each(es), many are sold in case quantities or even by pallets or truckloads.

Typical Staffing of a 503B Outsourcing Facility

Organizational Chart:

- Quality Assurance and Quality Control Unit Separate and independent
- Production Unit Compounding and operations

Personnel Background and Qualifications:

- Advanced degrees PhD, MS, PharmD, MD
- Specialized skills Microbiology, Chemistry, Engineering
- Robust backgrounds Pharmaceutical research and development, manufacturing

Role of a Pharmacist

Pharmacist Requirements to qualify for 503B exemptions - ...drug compounded by or under the direct supervision of a licensed pharmacist in a facility that elects to register as an outsourcing facility...

Roles Pharmacists are currently participating in Outsourcing Facilities:

- Senior Management CEO, VP, Director
- Pharmacovigilance
- Production or Quality Management
- Dispensing and Clinical Services

Licensure and Registration Requirements

503A Compounding Pharmacy

- No FDA registration required
- An application for licensure is reviewed and approved prior to issuance of a license by the Board.
- License is renewed annually by the Board.
 - An inspection is required annually if performing sterile compounding
 - Inspections are normally completed on one (1) business day onsite by one (1) inspector.

503B Outsourcing Facility

- Registered with the FDA annually. An inspection or preapproval is not required prior to registration.
 - Inspections are "risk based", normally once every 2-3 years.
- An application for licensure is reviewed and approved prior to issuance of a license by the Board.
- License is renewed annually by the Board.
 - An inspection is required annually
 - Inspections are normally completed in three (3) business days onsite by two (2) inspectors.

Current Outsourcing Facility Demographics

- Program Inception First license (OSF / NSF) issued in 6/2017
- Federally Registered Outsourcing Facilities 92
 - CA Licensed Resident Outsourcing Facilities 3
 - CA Licensed Non-Resident Outsourcing Facilities 20
- Newly FDA registered locations
 - 2024 19
 - 2025 11

Inspection Expectations – CFR and CGMP example

Facilities are required to follow:

- the Code of Federal Regulations (CFR)
- 21 CFR Part 210 and 211 describing Current Good Manufacturing Practices.

The CFR represents the required regulation

FDA Guidance for Industry Documents

- Clarify the CFR
- Describe the FDA's current thinking on a specific topic.

For example:

CFR 211.113(b) Control of Microbiological Contamination: Appropriate written procedures, designed to prevent microbiological contamination of drug products purporting to be sterile, shall be established and followed. Such procedures shall include validation of all aseptic and sterilization processes.

Question – How does one know what "appropriate" means?

Inspection Expectations – CFR and CGMP example (cont.)

Example excerpts related to CFR 211.113 from: FDA Guidance for Industry Current Good Manufacturing Practice – Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act; Draft Guidance January 2020. Revision 2.

- Facility Design -
 - ...Water used as cleaning or rinsing agent for any equipment or utensils that will not be subsequently disinfected or sterilized and depyrogenated must be sterile (see § 211.113(b))...
- Environmental and Personnel Monitoring
 - ...21 CFR 211.42(c)(10)(iv) requires establishing a system for monitoring environmental conditions in aseptic processing areas, and §§ 211.113(b) and 211.28(a) require personnel sanitation practices and gowning to be both acceptable and qualified for the operations they perform. For example, gowning procedures should ensure that there is no exposed skin on personnel involved in any production activities in, or that can directly affect, the ISO 5 area...
- Components
 - ...Controls over the source and quality of components are required (§§ 211.82, 211.84, 211.87, **211.113**). When producing sterile drug products, one aspect of such controls is the consideration of whether the incoming components are non-sterile...

Outsourcing Inspection Program Post Implementation Successes

- Maintained high expectations of compounded products provided to California patients and prescribers.
- Facilitated strong working relationship with the licensees to optimize drug supply during shortages especially during the COVID-19 pandemic.
- Served as the framework for several other State Boards of Pharmacies.

Outsourcing Inspection Program Challenges

- Time and Travel Inspections require greater time and effort by Board staff to complete. Inspections require more advanced planning.
- Level of Effort Firm sites are large, and their Quality Systems are complex requiring more inspection hours and resources.
- Documents and Record Review A robust volume of records supporting the processes are required and reviewed prior to the onsite visit.
- Asynchronous inspection timing with the FDA and other State Boards of Pharmacy – Other regulatory inspections or voluntary notifications (i.e., recalls) happen on a regular basis between inspection cycles.

Recommendations

- Post implementation of the program there may be opportunity for some minimal edits to statute to align language to current FDA requirements for clarification purposes.
- As an example, it might be beneficial for the Board to consider aligning the address requirements of an outsourcer in statute to current FDA requirements.

ThankYou

Attachment 3

Duty to Consult October 16, 2025

California State Board of Pharmacy



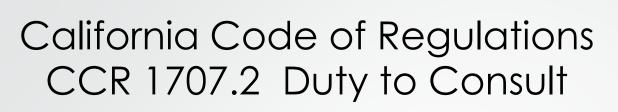




What is the Value of Consultation?

