California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

Enforcement and Compounding Committee Report
January 7, 2026

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. Discussion and Possible Action to Approve Minutes of the October 16, 2025, Enforcement and Compounding Committee Meeting

Attachment 1 includes a copy of the draft minutes.

IV. Discussion and Possible Action to Make a Recommendation to the Board to Amend Business and Professions Code (BPC) Sections 4034, 4129, 4129.1, 4129.2 and 4303.1 Related to Outsourcing Facilities

Relevant Law

BPC section 4034 provides the definition of an outsourcing facility for purposes of the Pharmacy Law. BPC sections 4129, 4129.1, and 4129.2 outline requirements governing resident and nonresident outsourcing facilities.

BPC section 4303.1 provides that if the federal Food and Drug Administration (FDA) cancels, revokes, or suspends an outsourcing facility's registration for any reason, any license issued pursuant to section 4129.2 shall be immediately canceled, revoked, or suspended by operation of law.

Background
During the October 2025 Enforcement and Compounding Committee meeting, the Committee received an educational presentation from staff on the Board's outsourcing program. The presentation included an overview of the Board's outsourcing program, Board licensure requirements, a comparison of 503A versus 503B facilities, and the types of drugs compounded by these facilities. Members noted that there may be opportunities for possible technical changes to the statutory provisions governing outsourcing facilities that might be discussed at a future Committee meeting. Board staff believes that these technical amendments to statute can be addressed through omnibus legislation.

For Committee Consideration and Discussion
During the meeting, the Committee will have the opportunity to discuss the issue and review suggested amendments to the above-referenced sections of law, which align the statutory language more closely with the federal definition of the term "outsourcing facility" and harmonize the provisions with other related provisions of the Business and Professions Code.

Should the Committee believe the draft amendments are ready for consideration and approval by the Board, the Committee will refer the draft amendment language to the full Board for a vote.

Attachment 2 includes a copy of the draft amendments.

V. Discussion Regarding Holding Possible Listening Session on Title 16, California Code of Regulations, Section 1707.2 Related to Duty to Consult

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
Strategic goal 2.11 to the Board's Strategic Plan for 2022-2026 states: "Enhance patient consultation compliance by evaluating barriers to consultation to provide patient education and reduce medication errors."

As discussed at the October 2025 Committee meeting, the Committee is interested in gathering more information to assist in its evaluation of whether the Board's current consultation requirements remain appropriate and to better understand what barriers exist to pharmacist-provided consultation. The Board is looking to the regulated public for feedback and knowledge on possible opportunities to:

- improve patient understanding of medications
- reduce medication errors
- educate patients on their medications, so they are taken safely and effectively

Further, the Committee believes receiving feedback from the regulated public regarding challenges and barriers to consultation is vital to gain insight before any possible changes to the regulation are considered.

For Committee Consideration and Discussion

Staff suggest the Board hold a listening session with public participation, where licensees can share their opinions and insights on the duty to consult. The purpose of the listening session would be to gather feedback in an open forum to ensure that diverse perspectives on consultation are considered.

To help guide the discussion, it may be appropriate for the Committee to consider the following questions to be put forward to solicit input from the public at a listening session:

1. The regulation specifies that a pharmacist shall provide consultation to his or her patient or the patient's agent in all settings:

   Q: As the pharmacist, how do non-pharmacist staff make you aware that consultation is needed or required?

   Q: Do non-pharmacist staff ask the patient whether they would like to speak with the pharmacist on a new prescription? (Is your pharmacy screening for consultation?)

   Q: Are patients told to "go to the window" for consultation or "go to the consultation area" for consultation by non-pharmacist staff? If so, how does the pharmacist know the patient is waiting?

   Q: If the patient is referred to the consultation window, does the clerk or technician hand out the medication to the patient prior to the required consultation being provided by the pharmacist?

   Q: Does your pharmacy have an adequate space to provide patient consultation in a confidential manner?

   Q: Should the Board further define the physical requirements of a consultation area (e.g. to ensure confidentiality)?

2. The regulation states that consultation shall be provided 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.

Q: Is consultation necessary if the patient has taken the drug before but the dosage form, strength or directions have changed?

3. The regulation specifies that when a patient or patient's agent is not present (including, but not limited to, a prescription drug that was shipped by mail or delivery), a pharmacy shall ensure that the patient receives written notice of their right to consultation.

   Q: By what method does your pharmacy mail or deliver prescriptions to patients?
   a. Do pharmacy employees deliver the medication to the patient(s)?
   b. Is the medication delivered by a private courier hired by the pharmacy?
   c. Is the medication mailed or delivered by a delivery company (example: USPS, UPS, FedEx, other)

   Q: How does your pharmacy provide written notice of the right to request consultation to patients on mailed or delivered prescriptions?

   Q: How does your pharmacy (pharmacist) provide consultation to patients on delivered or mailed prescriptions?

   Q: Do pharmacists/pharmacies know that a delivered or mail ordered prescription received consultation when needed or requested by a patient?

4. Miscellaneous/ General Questions:

   Q: The regulation does not specify that consultation should be documented. Should there be a requirement that the pharmacy document in a specified manner that consultation was provided?

   Q: Is consultation necessary if the medication is never dispensed to the patient, but rather administered to the patient by a nurse, doctor, or in a provider's office or clinic setting?

   Q: As a pharmacist, do you have enough time in your work day to provide consultation adequately and effectively to patients?

   Q: What makes it easy to provide consultation in your pharmacy? Is there a specific workflow or process that the pharmacy or pharmacy staff can share?

Q: What makes it challenging or difficult to provide consultation in your pharmacy?

Q: Is there anything in 16 CCR section 1707.2 (Duty to Consult) that is not realistic or is outdated given the state of pharmacy practice today?

Should the Committee decide that a listening session is appropriate the following motion may be used:

> **Suggested Motion**: Authorize staff to schedule and hold a listening session related to the duty to consult. Approve listening session questions [either "as presented" or "consistent with the Committee's discussion"]. Authorize the Committee Chair to work directly with staff on developing the format for the listening session and to approve any final edits to listening session questions.

VI. Discussion and Possible Action to Make a Recommendation to the Board Regarding Proposed Frequently Asked Questions Related to the Board's Regulations on Compounded Drug Preparations

Relevant Law

California Code of Regulations, title 16, sections 1735 through 1735.15 establishes requirements that apply to nonsterile compounding.

California Code of Regulations, title 16, sections 1736 through 1736.21 establishes requirements that apply to sterile compounding.

California Code of Regulations, title 16, sections 1737 through 1737.17 establishes requirements that apply to the compounding of Hazardous Drugs (HDs) or crushing or splitting tablets or opening capsules of antineoplastic HDs.

California Code of Regulations, title 16, sections 1738 thorough 1738.14 establishes requirements that apply to the processing of radiopharmaceuticals.

Background

As part of its licensee education efforts, the Board has a series of Frequently Asked Questions (FAQs) available on its website to assist licensees in understanding pharmacy law and regulations. The Board's new compounding regulations for nonsterile compounding, sterile compounding, compounding of HDs, and processing of radiopharmaceuticals became effective October 1, 2025. Staff is proposing a set of FAQs regarding the Board's new compounding regulations.

For Committee Consideration and Discussion

During the meeting, members will have the opportunity to review the proposed FAQs and provide feedback to staff.

After discussion, 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 proposed FAQs related to the Board's compounding regulations that took effect on October 1, 2025 [either "as presented" or "consistent with the Committee's discussion"] and refer the proposed FAQs to the Board for approval.

Attachment 3 includes a copy of the draft FAQs.

VII. Discussion and Possible Action to Make a Recommendation to the Board Regarding Updates to Community Pharmacy Self-Assessment/ Hospital Outpatient Pharmacy Self-Assessment

Relevant Law

BPC section 4102 requires the pharmacist-in-charge to complete a "Community Pharmacy Self-Assessment/Hospital Outpatient Self-Assessment" form by July 1 of every odd-numbered year, and within 30 days of certain triggering events.

Background

The Board requires specified licensees to periodically engage in the self-assessment process, defined as the process of self-evaluation of a facility's compliance with state and federal laws as a means to promote compliance through self-examination and education. (BPC section 4040.6.) The self-assessment forms include a compilation of relevant laws applicable to the license type. Historically, the Board's self-assessment requirements resided in various provisions of pharmacy law and regulations. The Board's sunset bill, Assembly Bill 1503 (Berman, Chapter 196, Statutes of 2025) centralized the self-assessment process into statute. New BPC section 4040.6 provides that the self-assessment process shall be performed on a form approved by the Board in consultation with stakeholders and posted on its internet website. As such, AB 1503 allows the Board to streamline the process of annually updating the forms and ensures consistency in the Board's approach to promoting licensee self-compliance. As part of the current round of updates, the Board is taking the opportunity to not only update the substance of the forms to reflect new laws and regulations but also to update the format of these compliance tools for ease of use by the regulated public.

For Committee Consideration and Discussion

During the meeting, members will have the opportunity to review the newly drafted Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment form. It is recommended that during the meeting, members provide staff with feedback to finalize the newly drafted forms. Should the Committee believe the self-

assessment forms are ready for consideration and approval by the Board, the following motion may be used:

> **Suggested Motion**: Recommend approval of the newly developed and updated Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment form [either "as presented" or "consistent with the Committee's discussion"] and refer the draft form to the Board for approval.

Attachment 4 include a draft of the newly developed self-assessment form.

VIII. Discussion of Enforcement Statistics

During the first five months of the fiscal year, the Board initiated 1,545 complaints and closed 1,271 investigations. The Board has issued 27 Letters of Admonishment and 196 citations and referred 118 cases to the Office of the Attorney General. The Board has revoked 22 licenses, accepted the disciplinary surrender of 8 licenses, formally denied 1 application, and imposed other levels of discipline against 29 licensees and/or applicants.

As of December 1, 2025, the Board had 1,784 field investigations pending. Following is a breakdown providing more detail in the various investigation processes:

	Jan. 1, 2025		Apr. 1, 2025		Jul. 1, 2025		Oct. 1, 2025		Dec. 1, 2025	
	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days
Awaiting Assignment	31	10	71	14	31	10	71	14	76	8
Cases Under Investigation	978	141	1,021	143	978	141	1,021	143	1,126	98
Pending Supervisor Review	173	62	295	70	173	62	295	70	425	102
Pending Second Level Review	116	64	93	68	116	64	93	68	121	50
Awaiting Final Closure	49	34	29	52	49	34	29	52	36	49

Attachment 5 includes the enforcement statistics.

IX. Advisement of Future Committee Meeting Dates

- April 16, 2026
- June 10, 2026
- October 1, 2026

X. Adjournment

Attachment 1

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

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

Date: October 16, 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. All Committee members participated from remote locations via Webex.

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
Jeff Hughes, Public Member
Seung Oh, PharmD, Licensee Member
Ricardo Sanchez, Public Member
Nicole Thibeau, PharmD, Licensee Member

Staff Present:
Anne Sodergren, Executive Officer
Julie Ansel, Deputy Executive Officer
Lori Martinez, Chief of Legislation, Policy and Public Affairs
Corinne Gartner, DCA Counsel
Jennifer Robbins, DCA Regulations Counsel
Julie McFall, Executive Specialist Manager

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

Chairperson Serpa called the meeting to order at approximately 9:00 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; Jeff Hughes, Public Member; Seung Oh, Licensee Member; Ricardo Sanchez, Public 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 participating in Sacramento and via Webex were provided the opportunity to comment; however, no comments were made.

III. Discussion and Possible Action to Approve Minutes of the June 11, 2025 Enforcement and Compounding Committee Meeting

The draft minutes of the June 11, 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 June 11, 2025 Enforcement and Compounding Committee meeting minutes as presented.

