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Business, Consumer Services and Housing Agency
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Enforcement and Compounding Committee Report

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a. Summary of Discussion Regarding and Possible Action 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.

Summary of Committee Discussion

During the January Committee meeting, members reviewed draft statutory amendments to the above-referenced sections of law. The suggested amendments are being recommended by Board staff to align the referenced provisions of the Business and Professions Code more closely with the federal definition of the term

"outsourcing facility" and to harmonize the provisions with other related language of the Business and Professions Code.

Members noted agreement with the proposed language, indicating the language is consistent with the Committee's prior discussion. .

Members of the public were provided the opportunity to comment on the draft statutory proposal; however, no comments were made.

Attachment 1 includes a copy of the draft amendments. Subsequent to the Committee's meeting, staff identified and incorporated into the proposal several technical changes.

> **Suggested Motion:** Authorize staff to work with the Legislature to secure statutory changes consistent with the proposal presented to the Board.

b. <u>Summary of Discussion and Possible Action Regarding Listening Session on CCR, Title 16, Section 1707.2 Related to Duty to Consult</u>

<u>Relevant Law:</u>
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.

<u>Background</u>
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 Committee 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.

<u>Summary of Committee Discussion</u>
During the January Committee meeting, members considered a staff recommendation to hold a listening session with public participation, where licensees

and consumers 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. The Committee noted the importance of engagement from a variety of groups including licensees and members of the public.

As part of its discussion, the Committee considered questions to be put forward to solicit input from the public during the listening session. After the Committee meeting, based on Committee discussion and public feedback, some questions were edited and added. The following list of questions reflects the updates and additions made after the meeting:

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

   Q 1a: As the pharmacist, how do non-pharmacist staff make you aware that consultation is needed or required?

   Q 1b: When your pharmacy reissues an ongoing prescription with a new prescription number, does this prompt a consultation for the patient?

   Q 1c: 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 1d: 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 1e: 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 1f: Does your pharmacy have an adequate space to provide patient consultation in a confidential manner?

   Q 1g: 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 1a: 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 3a: By what method does your pharmacy mail or deliver prescriptions to patients?
   i. Do pharmacy employees deliver the medication to the patient(s)?
   ii. Is the medication delivered by a private courier hired by the pharmacy?
   iii. Is the medication mailed or delivered by a delivery company? (example: USPS, UPS, FedEx, other)

   Q 3b: How does your pharmacy provide written notice of the right to request consultation to patients on mailed or delivered prescriptions?

   Q 3c: Should there be different requirements for access to consultation for pharmacies that routinely mail or deliver prescriptions versus providing such services occasionally?

   Q 3d: How does your pharmacy (pharmacist) provide consultation to patients on delivered or mailed prescriptions?

   Q 3e: 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 4a: Are you aware of any reimbursement mechanisms for pharmacist provided patient consultation?

   Q 4b: Should a requirement be established for comprehensive consultation including a patient's entire drug therapy list for high-risk patients?

Q 4c: 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 4d: 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 4e: As a pharmacist, do you have enough time in your work day to provide consultation adequately and effectively to patients?

Q 4f: 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 4g: What makes it challenging or difficult to provide consultation in your pharmacy?

Q 4h: Do you have examples of patient consultation that helped you identify medication errors before the patient left the pharmacy?

Q 4i: 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?

Members spoke in support of the listening session and suggested that multiple sessions be considered. Members considered if in addition to a listening session, releasing the questions as a survey might be possible or appropriate, with some members expressing concern that these questions are not suited to a survey as responses will be narrative and thus not be distinct data elements able to be counted and summarized. It was suggested that perhaps consultation requirements should focus on all patient medications and the potential for drug interactions. Members noted the importance of patients using a single pharmacy to allow pharmacists to have a complete list of all medications a patient is taking, including supplements. Members also noted the importance of patients participating in the listening session in addition to pharmacy professionals and other health care providers.

Members noted the importance of the questions in sections 2 and 3. Regarding section 3, members observed that it may be appropriate for the Board's patient consultation regulation to distinguish between a high volume mail order pharmacy versus a pharmacy that only on occasion provides mail order to meet a specific patient's need.