- Learn to take medication safely and effectively
- Personalized advice and/or tailored education about medication(s)
- Improves patient understanding of medication
- Addresses potential side effects or allergies
- Identifies and prevents drug interactions

- Discuss other medications or supplements
- Ask questions of a pharmacist
- Decreases risk of patient taking the wrong medication (medication error)
- Improves medication adherence, overall medication management and health outcomes





A pharmacist shall provide oral consultation to their patient or the patient's agent:

- Upon request
- Whenever the pharmacist deems it warranted in exercise of their professional judgment
- Whenever the prescription drug has not previously been dispensed to a patient
- Whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy

California Code of Regulations CCR 1707.2 Duty to Consult (continued)



When the patient or patient's agent is not present including mail order or delivery the pharmacy shall ensure:

- Patient receives written notice of the right to request consultation
- Patient receives written notice of hours of availability and phone number to obtain consultation from the pharmacist, who has access to the patient's record
- A pharmacist shall be available:
 - To speak with the patient or agent during regular hours within an average of 10 minutes or less, unless a return call is scheduled within one business hour
 - No less than six days a week
 - A minimum of 40 hours a week



CCR 1707.2 Consultation Violations

Fiscal Year 2022-2023

Fiscal Year 2023-2024

Fiscal Year 2024-2025

43

47

46

Consultation Violation Examples

Example #1: Pharmacy failed to provide consultation on a new prescription.

Example #2: Pharmacy failed to provide consultation on two new drugs. Technician told patient to go to consultation window to speak with pharmacist, however the technician did not alert the pharmacist that a patient was waiting.

Example #3: Pharmacy failed to provide consultation on a drug that was previously dispensed, but directions had changed.

Consultation Violation Examples (continued)

Example #4: Pharmacy failed to provide consultation on an oral suspension which was dispensed as a powder and not reconstituted.

Example # 5: Pharmacy failed to have a pharmacist available within an average of 10 minutes to speak to a patient or arrange a call back within one business hour for patients in need of consultation.

Example #6: Pharmacies failed to provide notice of right to consultation on mail order or delivered medications.





No Action

Close no Further Action
Subject Educated



Administrative Action Letter of Admonishment Citation no Fine Citation with Fine



Formal Discipline

Referral to Attorney General







Barriers to Consultation



Patient Related



System Related



Pharmacist Related Barriers



OR STRESS



TIME CONSTRAINTS



Patient Related Barriers



PRIVACY CONCERNS



PATIENT IMPATIENCE



PATIENT AWARENESS



System Related Barriers

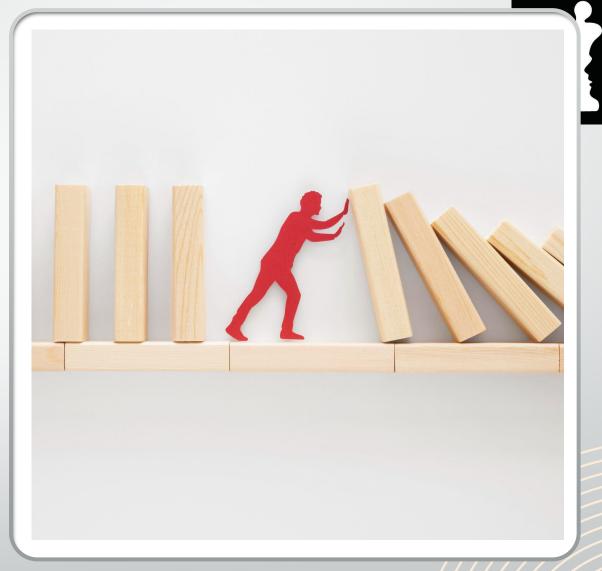


WORKFLOW: NON-PHARMACIST EMPLOYEES SCREENING FOR CONSULTATION



WORKLOAD: BUSY PHARMACY, HIGH VOLUME, STAFFING CONSTRAINTS

Breaking Down
Barriers to
Improve Patient
Consultation





Board Actions that Support Patient Consultation

- Updated the notice to consumer poster
- Point to your language notice
- Interpretive services for limited or no English proficiency
- Policies and procedures for interpretive services
- Patient centered labeling
- Option to receive translated directions upon request
- Written notice of consultation provided on mail order or delivered medications

ThankYou



Attachment 4

Department of Consumer Affairs Title 16. Pharmacy

Proposed Regulatory Language

Legend: Added text is indicated with an underline.

Amend 16 CCR § 1710 to Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

16 CCR § 1710

§ 1710. Hospital Pharmacy.

- (a) A hospital pharmacy which predominantly furnishes drugs to inpatients of that hospital may furnish drugs to outpatients or employees of that hospital or to walk-in customers, provided that sales to walk-in customers do not exceed one (1) percent of all the pharmacy's prescriptions. <u>Such a pharmacy is exempt</u> from the requirements of Business and Professions code section 4113.1.
- (b) A hospital pharmacy may process an order for filling patient cassettes by another pharmacy within this state, provided:
- (1) The pharmacy that is to fill the cassettes either has a contract with the ordering hospital pharmacy or has the same owner as the ordering inpatient hospital pharmacy,
- (2) The filled cassette is delivered directly from the filling pharmacy to the ordering hospital pharmacy,
- (3) Each cassette or container meets the requirements of Business and Professions Code section 4076,
- (4) Both pharmacies are responsible for ensuring that the order has been properly filled.
- (5) Both pharmacies shall maintain complete and accurate records of each cassette fill transaction, including the name of the pharmacist checking the cassettes at each pharmacy.
- (6) Prescription information shall be electronically transferred between the two pharmacies.