M/S: Sanchez/Oh

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

Support: 6 Oppose: 0 Abstain: 0 Not Present: 0

Board Member	Vote
Barker	Support
Hughes	Support
Oh	Support
Sanchez	Support
Serpa	Support
Thibeau	Support

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

Dr. Serpa provided background on Senate Bill 1193 (Hill, Chapter 484, Statutes of 2016), which added Article 7.7 (sections 4129 to 4129.9) to Chapter 9 of Division 2 of the Business and Professions Code. These statutory provisions require an outsourcing facility to be licensed by the Board before doing business in the State of California. The provisions further require that outsourcing facilities be inspected by the Board before prior to issuance or annual renewal of the license. Dr. Serpa noted that some members may be unfamiliar with the outsourcing program and therefore Board staff offered to provide the Committee with a presentation.

Dr. Serpa introduced Supervising Inspector Dr. JK Fujimoto, who oversees the Board's outsourcing facility field inspection program.

Dr. Fujimoto explained that the Drug Quality and Security Act defines an outsourcing facility as a facility located at a single geographic location or address that compounds sterile drugs, has chosen to register with the FDA as an outsourcing facility, and complies with all requirements outlined in section 503B of the federal Food, Drug, and Cosmetic Act. Dr. Fujimoto noted that drugs compounded by a 503B outsourcing facility can qualify for certain exemptions from FDA drug approval and labeling requirements, but they are not exempt from current good manufacturing practice (CGMP) requirements.

Dr. Fujimoto provided some comparisons between a 503A compounding pharmacy versus a 503B outsourcing facility, noting that 503A pharmacies are designed to serve individual patients and are primarily regulated by state

boards of pharmacy, while 503B facilities generally operate on a larger scale and therefore are regulated by both state boards and the FDA.

Dr. Fujimoto then provided an overview of the typical layout of an outsourcing facility along with a description of a standard staffing structure, noting one of the most important aspects is the separation of the quality assurance and quality control unit from the production unit to ensure proper oversight and maintain product quality.

Dr. Fujimoto further compared the different licensure and registration requirements that apply to compounding pharmacies and outsourcing facilities, noting that outsourcing facilities must register with the FDA every year and the annual Board inspections may last as long as three days with two inspectors.

Dr. Fujimoto then provided an overview of Code of Federal Regulations (CFR) and CGMP requirements that apply to outsourcing facilities.

Dr. Fujimoto concluded by noting he was proud of the success of the Board's outsourcing program, the dedication of the staff involved, and the commitment of the licensees who have worked diligently to meet the high standards. He then provided insight on the challenges faced by the Board's outsourcing inspection program, the steps taken to navigate those challenges, and provided recommendations for possible statutory amendments the Board could consider to better align the statutory language with current FDA requirements.

Dr. Serpa noted appreciation for the presentation and commended Dr. Fujimoto and his staff for the in-depth inspection process that has been implemented and noted that there may be opportunities to provide changes that will be addressed at future Committee meetings.

Members were provided the opportunity to comment. Members appreciated the presentation. A member noted that at a recent national conference some attendees remarked that their states rely on the California Board's inspections to evaluate outsourcing facilities for compliance.

A member requested information on what products can be compounded or manufactured at a 503B outsourcing facility. Dr. Fujimoto explained that, similar to 503A pharmacies, 503B outsourcing facilities have rules they must follow related to what they can and cannot compound. Dr. Fujimoto noted that 503B outsourcing facilities have a set of Active Pharmaceutical Ingredients (APIs) they can work with. Outsourcing facilities can also compound products that are in drug shortage, and engage in repackaging activities.

Dr. Serpa added that health systems commonly use outsourcing facilities to provide antibiotics, cardiac drips, controlled substance drips, and products to help with shortages.

Dr. Fujimoto added there is a high level of quality assurance that comes with an outsourcing facility's product and noted that products oftentimes have longer beyond-use dates or expiry dates than what a hospital might be able to provide, which helps free up labor for hospital systems. Dr. Fujimoto further noted that many 503B products contain RFID chips that are useful to many end users.

There were no public members in the Sacramento location. Members of the public participating via Webex were provided the opportunity to comment. Several commenters appreciated the presentation, noting it was excellent and professional. One commenter provided a personal recollection of the outsourcing model done by Kaiser in the 1980s. Another commenter appreciated hearing about the inspection process and looked forward to hearing future discussions about possible regulatory change.

V. 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

Dr. Serpa recalled at the July 2024 Enforcement and Compounding Committee meeting, strategic goal 2.11 was added to the Board's Strategic Plan for 2022-2026. This goal states: "Enhance patient consultation compliance by evaluating barriers to consultation to provide patient education and reduce medication errors."

Dr. Serpa noted that the Committee would be receiving a presentation on the duty to consult and after the presentation, the Committee would have the opportunity to discuss whether the Board's current consultation requirements remain appropriate, consider what barriers exist to pharmacist-provided consultation, and evaluate opportunities to improve patient understanding of medications, reduce medication errors, and best practices on educating patients on their medications.

Dr. Serpa welcomed Deputy Executive Officer, Julie Ansel.

Ms. Ansel thanked the members for the opportunity to discuss patient consultation and noted that the duty to consult was the best opportunity for patients to get to know their pharmacists and for pharmacists to provide education to patients about medications. Ms. Ansel discussed the value of consultation and provided information on the relevant pharmacy law related to the duty to consult. Additionally, Ms. Ansel provided data on consultation violations, gave examples of violations, and discussed violation outcomes.

Ms. Ansel then discussed barriers to consultation and provided a few examples in the areas of pharmacist related barriers, patient related barriers, and system related barriers. Ms. Ansel noted the Board has laws and regulations designed to reduce barriers, support effective patient-pharmacist interaction, and ensure that patients receive meaningful and appropriate consultation.

Ms. Ansel noted some actions the Board has taken to support consultation, including updates to the Notice to Consumer poster, which encourages patients to speak with their pharmacist and informs them of their right to consult a pharmacist regarding new medications; the Point to Your Language notice, which assists patients in identifying their preferred language so they can receive medication information in a language they understand; interpretive services for limited or no English proficiency patients; patient centered labeling to assist the patient; options to receive translated directions upon request; and the requirement of providing a written notice of consultation on mail-order and delivered prescriptions.

Members were provided the opportunity to comment. Members discussed whether mechanisms could be established to incentivize pharmacists to deliver consultation services (such as providing compensation/reimbursement for consultations) and finding alternative ways to consult. Members noted that workflow and staffing could also be a factor

in consultation and medication errors; for example, when a pharmacist gets pulled away from a task to provide consultation it may create an increased risk for medication errors, and this risk should be acknowledged in future discussions. Members also noted that future discussions should include possible exceptions to consultation and provided the example of a retail pharmacy filling a prescription for a long-acting injectable drug, which is then given to a physician to administer so there is no patient to consult. Members also discussed whether the regulation language should remain prescriptive as to what a consultation must include, or be changed to enable pharmacists to use their professional judgment to decide in each case what is important for the patient to know.

There were no public members in the Sacramento location. Members of the public participating via Webex were provided the opportunity to comment. Commenters appreciated the presentation. One commenter provided a personal historical recollection about when consultation was first introduced and noted a controlled study done by Kaiser that determined patient consultation reduced costs of medical care and improved patient outcomes. The commenter agreed that consultation was very important and encouraged the Board to continue discussions. Another commenter from CPhA agreed that the presentation accurately highlighted barriers to consultation in pharmacy practice today. The commenter agreed that there needs to be ways to incentivize patient care beyond dispensing, including consultation, counseling, prescribing, and monitoring. The commenter noted that CPhA remains committed to working with the Department of Managed Health Care on AB 317 pharmacists' reimbursement. Another commenter suggested that pharmacy technicians do not appear to initiate conversations with patients and managers of operations do not appear to be pursuing systems to improve patient care.

VI. Discussion of Hospital Pharmacy and Business and Professions Code Section 4113.1 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

Dr. Serpa recalled the Institute for Safe Medication Practices was approved by the Board as the entity to receive and review medication error reports under Business and Professions Code (BPC) section 4113.1. The Board refers to medication error reporting under section 4113.1 as the California Medication Error Reporting (CAMER) program. Subdivision (c) of section 4113.1 defines "community pharmacy" for purposes of section 4113.1 to include any

pharmacy that dispenses medication to an outpatient, but does not include facilities of the Department of Corrections and Rehabilitation.

Dr. Serpa noted that existing regulation, California Code of Regulations (CCR), title 16, section 1710, establishes the conditions and sets volume limits under which a hospital pharmacy may furnish drugs to outpatients or employees of the hospital or to walk-in customers.

Dr. Serpa further noted that there are also existing requirements that already apply to hospitals under the Health and Safety Code, including requirements to report adverse events and to adopt a formal plan to eliminate or substantially reduce medication-related errors.

Dr. Serpa noted the Board has received comments asking for clarity on whether hospital pharmacies are required to register and report to CAMER. Dr. Serpa further noted her belief that it is the policy of the Board that if a hospital pharmacy's 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. She continued that this policy was discussed at previous committee and Board meetings and she believes it was the Board's intent, but that staff is now requesting that the Committee confirm the Board's policy and, if appropriate, consider a change to the regulatory text of section 1710 to clarify to the 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 16 CCR section 1710.

Dr. Serpa referenced attachment 4 of the meeting materials, which included draft regulation language for the Committee's consideration. Dr. Serpa noted her agreement with the draft language and reminded the Committee that if members agree the language is ready for consideration and approval by the Board, a motion is not necessary to refer the item to the full Board.

Members were provided the opportunity to comment. Members expressed support for the proposed language and requested additional information on hospital dispensing volumes to outpatients, including data illustrating what the 1% threshold represents.

There were no public members in the Sacramento location. Members of the public participating via Webex were provided the opportunity to comment.

A commenter suggested a change to clarify what the 1% specifically refers to and to specify that walk-ins are not exempt from consultation.

Members were provided another opportunity to comment; however, no comments were made. The draft language will be sent to the full Board for consideration and possible action.

VII. 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)

Dr. Serpa recalled as part of the discussion on implementation of Assembly Bill 1286, Board staff developed FAQs that were updated and approved by the Board during the June 2025 Board meeting. Dr. Serpa noted that given the passage of the Board's sunset bill, Assembly Bill 1503, and other recent developments, Board staff have now proposed additional updates to the FAQs to provide further clarification on certain topics, including California Medication Error Reporting (CAMER), Pharmacy Technician Expanded Duties, Unprofessional Conduct and Surgical Clinic Requirements.

Dr. Serpa noted attachment 5 of the meeting materials includes a copy of the FAQs incorporating the proposed updates and highlighted the changes in questions 8, 9, 11, 21, 22, 26, 27, and 30.

Members were provided the opportunity to comment. Members noted the need to identify effective methods for disseminating the substantial amount of information included in the FAQs. Members also suggested that questions 14 and 15 be updated to reflect the changes in AB 1503 pursuant to which PICs now must make staffing decisions effective January 1, 2026; as well as reviewing question 17 as it was believed that AB 1503 also had updates regarding this question.

Motion: Recommend approval of the updated FAQs related to Assembly Bill 1286 consistent with the Committee's discussion, including updates to 14, 15 and possibly 17.

M/S: Oh/Barker

There were no public members in the Sacramento location. Members of the public participating via Webex were provided the opportunity to comment.

A member from CPhA commented in support of updating the FAQs and looks forward to further collaborations in the future.

Support: 6 Oppose: 0 Abstain: 0 Not Present: 0

Board Member	Vote
Barker	Support
Hughes	Support
Oh	Support
Sanchez	Support
Serpa	Support
Thibeau	Support

The Committee took a break from 10:53 a.m. to 11:10 a.m. Roll call was taken. The following members were present via Webex: Renee Barker, Licensee Member; Jeff Hughes, Public Member; Seung Oh, Licensee Member; Ricardo Sanchez, Public Member; Nicole Thibeau, Licensee Member; and Maria Serpa, Licensee Member.

