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

Enforcement and Compounding Committee Report

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a. Summary of Presentation on Board's Outsourcing Program

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

Background
The Drug Quality and Security Act (DQSA) was signed into law in 2013 and added section 503B to the Federal Food, Drug, and Cosmetic Act (FD&C Act). Section 503B created a new regulatory category of compounders called outsourcing facilities. A 503B facility or outsourcer produces sterile drugs in bulk without the need of a patient specific prescription. While an entity must be engaged in the compounding of sterile drugs to qualify as an outsourcing facility, outsourcing facilities are also permitted to compound nonsterile drugs. Because drugs compounded by outsourcing facilities are not exempt from section 501(a)(2)(B) of the FD&C Act, outsourcing facilities are subject to current good manufacturing practice (cGMP) requirements.

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

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

Summary of Committee Discussion
During the Committee's October 16, 2025, meeting, members received a presentation on outsourcing facilities from Supervising Inspector Dr. JK Fujimoto. As part of the presentation, members were provided an overview of the Board's outsourcing program, including Board licensure requirements, a comparison of 503A versus 503B facilities and types of drugs compounded and their ability to also provide patient specific prescriptions. There are currently 92 federally registered outsourcing facilities across the United States. Of those 92 federally registered facilities, three resident outsourcing facilities and 20 nonresident outsourcing facilities are licensed with the Board. Members were advised that outsourcing facilities are required to follow the Code of Federal Regulations (CFR) and cGMPs. Members received information on the Board's inspection expectations, successes, and challenges.

Members noted the important role outsourcing facilities serve for hospitals, that outsourcing inspections are complex, and not all states conduct outsourcing inspections. Some states rely on the Board's inspections to evaluate for compliance. Members were interested in the products produced by outsourcers and were advised that outsourcing facilities have a bulk drug substances list and can participate in certain repackaging activities, as well as compound during drug shortages. Further, members commented that large health systems and hospitals typically use outsourcers for antibiotics, drips, and various other products.

Finally, members noted that post implementation of the outsourcing program, there may be opportunity for some possible changes in law that may be appropriate to address at a future Committee meeting.

Attachment 1 includes a copy of the presentation.

b. Summary of Presentation on Duty to Consult and Discussion of California Regulations, Title 16, Section 1707.2

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

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

Provided below is the number of investigations conducted by the Board over the past

three fiscal years where violations of the duty to consult (16 CCR 1707.2) were substantiated:

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

Summary of Committee Discussion:
During the Committee's October 16, 2025, meeting, members received a presentation on the duty to consult from Deputy Executive Offer Julie Ansel. The presentation discussed the value of consultation and associated regulation requirements, including barriers to consultation and Board actions that support patient consultation. Additionally, consultation violation examples and outcomes were shared with members.

Members were concerned that without reimbursement for consultation, it continues to be difficult for pharmacies to prioritize time for consultations. Members expressed that the regulations should potentially move to a standard of care enforcement model and it may be appropriate to consider whether the current regulation might be amended to be less prescriptive and to empower pharmacists to use their professional judgement to determine what a patient needs to know and how they receive information.

Further, members expressed concern that screening for consultation is an ongoing issue, staff asks patients "if they want to speak with a pharmacist" and patients may not understand the benefits of consultation with a pharmacist. Pharmacy software is commonly used to override and release a prescription where consultation has been flagged as required. Members noted that challenges with workflow and staffing are contributing factors. In addition, interruptions in the pharmacy workflow to provide consultation can be an unintended contributor to medication errors. Members commented it may be appropriate to consider an exemption to the consultation requirements, in instances where a drug is filled by a pharmacy for administration by a healthcare provider in a medical office or clinic.

Public comment similarly expressed the importance of consultation, that barriers articulated in the presentation are real and that without proper reimbursement challenges will remain.

Following discussion and public comment the Committee noted that discussion on this topic will continue at a future meeting.

Attachment 2 includes a copy of the presentation.

c. Summary of Discussion on Hospital Pharmacies and Business and Professions Code Section 4113.1 Medication Error Reporting, Including Possible Action to Initiate a Rulemaking to Amend California Code of Regulations, Title 16, Section 1710

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

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

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

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

Summary of Committee Discussion:
During the meeting, the Committee had the opportunity to discuss the issue. The Committee also considered draft regulation language proposing an amendment to 16 CCR section 1710. Members were supportive of the proposed language and there was general consensus that the language was representative of the Board's policy. Members also expressed interest in Board staff learning more about hospitals dispensing prescriptions to outpatients to better understand what volume this represents. The Committee agreed to refer the draft language to the full Board.