Credits

Note: Authority cited: Sections 4005 and 4118 Business and Professions Code. Reference: Sections 4005, 4029, 4076, $\underline{4113.1}$, $\underline{4118}$ and 4380, Business and Professions Code.

Attachment 5

<u>DRAFT Frequently Asked Questions – Assembly Bill 1286 (Haney, Chapter 470, Statutes of 2023)</u>

Assembly Bill 1286, which became effective January 1, 2024, includes several patient safety provisions. Given the encompassing nature of the measure, the Board is releasing this FAQ to assist licensees with understanding the bill. To facilitate use of this document, short titles will be used to reference the various topics. Please note this is a dynamic document and may be updated periodically to reflect changes or new information.

Medication Error Reporting

1. Q: What types of licensees are required to report medication errors under AB 1286?

A: A community pharmacy licensed pursuant to Article 7 of Chapter 9 of Division 2 of the Business and Professions Code (BPC) is required to report medication errors under AB 1286. For purposes of the measure, the term "community pharmacy" includes any pharmacy that dispenses medication to an outpatient, including both resident and nonresident pharmacies, but not including facilities of the California Department of Corrections and Rehabilitation.

[Reference: BPC 4113.1(a) and (c)]

2. Q: What is considered a medication error for purposes of AB 1286 reporting?

A: For purposes of AB 1286 reporting, the term "medication error" includes 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, but does not include any variation that is corrected prior to dispensing to the patient or patient's agent or any variation allowed by law.

[Reference: BPC 4113.1(d)]

3. Q: AB 1286 requires a community pharmacy to report medication errors to an entity approved by the Board. What is the name of the approved entity

A: The Board approved the Institute for Safe Medication Practices (ISMP) as the entity to receive medication error reports from community pharmacies under BPC 4113.1.

[Reference: BPC 4113.1(a) and (b)]

4. Q: When do community pharmacies have to start reporting medication errors under BPC 4113.1?

A: The Board has announced that medication errors occurring on or after September 1, 2025, must be reported under BPC 4113.1. The Board will use a variety of means to communicate any further updates to the implementation timeframe for BPC 4113.1 medication error reporting, including through the Board's subscriber alert system and

posting information on the <u>California Medication Error Reporting (CAMER) page</u> on its website.

5. Q: How do I register with ISMP for medication error reporting?

A: A link to the ISMP registration portal can be found on the <u>California Medication Error</u> Reporting (CAMER) page on the Board's website.

6. Q: Is there a fee for medication error reporting under BPC 4113.1?

A: Per the contract between the Board and ISMP, ISMP will charge community pharmacies an initial registration fee of \$70 for the first contract year, and a renewal fee of \$47 per year for the second and third contract years.

7. Q: I work in an outpatient hospital pharmacy. Am I required to report all medication errors to the Board-approved entity under the provisions of AB 1286?

A: It depends. AB 1286 generally requires a community pharmacy licensed by the Board to report, either directly or through a designated third party, all medication errors to an entity approved by the Board; however, subdivision (e) of BPC 4113.1 establishes a limited exemption from the reporting requirements, and specifies that an outpatient hospital pharmacy shall not be required to report a medication error that meets the requirements of an adverse event that has been reported to the State Department of Public Health pursuant to HSC 1279.1.

New Question:

8. Q: My hospital pharmacy holds an HSP license type but periodically dispenses outpatient prescriptions to discharge patients, emergency room patients or hospital employees. The volume of prescriptions dispensed to outpatients is within the limit set forth in California Code of Regulations, title 16, section 1710 and does not require us to have a separate PHY license type. Do I need to register the HSP with and report to ISMP?

A: No, it is the policy of the Board that if the hospital pharmacy dispensing volume to outpatients is within the limit set forth in California Code of Regulations, title 16, section 1710, the pharmacy is not required to report medication errors through the CAMER program. It is anticipated that the Board will pursue a regulatory change to document this policy.

New Question:

9. Q: I work at an infusion center pharmacy that is government owned with a PHE license. Additionally, our entity also has investigational drug pharmacies with a PHE license type. Are these pharmacies subject to CAMER reporting requirements?

A: If the facility meets the definition of a "community pharmacy" under BPC section 4113.1, the facility is required to report medication errors through the CAMER program. It is the responsibility of the pharmacist-in-charge to determine whether the facility is a "community pharmacy" as defined by BPC section 4113.1.

[Reference: BPC 4113.1]

10. Q: If I am reporting medication errors to an entity approved by the Board, am I still required to complete a quality assurance review and report?

A: Yes. The Board's quality assurance regulations remain in place and pharmacies are still required to comply with those regulations.

[Reference: 16 CCR 1711]

Response Updated:

11.Q: Are nonresident pharmacies required to report all medication errors to the Board-approved entity under the provisions of AB 1286?

A: Subdivision (f) of BPC 4113.1 (which was added by Assembly Bill 1503 (Berman, Chapter 196, Statutes of 2025), and which becomes effective on January 1, 2026) states that a pharmacy licensed pursuant to BPC 4112 shall only be required to report medication errors related to prescriptions dispensed to California residents.