VIII. Discussion of Enrolled or Recently Signed Legislation Impacting the Practice of Pharmacy

Dr. Serpa noted AB 1503 implementation recommendations were discussed at the Licensing Committee meeting on October 15, 2025, and further noted that in the meeting materials, staff are offering recommendations on implementation activities and other recommendations pertaining to the measures that will be discussed today.

a. Assembly Bill 82 (Ward, Chapter 679, Statutes of 2025) Health Care: Legally Protected Health Care Activity

Dr. Serpa noted that the bill was amended to its current version before the June Board meeting, and neither the Committee nor the Board had previously considered this bill. Dr. Serpa detailed that the bill expands the address confidentiality program to a gender-affirming health care provider, employee, or volunteer who faces threats of violence or harassment from the public because of their affiliation with a gender-affirming health care services facility and prohibits a prescription for or the dispensing of testosterone or mifepristone from being reported to the Department of Justice, CURES, or a contractor. This measure was signed and chaptered on October 13, 2025. Dr. Serpa agreed that the implementation activities identified by staff were appropriate.

Members were provided the opportunity to comment. Members agreed with the recommendations and noted how important this bill is for people who provide gender-affirming care.

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

b. <u>Assembly Bill 144 (Committee on Budget, Chapter 105, Statutes of 2025) Health</u>

Dr. Serpa noted AB 144 authorizes pharmacists to independently initiate and administer immunizations that, as of January 1, 2025, have a federal ACIP recommendation or are recommended by the California Department of Public Health. Dr. Serpa noted that this bill was amended to its current version in September, and neither the Committee nor the Board had previously considered this bill. Dr. Serpa detailed that this measure was signed and chaptered on September 17, 2025, and a pharmacy alert was sent to licensees on September 18, 2025. Dr. Serpa agreed that the implementation activities identified by staff were appropriate.

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

There were no public members in the Sacramento location. Members of the public participating via Webex were provided the opportunity to comment. A representative of CPhA commented that a care gap for vaccinations existed because of differing recommendations and they believe this care gap has now been bridged.

c. <u>Assembly Bill 260 (Aguiar-Curry, Chapter 136, Statutes of 2025) Sexual and Reproductive Health Care</u>

Dr. Serpa noted that the bill was amended to its current version before the June Board meeting, and neither the Committee nor the Board had previously considered this bill. Dr. Serpa detailed that the measure was signed and chaptered on September 26, 2025. Dr. Serpa agreed that the implementation activities identified by staff were appropriate.

Members were provided the opportunity to comment. Members noted the importance of this bill to allow patients to maintain access to reproductive healthcare.

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

d. <u>Assembly Bill 309 (Zbur, Chapter 685, Statutes of 2025) Hypodermic Needles and Syringes</u>

Dr. Serpa noted that the measure was signed and chaptered on October 13, 2025. Dr. Serpa agreed that the implementation activities identified by staff were appropriate.

Members were provided the opportunity to comment. A member noted that with the enactment of AB 1503, all pharmacists may be able to furnish prescribed hypodermic needles and syringes as well, providing more opportunities for pharmacies to be able to assist patients with obtaining needles and syringes.

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

e. <u>Assembly Bill 447 (González, Chapter 363, Statutes of 2025) Emergency Room Patient Prescriptions</u>

Dr. Serpa noted this 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. Dr. Serpa further noted such drugs must have been administered from single patient use multidose packaging (like an inhaler or eye drop), can be self-administered by the patient, and must be fully labeled as a prescription.

Dr. Serpa indicated this measure also makes changes to certain AUD licensure in hospital emergency rooms.

Dr. Serpa noted the measure was signed and chaptered on October 6, 2025. Dr. Serpa agreed that the implementation activities identified by staff were appropriate.

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

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

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

Dr. Serpa noted that the bill was vetoed by the governor on October 13, 2025, and therefore, the staff's recommended implementation activities were no longer applicable.

g. Senate Bill 40 (Wiener, Chapter 737, Statutes of 2025) Health Care Coverage: Insulin

Dr. Serpa noted the measure was signed and chaptered on October 13, 2025. Dr. Serpa agreed that the implementation activities identified by staff were appropriate.

Members were provided the opportunity to comment. A member noted that a separate executive order on insulin and epinephrine pricing applies to Federally Qualified Health Centers and that such clinics must comply with both the executive order and this bill. The member suggested this information be included in the Board's educational materials regarding SB 40.

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

h. Senate Bill 41 (Wiener, Chapter 605, Statutes of 2025) Pharmacy Benefits

Dr. Serpa noted the measure was signed and chaptered on October 11, 2025. Dr. Serpa agreed that the implementation activities identified by staff were appropriate.

Members were provided the opportunity to comment. Members noted that some provisions of the bill may necessitate coordination with the Department of Managed Health Care regarding consumer facing benefits.

There were no public members in the Sacramento location. Members of the public participating via Webex were provided the opportunity to comment. A commenter agreed with dissemination of information on this bill to pharmacists but also recommended putting selected provisions of the bill into the pharmacy law book. A representative of CPhA noted their support of the implementation plan and collaboration with DMHC.

i. <u>Senate Bill 306 (Becker, Chapter 408, Statutes of 2025) Health Care Coverage: Prior Authorizations</u>

Dr. Serpa noted the bill requires health care service plans and insurers to temporarily exempt certain services from requiring prior authorization if 90% or more of requests for those services were approved in the previous calendar year. Dr. Serpa further noted the measure was signed and chaptered on October 6, 2025. Dr. Serpa agreed that the implementation activities identified by staff were appropriate.

Member Barker left the meeting at 11:30 a.m.

Members were provided the opportunity to comment. Members discussed the need for this legislation and provided examples.

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

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

Dr. Serpa noted that the bill was amended to its current version after the June Board meeting, and neither the Committee nor the Board had previously considered this bill. Dr. Serpa noted that the bill was vetoed by the governor on October 13, 2025, and therefore, the staff's recommended implementation activities were no longer applicable.

k. <u>Senate Bill 470 (Laird, Chapter 222, Statutes of 2025) Healing Arts: Bagley-Keene Open Meeting Act: Teleconferencing</u>

Dr. Serpa noted the measure was signed and chaptered on October 1, 2025. Dr. Serpa agreed that the implementation activities identified by staff were appropriate.

Members were provided the opportunity to comment. Members were grateful and noted it allows accessibility for board members.

There were no public members in the Sacramento location. Members of the public participating via Webex were provided the opportunity to comment. A commenter requested the Board clarify how the provisions of the law will apply to committee meetings.

l. <u>Senate Bill 497 (Wiener, Chapter 764, Statutes of 2025) Legally Protected Health Care Activity</u>

Dr. Serpa noted the measure was signed and chaptered on October 13, 2025. Dr. Serpa agreed that the implementation activities identified by staff were appropriate.

Members were provided the opportunity to comment. Members noted it may be helpful to have an FAQ related to what information and under which conditions pharmacists are required to provide information and further noted that some pharmacy software may share records across state lines. Members discussed providing examples and guidance with general scenarios beyond just the changes in the legislation.

There were no public members in the Sacramento location. Members of the public participating via Webex were provided the opportunity to comment. A commenter agreed with members and requested that the Board issue guidance to help pharmacies understand the new law. Another commenter agreed there could be confusion and FAQs with examples would be very helpful.

m. <u>Senate Bill 568 (Niello, Chapter 322, Statutes of 2025) Pupil Health: Epinephrine Delivery Systems: School Sites and Childcare Programs</u>

Dr. Serpa noted that neither the Committee nor the Board had previously considered this bill. Dr. Serpa detailed the bill expands the authority for pharmacies to provide a broader range of epinephrine delivery devices to local educational agencies, including school districts, county offices of

education, and charter schools, under existing safety and training requirements.

Dr. Serpa noted the measure was signed and chaptered on October 3, 2025. Dr. Serpa agreed that the implementation activities identified by staff were appropriate.

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

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

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

Dr. Serpa noted that the bill was vetoed by the governor on October 13, 2025, and therefore, the staff's recommended implementation activities are no longer applicable.

XI. Discussion of Enforcement Statistics

Dr. Serpa advised the meeting materials included a summary of enforcement statistics for the first three months of fiscal year 2025/26. The Board initiated 914 complaints and closed 747 investigations. As of September 30, 2025, the Board had 1,736 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.

There were no public members in the Sacramento location. Members of the public participating via Webex were provided the opportunity to comment. A commenter suggested adding which enforcement actions were related to the standard of care.

XII. Advisement of Future Committee Meeting Dates

Dr. Serpa advised the next meeting was scheduled for January 7, 2026.

XIII. Adjournment

The meeting adjourned at 11:46 a.m.

Attachment 2

Recommended Statutory Changes Related to Outsourcing Facilities
Business and Professions Code (BPC), Division 2, Chapter 9

Article 2

§ 4034. Outsourcing Facility

"Outsourcing facility" means a facility that meets all of the following:

(a) Is located within the United States of America at one geographic location or address that is engaged in the compounding of sterile drugs and nonsterile drugs.

(b) Has registered as an outsourcing facility with the federal Food and Drug Administration under Section 503B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 353b).

(c) Is doing business within or into California.

(d) Is licensed with the board as an outsourcing facility pursuant to Article 7.7 (commencing with Section 4129).

Article 7.7

§ 4129. Outsourcing Facility; License Required

(a) A facility registered as an outsourcing facility with the federal Food and Drug Administration (FDA) shall be concurrently licensed with the board as an outsourcing facility if it compounds sterile medication or nonsterile medication for ~~nonpatient-specific~~ distribution within or into California.

(b) A facility premises licensed with the board as a sterile compounding pharmacy shall not be concurrently licensed with the board as an outsourcing facility at the same location.

(c) The board may adopt regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) to establish policies, guidelines, and procedures to implement this article.

(d) The board shall review any formal requirements or guidance documents developed by the FDA regarding outsourcing facilities within 90 days after their release in order to determine whether revisions are necessary for any regulations promulgated by the board.

(e) An outsourcing facility licensed by the board dispensing patient-specific compounded preparations pursuant to a prescription for an individual patient shall not be required to be licensed as a pharmacy, but shall otherwise comply with the same requirements of a pharmacy.

§ 4129.1. Licensing Requirements

(a) An outsourcing facility that is ~~licensed~~ registered with the federal Food and Drug Administration (FDA) and with a~~n~~ geographical location or address in this state shall also be licensed by the board as an outsourcing facility before doing business within this state. The license shall be renewed annually and is not transferable.

(b) An outsourcing facility shall compound all sterile products and nonsterile products in compliance with regulations issued by the board and with federal current good manufacturing practices applicable to outsourcing facilities.

(c) An outsourcing facility license shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.

(d) An outsourcing facility license shall not be issued or renewed until the board does all of the following:

(1) Prior to inspection, reviews a current copy of the outsourcing facility's policies and procedures for sterile compounding and nonsterile compounding.

(2) Is provided with copies of all federal and state regulatory agency inspection reports, as well as accreditation reports, and certification reports of facilities or equipment of the outsourcing facility's premises conducted in the prior 12 months.

(3) Prior to inspection, receives a list of all sterile drugs and nonsterile drugs compounded by the outsourcing facility as reported to the FDA in the last 12 months.

(e) An outsourcing facility licensed pursuant to this section shall provide the board with all of the following:

(1) A copy of any disciplinary or other action taken by another state or the FDA within 10 days of the action.

(2) Notice within 24 hours of any recall notice issued by the outsourcing facility.

(3) A copy of any clinically related complaint it receives involving an outsourcing facility's compounded products from or involving any provider, pharmacy, or patient in California within 72 hours of receipt.

(4) Notice within 24 hours after learning of adverse effects reported or potentially attributable to the outsourcing facility's products.

§ 4129.2. Nonresident Outsourcing Facility; License Required

(a) An outsourcing facility that is ~~licensed~~ registered with the federal Food and Drug Administration (FDA) as an outsourcing facility and has a~~n~~ geographical location or address outside of this state but in the United States of America is a nonresident outsourcing facility. A nonresident outsourcing facility shall not compound sterile drug products or nonsterile drug products for distribution or use into this state without an outsourcing license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable.