Members also suggested the Communication and Public Education Committee should develop a campaign to highlight the value of medication consultation by a pharmacist.

Public comment stated the Board needs to transition to a standard of care model for patient consultation and focus less on the details in regulations. Board members agreed that having less detailed requirements and pharmacist evaluation of the patient's needs in consultation might be appropriate.

Public comment additionally noted that software challenges also exist.

The Committee did not take action on this item.

Should the Board believe listening session(s) are appropriate, the following motion could be used:

> **Suggested Motion:** Delegate to the Chair of the Enforcement and Compounding Committee to work with staff to conduct listening session(s) on the duty to consult [possibly one for tailored to licensees and one tailored to consumers]. Authorize the Chair to modify listening session questions according to the intended audience [licensees or consumers].

c. <u>Summary of Discussion and Possible Action Regarding Proposed Frequently Asked Questions Related to the Board's Regulations on Compounded Drug Preparations</u>

<u>Relevant Law</u>
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.

<u>Background</u>
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.

Summary of Committee Discussion and Action
During the meeting, members reviewed proposed FAQs covering the Board's compounding regulations. Discussion included reviewing the use of acronyms to assure the full name is included in the document and in the questions appropriately so that users don't have to hunt through the entire document to know what an acronym stands for.

Members of the public were provided the opportunity to comment on the draft FAQs; however, no comments were made.

> **Committee Motion**: Recommend approval of the proposed FAQs related to the Board's compounding regulations that took effect on October 1, 2025, consistent with the Committee's discussion and refer the proposed FAQs to the Board for approval.

Attachment 2 includes a copy of the draft FAQs that incorporates the change made based on the Committee's discussion.

d. Summary of Discussion and Possible Action 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.

Summary of Committee Discussion and Action
During the meeting, members reviewed the newly drafted Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment form.

Members spoke in support of the new format of the self-assessment form and provided additional feedback on improving the format. This new format will be used in future self-assessment forms.

Public comment noted support of the new form format and that it strikes a good balance . Public comment also recommended, and members agreed, that modifications to certain specific questions be made.

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

Attachment 3 includes a draft of the updated Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment form that incorporates the changes made following the Committee meeting.

e. Summary of Discussion of Enforcement Statistics

During the first six months of the fiscal year, the Board initiated 1,857 complaints and closed 1,505 investigations. The Board has issued 32 Letters of Admonishment and 258 citations and referred 138 cases to the Office of the Attorney General. The Board has revoked 30 licenses, accepted the disciplinary surrender of 12 licenses, formally denied 4 applications, and imposed other levels of discipline against 37 licensees and/or applicants.

As of December 31, 2025, the Board had 1,883 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		Jan. 1, 2025	
	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days
Awaiting Assignment	31	10	71	14	107	10	125	7	107	9
Cases Under Investigation	978	141	1,021	143	957	137	987	110	1,189	112

Pending Supervisor Review	173	62	295	70	322	65	401	76	410	119
Pending Second Level Review	116	64	93	68	161	41	165	50	148	40
Awaiting Final Closure	49	34	29	52	35	42	58	29	29	45

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

Attachment 4 includes the enforcement statistics.

Attachment 1

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~~ geographic 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~~ geographic 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 2

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 Compounded Non-sterile Preparations (CNSPs)/ Compounded Sterile Preparations (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 3

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

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; (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.**

Please mark the appropriate box (Yes, No, or N/A) for each question. If "No," enter an explanation in the "Corrective Action Plan" section. If the specific legal requirement referenced in the question clearly and objectively does not apply to your pharmacy, then mark the box "N/A". If more space is needed, you may add additional sheets. 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. A new self-assessment form must be filled out each time the self-assessment process is required to be completed; do not use or copy from a previous self-assessment form. Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Notes:

- Any pharmacy that compounds drug products must also complete the Compounding Self-Assessment (Form 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 (Form 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.