[Reference: Stats. 2025, Ch. 196, Sec. 34 (AB 1503), effective January 1, 2026]

Minimum Staffing Provisions

12. Q: What minimum staffing requirements does AB 1286 establish?

A: Effective January 1, 2024, a chain community pharmacy subject to BPC 4113.5 is required to be staffed at all times during normal business hours (defined as 8:00 am to 7:00 pm) with at least one clerk or pharmacy technician fully dedicated to performing pharmacy-related services, unless any of the following conditions apply:

- The pharmacist on duty waives the requirement in writing during specified hours based on workload need.
- The pharmacy is open beyond normal business hours, which is before 8:00 am and after 7:00 pm, in which case the minimum staffing requirement does not apply during the hours before 8:00 am and after 7:00 pm.
- 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, CLIA-waived tests, or any
 other ancillary services provided by law, this exemption does not apply.

In addition, 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.

Note: Additional minimum staffing requirements are detailed under "Pharmacy

Technician Expanded Duties" below.

[Reference: BPC 4113.6]

13. Q. If a pharmacist is solely scheduled with an intern, does that meet the minimum staffing requirement established in BPC 4113.6(a)?

A: AB 1286 is silent about the impact to the minimum staff requirement when interns are present. As stated in the prior question, a pharmacist on duty may waive the BPC 4113.6(a) minimum staffing requirement during specified hours based on workload need.

[Reference: BPC 4113.6(a)]

Staffing Decisions

14.Q: I am the pharmacist-in-charge (PIC) of a pharmacy. What changes does AB 1286 make as far as my ability to make staffing decisions?

A: Effective January 1, 2024, the law explicitly provides that the PIC may 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 Board recommends that the PIC document their efforts to ensure sufficient staff are present.

Note: These provisions do not apply to facilities of the Department of Corrections and Rehabilitation.

[Reference: BPC 4113(c)(2)]

15.Q: I am the pharmacist on duty and the PIC is not available. Do I have the authority to adjust staffing?

A: Effective January 1, 2024, if the PIC is not available, a pharmacist on duty may adjust staffing according to workload if needed. The Board recommends that the pharmacist on duty document their efforts to adjust staffing.

Note: These provisions do not apply to facilities of the Department of Corrections and Rehabilitation.

[Reference: BPC 4113(c)(2)]

Unsafe Pharmacy Conditions

16.Q: I am concerned that the working conditions of the pharmacy are harmful. What should I do?

A: Effective January 1, 2024, the pharmacist-in-charge or pharmacist on duty is required 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. 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:

- Workplace safety and health hazards that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff.
- Sustained temperatures that could impact ambient temperature drug stability according to manufacturer data on acceptable drug storage conditions.
- Vermin infestation that poses a risk to the safety or efficacy of medicine.

The Board recommends that the PIC or pharmacist on duty document any such notification made by them to store management. The Board also recommends that pharmacies establish policies and procedures for the notification process to ensure reporting personnel and store management have a common understanding of the process to be used.

[Reference: BPC 4113(d)]

17. Q: Is store management required to take action based on my report?

A: Yes. Effective January 1, 2024, store management is required to 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. The pharmacy owner may also close a pharmacy to mitigate against a perceived immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff.

[Reference: BPC 4113(d)]

18. Q: I made a report, but the conditions remain. What should I do?

A: Effective January 1, 2024, the law states that if the conditions are not resolved within 24 hours, the PIC or pharmacist on duty shall ensure the Board is timely notified.

[Reference: BPC 4113(d)]

19. Q: How do I make a report to the Board?

A: The Board has established a dedicated email for such reporting: — PharmacyAlert@dca.ca.gov. The Board requests that the following information be provided with the notification:

- Name and license number of pharmacy,
- Name and contact information for reporting party,
- Name and contact information for store management that received the initial notification,
- Copy of the notification provided to store management,
- Documentation of the conditions including photographs, temperature logs, etc.

[Reference: BPC 4113(d)]

20. Q: Do these requirements apply to all pharmacies?

A: No, facilities of the Department of Corrections and Rehabilitation are exempt from these requirements.

[Reference: BPC 4113(d)(6)]

Pharmacy Technician Expanded Duties

Response Updated:

21. Q: In addition to the traditional tasks pharmacy technicians may perform pursuant to BPC 4115(a) (i.e., packaging, manipulative, repetitive, or other nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist), what are the expanded duties pharmacy technicians may now perform?

A: BPC 4115(b) was clarified by Assembly Bill 1503 (Berman, Chapter 196, Statutes of 2025). Under these updates, which become effective January 1, 2026, a certified pharmacy technician as defined in BPC 4202 may perform the following duties <u>under specified conditions</u>:

- Prepare and administer influenza and COVID-19 vaccines via injection or intranasally
- Prepare and administer epinephrine
- Perform specimen collection for tests that are classified as CLIA
- Initiate and receive prescription transfers and accept clarification on prescriptions
 [Reference: BPC 4115(b); see also Stats. 2025, Ch. 196, Sec. 36 (AB 1503), effective January 1, 2026]

Response Updated:

22. Q: What are the specified conditions that must be met for a pharmacy technician to perform the expanded duties?

A: The law establishes several conditions, as follows:

- The duties are performed under the direct supervision and control of a pharmacist.
- The pharmacy has scheduled another pharmacy technician to assist the pharmacist by performing the tasks provided in BPC 4115(a) (i.e., packaging, manipulative, repetitive, or other nondiscretionary tasks).
- The pharmacy technician is certified pursuant to the provisions of BPC 4202(a)(4) and maintains the certification.
- Assembly Bill 1503 (Berman, Chapter 196, Statutes of 2025), which takes effect on January 1, 2026, clarifies the conditions for technicians performing administration of vaccines (or epinephrine):
 - Prior to performing administration of vaccines, the pharmacy technician has successfully completed at least six hours of

practical training approved by the Accreditation Council for Pharmacy Education that includes hands-on injection technique, the recognition and treatment of emergency reactions to vaccines, and an assessment of the pharmacy technician's injection technique.