Public comment stated that it should be clear that consultation was provided with hospital outpatient prescriptions, and that documentation of consultation is appropriate as it occurs in other jurisdictions.

Should members agree the regulatory change is appropriate, the following motion could be used to initiate the formal rulemaking process:

> **Suggested Motion**: Initiate a rulemaking to amend California Code of Regulations, Title 16, section 1710 [either "as proposed" or "consistent with the Board's

discussion"]. Authorize the executive officer to further refine the language consistent with the Board's discussion. Direct staff to submit the text to the Director of the Department of Consumer Affairs and the Business, Consumer Services, and Housing Agency for review, and authorize the executive officer to take all steps necessary to initiate the rulemaking process, make any technical or nonsubstantive changes to the package, and set the matter for hearing, if requested. If, during the 45-day comment period, the Board does not receive any comments providing objections or adverse recommendations specifically directed at the proposed action or to the procedures followed by the Board in proposing or adopting the action, and no hearing is requested, authorize the executive officer to take all steps necessary to complete the rulemaking and adopt the proposed regulation at Section 1710.

Attachment 3 includes a copy of the proposed regulation text.

d. Summary of Discussion on Frequently Asked Questions Related to Assembly Bill 1286 (Haney, Chapter 470, Statutes of 2023), Including Possible Action to Approve Proposed Updates to FAQs

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

Summary of Committee Discussion:
During the Committee meeting, members reviewed proposed updates to the FAQs and provided feedback to staff. The updates to the FAQs pertained to the topics of California Medication Error Reporting (CAMER), Pharmacy Technician Expanded Duties, Unprofessional Conduct, and Surgical Clinic Provisions. Some of the proposed changes were suggested due to changes enacted by the Board's sunset bill, AB 1503 (Berman, Chapter 196, Statutes of 2025). Members also commented that the Board should assess a better way to disseminate information about enacted legislation and suggested that in the future a better approach to FAQs might be to organize them around topic/subject matter rather than around specific bills.

Committee Motion: Recommend approval of the updated FAQs related to Assembly Bill 1286 consistent with the Committee's discussion.

Attachment 4 includes a copy of the updated FAQs, reflecting further updates made after the Committee meeting based on the Committee's feedback.

e. Summary of Discussion of Recently Signed Legislation Impacting the Practice of Pharmacy, Including Possible Discussion and Action on Proposed Implementation Activities

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

Summary: This bill expands the address confidentiality program to a gender-affirming health care provider, employee, or volunteer, as defined, who faces threats of violence or harassment from the public because of their affiliation with a gender-affirming health care services facility. Additionally, this bill prohibits a prescription for or the dispensing of testosterone or mifepristone from being reported to the Department of Justice, CURES, or a contractor, as specified.
Implementation: Staff recommend that implementation activities focus on education on the provisions, including highlighting the provisions in the Board's Annual Changes in Pharmacy Law webinar, and information in the upcoming issue of *The Script*. Additionally, staff recommend collaboration with the Department of Justice regarding CURES reporting and the dissemination of information to licensees. Additionally, staff will reach out to the Department of Consumer Affairs (DCA) for information on implementation amongst other healing arts boards possibly affected by the bill.
Summary of Committee Discussion: Members highlighted the importance of this legislation and noted agreement with the staff-recommended implementation activities. No public comment was received on this item.

ii. Assembly Bill 144 (Committee on Budget, Chapter 105, Statutes of 2025) Health