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.	
	Chain Community
	Non-Chain Community
	Mail Order
	Call Center
	Board and Care
	Skilled Nursing Facility
	Correctional Facility
	Central Fill
	Specialty Pharmacy
	Home Health Care/ Infusion Center
	List Others

*Pharmacies are not legally required to identify the services they provide; however, this can be helpful to both the Board and the licensee in assessing compliance.

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

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

References:

Abbreviation	Full Reference
BPC	Business and Professions Code
CCR	Title 16 California Code of Regulations
CC	Civil Code
HSC	Health and Safety Code
USC	United State Code
CFR	Code of Federal Regulations

Table of Contents

Section 1: Facility Requirements/Operations Standards/Security

	Reference	Topic	Yes	No	N/A	Corrective Action Plan
1.1	CCR 1764 CCR 1714	The pharmacy has an area suitable for confidential patient consultation				
1.2	BPC 4116 BPC 4059.5 CCR 1714	The pharmacy is secure to prevent unauthorized access and effective control to prevent theft				
1.3	CCR 1714	The pharmacy is clean, orderly, and free of pests				
1.4	CCR 1714	The pharmacy is equipped with a sink with hot and cold running water for pharmaceutical purposes.				
1.5	BPC 4122 BPC 4058 BPC 4032 CCR 1707.6	The pharmacy has required notices and licenses posted in public view allowing for use of the notices as intended.				
1.6	BPC 4013	The pharmacy is subscribed to the Board's email notification system.				
1.7	BPC 4113.7 BPC 4317	If the pharmacy is a chain community pharmacy, as defined in BPC 4001(c), it does not establish quotas related to the duties for which a pharmacist or pharmacy technician license is required.				
1.8	BPC 4113	The Pharmacy notifies the Board when a change in PIC occurs.				

	Reference	Topic	Yes	No	N/A	Corrective Action Plan
1.9	CC 56.10 CC 56.101 CCR 1717.1 CCR 1717.4 CCR 1764	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.				

Section 2: Delivery of Drugs/Drug Stock

	Reference	Item	Yes	No	N/A	Corrective Action Plan
2.1	BPC 4059.5 HSC 11209	The pharmacy receives dangerous drugs and devices consistent with legal requirements.				
2.2	21 USC 360eee-1	The pharmacy complies with Drug Supply Chain Security Act provisions.				
2.3	21 USC 331 21 USC 351 21 USC 352 BPC 4059.5 BPC 4169 BPC 4342 HSC 111255 HSC 111335 CCR 1714	The drug stock is within expiry and maintained to prevent misbranding and adulteration.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
2.4	BPC 4126.5 BPC 4059 BPC 4059.5 BPC 4163	Dangerous drugs and devices are only obtained from or furnished to persons or entities authorized by pharmacy law.				

Section 3: Pharmacist-in-Charge (PIC)

	Reference	Item	Yes	No	N/A	Corrective Action Plan
3.1	BPC 4113 CCR 1709.1	The pharmacy has designated a PIC and vested the PIC with adequate authority to assure the pharmacy's compliance with relevant laws.				
3.2	CCR 1709.1	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.				
3.3	BPC 4113	The PIC has adequate authority to establish staffing levels, and actually makes staffing decisions.				
3.4	BPC 4113	The PIC has adequate authority to establish the pharmacist to pharmacy technician ratio, and actually determines the ratio in accordance with law.				

Section 4: Pharmacy Personnel

	Reference	Item	Yes	No	N/A	Corrective Action Plan
4.1	BPC 4113.5 BPC 4113.6 BPC 4114 BPC 4115 BPC 4115.5 BPC 4301 CCR 1714.3	The pharmacy complies with applicable staffing requirements.				
4.2	BPC 680 CCR 1793.7	Pharmacy personnel are appropriately identified.				
4.3	BPC 4113	The PIC or pharmacist on duty (1) immediately notifies store management or the building owner of any conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff, and (2) if the conditions are not resolved within 24 hours, ensures the Board is timely notified.				
4.4	BPC 4052 BPC 4301	Pharmacists have adequate authority to exercise professional judgement and comply with the law.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
4.5	BPC 4023.5 BPC 4038 BPC 4114 BPC 4115 BPC 4115.5 CCR 1726 CCR 1793 CCR 1793.2 CCR 1793.7	Intern pharmacists, pharmacy technicians and pharmacy technician trainees are solely performing authorized duties under the supervision of a pharmacist.				
4.6	CCR 1717 CCR 1712 CCR 1793.7	All prescriptions filled or refilled by nonpharmacist authorized personnel are checked by a pharmacist and documented.				
4.7	BPC 4115.5	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.				
4.8	CCR 1793.7	The pharmacy has a job description for pharmacy technicians.				
4.9	CCR 1793.3	Non-licensed personnel are supervised by pharmacists and are permitted to perform the duties specified in CCR section 1793.3(a).				