• The pharmacy technician is certified in basic life support.

[Reference: BPC 4115(b); see also Stats. 2025, Ch. 196, Sec. 36 (AB 1503), effective January 1, 2026]

<u>Unprofessional Conduct</u>

23. Q: As a pharmacist, I know I am responsible for using professional judgment when taking care of patients. I believe my employer has implemented a policy that undermines my professional judgment. Does AB 1286 address this?

A: Yes. Effective January 1, 2024, the unprofessional conduct code was amended to expand the list of specified actions that constitute unprofessional conduct to include actions or conduct that would subvert the efforts of a pharmacist or PIC to comply with laws and regulations, or exercise professional judgment.

[Reference: BPC 4301(v) and (w)]

24. Q: If I believe the pharmacy is violating the law, how do I file a complaint with the Board?

A: A consumer or licensee may file a complaint with the Board <u>online</u>. Fill out the boxes on the form that apply to your complaint. The Board requests that documentation or other evidence that support your allegations be retained and provided to the Board if requested.

25. Q: Can I file a complaint anonymously?

A: Yes. The Board welcomes and investigates complaints received, including anonymous complaints. However, anonymous complaints may limit the Board's ability to investigate.

New Question:

26. Q: Is a chain community pharmacy required to post a notice for pharmacy personnel that provides information on how to file a complaint?

A: Subdivision (c) of BPC 4113.6 (which was added by Assembly Bill 1503 (Berman, Chapter 196, Statutes of 2025), and which becomes effective on January 1, 2026) provides that a chain community pharmacy is required to post, in a prominent place for pharmacy personnel, a notice that provides information on how to file a complaint with the Board.

[Reference: Stats. 2025, Ch. 196, Sec. 35 (AB 1503), effective January 1, 2026]

Surgical Clinic Provisions

Response Updated:

27.Q: Under new requirements established by AB 1286, a surgical clinic is required to complete a Surgical Clinic Self-Assessment Form. Where can I find that form?

A: The Surgical Clinic Self-Assessment Form can be found <u>here</u> on the Board's website.

[Reference: BPC 4192(b)]

28. Q: It is my understanding that AB 1286 makes changes to the renewal requirements for surgical clinics. Please provide me with an explanation of the changes.

A: Effective January 1, 2024, as part of the renewal process for a surgical clinic, the consulting pharmacist must certify compliance with the quarterly inspections as required by BPC 4192. Further, as part of the renewal process of every odd-numbered year, the most recent self-assessment form completed as provided in BPC 4192 must be provided to the Board.

[Reference: BPC 4204(c)]

29. Q: How does the consulting pharmacist certify compliance with the quarterly inspection requirements?

A: The renewal application form includes a statement that must be completed by the consulting pharmacist as part of the renewal process. As a reminder, the Board has a policy to accept digital signatures. The policy is available <u>here.</u>

[Reference: BPC 4192(b), 4204(c)]

Response Updated:

30. Q: How do I submit a copy of the completed self-assessment form with our renewal application?

A: A copy of the completed self-assessment form can be mailed along with the renewal application form and renewal fee to the Board's office at 2720 Gateway Oaks Drive, Suite 100, Sacramento, CA 95833.

Alternatively, the self-assessment form may be emailed to surgicalclinicselfassessment@dca.ca.gov and the renewal application form and fee may be mailed to the Board's office.

[Reference: BPC 4204(c))

Draft Rev. October 16, 2025

Attachment 6

Board of Pharmacy

Enforcement Workload Statistics FY 2025/26

Complaint Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	914	0	0	0	914
Closed	747	0	0	0	747
					Quarter
					Ending
Pending	2,414	0	0	0	2,414
Average Days for Investigation	283	0	0	0	283

					Quarter
Cases Under Investigation (By Team)	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Ending
Compliance / Routine	1,133	0	0	0	1,133
Drug Diversion / Fraud	219	0	0	0	219
Prescription Drug Abuse	195	0	0	0	195
Compounding	83	0	0	0	83
Outsourcing	5	0	0	0	5
Probation / PRP	42	0	0	0	42
Enforcement	78	0	0	0	78
Criminal Conviction	657	0	0	0	657

Application Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	53	0	0	0	53
Closed					
Approved	19	0	0	0	19
Denied	28	0	0	0	28
Total Closed (includes withdrawn)	47	0	0	0	47
Pending	106	0	0	0	106

Complaint Closure Outcomes Not Resulting in					
Further Action	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Insufficient Evidence	371	0	0	0	371
Non-Jurisdictional	93	0	0	0	93
No Violation	20	0	0	0	20
No Further Action	56	0	0	0	56
Other / Non-Substantiated	26	0	0	0	26
Subject Educated	25	0	0	0	25