Summary: The bill provides authority for pharmacists to independently initiate and administer an immunization that, as of January 1, 2025, had a federal Advisory Committee on Immunization Practices (ACIP) recommendation in effect or is recommended by the California Department of Public Health. Additionally, the bill includes provisions requiring Medi-Cal coverage of vaccines and immunizations in accordance with the recommendations above. Finally, this bill exempts health care practitioners licensed in another state, territory, or country from specific healing arts licensure, certification, or registration requirements, while providing professional services at Olympic and Paralympic activities, as defined, if the Los Angeles Organizing Committee has invited the health care practitioner for the 2028 Olympic and Paralympic Games to provide those services and the committee provides specified information to the Director of Consumer Affairs.
Implementation: Staff recommend that implementation activities focus on education on the provisions, including highlighting the provisions in the Change in Pharmacy Law webinar, and information in the upcoming issue of *The Script*. The Board created a dedicated webpage with updated information on pharmacist authority to administer vaccines. A pharmacy alert was sent to licensees on September 18, 2025, and October 6, 2025.
Summary of Committee Discussion: Members noted agreement with the staff-recommended implementation activities. Public comment noted a vaccination

care gap existed because of differing recommendations and the passage of this bill bridged that gap.

iii. **Assembly Bill 260 (Aguiar-Curry, Chapter 136, Statutes of 2025) Sexual and Reproductive Health Care**

Summary: This bill authorizes pharmacists to dispense medication abortion drugs—such as mifepristone—without including the patient's name, the prescriber's name, or the pharmacy's identifying information on the label. Pharmacists must maintain a confidential log of these transactions, which is shielded from law enforcement access unless a subpoena is issued, and cannot be disclosed to out-of-state entities. The bill also provides legal protections for pharmacists, protecting them from criminal or civil liability and professional discipline when dispensing these medications in compliance with California law. Additionally, the California Department of Public Health is granted the authority to regulate the inclusion or exclusion of these drugs from specific labeling laws, particularly in the event of changes in federal approval.

Implementation: Staff recommend that implementation activities focus on education on the provisions, including highlighting the provisions in the Change in Pharmacy Law webinar, and information in the upcoming issue of *The Script*. Additionally, staff will reach out to DCA for information on implementation amongst other healing arts boards possibly affected by the bill.

Summary of Committee Discussion: Members noted the importance of this legislation to maintain access to reproductive healthcare and agreement with the staff-recommended implementation activities. No public comment was received on this item.

iv. **Assembly Bill 309 (Zbur, Chapter 685, Statutes of 2025) Hypodermic Needles and Syringes**

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

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

Summary of Committee Discussion: Members noted agreement with the staff-recommended implementation activities. Members also commented that given the enactment of AB 1503 (Berman, Chapter 196, Statutes of 2025), there are even more opportunities for pharmacists to provide needles and syringes. No public comment was received on this item.

v. **Assembly Bill 447 (Gonzalez, Chapter 363, Statutes of 2025) Emergency Room Patient Prescriptions**

Summary: The bill allows prescribers to dispense the unused portion of a dangerous drug as defined—excluding controlled substances—that the hospital

pharmacy acquired, to emergency room patients upon discharge, provided it is necessary to continue treatment. Such drugs must have been administered from single patient use multidose packaging and can be self-administered by the patient, including, but not limited to, an inhaler, eye drop, ear drop, nose drop or spray, topical product, or liquid product and must have a label on the drug containing all of the information required by BPC section 4076. Additionally, the bill exempts certain automated unit dose systems (AUDS) from licensure requirements when used to dispense drugs to emergency room patients, provided specific conditions are met.
Implementation: Staff recommend that implementation activities focus on education on the provisions, including updating the ADDS FAQs, highlighting the provisions in the Change in Pharmacy Law webinar, and information in the upcoming issue of *The Script*.
Summary of Committee Discussion: Members noted agreement with the staff-recommended implementation activities. No public comment was received on this item.

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

Summary: This bill prohibits a health care service plan or health insurer from imposing step therapy as a prerequisite to authorizing coverage of insulin and, generally, prohibits a health care service plan contract or health insurance policy issued, amended, delivered, or renewed on or after January 1, 2026, from imposing a copayment, coinsurance, deductible, or other cost sharing of more than $35 for a 30-day supply of an insulin prescription drug, except as specified.
Implementation: Staff recommend that implementation activities focus on education on the provisions, including highlighting the provisions in the Change in Pharmacy Law webinar, and information in the upcoming issue of *The Script*. Additionally, staff recommend consumer-facing education activities.
Summary of Committee Discussion: Members noted agreement with the staff-recommended implementation activities. Members also highlighted that for Federally Qualified Health Centers (FQHC) that purchase insulin at 340B prices, there are separate requirements based on a White House Executive Order. This should also be included in information provided to licensees and the public. No public comment was received on this item.