Section 5: Prescription Requirements

	Reference	Item	Yes	No	N/A	Corrective Action Plan
5.1	BPC 4052 BPC 4069 CCR 1707.2 CCR 1707.3 CCR 1707.5 CCR 1714 CCR 1764	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.				
5.2	CCR 1707.2	If prescription medication is mailed or delivered, written notice about the availability of consultation is provided.				
5.3	CCR 1707.1	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.				
5.4	BPC 688	The pharmacy has the capability to receive an electronic prescription on behalf of a patient.				
5.5	CCR 1707.3	A pharmacist reviews a patient's drug therapy and medication record prior to consultation.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
5.6	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	Prescriptions are appropriately labeled, and appropriate warning labels are affixed.				
5.7	BPC 4040 BPC 4070 BPC 4071 CCR 1712 CCR 1717	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.				
5.8	BPC 4067	Internet prescriptions for delivery in this state are only dispensed or furnished pursuant to an appropriate prior examination of the human or animal.				
5.9	BCP 4073 BCP 4073.5	The pharmacy complies with generic substitution requirements.				
5.10	15 USC 1473 16 CFR 1700.15 CCR 1717	The pharmacy complies with child-resistant container and senior-adult ease-of-opening tested container requirements.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
5.11	21 CFR 310.515 21 CFR 208.24	Medication guides and package inserts are provided as required by law.				
5.12	BPC 4119.2 BPC 4119.4 BPC 4119.8 BPC 4119.9 EDC 49414 EDC 49414.3 EDC 49414.7	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.				
5.13	BPC 4062 BPC 4064	The pharmacy follows emergency refill provisions.				
5.14	CCR 1717.5	The pharmacy's auto-refill program meets the requirements of the law.				
5.15	CCR 1761	Prior to dispensing a prescription, where necessary, a pharmacist contacts the prescriber to obtain information needed to validate the prescription.				
5.16	BPC 688 BPC 733 BPC 4115 CCR 1717 CCR 1717.1	A prescription is transferred at the request of the patient.				

Section 6: Quality Assurance/Medication Error Reporting Requirements

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

Section 7: Record Keeping Requirements

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

Section 8: Policies and Procedures

The pharmacy has policies and procedures covering the following matters:

	Reference	Item	Yes	No	N/A	Corrective Action Plan
8.1	BPC 4104	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.				
8.2	BPC 4104	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.				
8.3	CCR 1714.1	Operation of the pharmacy during the temporary absence of a pharmacist for breaks and meal periods.				
8.4	CCR 1717.1 CC 56.10 CC 56.101	Confidentiality of medical information				
8.5	BPC 4059.5	Delivery of dangerous drugs to a secure storage facility when the pharmacy is closed.				
8.6	BPC 733	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				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
8.7	CCR 1707.5	Helping patients with limited or no English proficiency to understand information on the prescription label				
8.8	CCR 1715.65	Inventory reconciliation reporting requirements.				
8.9	BPC 4081 CCR 1793.7	Pharmacy personnel and operations				
8.10	CCR 1717.5	Auto-refill program				
8.11	CCR 1711	Quality assurance for medication errors				
8.12	BPC 4113.5 CCR 1714.3	Community pharmacy staffing				
8.13	BPC 4119.3[1]	Repackaging services				