(b) A nonresident outsourcing facility shall compound all sterile products and nonsterile products to be distributed or used in this state in compliance with regulations of the board and with federal current good manufacturing practices applicable to outsourcing facilities.

(c) A license for a nonresident outsourcing facility shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and any regulations adopted by the board. The nonresident outsourcing facility shall reimburse the board for all actual and necessary costs incurred by the board in conducting an inspection of the nonresident outsourcing facility at least once annually pursuant to subdivision (x) of Section 4400.

(d) A license for a nonresident outsourcing facility shall not be issued or renewed until the board:

(1) Prior to inspection, reviews a current copy of the nonresident outsourcing facility's policies and procedures for sterile compounding and nonsterile compounding.

(2) (A) Is provided with copies of all federal and state regulatory agency inspection reports, as well as accreditation reports, and certification reports of facilities or equipment of the nonresident outsourcing facility's premises conducted in the prior 12 months.

(B) For purposes of this paragraph, "state" refers to the state in which the nonresident outsourcing facility resides.

(3) Prior to inspection, receives a list of all sterile drug products and nonsterile drug products compounded by the pharmacy as reported to the FDA within the prior 12 months.

(e) A nonresident outsourcing facility licensed pursuant to this section shall provide the board with all of the following:

(1) A copy of any disciplinary or other action taken by another state or the FDA within 10 days of the action.

(2) Notice within 24 hours of any recall notice issued by the nonresident outsourcing facility.

(3) A copy of any complaint it receives involving an outsourcing facility's compounded products from or involving any provider, pharmacy, or patient in California within 72 hours of receipt.

(4) Notice within 24 hours after learning of adverse effects reported or potentially attributable to a nonresident outsourcing facility's products.

Article 19

§ 4303.1 Outsourcing Facility: License Canceled, Revoked or Suspended by Operation of Law

If the federal Food and Drug Administration (FDA) cancels, revokes, or suspends an outsourcing facility's registration for any reason, any license issued pursuant

to Section 4129.1 or 4129.2 shall be immediately canceled, revoked, or suspended by operation of law.

Attachment 3

Compounding Regulations Frequently Asked Questions (FAQs) *DRAFT*

Title 16, California Code of Regulations (CCR),
Sections 1735 et seq., 1736 et seq., 1737 et seq., and 1738 et seq.

Regulations Effective October 1, 2025

This document is intended solely to assist pharmacists and pharmacies with understanding the California regulations governing nonsterile compounding, sterile compounding, hazardous drugs, and radiopharmaceuticals that took effect on October 1, 2025. It is not nor is it a substitute for legal advice. References to specific sections of the regulations are provided to aid the users of this document. Licensees are strongly encouraged to read the regulations in their entirety to have full understanding of the requirements. Licensees are also reminded that the regulations are in addition to (not in replacement of) applicable state and federal law and USP standards, and are advised that this document only addresses the additional requirements that apply under the regulations. All references in this document to California Business and Professions Code (BPC) sections are in Division 2, Chapter 9. All references in this document to California Code of Regulations (CCR) sections are in Title 16. Licensees are also advised that this is a dynamic document, which may be updated periodically.

General Compounding FAQs:

1) **Question: How do the previous California regulations addressing compounding correspond to the current compounding regulations that took effect on October 1, 2025?**

   Answer:

Type of Compounding	Previous CCR	Current CCR	USP Related Chapters
Nonsterile compounding	1735 - 1735.8	1735 – 1735.15	USP 795
Sterile compounding	1735 – 1735.8 and 1751 – 1751.10	1736 – 1736.21	USP 797
Handling of hazardous drugs	1735 – 1735.8 and 1751 – 1751.10	1737 – 1737.17	USP 800

Radiopharmaceutical-preparation, compounding, dispensing and repackaging	1708.3 - 1708.5, 1735 – 1735.8, and 1751 -1751.10	1738 – 1738.14	USP 825

2) Question: Can a facility have more than one designated person (DP) and does the DP need to be a pharmacist?

Answer:
For nonsterile and sterile compounding, "designated person(s)" means one or more individuals assigned by the pharmacist-in-charge (PIC) to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of the compounded nonsterile preparations (CNSPs)/ compounded sterile preparations (CSPs), as applicable. Nothing in this definition allows for a designated person to exceed the scope of their issued license. When the designated person is not a pharmacist, the PIC must review all practices related to the operations of the facility that require the professional judgment of a pharmacist. Nothing in this definition prohibits the PIC from also serving as the designated person.

For hazardous drugs (HDs), in a pharmacy, the "designated person(s)" must be approved by the PIC to be responsible and accountable for the performance and operation of the facility and personnel as related to the handling of HDs. The designated person(s) shall not exceed the scope of their issued license. When a designated person is not a pharmacist, the PIC must review all practices related to the operations of the facility that require the judgment of a pharmacist.

For radiopharmaceuticals, "designated person" means a pharmacist identified as assigned, responsible, and accountable for the performance and operation of the radiopharmaceutical processing facility and for personnel who prepare, compound, dispense, and repackage radiopharmaceuticals. Nothing in this definition prohibits the PIC from also serving as the designated person.

[Reference: CCR 1735(b), 1736(c), 1737.2(a)(1), 1738(c)]

3) Question: When can a facility compound a drug in shortage?

Answer:
For nonsterile compounding: A facility may compound a drug in shortage

when the drug product appears in an American Society of Health-System Pharmacists (ASHP) Drug Shortages List or FDA Drug Shortages Database of drugs that are in short supply at the time of compounding or within 60 days of the end of the shortage, or in a health care facility licensed pursuant to Health and Safety Code Section 1250 where the drug product cannot be obtained from the manufacturer or wholesaler and documentation is maintained.

For sterile compounding: A facility may compound a drug in shortage when that drug product appears in an ASHP Drug Shortages List or FDA Drug Shortages Database of drugs that are in short supply at the time of compounding and at the time of dispensing, or in a health care facility licensed pursuant to Health and Safety Code Section 1250 where the drug product cannot be obtained from the manufacturer or wholesaler and documentation is maintained.

[Reference: CCR 1735.1(e)(1)(A), 1736.1(e)(1)(A)]

4) **Question: Is an audit trail required if I make a change on any of my compounding records?**

Answer: For nonsterile compounding, sterile compounding, and the processing of radiopharmaceuticals, the regulations require that records be created and maintained in a manner to provide an audit trail for revisions and updates of each record document. Prior versions of each record must be maintained for at least three years from the date the record was created, modified, or relied on, in a readily retrievable format and include the changes to the document, identification of the individual who made each change, and the date of each change.

[Reference: CCR 1735.14(b), 1736.20(b), 1738.9(d)]

5) **Question: Where can I submit licensing questions to the Board?**

Answer: Questions regarding your compounding license, license renewal, or general licensing questions can be submitted to Compounding.Pharmacy@dca.ca.gov.

6) **Question: How do the regulations define "essentially a copy" of a commercially available drug product for purposes of nonsterile or sterile compounding?**

Answer:

Under the regulations, "essentially a copy" of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (API(s)) as the commercially available drug product, except that it does not include any preparation in which there has been a change made for an identified individual patient that produces for that patient a clinically significant difference, as verified and documented by the pharmacist, between that compounded preparation and the comparable commercially available drug product.

[Reference: CCR 1735(d), 1736(e)]

7) **Question: What is required before a trainer is allowed to provide training to other pharmacy staff performing nonsterile or sterile compounding duties?**

Answer:
Any person assigned to provide the training specified in section 1735.2 (applicable to nonsterile compounding) or section 1736.2 (applicable to sterile compounding) shall have demonstrated competency in the skills in which the person will provide training or observe and measure competency described in the facility's standard operating procedures (SOPs).

[Reference: CCR 1735.2(c), 1736.2(e)]

8) **Question: As the designated person, how do I document a garbing accommodation?**

Answer: For nonsterile or sterile compounding, any garbing accommodations provided by the designated person shall be documented, and the documentation shall include the name of the individual granted the accommodation, date granted and description of the reasons for granting the accommodation.

[Reference: CCR 1735.3(f), 1736.3(e)]

9) **Question: Does the compounding record (CR) need to be one document?**

Answer:
For nonsterile or sterile compounding, a CR shall, upon request, be produced as a single document.

[Reference: CCR 1735.7(c), 1736.11(c)]

10) Question: Are a facility's SOPs required to address the handling of temperature sensitive CNSPs/CSPs?

Answer: The facility's SOPs for nonsterile compounding must describe the validated processes for storage, for shipping containers (as applicable), and for transportation of temperature sensitive CNSPs (as applicable) to preserve quality standards for integrity, quality and labeled strength. For sterile compounding, there must be written procedures for qualification of storage, shipping containers and transportation of temperature sensitive CSPs to preserve quality standards for integrity, quality, and labeled strength.

[Reference: CCR 1735.11(a)(2)(D), 1736.17(g)]

Nonsterile Compounding FAQs

11) Question: If the pharmacist does not follow the manufacturer's instructions when reconstituting a commercially available drug product, is this considered compounding?

Answer:
Yes, reconstitution of a conventionally manufactured drug product that is not done in accordance with the FDA approved directions is considered compounding.

[Reference: CCR 1735.1(b)]

12) Question: How much CNSP can a pharmacy compound in advance and store in the pharmacy prior to receiving a patient-specific prescription for the CNSP?

Answer:
A limited quantity of a CNSP may be prepared and stored in advance of receipt of a patient specific prescription document where it is necessary, and solely in such quantity to ensure continuity of care of individual patients based on a documented history of prescriptions for those patient populations.

[Reference: CCR 1735.1(c)]

13) Question: How much CNSP can a pharmacy furnish to a veterinary office

for use by the veterinarian?

Answer:
A reasonable quantity of CNSP may be furnished to a veterinary office for use by the veterinarian that is sufficient:

(1) for administration or application to veterinary patients solely in the veterinarian's office.

(2) for furnishing of no more than a 14-day supply, for an individual patient, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing.

[Reference: CCR 1735.1(d)]

14) Question: Do gloves need to be wiped or changed when performing nonsterile compounding?

Answer:
Gloves must be wiped or replaced before beginning a CNSP that contains different components.

[Reference: CCR 1735.3(d)]

15) Question: How long is the pharmacy required to maintain the source referenced to support the assigned beyond-use date (BUD)?

Answer:
If a source is referenced to support an assigned BUD, the source referenced must be readily retrievable at the time of compounding and must be maintained for three (3) years from the date each CNSP is dispensed.

[Reference: CCR 1735.7(a)(1)]

16) Question: If the names of the compounding facility and the dispensing facility is different, are they both required to be included on a CNSP's label?

Answer:

Yes, a CSNP's label shall include the name of the compounding facility and the name of the dispensing facility, if different.

[Reference: CCR 1735.9(a)(2)]

17) Question: Can a facility use antimicrobial effectiveness testing provided by a current FDA-registered drug establishment or an outsourcing facility?

Answer: Yes, if the testing is compliant with USP Chapter 51, Antimicrobial Effectiveness Testing. If such testing is used, or if relying upon current published peer-reviewed literature sources, the reference or test in its entirety shall be readily retrievable in accordance with Business and Professions Code section 4081 for three years from the last date the CNSP was dispensed.

[Reference: CCR 1735.10(c)]

18) Question: Prior to compounding, must the facility's SOPs for nonsterile compounding include how the facility selected the ingredients for each CNSP?

Answer: Yes, the facility's SOPs for nonsterile compounding must include the methods a pharmacist will use to determine and approve the ingredients and the compounding process for each preparation before compounding begins.

[Reference: CCR 1735.11(a)(2)(C)]

19) Question: What do the regulations say about adding flavoring?

Answer:
Under the regulations, a facility that limits its compounding to combining a flavoring agent with a prescribed FDA approved drug in an oral liquid dosage form at the request of a prescriber, patient, or patient's agent is exempt from certain sections of the regulations, as specified in subdivision (i) of section 1735.1. However, for such facilities, section 1735.15 requires, among other things, that the pharmacist adding the flavoring agent must document the compounding in the prescription or compounding record.