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

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

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

Summary of Committee Discussion: Members noted agreement with the staff-recommended implementation activities and highlighted some provisions necessitate coordination with DMHC regarding consumer facing benefits. Public comment agreed on the Board coordinating with DMHC and mentioned that these protections will improve patient access and patient centered care.

viii. Senate Bill 306 (Becker, Chapter 408, Statutes of 2025) Health Care Coverage: Prior Authorizations

Summary: This bill requires health plans and insurers to temporarily exempt certain services from prior authorization if 90% or more of requests for those services were approved in the previous calendar year. The bill also directs the Department of Managed Health Care and the California Department of Insurance to evaluate long-term data and, by January 1, 2028, establish a permanent list of services that must be exempt from prior authorization. Certain exceptions remain, such as for high-tier prescription drugs and off-label uses not approved by the FDA. Additionally, health plans may petition to reinstate prior authorization for specific services if there is clear evidence of fraud or misuse. A comprehensive impact report is required within four years to assess the effectiveness of these reforms.
Implementation: Staff recommend that implementation activities focus on education on the provisions, including highlighting the provisions in the Board's Annual Changes in Pharmacy Law webinar, and information in the upcoming issue of *The Script*. Additionally, staff recommend consumer-facing education activities.
Summary of Committee Discussion: Members noted agreement with the staff-recommended implementation activities and the importance of this legislation to provide lifesaving medication to patients. No public comment was received on this item.

ix. Senate Bill 470 (Laird, Chapter 222, Statutes of 2025) Bagley-Keene Open Meeting Act: Teleconferencing

Summary: This bill authorizes state bodies and advisory boards to conduct public meetings via teleconference through January 1, 2030, under specific conditions, including requiring a majority of members to be physically present at a designated location and ensuring that members appear visibly on camera during publicly accessible portions of the meetings. It also permits remote participation from private locations under certain circumstances, while maintaining transparency and public access by requiring clear notice and opportunities for

public comment.
Implementation: Staff recommend that implementation activities focus on education on the provisions, including highlighting the provisions in the Board's Annual Changes in Pharmacy Law webinar, and information in the upcoming issue of *The Script*.
Summary of Committee Discussion: Members noted agreement with the staff-recommended implementation activities and expressed gratitude for the increased accessibility remote participation can provide for Board members. Public comment requested clarity on how this applies to Board and Committee meetings.

Subsequent to the Committee Meeting, staff suggested that the Board might consider changing the Board Member Procedure Manual *Frequency of Meetings* policy from an interim to a permanent policy through January 1, 2030. Should the Board believe the proposed update to the Manual is ready for approval, the following motion may be appropriate:

> **Suggested Motion**: Approve the proposed update to the Board Member Procedure Manual Frequency of Meetings policy from an interim to a permanent policy through January 1, 2030.

Attachment 5 includes the proposed update to the Board Member Procedure Manual.

x. Senate Bill 497 (Wiener, Chapter 764, Statutes of 2025) Legally Protected Health Care Activity

Summary: This bill prohibits health care providers, insurers, contractors, and employers from disclosing medical information in response to civil or criminal actions—including foreign subpoenas—based on laws from other states that penalize such care. It also bars cooperation with out-of-state or, where permitted, federal law enforcement agencies attempting to identify individuals involved in legally protected health care activities. The bill has an urgency clause and took effect immediately upon being signed by the governor and chaptered by the Secretary of State on October 13, 2025.
Implementation: Staff recommend that implementation activities focus on education on the provisions, including highlighting the provisions in the Board's Annual Changes in Pharmacy Law webinar, and information in the upcoming issue of *The Script*.
Summary of Committee Discussion: Members noted agreement with the staff-recommended implementation activities and suggested some education or guidance on this topic may be appropriate. Public comment mentioned the intent of the law is for the privacy of patients and agreed that licensees are confused about what information is required or authorized to be released. FAQs and examples would be helpful to the regulated public.

xi. **Senate Bill 568 (Niello, Chapter 322, Statutes of 2025) Pupil Health: Epinephrine Delivery Systems: Schoolsites and Childcare Programs**
Summary: This bill expands the authority of pharmacies to provide a broader range of epinephrine delivery devices, including those other than auto-injectors, to local educational agencies—including school districts, county offices of education, and charter schools—under existing safety and training requirements.
Implementation: Staff recommend that implementation activities focus on education on the provisions, including highlighting the provisions in the Change in Pharmacy Law webinar, and information in the upcoming issue of *The Script*.
Summary of Committee Discussion: Members noted agreement with the staff-recommended implementation activities. No public comment was received on this item.

f. Summary of Discussion of Enforcement Statistics

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

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

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

Attachment 6 includes the enforcement statistics for fiscal year 2025-26, through September 30, 2025.