[1] Formerly BPC 4052.7

Section 9: Controlled Substances

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

	Reference	Item	Yes	No	N/A	Corrective Action Plan
9.8	HSC 11200	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.				
9.9	HSC 11200	Refills for schedule II controlled substances are prohibited.				
9.10	HSC 11167	The pharmacy is in compliance with the limitations for dispensing a schedule II prescription upon an oral order, in an emergency.				
9.11	HSC 11159.2 CCR 1745 21 CFR 1306.11	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.				
9.12	HSC 11159.2 HSC 11159.3 HSC 11162.1 HSC 11164 HSC 11167.5	All written controlled substances prescriptions are on California Security Prescription Forms and signed and dated by the prescriber, unless other exceptions exist.				
9.13	HSC 11166	No controlled substance prescription is filled after six months have elapsed from the date written on the prescription by the provider.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
9.14	HSC 11167.5 21 CFR 1306.11	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.				
9.15	CCR 1745 21 CFR 1306.13	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.				
9.16	21 USC 829 21 CFR 1306.13 BPC 4052.10	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).				
9.17	HSC 11159.2 21 CFR 1306.13 CCR 1745	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).				

Section 10: Operations

	Reference	Item	Yes	No	N/A	Corrective Action Plan
10.1	BPC 4169 HSC 111250 et seq. HSC 111330 et seq.	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.				
10.2	21 CFR Part 210 BPC 4119.3[2] BPC 4342 HSC 110105 HSC 111430	Drugs are repackaged for dispensing consistent with Current Good Manufacturing Practices and labeling requirements.				
10.3	21 CFR Part 210 21 CFR Part 211	A log is maintained for drugs pre-packed for future dispensing.				
10.4	BPC 4119.3[3]	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.				

[2] Formerly BPC 4052.7
[3] Formerly BPC 4052.7

Section 11: Prescription Drug Take Back Services

	Reference	Item	Yes	No	N/A	Corrective Action Plan
11.1	CCR 1776 CCR 1776.1 CCR 1776.2 CCR 1776.3 CCR 1776.4 CCR 1776.5 CCR 1776.6	The pharmacy participates in a Prescription Drug Take-Back Program and adheres to all federal, state and local requirements.				
11.2	CCR 1776.1 CCR 1776.2 CCR 1776.6	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.				
11.3	21 CFR 1317.30 21 CFR 1317.40 CCR 1776	The pharmacy is registered with DEA as a collector for purposes of maintaining a prescription drug take-back collection receptacle.				
11.4	CCR 1776.1	The pharmacy has notified the board in writing within 30 days of establishing the collection program.				
11.5	CCR 1776.1 CCR 1776.6	The pharmacy has notified the board in writing within 30 days of ceasing to maintain a drug take-back receptacle.				
11.6	CCR 1776.1 CCR 1776.6	If the pharmacy provides take-back services to consumers neither the pharmacy nor the PIC is on probation with the board.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
11.7	CCR 1776.4 CCR 1776.6	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.				
11.8	CCR 1776.4 CCR 1776.6	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.				
11.9	CCR 1776.1	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
BPC 4064	Emergency Refill of Prescription without Prescriber Authorization
BPC 4064.5	Refill Consolidation by a Pharmacist; Requirements and Exceptions

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 4

Board of Pharmacy

Enforcement Workload Statistics FY 2025/26

Complaint Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	965	892	0	0	1,857
Closed	750	755	0	0	1,505
					Quarter Ending
Pending	2,414	2,606	0	0	2,606
Average Days for Investigation	286	298	0	0	298

Cases Under Investigation (By Team)	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Compliance / Routine	1,133	1,246	0	0	1,246
Drug Diversion / Fraud	219	231	0	0	231
Prescription Drug Abuse	195	233	0	0	233
Compounding	83	102	0	0	102
Outsourcing	5	6	0	0	6
Probation / PRP	42	37	0	0	37
Enforcement	78	51	0	0	51
Criminal Conviction	657	700	0	0	700

Application Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	53	37	0	0	90
Closed					
Approved	19	40	0	0	59
Denied	28	22	0	0	50
Total Closed (includes withdrawn)	***47***	***62***	***0***	***0***	***109***
Pending	106	84	0	0	84