Letter of Admonishments / Citations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
LOA Issued	12	0	0	0	12
Citations Issued	95	0	0	0	95
Proof of Abatement Requested	12	0	0	0	12
Appeals Referred to AG's Office	2	0	0	0	2
Dismissed	3	0	0	0	3
Total Fines Collected	\$427,755	\$0	\$0	\$0	\$427,755

Administrative Cases	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Referred to the AG's Office	75	0	0	0	75
Pleadings Filed	46	0	0	0	46
Total Closed	54	0	0	0	54
					Quarter
Pending					Ending
Pre-Accusation	109	0	0	0	109
Post-Accusation	133	0	0	0	133
Total Pending	242	0	0	0	242

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation					
Pharmacist	2	0	0	0	2
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	16	0	0	0	16
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	1	0	0	0	1
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	19	0	0	0	19

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation, stayed, suspension/probation					
Pharmacist	0	0	0	0	0
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	0	0	0	0	0
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	0	0	0	0	0
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	0	0	0	0	0

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation, stayed, probation					
Pharmacist	6	0	0	0	6
Intern Pharmacist	1	0	0	0	1
Pharmacy Technician	6	0	0	0	6
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	2	0	0	0	2
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	15	0	0	0	15

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Surrender / Voluntary Surrender					
Pharmacist	1	0	0	0	1
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	4	0	0	0	4
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	1	0	0	0	1
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	6	0	0	0	6

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Public Reproval / Reprimand					
Pharmacist	0	0	0	0	0
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	1	0	0	0	1
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	3	0	0	0	3
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	4	0	0	0	4

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Granted (with or w/o conditions)					
Pharmacist	0	0	0	0	0
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	2	0	0	0	2
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	0	0	0	0	0
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	2	0	0	0	2

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Denied					
Pharmacist	0	0	0	0	0
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	1	0	0	0	1
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	0	0	0	0	0
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	1	0	0	0	1

Administrative Case Cost Recovery Efforts	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Cost Recovery Requested	\$184,235	\$0	\$0	\$0	\$184,235
Cost Recovery Collected	\$211,155	\$0	\$0	\$0	\$211,155

Immediate Public Protection Sanctions	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Interim Suspension Orders	3	0	0	0	3
Automatic Suspension Orders	0	0	0	0	0
Penal Code 23 Restrictions	2	0	0	0	2
Cease and Desist - Outsourcing	0	0	0	0	0
Cease and Desist - Unlicensed Activity	1	0	0	0	1
Cease and Desist - Sterile Compounding	0	0	0	0	0

					Quarter
Probation Statistics	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Ending
Licenses on Probation					
Pharmacist	138	0	0	0	138
Advanced Practice Pharmacist	2	0	0	0	2
Intern Pharmacist	5	0	0	0	5
Pharmacy Technician	42	0	0	0	42
Designated Representative	1	0	0	0	1
Wholesaler / 3PL	0	0	0	0	0
Pharmacy	43	0	0	0	43
Sterile Compounding	7	0	0	0	7
Outsourcing	0	0	0	0	0
Total	238	0	0	0	238
Probation Compliance Measures					Total
Probation Office Conferences	23	0	0	0	23
Probation Interviews / Site Inspections	133	0	0	0	133
Probation Terminated / Completed	15	0	0	0	15
Referred to AG for Non-Compliance	1	0	0	0	1

As of 9/30/2025

Board of Pharmacy

Citation and Fine Statistics FY 2025/26

Citation Outcomes	July - Sept	Oct - Dec	Jan - Mar	Apr - Jun	Total
Pharmacist with Fine	2	0	0	0	2
Pharmacist-in-Charge with Fine*	1	0	0	0	1
Pharmacist no Fine	7	0	0	0	7
Pharmacist-in-Charge no Fine*	8	0	0	0	8
Pharmacy with Fine	57	0	0	0	57
Pharmacy no Fine	16	0	0	0	16
Pharmacy Technician with Fine	1	0	0	0	1
Pharmacy Technician no Fine	6	0	0	0	6
Wholesalers	0	0	0	0	0
Designated Representative	1	0	0	0	1
Clinics	0	0	0	0	0
Drug Room	0	0	0	0	0
Exempt Hospital	0	0	0	0	0
Hospital Pharmacy	1	0	0	0	1
Miscellaneous**	9	0	0	0	9
Unlicensed Premises	1	0	0	0	1
Unlicensed Person	1	0	0	0	1
TOTAL	111	0	0	0	111

^{*}These numbers are also represented in the RPH columns, but reflect how many RPHs were cited as PICs **Intern Pharmacist, Licensed Correctional Facilities, Exempt Pharmacies, Non-Resident Pharmacies, and Vet Retailers