Attachment 1

503B Outsourcing Facility Program Overview

JK Fujimoto, PharmD, MBA, BCSCP

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CALIFORNIA STATE BOARD OF PHARMACY
Be aware and take care. Talk to your Pharmacist!

What is a 503B Outsourcing Facility?

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

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

What is a 503B Outsourcing Facility?

Outsourcing facilities:

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

503A Compounding Pharmacy Versus 503B Outsourcing Facility

503A Compounding Pharmacy

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

503B Outsourcing Facility

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

What do they Compound?

Sterile Preparations

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

Non-Sterile Preparations

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

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

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

Typical Staffing of a 503B Outsourcing Facility

Organizational Chart:

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

Personnel Background and Qualifications:

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

Role of a Pharmacist

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

Roles Pharmacists are currently participating in Outsourcing Facilities:

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

Licensure and Registration Requirements

503A Compounding Pharmacy

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

503B Outsourcing Facility

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

Current Outsourcing Facility Demographics

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

Inspection Expectations – CFR and CGMP example

Facilities are required to follow:

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

The CFR represents the required regulation

FDA Guidance for Industry Documents

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

For example:

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

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

Inspection Expectations – CFR and CGMP example (cont.)

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

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

Outsourcing Inspection Program Post Implementation Successes

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

Outsourcing Inspection Program Challenges

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

Recommendations

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

Thank You

Attachment 2

Duty to Consult

October 16, 2025

California State Board of Pharmacy

What is the Value of Consultation?

- Learn to take medication safely and effectively
- Personalized advice and/or tailored education about medication(s)
- Improves patient understanding of medication
- Addresses potential side effects or allergies
- Identifies and prevents drug interactions
- Discuss other medications or supplements
- Ask questions of a pharmacist
- Decreases risk of patient taking the wrong medication (medication error)
- Improves medication adherence, overall medication management and health outcomes

California Code of Regulations CCR 1707.2 Duty to Consult

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

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

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

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

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

CCR 1707.2 Consultation Violations

Fiscal Year 2022-2023	Fiscal Year 2023-2024	Fiscal Year 2024-2025
43	47	46

Consultation Violation Examples

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

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

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

Consultation Violation Examples (continued)

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

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

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

Violation Outcomes

No Action	Close no Further Action Subject Educated
Administrative Action	Letter of Admonishment Citation no Fine Citation with Fine
Formal Discipline	Referral to Attorney General

Barriers to Consultation

- Pharmacist Related
- Patient Related
- System Related

Pharmacist Related Barriers

EMPLOYEE BURNOUT OR STRESS

TIME CONSTRAINTS

Patient Related Barriers

PRIVACY CONCERNS

PATIENT IMPATIENCE

PATIENT AWARENESS

System Related Barriers

WORKFLOW: NON-PHARMACIST EMPLOYEES SCREENING FOR CONSULTATION

WORKLOAD: BUSY PHARMACY, HIGH VOLUME, STAFFING CONSTRAINTS

Breaking Down Barriers to Improve Patient Consultation

Board Actions that Support Patient Consultation

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

Thank You

Attachment 3

Department of Consumer Affairs
Title 16. Pharmacy

Proposed Regulatory Language

Legend: Added text is indicated with an underline.

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

16 CCR § 1710

§ 1710. Hospital Pharmacy.

(a) A hospital pharmacy which predominantly furnishes drugs to inpatients of that hospital may furnish drugs to outpatients or employees of that hospital or to walk-in customers, provided that sales to walk-in customers do not exceed one (1) percent of all the pharmacy's prescriptions. Such a pharmacy is exempt from the requirements of Business and Professions code section 4113.1.

(b) A hospital pharmacy may process an order for filling patient cassettes by another pharmacy within this state, provided:

(1) The pharmacy that is to fill the cassettes either has a contract with the ordering hospital pharmacy or has the same owner as the ordering inpatient hospital pharmacy,

(2) The filled cassette is delivered directly from the filling pharmacy to the ordering hospital pharmacy,

(3) Each cassette or container meets the requirements of Business and Professions Code section 4076,

(4) Both pharmacies are responsible for ensuring that the order has been properly filled.