A facility that performs any other form of nonsterile compounding at any time does not qualify for the exemption described above.

Licensees are advised to read the regulations referenced below in their entirety for a full understanding of the requirements regarding adding flavoring agents.

[Reference: CCR 1735.1(i), 1735.15]

Sterile Compounding FAQs

20) Question: When can a pharmacy compound for immediate administration or immediate use?

Answer:
Except as described in the two bullet points below, compounded sterile preparations (CSPs) for direct and immediate administration as provided in USP Chapter 797 shall only be compounded in those limited situations where the failure to administer such CSP could result in loss of life or intense suffering of an identifiable patient.

- If the sterile compounding equipment or environment fail(s) to meet any required specification, after attempts to remediate pursuant to the facility's SOPs are unsuccessful, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering of an identifiable patient; however, this provision may only be used for 48 hours after such failure(s).

- If the sterile compounding equipment or environment fail(s) to meet any required specification in a critical access hospital, as defined in section 1395i-4(c)(2)(B) of title 42, United States Code, after attempts to remediate pursuant to the facility's SOPs are unsuccessful, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering of an identifiable patient; however, this provision may only be used for 120 hours after such failure(s).

  Licensees are advised to read the regulation in its entirety for a full understanding of the requirements that apply to immediate-use CSPs.

  [Reference: CCR 1736.1(b)]

21) Question: How much CSP can a pharmacy furnish to a veterinary office for use by the veterinarian?

Answer:

A reasonable quantity of a CSP may be furnished to a veterinary office for use by the veterinarian that is sufficient:

(1) for administration or application to veterinary patients solely in the veterinarian's office.

(2) for furnishing of not more than a 7-day supply for an individual patient, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing, with the exception of a topical ophthalmic where up to a 28-day supply may be furnished to the veterinarian's office for an individual patient; provided that such topical ophthalmics shall be compliant with USP Chapter 797 section 14.5, Multiple-Dose CSPs.

[Reference: CCR 1736.1(d)]

22) Question: Can garbing and hand hygiene competencies and aseptic manipulation competencies from one premises be used for another premises?

Answer:
Yes, if all of the following conditions are met:

- The Standard Operating Procedures (SOPs) required by section 1736.17 related to compounding are identical.
- The Secondary Engineering Control (SEC) facility designs are sufficiently similar to accommodate the use of the same SOPs.
- The Primary Engineering Controls (PECs) are of the same type and sufficiently similar to accommodate the use of the same SOPs describing use and cleaning.

[Reference: CCR 1736.2(b)]

23) Question: What happens if compounding personnel fail any part of aseptic manipulation training and competency evaluation?

Answer:
Compounding personnel or persons with direct supervision and control of compounding personnel who fail any aspect of the aseptic manipulation ongoing training and competency evaluation shall not be involved in compounding of a CSP until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs.

A person with only direct supervision and control of personnel who fails any aspect of the aseptic manipulation ongoing training and competency evaluation may continue to provide only direct supervision and control of personnel for no more than 30 days after a failure of any aspect while applicable aseptic manipulation ongoing training and competency evaluation results are pending.

[Reference: CCR 1736.2(d)]

24) Question: If the pharmacy uses a Segregated Compounding Area (SCA), can a wall be considered part of the SCA?

Answer: Yes, as long as the wall is smooth, impervious, free from cracks and crevices, and non-shedding so it can be easily cleaned and disinfected and to minimize spaces in which microorganisms and other contaminants can accumulate.

[Reference: CCR 1736.4(b)]

25) Question: Does the temperature in the designated compounding area, such as an SCA, need to be monitored?

Answer: The temperature shall be monitored in each room of the designated compounding area each day that compounding is performed, either manually or by a continuous recording device.

[Reference: CCR 1736.4(c)]

26) Question: If on October 1, 2025, a pharmacy has an existing secondary engineering control that has a pass-through that is not an interlocking device, is the pharmacy required to install an interlocking device?

Answer:
No, an existing secondary engineering control that has a pass-through that is not an interlocking device may continue to be used if the SOPs document that two doors may not be opened at the same time.

Where a pass-through is installed in a secondary engineering control After October 1, 2025, the doors must be interlocking.

[Reference: CCR 1736.4(d)]

27) Question: What standards apply to the certification and testing of the pharmacy's classified compounding areas?

Answer:
In addition to the requirements of USP Chapter 797, testing and certification of all ISO classified areas shall be performed by a qualified technician in accordance with Controlled Environment Testing Association's (CETA) Certification Guide for Sterile Compounding Facilities (CAG-003, Revised October 2022). The CETA standard(s) used to perform certification testing in all ISO classified areas shall be recorded on the report issued by the certifying technician in accordance with the Certification Guide for Sterile Compounding Facilities.

[Reference: CCR 1736.5]

28) Question: What standards apply to environmental sampling?

Answer:
In addition to the requirements of USP Chapter 797, environmental sampling shall be done in accordance with the Controlled Environment Testing Association's Certification Application Guide USP <797> Viable Environmental Monitoring for Sterile Compounding Facilities (CAG-009, Revised September 2020).

[Reference: CCR 1736.6]

29) Question: If the pharmacy is using an incubator, how should the incubator be maintained?

Answer:
Incubators used by the facility shall be cleaned, maintained, calibrated, and operated in accordance with manufacturers' specifications. For incubators without specific manufacturers' specifications, cleaning shall take place at least every 30 days and calibration shall take place at least every 12 months. Temperatures must be monitored either manually or by a continuous recording device during incubation, and the results shall be reviewed and documented as described in the facility's SOPs.

[Reference: CCR 1736.9(b)]

30) Question: Can facilities compound with FDA Category 1 bulk drug substances?

Answer:

If a component included in the published 503A Category 1 Bulk Drug Substances List is used, it must be found suitable for sterile drug preparations as provided in USP Chapter 797, Section 9.3 Components. The facility's SOPs shall establish a process to determine the quality of the API, and the SOPs, which must comply with USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding, must define both the methods by which the pharmacist compounding or supervising the compounding will ensure the quality of compounded drug preparations and the methods used to determine and approve components and the compounding process for each preparation before compounding begins.

Licensees are advised to read Article 4.6 (Sterile Compounding) of the regulations in its entirety for a full understanding of the requirements that apply to components used to compound CSPs.

[Reference: CCR 1736.9(f), 1736.17(a)]

31) Question: Can a pharmacy compounding CSP from a nonsterile component send the CSP to another facility for sterilization (for example, by e-Beam radiation)?

Answer:
Section 1736.10 of the regulations describes requirements, in addition to the requirements in USP Chapter 797, that apply to sterilization and depyrogenation. Subdivision (e) of section 1736.10 states that no compound of a CSP from nonsterile components shall be prepared when the licensed location cannot also sterilize the CSP as described in section 1736.10.

[Reference: CCR 1736.10(e)]

32) Question: Is a USP Category 1 injectable CSP compounded from a nonsterile component required to be tested for endotoxins prior to dispensing?

Answer:
Yes. A pharmacist performing or who has direct supervision and control of compounding personnel is responsible for ensuring injectable CSPs made from nonsterile components, regardless of the USP Category, are tested to ensure that they do not contain excessive bacterial

endotoxins, as established in USP Chapter 85, Bacterial Endotoxins. Results shall be
reviewed and documented in the compounding record prior to furnishing.

[Reference: CCR 1736.12(c)]

33) Question: Can a CNSP compounded following USP 795 be used as a stock solution to compound a CSP?

Answer:
A compounded stock solution intended for use in a CSP must comply with all provisions of Article 4.6 (Sterile Compounding) of the regulations and USP Chapter 797 Category 1, Category 2, or Category 3.

[Reference: CCR 1736.16(a)]

34) Question: Can a pharmacy obtain a CSP for use as a component from an outsourcing facility?

Answer:
Yes, as long as the outsourcing facility is licensed in California.

Note: To verify if an outsourcing facility is licensed in California, go to: https://search.dca.ca.gov/?BD=7200&TP=180

[Reference: CCR 1736.16(b)]

HAZARDOUS DRUGS (HD) FAQs

35) Question: Our facility compounds HD in a containment secondary engineering control (C-SEC) which has a pass-through without interlocking doors. Under the regulations that took effect on October 1, 2025, is our facility exempt from changing to interlocking doors since the facility has an existing sterile compounding license?

Answer:
No, although the regulations provide a grace period to come into compliance. Where there is a pass-through in a C-SEC, the doors must be gasketed and interlocking by January 1, 2027.

[Reference: CCR 1737.5(c)]

36) Question: Our facility installed a pass-through in our cleanroom, but it is not a HEPA purge type pass-through. Do the regulations that took effect on October 1, 2025, require that we replace and install a new pass-through?

Answer:
On or after January 1, 2028, prior to installing a new pass-through, a facility must consider the use of a HEPA purge type pass-through. Documentation shall be maintained showing compliance with this requirement if such a pass-through is not used.

[Reference: CCR 1737.5(d)]

Attachment 4

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

Draft Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment

Business and Professions Code Section 4102 requires the pharmacist-in-charge of each pharmacy licensed under Chapter 9 of Division 2 of the Business and Professions Code to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed by July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days of any of the following: (1) a new pharmacy license is issued; (2) there is a change of pharmacist-in-charge, and they become the new pharmacist-in-charge of a pharmacy; or (3) there is a change in the location of the pharmacy to a new address. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

The self-assessment must be completed in its entirety. It may be completed online and printed, initialed, and signed (use original signatures or digital signatures that comply with California Code of Regulations, title 16, section 1700). The completed form shall be kept on file in the pharmacy and made available to the Board upon request. Do not copy a previous assessment.

Notes:

- **If a hospital pharmacy dispenses prescriptions for discharge patients/outpatients/employees/walk-in patients, it must complete both this self-assessment and the Hospital Pharmacy Self-Assessment, which includes the section titled dispenses discharge/outpatient/employee/walk-in customer prescriptions (17M-14).**
- **Any pharmacy that compounds drug products must also complete the Compounding Self-Assessment (17M-39).**
- **Any pharmacy that operates an automated unit dose system (AUDS) and/or an automated patient dispensing system (APDS) must also complete the Automated Drug Delivery System (ADDS) Self-Assessment (17M-112).**
- **This self-assessment is not an all-inclusive compilation of all pharmacy laws and regulations. The pharmacist-in-charge is responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy, regardless of whether such laws or regulations are referenced on this self-assessment.**

Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Pharmacy Name:				
Address:		**Telephone:**		
License #:		**Expiration Date:**		
Other Permit #:		**Expiration Date:**		
Licensed Sterile Compounding License#		**Expiration Date:**		
Licensed Remote Dispensing Site Pharmacy License #		**Expiration Date:**		
ADDS License(s)		**Expiration Date**		
DEA Registration #		**Expiration Date:**		
Date of DEA Inventory:				
Hours:	Weekdays	Saturday	Sunday	24 Hours
Pharmacist-in-Charge:		**License#:**		
		Expiration Date:		

Services to be Provided Check all that apply.	
	Retail
	Mail Order
	Call Center
	Board and Care
	Skilled Nursing Facility
	Correctional Facility
	Central Fill
	Specialty Pharmacy
	Home Health Care/ Infusion Center
	List Others

Pharmacy Staff (pharmacists, intern pharmacists, pharmacy technicians):

Attach additional sheets as necessary

(**APH**=Advanced Pharmacist Practitioner **DEA**= Drug Enforcement Administration **INT**=Intern **TCH**=Technician)

Name:		**RPH#:**		**Expiration Date:**	
		APH#:		**Expiration Date:**	
		DEA#:		**Expiration Date:**	
Name:		**RPH#:**		**Expiration Date:**	
		APH#:		**Expiration Date:**	
		DEA#:		**Expiration Date:**	
Name:		**RPH#:**		**Expiration Date:**	
		APH#:		**Expiration Date:**	
		DEA#:		**Expiration Date:**	
Name:		**RPH#:**		**Expiration Date:**	
		APH#:		**Expiration Date:**	
		DEA#:		**Expiration Date:**	
Name:		**RPH#:**		**Expiration Date:**	
		APH#:		**Expiration Date:**	
		DEA#:		**Expiration Date:**	

Continue on next page.