Complaint Closure Outcomes Not Resulting in Further Action	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Insufficient Evidence	372	397	0	0	769
Non-Jurisdictional	94	68	0	0	162
No Violation	20	22	0	0	42
No Further Action	56	51	0	0	107
Other / Non-Substantiated	27	43	0	0	70
Subject Educated	26	29	0	0	55

Letter of Admonishments / Citations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
LOA Issued	12	20	0	0	32
Citations Issued	95	163	0	0	258
Proof of Abatement Requested	12	27	0	0	39
Appeals Referred to AG's Office	2	10	0	0	12
Dismissed	3	2	0	0	5
Total Fines Collected	***$427,755***	***$680,434***	***$0***	***$0***	***$1,108,189***

Administrative Cases	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Referred to the AG's Office	75	63	0	0	138
Pleadings Filed	46	45	0	0	91
Total Closed	54	44	0	0	98
Pending					Quarter Ending
Pre-Accusation	109	127	0	0	127
Post-Accusation	133	134	0	0	134
Total Pending	**242**	**261**	**0**	**0**	**261**

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	10	0	0	26
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***	***11***	***0***	***0***	***30***

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	5	0	0	11
Intern Pharmacist	1	0	0	0	1
Pharmacy Technician	6	4	0	0	10
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	1	0	0	1
Total	***15***	***11***	***0***	***0***	***26***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Surrender / Voluntary Surrender					
Pharmacist	1	1	0	0	2
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	4	3	0	0	7
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	1	2	0	0	3
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***6***	***6***	***0***	***0***	***12***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Public Reproval / Reprimand					
Pharmacist	0	1	0	0	1
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***	***2***	***0***	***0***	***6***

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	1	0	0	3
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***	***3***	***0***	***0***	***5***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Denied					
Pharmacist	0	1	0	0	1
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	1	2	0	0	3
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***	***3***	***0***	***0***	***4***

Administrative Case Cost Recovery Efforts	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Cost Recovery Requested	***$184,235***	***$275,964***	***$0***	***$0***	***$460,200***
Cost Recovery Collected	***$211,155***	***$175,314***	***$0***	***$0***	***$386,468***

Immediate Public Protection Sanctions	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Interim Suspension Orders	3	4	0	0	7
Automatic Suspension Orders	0	1	0	0	1
Penal Code 23 Restrictions	2	1	0	0	3
Cease and Desist - Outsourcing	0	0	0	0	0
Cease and Desist - Unlicensed Activity	1	2	0	0	3
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	130	0	0	130
Advanced Practice Pharmacist	2	2	0	0	2
Intern Pharmacist	5	5	0	0	5
Pharmacy Technician	42	41	0	0	41
Designated Representative	1	1	0	0	1
Wholesaler / 3PL	0	0	0	0	0
Pharmacy	43	38	0	0	38
Sterile Compounding	7	5	0	0	5
Outsourcing	0	1	0	0	1
Total	***238***	***223***	***0***	***0***	***223***
Probation Compliance Measures					Total
Probation Office Conferences	23	8	0	0	31
Probation Interviews / Site Inspections	133	101	0	0	234
Probation Terminated / Completed	15	27	0	0	42
Referred to AG for Non-Compliance	1	2	0	0	3

As of 12/31/2025

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	10	0	0	12
Pharmacist-in-Charge with Fine*	1	1	0	0	2
Pharmacist no Fine	7	54	0	0	61
Pharmacist-in-Charge no Fine*	8	41	0	0	49
Pharmacy with Fine	57	43	0	0	100
Pharmacy no Fine	16	22	0	0	38
Pharmacy Technician with Fine	1	2	0	0	3
Pharmacy Technician no Fine	6	10	0	0	16
Wholesalers	0	2	0	0	2
Designated Representative	1	4	0	0	5
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	17	0	0	26
Unlicensed Premises	1	7	0	0	8
Unlicensed Person	1	0	0	0	1
TOTAL	**111**	**215**	**0**	**0**	**326**