(5) Both pharmacies shall maintain complete and accurate records of each cassette fill transaction, including the name of the pharmacist checking the cassettes at each pharmacy.

(6) Prescription information shall be electronically transferred between the two pharmacies.

Credits

Note: Authority cited: Sections 4005 and 4118 Business and Professions Code. Reference: Sections 4005, 4029, 4076, 4113.1, 4118 and 4380, Business and Professions Code.

Attachment 4

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

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

Medication Error Reporting

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

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

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

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

A: For purposes of AB 1286 reporting, the term "medication error" includes any variation from a prescription drug order not authorized by the prescriber, including, but not limited to, errors involving the wrong drug, the wrong dose, the wrong patient, the wrong directions, the wrong preparation, or the wrong route of administration, but does not include any variation that is corrected prior to dispensing to the patient or patient's agent or any variation allowed by law.

[Reference: BPC 4113.1(d)]

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

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

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

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

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

posting information on the California Medication Error Reporting (CAMER) page on its website.

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

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

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

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

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

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

New Question:

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

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

New Question:

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

A: If the facility meets the definition of a "community pharmacy" under BPC section 4113.1, the facility is required to report medication errors through the CAMER program. It

is the responsibility of the pharmacist-in-charge to determine whether the facility is a "community pharmacy" as defined by BPC section 4113.1.

[Reference: BPC 4113.1]

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

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

[Reference: 16 CCR 1711]

Response Updated:

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

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

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

Minimum Staffing Provisions

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

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

- The pharmacist on duty waives the requirement in writing during specified hours based on workload need.
- The pharmacy is open beyond normal business hours, which is before 8:00 am and after 7:00 pm, in which case the minimum staffing requirement does not apply during the hours before 8:00 am and after 7:00 pm.
- The pharmacy's prescription volume per day on average is less than 75 prescriptions per day based on the average daily prescription volume for the past calendar year. However, if the pharmacist is also expected to provide additional pharmacy services such as immunizations, CLIA-waived tests, or any other ancillary services provided by law, this exemption does not apply.

In addition, where staffing of pharmacist hours within a chain community pharmacy does not overlap sufficiently, scheduled closures for lunch time for all pharmacy staff shall be established and publicly posted and included on the outgoing telephone

message.

Note: Additional minimum staffing requirements are detailed under "Pharmacy Technician Expanded Duties" below.

[Reference: BPC 4113.6]

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

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

[Reference: BPC 4113.6(a)]

Staffing Decisions

Response Updated:

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

A: AB 1286 amended BPC section 4113 to explicitly provide that the PIC "may" make staffing decisions to ensure sufficient personnel are present in the pharmacy to prevent fatigue, distraction, or other conditions that may interfere with a pharmacist's ability to practice competently and safely. Assembly Bill 1503 (Berman, Chapter 196, Statutes of 2025) further amended section 4113 to state that the PIC "shall" (instead of "may") make staffing decisions. This change becomes effective on January 1, 2026. The Board recommends that the PIC document their efforts to ensure sufficient staff are present.

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

[Reference: BPC 4113(c)(2); see also Stats. 2025, Ch. 196, Sec. 33 (AB 1503), effective January 1, 2026]

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

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

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

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

Unsafe Pharmacy Conditions

Response Updated:

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

A: AB 1286 added new subdivision (d) to BPC section 4113, pursuant to which the pharmacist-in-charge or pharmacist on duty is required to immediately notify store management of any conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff. Assembly Bill 1503 (Berman, Chapter 196, Statutes of 2025) further amended subdivision (d) to state that the PIC or pharmacist on duty shall immediately notify store management "or the building owner or a similar entity" of any such conditions. This change becomes effective on January 1, 2026.

Conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff may include, but are not limited to, any of the following:

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

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

[Reference: BPC 4113(d); see also Stats. 2025, Ch. 196, Sec. 33 (AB 1503), effective January 1, 2026]

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

A: Yes. Effective January 1, 2024, store management is required to take immediate and reasonable steps to address and resolve the conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff. The pharmacy owner may also close a pharmacy to mitigate against a perceived immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff.