PIC Initials: Date:

Name:		**INT#:**		**Expiration Date:**	
Name:		**INT#:**		**Expiration Date:**	
Name:		**INT#:**		**Expiration Date:**	
Name:		**INT#:**		**Expiration Date:**	

Name:		**TCH#:**		**Expiration Date:**	
Name:		**TCH#:**		**Expiration Date:**	
Name:		**TCH#:**		**Expiration Date:**	
Name:		**TCH#:**		**Expiration Date:**	
Name:		**TCH#:**		**Expiration Date:**	
Name:		**TCH#:**		**Expiration Date:**	
Name:		**TCH#:**		**Expiration Date:**	
Name:		**TCH#:**		**Expiration Date:**	

Please mark the appropriate box for each question. If "No," enter an explanation in the "Corrective Action Plan" section. If more space is needed, you may add additional sheets.

All references to California Code of Regulations (CCR) are to Title 16 unless otherwise noted. Additionally, Business and Professions Code is referenced as BPC. Read references to understand all the requirements of law and regulations.

Facility Requirements/Operations Standards/Security

Reference	Question #	Topic	Yes	No	N/A	Corrective Action Plan
CCR 1764 CCR 1714	1.1	The pharmacy has an area suitable for confidential patient consultation				
BPC 4116 BPC 4059.5 CCR 1714	1.2	The pharmacy is secure to prevent unauthorized access and effective control to prevent theft				
CCR 1714	1.3	The pharmacy is clean, orderly, and free of pests				
CCR 1714	1.4	The pharmacy is equipped with a sink with hot and cold running water for pharmaceutical purposes.				
BPC 4122 BPC 4058 BPC 4032 CCR 1707.6	1.5	The pharmacy has required notices and licenses posted in public view allowing for use of the notices as intended.				
BPC 4013	1.6	The pharmacy is subscribed to the Board's email notification system.				

Please mark the appropriate box for each question. If "No," enter an explanation in the "Corrective Action Plan" section. If more space is needed, you may add additional sheets.

Reference	Question #	Topic	Yes	No	N/A	Corrective Action Plan
BPC 4113.7 BPC 4317	1.7	The pharmacy does not establish quotas related to pharmacy personnel tasks or duties.				
BPC 4113	1.8	The pharmacy notifies the Board when a change in PIC occurs.				
CC 56.10[1] CC 56.101 CCR 1717.1 CCR 1717.4 CCR 1764	1.9	Pharmacy records and prescriptions are maintained in a secure and confidential manner, and any destruction of records containing medical information is done in a manner that preserves the confidentiality of the information contained therein.				

[1] California Civil Code is referenced as CC

Please mark the appropriate box for each question. If "No," enter an explanation in the "Corrective Action Plan" section. If more space is needed, you may add additional sheets.

Delivery of Drugs/Drug Stock

Reference	Question #	Item	Yes	No	N/A	Corrective Action Plan
BPC 4059.5 HSC 11209[2]	2.1	The pharmacy receives dangerous drugs and devices consistent with legal requirements.				
21 USC 360eee-1[3]	2.2	The pharmacy complies with Drug Supply Chain Security Act provisions.				
21 USC 331 21 USC 351 21 USC 352 BPC 4059.5 BPC 4169 BPC 4342 HSC 111255 HSC 111335 CCR 1714	2.3	The drug stock is within expiry and maintained to prevent misbranding and adulteration.				
BPC 4126.5 BPC 4059 BPC 4059.5 BPC 4163	2.4	Dangerous drugs and devices are only obtained from or furnished to persons or entities authorized by pharmacy law.				

[2] California Health and Safety Code is referenced as HSC
[3] United States Code is referenced as USC

Please mark the appropriate box for each question. If "No," enter an explanation in the "Corrective Action Plan" section. If more space is needed, you may add additional sheets.

Pharmacist-in-Charge (PIC)

Reference	Question #	Item	Yes	No	N/A	Corrective Action Plan
BPC 4113 CCR 1709.1	3.1	The pharmacy has designated a PIC and vested the PIC with adequate authority to assure the pharmacy's compliance with relevant laws.				
CCR 1709.1	3.2	The PIC only serves as PIC of this pharmacy, or if they serve as PIC of another pharmacy, that pharmacy is separated from this pharmacy by a driving distance of no more than 50 miles.				
BPC 4113	3.3	The PIC has adequate authority to establish staffing levels, and actually makes staffing decisions.				
BPC 4113	3.4	The PIC has adequate authority to establish the pharmacist to pharmacy technician ratio, and actually determines the ratio in accordance with law.				

Please mark the appropriate box for each question. If "No," enter an explanation in the "Corrective Action Plan" section. If more space is needed, you may add additional sheets.

Pharmacy Personnel

Reference	Question #	Item	Yes	No	N/A	Corrective Action Plan
BPC 4113.5 BPC 4113.6 BPC 4114 BPC 4115 BPC 4115.5 BPC 4301 CCR 1714.3	4.1	The pharmacy complies with applicable staffing requirements.				
BPC 680 CCR 1793.7	4.2	Pharmacy personnel are appropriately identified.				
BPC 4113	4.3	The pharmacy has trained personnel on the requirements to notify store management of any conditions that present an immediate risk of death, illness, or irreparable harm.				
BPC 4052 BPC 4301	4.4	Pharmacists have adequate authority to exercise professional judgement and comply with the law.				
BPC 4023.5 BPC 4038 BPC 4114 BPC 4115 BPC 4115.5 CCR 1726 CCR 1793 CCR 1793.2 CCR 1793.7	4.5	Intern pharmacists, pharmacy technicians and pharmacy technician trainees are solely performing authorized duties under the supervision of a pharmacist.				

Please mark the appropriate box for each question. If "No," enter an explanation in the "Corrective Action Plan" section. If more space is needed, you may add additional sheets.

Reference	Question #	Item	Yes	No	N/A	Corrective Action Plan
CCR 1717 CCR 1712 CCR 1793.7	4.6	All prescriptions filled or refilled by nonpharmacist authorized personnel are checked by a pharmacist and documented.				
BPC 4115.5	4.7	Externships in which a pharmacy technician trainee is participating are for a period of no fewer than 120 hours and no more than 140 hours, unless the training involves rotation between a community and hospital pharmacy, in which case the externship does not exceed 340 hours.				
CCR 1793.7	4.8	The pharmacy has a job description for pharmacy technicians.				
CCR 1793.3	4.9	Non-licensed personnel are supervised by pharmacists and are permitted to perform the duties specified in CCR section 1793.3(a).				

Please mark the appropriate box for each question. If "No," enter an explanation in the "Corrective Action Plan" section. If more space is needed, you may add additional sheets.

Prescription Requirements

Reference	Question #	Item	Yes	No	N/A	Corrective Action Plan
BPC 4052 BPC 4069 CCR 1707.2 CCR 1707.3 CCR 1707.5 CCR 1714 CCR 1764	5.1	A pharmacist provides patient consultation as required by law, including any time a pharmacist deems it warranted in the exercise of his or her professional judgment, and in a confidential manner.				
CCR 1707.2	5.2	If prescription medication is mailed or delivered, written notice about the availability of consultation is provided.				
CCR 1707.1	5.3	The pharmacy maintains medication profiles on all patients who have prescriptions filled in that pharmacy except when the pharmacist has reasonable belief that the patient will not continue to obtain prescription medications from that pharmacy.				
BPC 688	5.4	The pharmacy has the capability to receive an electronic prescription on behalf of a patient.				

Please mark the appropriate box for each question. If "No," enter an explanation in the "Corrective Action Plan" section. If more space is needed, you may add additional sheets.

Reference	Question #	Item	Yes	No	N/A	Corrective Action Plan
CCR 1707.3	5.5	A pharmacist reviews a patient's drug therapy and medication record prior to consultation.				
BPC 4073 BPC 4074 BPC 4076 BPC 4076.5 BPC 4076.6 BPC 4076.7 BPC 4076.8 CCR 1707.5 CCR 1717 CCR 1744 21 CFR 290.5	5.6	Prescriptions are appropriately labeled, and appropriate warning labels are affixed.				
BPC 4040 BPC 4070 BPC 4071 CCR 1712 CCR 1717	5.7	Orally or electronically transmitted prescriptions transmitted by the prescriber or prescriber's agent are only received by a pharmacist or pharmacy intern and document the required information.				
BPC 4067	5.8	Internet prescriptions for delivery in this state are only dispensed or furnished pursuant to an appropriate prior examination of the human or animal.				

Please mark the appropriate box for each question. If "No," enter an explanation in the "Corrective Action Plan" section. If more space is needed, you may add additional sheets.

Reference	Question #	Item	Yes	No	N/A	Corrective Action Plan
BCP 4073 BCP 4073.5	5.9	The pharmacy complies with generic substitution requirements.				
15 USC 1473 16 CFR[4] 1700.15 CCR 1717	5.10	The pharmacy complies with child-resistant container and senior-adult ease-of-opening tested container requirements.				
21 CFR 310.515 21 CFR 201.57 21 CFR 208.24	5.11	Package inserts, black box warnings, and medication guides are provided as required.				
BPC 4064 BPC 4064.5	5.12	The pharmacy dispenses not more than a 90-day supply of dangerous drugs where allowed.				
BPC 4119.2 BPC 4119.4 BPC 4119.8 BPC 4119.9 EDC 49414[5] EDC 49414.3 EDC 49414.7	5.13	The pharmacy furnishes albuterol, naloxone hydrochloride and/or epinephrine to a school or other authorized entity pursuant to a standing order or as otherwise authorized by law.				
BPC 4062 BPC 4064	5.14	The pharmacy follows emergency refill provisions.				

[4] Code of Federal Regulations is referenced as CFR
[5] California Education Code is referenced as EDC

Please mark the appropriate box for each question. If "No," enter an explanation in the "Corrective Action Plan" section. If more space is needed, you may add additional sheets.

Reference	Question #	Item	Yes	No	N/A	Corrective Action Plan
CCR 1717.5	5.15	The pharmacy's auto-refill program meets the requirements of the law.				
CCR 1761	5.16	Prior to dispensing a prescription, where necessary, a pharmacist contacts the prescriber to obtain information needed to validate the prescription.				
BPC 688 BPC 733 BPC 4115 CCR 1717 CCR 1717.1	5.17	A prescription is transferred at the request of the patient.				

Quality Assurance/Medication Error Reporting Requirements

Reference	Question #	Item	Yes	No	N/A	Corrective Action Plan
BPC 4125 CCR 1711	6.1	The pharmacy has a quality assurance program that meets the requirements of the law and regulation.				
BPC 4113.1	6.2	The pharmacy reports medication errors to an entity approved by the Board as required by law.				
CCR 1711	6.3	The pharmacist communicates with the patient or patient's agent and physician that a medication error has occurred.				

Please mark the appropriate box for each question. If "No," enter an explanation in the "Corrective Action Plan" section. If more space is needed, you may add additional sheets.

Record Keeping Requirements

Reference	Question #	Item	Yes	No	N/A	Corrective Action Plan
BPC 4081 BPC 4105 BPC 4052.04 BPC 4059.5 BPC 4113.1 CCR 1717.1 CCR 1717.5 CC 56.101	7.1	Pharmacy records are maintained, able to be readily retrieved, and retained as required by law				
BPC 4081 BPC 4105	7.2	The pharmacy has digitized its records consistent with legal provisions.				
BPC 4105 CCR 1707	7.3	The pharmacy has received a waiver to store records off-site and maintains records on the licensed premises as required by law.				