*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 12/31/2025

Top Ten Violations by License Type

Pharmacists	%	Pharmacies	%	Pharmacists In Charge	%
4169(a)(1)/4301(j)/4126.5(a)(4)(5)(7) - Prohibited Acts; Purchase, trade, sell, or transfer dangerous drugs to unlicensed person or entity…/ Unprofessional Conduct - Violation of any statutes of this	17%	1716 - Variation from prescription	28%	1714(d) - Operational Standards and Security; Pharmacist responsible for pharmacy security	27%
4301(o)/4126.5(a)(4) - Unprofessional conduct; assist in violation / Furnishing Dangerous Drugs by Pharmacy; pharmacy or wholesale… alleviate temporary shortage	17%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	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	14%
4059.5(e)/4301(j)/4301(o) - Dangerous drugs or devices shall not be transferred, sold, or delivered to any person outside this state… / Unprofessional Conduct - Violation of any statutes of this stat	11%	1707.2(a) - Duty to consult: A pharmacist shall provide oral consultation to his or her patient or the agent of patient in all care settings	9%	4126.8 - Standards for compounding of drug preparations: The compounding of drug preparations by a pharmacy for furnishing, distribution, or use in this state shall be consistent with standards established	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%	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	9%	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%
4059.5(e)/4301(j) - Dangerous drugs or devices shall not be transferred, sold, or delivered to any person outside this state… / Unprofessional Conduct - Violation of any statutes of this state or of	9%	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	9%	4081(a) - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory	8%
1714(d) - Operational Standards and Security; Pharmacist responsible for pharmacy security	9%	4126.8 - Standards for compounding of drug preparations: The compounding of drug preparations by a pharmacy for furnishing, distribution, or use in this state shall be consistent with standards established	7%	1714(c) - Operational Standards and Security; pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition	8%
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	7%	1714(c) - Operational Standards and Security; pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition	7%	1715(a) - Self-assessment form of a pharmacy by the pharmacist-in-charge; shall complete a self-assessment of pharmacy compliance with federal and state pharmacy law	5%
4301(o)/4301(j) - Unprofessional Conduct - Assist in the violation/Unprofessional Conduct - Violation of any statutes of this state or of the United States regulation controlled substances or dangerous	7%	1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	7%	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	5%
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	6%	1715.65(a)(1) - Inventory Activities and Inventory Reconciliation reports... (a) Every pharmacy, and every clinic licensed under section 4180 or 4190 of the Business and Professions Code, shall perform	5%
1716 - Variation from prescription	5%	1304.11(c) - Inventory Requirements; Biennial inventory date	6%	1711(d) - Quality assurance program finding shall be used to develop systems to prevent medication errors…	5%

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 December 2025.