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		Top Ten Violations by License T	Type		
Pharmacists	%	Pharmacies	%	Pharmacists In Charge	%
1304.11(c) - Inventory Requirements; Biannual inventory date	15%	1716 - Variation from prescription	32%	1304.11(c) - Inventory Requirements; Biannual inventory date	17%
1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	15%	4301(o) - Unprofessional conduct; assist in violation	10%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	17%
1716 - Variation from prescription	15%	4301(c)(d)(j)(o) - Unprofessional Conduct - Gross negligence/excessive furnishing of controlled substances/Violation of any statutes of this state or of the United States regulation controlled substance	%8	1715.65(a)(1) - Inventory Activities and Inventory Reconciliation reports (a) Every pharmacy, and every clinic licensed under section 4180 or 4190 of the Business and Professions Code, shall perform	%8
4306.5(a) - Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist	%8	1761(a)(b) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission/A pharmacist shall not compound or dispense a prescription for a controlled substance	%8	1715(a) - Self-assessment form of a pharmacy by the pharmacist-in-charge; shall complete a self-assessment of pharmacy compliance with federal and state pharmacy	%8
1715.65(a)(2) - Inventory Activities and Inventory Reconciliation reports (a) Every pharmacy, and every clinic licensed under section 4180 or 4190 of the Business and Professions Code, shall perform	%8	4126.5(a)(5)(c) - A Pharmacy may furnish dangerous drugs only to the following: (5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law. (c) Notwithstanding any other law	%8	1714(d)(e) - Operational Standards and Security: Each Pharmacist when on duty is responsibleThe Pharmacy Owner is responsible	%8
1715(a) - Self-assessment form of a pharmacy by the pharmacist-in-charge; shall complete a self-assessment of pharmacy compliance with federal and state pharmacy law	%8	4059(a) - Furnishing dangerous drugs without a prescription	%8	1714(d) - Operational Standards and Security; Pharmacist responsible for pharmacy security	%8
1714(d)(e) - Operational Standards and Security: Each Pharmacist when on duty is responsibleThe Pharmacy Owner is responsible	%8	11153(a) - Responsibility for legitimacy of prescription; a prescription for a controlled substance shall only be issued for a legitimate medical purpose	%8	1714(c)(d) - Operational Standards and Security; pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition/Operational Standards and Security; Pharmacist responsible for	%8
1714(d) - Operational Standards and Security; Pharmacist responsible for pharmacy security	%8	1764/56.10(a) - Unauthorized disclosure of prescription and medical information	%2	1714(c) - Operational Standards and Security; pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition	%8
1714(c)(d) - Operational Standards and Security; pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition/Operational Standards and Security; Pharmacist responsible for	%8	1714(c) - Operational Standards and Security; pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition	2%	1707.2(b)(1)(C) - In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in	%8
1707.2(b)(1)(C) - In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in	%8	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	2%	1793.2(b) - Duties of a pharmacy technician - Counting, pouring, or mixing pharmaceuticals;	%8

California State Board of Pharmacy SB 1441 Uniform Standards

The data includes licensees participating in the Pharmacist Recovery Program (PRP) and licensees on probation with substance use disorders. This data includes July 2025 through September 2025.

PRP Self-Referrals				
PRP Probation Referrals PRP Under Investigation	1			
PRP In Lieu Of (investigation conducted)		1		
Total Number of PRP Intakes	1			1
New Probationers			<u>'</u>	
Pharmacists	1			1
Intern Pharmacists	1			1
Pharmacy Technicians	6			6
Total New Probationers	8			8
PRP Participants and Recovery Agreements			<u>, </u>	
Total PRP Participants	28			N/A
Recovery Agreements Reviewed	18			18
Probationers and Inspections			<u> </u>	
Total Probationers	60			N/A
Inspections Completed	30			30
Referrals to Treatment				
Referrals to Treatment (PRP and Probationers)				
Drug Tests			<u> </u>	
Drug Test Ordered (PRP and Probationers)	519			519
Drug Tests Conducted (PRP and Probationers)	506			506
Relapses (Break in Sobriety)				
Relapsed (PRP and Probationers)	3			3
Major Violation Actions				
Cease Practice/Suspension (PRP and Probationers)	6			6
Termination from PRP				
Probationers Referred for Discipline	1			1
Closure or Noncompliance			<u> </u>	
Successful Completion (PRP and Probationers)	1			1
Termination (Probation)				
Voluntary Surrender (Probation)	1			1
Surrender as a result of PTR (Probation)				
Closed Public Risk (PRP)				
Non-compliance in PRP or Probation	18			18
Other (PRP)	3			3
Patients Harmed				
Number of Patients Harmed (PRP and Probationers)				Zero

SB 1441 Uniform Standards

The data includes licensees participating in the Pharmacist Recovery Program (PRP) and licensees on probation with substance use disorders. This data includes July 2025 through September 2025.