Please mark the appropriate box for each question. If "No," enter an explanation in the "Corrective Action Plan" section. If more space is needed, you may add additional sheets.

Policies and Procedures

The pharmacy has policies and procedures covering the following matters:

Reference	Question #	Item	Yes	No	N/A	Corrective Action Plan
BPC 4104	8.1	Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired.				
BPC 4104	8.2	Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs.				
CCR 1714.1	8.3	Operation of the pharmacy during the temporary absence of a pharmacist for breaks and meal periods.				
CCR 1717.1 CC 56.10 CC 56.101	8.4	Confidentiality of medical information				
BPC 4059.5	8.5	Delivery of dangerous drugs to a secure storage facility when the pharmacy is closed.				

Please mark the appropriate box for each question. If "No," enter an explanation in the "Corrective Action Plan" section. If more space is needed, you may add additional sheets.

Reference	Question #	Item	Yes	No	N/A	Corrective Action Plan
BPC 733	8.6	Actions to be taken to ensure that patients have timely access to prescribed drugs and devices despite a pharmacist's refusal to dispense on ethical, moral or religious grounds				
CCR 1707.5	8.7	Helping patients with limited or no English proficiency to understand information on the prescription label				
CCR 1715.65	8.8	Inventory reconciliation reporting requirements.				
BPC 4081 CCR 1793.7	8.9	Pharmacy personnel and operations				
CCR 1717.5	8.10	Auto-refill program				
CCR 1711	8.11	Quality assurance for medication errors				
BPC 4113.5 CCR 1714.3	8.12	Community pharmacy staffing				
BPC 4119.3[6]	8.13	Repackaging services				

[6] Formerly BPC 4052.7.

Please mark the appropriate box for each question. If "No," enter an explanation in the "Corrective Action Plan" section. If more space is needed, you may add additional sheets.

Controlled Substances

Reference	Question #	Item	Yes	No	N/A	Corrective Action Plan
21 CFR 1304.04 21 CFR 1304.11	9.1	The pharmacy completes an inventory of all controlled substances every two years.				
CCR 1715.65	9.2	The pharmacy complies with inventory activities and reconciliation requirements.				
CCR 1715.6	9.3	The pharmacy reports drug losses to the Board within the time limits required by law and regulation.				
HSC 11165	9.4	The pharmacy reports to the CURES system within one working day.				
21 CFR 1304.04 21 CFR 1305.03 21 CFR 1305.12 21 CFR 1305.13 21 CFR 1305.21 21 CFR 1305.22	9.5	The pharmacy complies with applicable federal laws related to the ordering and storing of controlled substances.				
21 CFR 1307.11 BPC 4160	9.6	The pharmacy's sales of controlled substances to other pharmacies or prescribers does not exceed five percent of the total number of controlled substances dosage units dispensed per calendar year.				
HSC 11200	9.7	Controlled substance prescriptions are not filled or refilled more than six months from the date written.				

Please mark the appropriate box for each question. If "No," enter an explanation in the "Corrective Action Plan" section. If more space is needed, you may add additional sheets.

Reference	Question #	Item	Yes	No	N/A	Corrective Action Plan
HSC 11200	9.8	Refills for schedule III-IV controlled substance prescriptions are limited to a maximum of five times and in an amount, for all refills of that prescription taken together, not exceeding a 120-day supply.				
HSC 11200	9.9	Refills for schedule II controlled substances are prohibited.				
HSC 11167	9.10	The pharmacy is in compliance with the limitations for dispensing a schedule II prescription upon an oral order, in an emergency.				
HSC 11159.2 CCR 1745 21 CFR 1306.11	9.11	Controlled substance prescriptions written with the "11159.2 exemption" for terminally ill patients are only dispensed when the original prescription is received consistent with legal requirements.				
HSC 11159.2 HSC 11159.3 HSC 11162.1 HSC 11164 HSC 11167.5	9.12	All written controlled substances prescriptions are on California Security Prescription Forms and signed and dated by the prescriber, unless other exceptions exist.				
HSC 11166	9.13	No controlled substance prescription is filled after six months have elapsed from the date written on the prescription by the provider.				

Please mark the appropriate box for each question. If "No," enter an explanation in the "Corrective Action Plan" section. If more space is needed, you may add additional sheets.

Reference	Question #	Item	Yes	No	N/A	Corrective Action Plan
HSC 11167.5 21 CFR 1306.11	9.14	An oral or electronically transmitted prescription for a schedule II controlled substance for a patient in a licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or a licensed hospice care is dispensed only after the pharmacist has reduced the prescription to writing on a pharmacy-generated prescription form and obtained a signature of the prescriber.				
CCR 1745 21 CFR 1306.13	9.15	If unable to supply the full quantity, the pharmacist partially fills a schedule II prescription and is aware that if the remaining portion of the prescription is to be filled, it must be filled within 72 hours.				
21 USC 829 21 CFR 1306.13 BPC 4052.10	9.16	Where requested by the patient or the patient's prescriber, the pharmacist partially fills a schedule II prescription and maintains the records for each such fill (filled within 30 days from the date of prescription issuance).				

Please mark the appropriate box for each question. If "No," enter an explanation in the "Corrective Action Plan" section. If more space is needed, you may add additional sheets.

Reference	Question #	Item	Yes	No	N/A	Corrective Action Plan
HSC 11159.2 21 CFR 1306.13 CCR 1745	9.17	For patients in a skilled nursing facility or terminally ill, the pharmacist partially fills a schedule II prescription and maintains the records for each such fill (filled within 60 days from the date of prescription issuance).				

Please mark the appropriate box for each question. If "No," enter an explanation in the "Corrective Action Plan" section. If more space is needed, you may add additional sheets.

Operations

Reference	Question #	Item	Yes	No	N/A	Corrective Action Plan
BPC 4169 HSC 111250 et seq. HSC 111330 et seq.	10.1	The automated drug delivery system used within the pharmacy to select, count, package and label dangerous drugs, is used consistent with legal provisions to avoid misbranding and adulteration.				
21 CFR Part 210 BPC 4119.3[7] BPC 4342 HSC 110105 HSC 111430	10.2	Drugs are repackaged for dispensing consistent with Current Good Manufacturing Practices and labeling requirements.				
21 CFR Part 210 21 CFR Part 211	10.3	A log is maintained for drugs pre-packed for future dispensing.				
BPC 4119.3[8]	10.4	Drugs previously dispensed by another pharmacy are re-packaged at the patient's request and labeled to include the names and addresses of both pharmacies and meet other requirements.				

[7] Formerly BPC 4052.7
[8] Formerly BPC 4052.7

Please mark the appropriate box for each question. If "No," enter an explanation in the "Corrective Action Plan" section. If more space is needed, you may add additional sheets.

Prescription Drug Take Back Services

Reference	Question #	Item	Yes	No	N/A	Corrective Action Plan
CCR 1776 CCR 1776.1 CCR 1776.2 CCR 1776.3 CCR 1776.4 CCR 1776.5 CCR 1776.6	11.1	The pharmacy participates in a Prescription Drug Take-Back Program and adheres to all federal, state and local requirements.				
CCR 1776.1 CCR 1776.2 CCR 1776.6	11.2	The pharmacy provides prescription drug take-back preaddressed mailing envelopes or packages to consumers to return prescription drugs to an authorized destruction location and complies with all legal requirements.				
21 CFR 1317.30 21 CFR 1317.40 CCR 1776	11.3	The pharmacy is registered with DEA as a collector for purposes of maintaining a prescription drug take-back collection receptacle.				
CCR 1776.1	11.4	The pharmacy has notified the board in writing within 30 days of establishing the collection program.				
CCR 1776.1 CCR 1776.6	11.5	The pharmacy has notified the board in writing within 30 days of ceasing to maintain a drug take-back receptacle.				

Please mark the appropriate box for each question. If "No," enter an explanation in the "Corrective Action Plan" section. If more space is needed, you may add additional sheets.

Reference	Question #	Item	Yes	No	N/A	Corrective Action Plan
CCR 1776.1 CCR 1776.6	11.6	If the pharmacy provides take-back services to consumers neither the pharmacy nor the PIC is on probation with the board.				
CCR 1776.4 CCR 1776.6	11.7	The pharmacy provides mail back envelopes or packages to skilled nursing facility employees or persons lawfully entitled to dispose of a resident decedent's property to dispose of unwanted or unused prescription drugs and complies with all legal requirements.				
CCR 1776.4 CCR 1776.6	11.8	The pharmacy has established a collection receptacle in a skilled nursing facility for the collection and ultimate disposal of unwanted prescription drugs and complies with all legal requirements.				
CCR 1776.1	11.9	Only prescription drugs dispensed by any pharmacy or practitioner to a consumer are eligible for collection as part of the drug take-back services maintained by the pharmacy.				

Additional References

Licensees are encouraged to review the additional references provided below for more information about the listed topics. Licensees are advised that the below is a list of selective references that licensees may find helpful, but not an exhaustive list of all pharmacy laws and regulations that may apply to any given topic or in any specific case.

Reference	Topic
BPC 4016.5 BPC 4052.6 BPC 4210	Advanced Pharmacist Practitioners
HSC 150200	Voluntary Drug Repository and Distribution Program
CCR 1707.4	Refill Pharmacies
HSC 125286.10 HSC 125286.20 HSC 125286.25	Standards of Service for Providers of Blood-Clotting Products for Home Use
BPC 4067	Internet; Dispensing Dangerous Drugs and Dangerous Devices without Prescription
BPC 4130 BPC 4131 BPC 4132 BPC 4133 BPC 4134 BPC 4135	Remote Dispensing Site Pharmacies
CCR 1708.4 CCR 1708.5 CCR 1751 et al	Nuclear Pharmacies
BPC 4119	CLIA-waived testing
BPC 4115	Technician Administration of Vaccines
CCR 1708.1	Temporary Closures
BPC 22949.92.1	Pharmacy Closures
BPC 4107.5	Counterfeit Drugs; Required Notice to Board
CCR 1709.1	Serving as a PIC in more than one Location
BPC 4119	Furnishing of Emergency Medical Supplies for Local Emergency Medical Services Agency

Reference	Topic
BPC 4076	Expedited Partner Therapy
BPC 4145.5	Hypodermic Needles and Syringes Furnished without a Prescription
HSC 11153 Precedential Decision 21 CFR 1306.04	Corresponding Responsibility Requirements
BPC 688 21 CFR 1306.08 21 CFR Part 1311	Electronic Prescription Requirements

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge to the best of my professional ability. Any deficiency identified herein will be corrected by _____(date). I understand that all responses are subject to verification by the Board of Pharmacy. I acknowledge the self-assessment will be readily available for review during any inspection by the Board. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self-assessment form is true and correct.

Signature* _____ Date: _____
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY PHARMACY OWNER OR HOSPITAL ADMINISTRATOR:

I, (please print) _____, hereby certify that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in action by the California State Board of Pharmacy.

Signature* _____ Date: _____
Pharmacy Owner or Hospital Administrator

*Consistent with 16 CCR Section 1700, the Board will accept digital signatures.