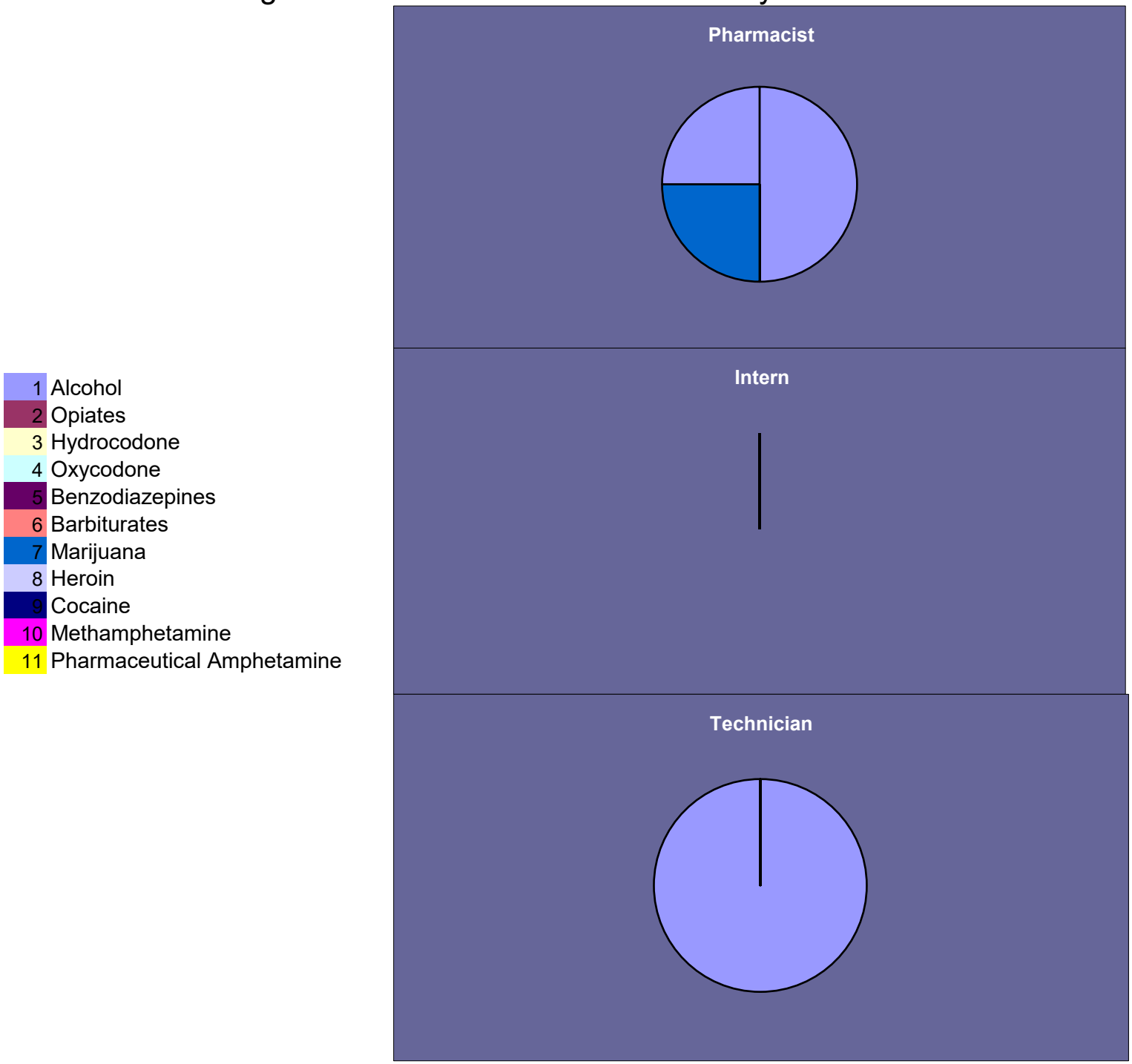
Board of Pharmacy	July -Sep	Oct Dec	Jan Mar	Apr Jun	25/26
PRP Intakes					
PRP Self-Referrals					
PRP Probation Referrals	1	1			2
PRP Under Investigation		1			1
PRP In Lieu Of (investigation conducted)					
Total Number of PRP Intakes	1	2			3
New Probationers					
Pharmacists	1	2			3
Intern Pharmacists	1				1
Pharmacy Technicians	6	3			9
Total New Probationers	8	5			13
PRP Participants and Recovery Agreements					
Total PRP Participants	28	27			N/A
Recovery Agreements Reviewed	18	27			45
Probationers and Inspections					
Total Probationers	60	60			N/A
Inspections Completed	30	32			62
Referrals to Treatment					
Referrals to Treatment (PRP and Probationers)		1			1
Drug Tests					
Drug Test Ordered (PRP and Probationers)	519	537			1056
Drug Tests Conducted (PRP and Probationers)	506	507			1013
Relapses (Break in Sobriety)					
Relapsed (PRP and Probationers)	3	1			4
Major Violation Actions					
Cease Practice/Suspension (PRP and Probationers)	6	8			14
Termination from PRP		1			1
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)		1			1
Non-compliance in PRP or Probation	18	25			43
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 December 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			2
Ambien					
Opiates					
Hydrocodone					
Oxycodone					
Morphine					
Benzodiazepines		1			1
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine		1			1
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	3			9
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 December 2025



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