Board of Pharmacy	July -Sep	Oct Dec	Jan Mar	Apr Jun	25/26
	hoice at PRP Int				
Pharmacists	July-Sep	Oct-Dec	Jan-Mar	Apr-Jun	Total 25/26
Alcohol	1				1
Ambien					
Opiates					
Hydrocodone					
Oxycodone					
Morphine Benzodiazepines	+				
Barbiturates	+				
Marijuana	+				
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol	+				
Phendimetrazine Promethazine w/Codeine					
Intern Pharmacists	July-Sep	Oct-Dec	Jan-Mar	Apr-Jun	Total 25/26
Alcohol	July Sep	Out Dec	Juli Iviui	7101 3411	10141 23/ 20
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine	+				
Phentermine Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam Tramadol					
Clonazepam					
Clonazepam Tramadol Carisprodol Phendimetrazine					
Clonazepam Tramadol Carisprodol Phendimetrazine Promethazine w/Codeine					
Clonazepam Tramadol Carisprodol Phendimetrazine Promethazine w/Codeine Pharmacy Technicians	July-Sep	Oct-Dec	Jan-Mar	Apr-Jun	Total 25/26
Clonazepam Tramadol Carisprodol Phendimetrazine Promethazine w/Codeine Pharmacy Technicians Alcohol	July-Sep 6	Oct-Dec	Jan-Mar	Apr-Jun	Total 25/26
Clonazepam Tramadol Carisprodol Phendimetrazine Promethazine w/Codeine Pharmacy Technicians Alcohol Opiates		Oct-Dec	Jan-Mar	Apr-Jun	
Clonazepam Tramadol Carisprodol Phendimetrazine Promethazine w/Codeine Pharmacy Technicians Alcohol Opiates Hydrocodone		Oct-Dec	Jan-Mar	Apr-Jun	
Clonazepam Tramadol Carisprodol Phendimetrazine Promethazine w/Codeine Pharmacy Technicians Alcohol Opiates Hydrocodone Oxycodone		Oct-Dec	Jan-Mar	Apr-Jun	
Clonazepam Tramadol Carisprodol Phendimetrazine Promethazine w/Codeine Pharmacy Technicians Alcohol Opiates Hydrocodone Oxycodone Benzodiazepines		Oct-Dec	Jan-Mar	Apr-Jun	
Clonazepam Tramadol Carisprodol Phendimetrazine Promethazine w/Codeine Pharmacy Technicians Alcohol Opiates Hydrocodone Oxycodone Benzodiazepines Barbiturates		Oct-Dec	Jan-Mar	Apr-Jun	
Clonazepam Tramadol Carisprodol Phendimetrazine Promethazine w/Codeine Pharmacy Technicians Alcohol Opiates Hydrocodone Oxycodone Benzodiazepines Barbiturates Marijuana		Oct-Dec	Jan-Mar	Apr-Jun	
Clonazepam Tramadol Carisprodol Phendimetrazine Promethazine w/Codeine Pharmacy Technicians Alcohol Opiates Hydrocodone Oxycodone Benzodiazepines Barbiturates Marijuana Heroin		Oct-Dec	Jan-Mar	Apr-Jun	
Clonazepam Tramadol Carisprodol Phendimetrazine Promethazine w/Codeine Pharmacy Technicians Alcohol Opiates Hydrocodone Oxycodone Benzodiazepines Barbiturates Marijuana		Oct-Dec	Jan-Mar	Apr-Jun	
Clonazepam Tramadol Carisprodol Phendimetrazine Promethazine w/Codeine Pharmacy Technicians Alcohol Opiates Hydrocodone Oxycodone Benzodiazepines Barbiturates Marijuana Heroin Cocaine Methamphetamine		Oct-Dec	Jan-Mar	Apr-Jun	
Clonazepam Tramadol Carisprodol Phendimetrazine Promethazine w/Codeine Pharmacy Technicians Alcohol Opiates Hydrocodone Oxycodone Benzodiazepines Barbiturates Marijuana Heroin Cocaine		Oct-Dec	Jan-Mar	Apr-Jun	
Clonazepam Tramadol Carisprodol Phendimetrazine Promethazine w/Codeine Pharmacy Technicians Alcohol Opiates Hydrocodone Oxycodone Benzodiazepines Barbiturates Marijuana Heroin Cocaine Methamphetamine Pharmaceutical Amphetamine		Oct-Dec	Jan-Mar	Apr-Jun	
Clonazepam Tramadol Carisprodol Phendimetrazine Promethazine w/Codeine Pharmacy Technicians Alcohol Opiates Hydrocodone Oxycodone Benzodiazepines Barbiturates Marijuana Heroin Cocaine Methamphetamine Pharmaceutical Amphetamine Phentermine Methadone Zolpidem Tartrate		Oct-Dec	Jan-Mar	Apr-Jun	
Clonazepam Tramadol Carisprodol Phendimetrazine Promethazine w/Codeine Pharmacy Technicians Alcohol Opiates Hydrocodone Oxycodone Benzodiazepines Barbiturates Marijuana Heroin Cocaine Methamphetamine Pharmaceutical Amphetamine Phentermine Methadone Zolpidem Tartrate Hydromorphone		Oct-Dec	Jan-Mar	Apr-Jun	
Clonazepam Tramadol Carisprodol Phendimetrazine Promethazine w/Codeine Pharmacy Technicians Alcohol Opiates Hydrocodone Oxycodone Benzodiazepines Barbiturates Marijuana Heroin Cocaine Methamphetamine Pharmaceutical Amphetamine Phentermine Methadone Zolpidem Tartrate		Oct-Dec	Jan-Mar	Apr-Jun	

SB 1441 Uniform Standards

The data includes licensees participating in the Pharmacist Recovery Program (PRP) and licensees on probation with substance use disorders. This data includes July 2025 through September 2025.

Board of Pharmacy	July -Sep	Oct Dec	Jan Mar	Apr Jun	25/26
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					

Drug Of Choice - Data entered from July 2025 to September 2025

1 Alcohol2 Opiates3 Hydrocodone4 Oxycodone

5 Benzodiazepines6 Barbiturates7 Marijuana8 Heroin9 Cocaine

10 Methamphetamine

11 Pharmaceutical Amphetamine