Attachment 5

Board of Pharmacy

Enforcement Workload Statistics FY 2025/26

Complaint Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	965	580	0	0	1,545
Closed	751	520	0	0	1,271
					Quarter Ending
Pending	2,414	2,479	0	0	2,479
Average Days for Investigation	286	290	0	0	290

Cases Under Investigation (By Team)	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Compliance / Routine	1,133	1,196	0	0	1,196
Drug Diversion / Fraud	219	226	0	0	226
Prescription Drug Abuse	195	184	0	0	184
Compounding	83	99	0	0	99
Outsourcing	5	7	0	0	7
Probation / PRP	42	36	0	0	36
Enforcement	78	43	0	0	43
Criminal Conviction	657	688	0	0	688

Application Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	53	18	0	0	71
Closed					
Approved	19	27	0	0	46
Denied	28	13	0	0	41
Total Closed (includes withdrawn)	***47***	***42***	***0***	***0***	***89***
Pending	106	88	0	0	88

Complaint Closure Outcomes Not Resulting in Further Action	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Insufficient Evidence	372	296	0	0	668
Non-Jurisdictional	94	34	0	0	128
No Violation	20	12	0	0	32
No Further Action	56	36	0	0	92
Other / Non-Substantiated	27	30	0	0	57
Subject Educated	26	7	0	0	33

Letter of Admonishments / Citations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
LOA Issued	12	15	0	0	27
Citations Issued	95	101	0	0	196
Proof of Abatement Requested	12	13	0	0	25
Appeals Referred to AG's Office	2	4	0	0	6
Dismissed	3	1	0	0	4
Total Fines Collected	***$427,755***	***$414,434***	***$0***	***$0***	***$842,189***

Administrative Cases	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Referred to the AG's Office	75	43	0	0	118
Pleadings Filed	46	23	0	0	69
Total Closed	54	21	0	0	75
Pending					Quarter Ending
Pre-Accusation	109	130	0	0	109
Post-Accusation	133	136	0	0	133
Total Pending	**242**	**266**	**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	2	0	0	18
Designated Representative	0	1	0	0	1
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***	***3***	***0***	***0***	***22***

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	2	0	0	8
Intern Pharmacist	1	0	0	0	1
Pharmacy Technician	6	2	0	0	8
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	2	1	0	0	3
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***15***	***5***	***0***	***0***	***20***

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	2	0	0	6
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***	***2***	***0***	***0***	***8***

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	1	0	0	4
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***4***	***1***	***0***	***0***	***5***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Granted (with or w/o conditions)					
Pharmacist	0	1	0	0	1
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	1	0	0	1
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***2***	***2***	***0***	***0***	***4***

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***	***$94,637***	***$0***	***$0***	***$278,872***
Cost Recovery Collected	***$211,155***	***$140,872***	***$0***	***$0***	***$352,026***

Immediate Public Protection Sanctions	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Interim Suspension Orders	3	3	0	0	6
Automatic Suspension Orders	0	1	0	0	1
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

Probation Statistics	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Licenses on Probation					
Pharmacist	138	131	0	0	138
Advanced Practice Pharmacist	2	2	0	0	2
Intern Pharmacist	5	5	0	0	5
Pharmacy Technician	42	39	0	0	42
Designated Representative	1	1	0	0	1
Wholesaler / 3PL	0	0	0	0	0
Pharmacy	43	41	0	0	43
Sterile Compounding	7	7	0	0	7
Outsourcing	0	0	0	0	0
Total	***238***	***226***	***0***	***0***	***238***
Probation Compliance Measures					Total
Probation Office Conferences	23	2	0	0	25
Probation Interviews / Site Inspections	133	60	0	0	193
Probation Terminated / Completed	15	17	0	0	32
Referred to AG for Non-Compliance	1	2	0	0	3

As of 11/30/2025

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	1	0	0	3
Pharmacist-in-Charge with Fine*	1	1	0	0	2
Pharmacist no Fine	7	32	0	0	39
Pharmacist-in-Charge no Fine*	8	27	0	0	35
Pharmacy with Fine	57	28	0	0	85
Pharmacy no Fine	16	20	0	0	36
Pharmacy Technician with Fine	1	2	0	0	3
Pharmacy Technician no Fine	6	6	0	0	12
Wholesalers	0	2	0	0	2
Designated Representative	1	1	0	0	2
Clinics	0	1	0	0	1
Drug Room	0	0	0	0	0
Exempt Hospital	0	1	0	0	1
Hospital Pharmacy	1	0	0	0	1
Miscellaneous**	9	11	0	0	20
Unlicensed Premises	1	4	0	0	5
Unlicensed Person	1	0	0	0	1
TOTAL	**111**	**137**	**0**	**0**	**248**

*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

As of 11/30/2025

Top Ten Violations by License Type

Pharmacists	%	Pharmacies	%	Pharmacists In Charge	%
1714(d) - Operational Standards and Security; Pharmacist responsible for pharmacy security	14%	1716 - Variation from prescription	33%	1714(d) - Operational Standards and Security; Pharmacist responsible for pharmacy security	22%
1716 - Variation from prescription	11%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	12%	4081(a) - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory	11%
4081(a) - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory	11%	1715.65(a) - Inventory Reconciliation Report of Controlled Substances; Every pharmacy shall perform periodic inventory reconciliation functions to detect and prevent the loss of controlled substances	10%	1715.65(a) - Inventory Reconciliation Report of Controlled Substances; Every pharmacy shall perform periodic inventory reconciliation functions to detect and prevent the loss of controlled substances	11%
4301(g) - Unprofessional Conduct - Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts	11%	1714(c) - Operational Standards and Security; pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition	10%	1714(c) - Operational Standards and Security; pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition	11%
1793.7(b) - Requirements for pharmacies employing pharmacy technicians - Pharmacy technicians must work under the direct supervision of a pharmacist and in such a relationship that the supervising pharmacist	11%	1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	10%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	7%
1715.65(a) - Inventory Reconciliation Report of Controlled Substances; Every pharmacy shall perform periodic inventory reconciliation functions to detect and prevent the loss of controlled substances	11%	4081(a) - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory	7%	1301.12(a) - A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributor	7%
1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	11%	1707.3/1761(a) - Duty to review drug therapy/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	5%	4301(g) - Unprofessional Conduct - Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts	7%
1714(c) - Operational Standards and Security; pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition	7%	1711(d) - Quality assurance program finding shall be used to develop systems to prevent medication errors…	5%	1711(d) - Quality assurance program finding shall be used to develop systems to prevent medication errors…	7%
4077(a) - Dispensing Dangerous Drug in Incorrectly Labeled Container	7%	1713(a)/4126.5(a)(5)/111295 - No licensee shall participate in any arrangement or agreement, whereby prescriptions or prescription medications may be left at, picked up from, accepted by, or delivered	5%	1713(a)/4126.5(a)(5)/111295 - No licensee shall participate in any arrangement or agreement, whereby prescriptions or prescription medications may be left at, picked up from, accepted by, or delivered	7%
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	7%	1714(d) - Operational Standards and Security; Pharmacist responsible for pharmacy security	5%	1714(d)/1301.75(b) - Operational Standards and Security; Pharmacist responsible for pharmacy security/Controlled substances listed in schedules II, III, IV, and V shall be stored in a securely locked,	7%

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 November 2025.

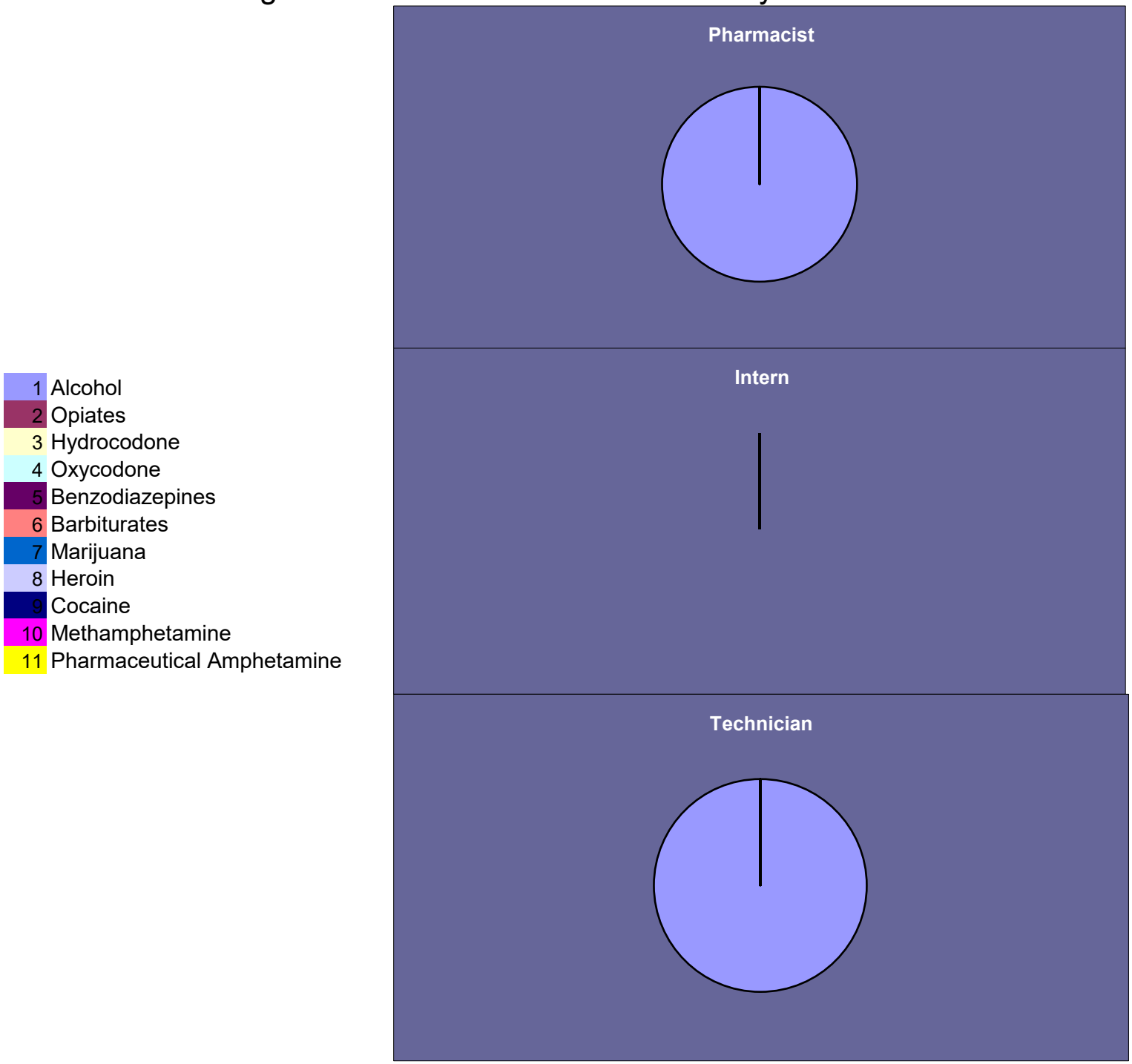
PRP Self-Referrals					
PRP Probation Referrals	1				
PRP Under Investigation					
PRP In Lieu Of (investigation conducted)					
Total Number of PRP Intakes	1				1
New Probationers					
Pharmacists	1	2			3
Intern Pharmacists	1				1
Pharmacy Technicians	6	1			7
Total New Probationers	8	3			11
PRP Participants and Recovery Agreements					
Total PRP Participants	28	28			N/A
Recovery Agreements Reviewed	18	19			37
Probationers and Inspections					
Total Probationers	60	59			N/A
Inspections Completed	30	15			45
Referrals to Treatment					
Referrals to Treatment (PRP and Probationers)					
Drug Tests					
Drug Test Ordered (PRP and Probationers)	519	371			890
Drug Tests Conducted (PRP and Probationers)	506	346			852
Relapses (Break in Sobriety)					
Relapsed (PRP and Probationers)	3	1			4
Major Violation Actions					
Cease Practice/Suspension (PRP and Probationers)	6	4			10
Termination from PRP					
Probationers Referred for Discipline	1				1
Closure or Noncompliance					
Successful Completion (PRP and Probationers)	1	5			6
Termination (Probation)					
Voluntary Surrender (Probation)	1	1			2
Surrender as a result of PTR (Probation)					
Closed Public Risk (PRP)					
Non-compliance in PRP or Probation	18	15			33
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 November 2025.

Board of Pharmacy	July -Sep	Oct Dec*	Jan Mar	Apr Jun	25/26
Drug of Choice at PRP Intake or Probation					
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					
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Pharmacy Technicians	**July-Sep**	**Oct-Dec***	**Jan-Mar**	**Apr-Jun**	**Total 25/26**
Alcohol	6	1			7
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					

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



Printed on 12/18/2025