[Reference: BPC 4113(d)]

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

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

[Reference: BPC 4113(d)]

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

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

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

[Reference: BPC 4113(d)]

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

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

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

Pharmacy Technician Expanded Duties

Response Updated:

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

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

- Prepare and administer influenza and COVID-19 vaccines via injection or intranasally
- Prepare and administer epinephrine
- Perform specimen collection for tests that are classified as CLIA
- Initiate and receive prescription transfers and accept clarification on prescriptions

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

Response Updated:

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

A: The law establishes several conditions, as follows:

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

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

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

Unprofessional Conduct

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

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

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

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

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

25. Q: Can I file a complaint anonymously?

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

New Question:

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

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

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

Surgical Clinic Provisions

Response Updated:

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

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

[Reference: BPC 4192(b)]

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

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

[Reference: BPC 4204(c)]

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

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

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

Response Updated:

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

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

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

[Reference: BPC 4204(c))

Draft Rev. November 6, 2025

Attachment 5

Chapter 2

BOARD MEETING PROCEDURES

Frequency of Meetings

(B&P Code Section 4002(b))

The board is required by law to meet at least once every four months and may meet more often as it determines necessary. Full board meetings are generally two days and are held in northern and southern California on an alternating basis when possible. Additionally, the board, or a committee of the board, shall meet once per quarter to hear petitions for modification of probation and license reinstatement. The board welcomes and encourages public participation at its meetings and provides for public participation via WebEx. The Board may, if necessary to address a time sensitive issue (i.e., in response to a declared disaster, to meet specified times established in the Administrative Procedures Act for enforcement related matters or regulations, etc.) may convene additional board meetings.

The board has established the following policy until January 1, 2030:

Committee meetings will be convened via teleconference consistent with Government Code section 11123.5.

- Petitions for modification of probation and license reinstatements will be considered by a committee of the board consistent with Business and Professions Code Section 4309(c).
- Board meetings will be convened with a public location where a quorum of the board is present. Additional members may participate from a non-public remote location consistent with the provisions of Government Code Section 11123.2(j)(1). Where an in-person quorum cannot be achieved, the Board will determine if conditions exist to convene the meeting consistent with Government Code Section 11123.2(j)(2).

Board Member Attendance at Board Meetings

(Board Policy)

Board members shall attend each meeting of the board. If a member is unable to attend, they must contact the board president and the executive officer and ask to be excused from the meeting for a specific reason. Minutes will reflect when a member is not present for a meeting. Two consecutive non-excused absences may result in a request to the appointing authority that the member be replaced.

Board Member Participation

(B & P Code Sections 106 and 106.5)

The appointing authority has the power to remove from office at any time any member of any board appointed by the appointing authority for continued neglect of duties required by law, or for incompetence, or unprofessional or dishonorable conduct. The governor may also remove from office a board member who directly or

Attachment 6

Board of Pharmacy

Enforcement Workload Statistics FY 2025/26

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As of 9/30/2025

Board of Pharmacy

Citation and Fine Statistics FY 2025/26

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

*These numbers are also represented in the RPH columns, but reflect how many RPHs were cited as PICs

**Intern Pharmacist, Licensed Correctional Facilities, Exempt Pharmacies, Non-Resident Pharmacies, and Vet Retailers

Top Ten Violations by License Type

Pharmacists	%	Pharmacies	%	Pharmacists In Charge	%
1304.11(c) - Inventory Requirements; Biannual inventory date	15%	1716 - Variation from prescription	32%	1304.11(c) - Inventory Requirements; Biannual inventory date	17%
1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	15%	4301(o) - Unprofessional conduct; assist in violation	10%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	17%
1716 - Variation from prescription	15%	4301(c)(d)(j)(o) - Unprofessional Conduct - Gross negligence/excessive furnishing of controlled substances/Violation of any statutes of this state or of the United States regulation controlled substance	8%	1715.65(a)(1) - Inventory Activities and Inventory Reconciliation reports... (a) Every pharmacy, and every clinic licensed under section 4180 or 4190 of the Business and Professions Code, shall perform	8%
4306.5(a) - Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist	8%	1761(a)(b) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…/A pharmacist shall not compound or dispense a prescription for a controlled substance	8%	1715(a) - Self-assessment form of a pharmacy by the pharmacist-in-charge; shall complete a self-assessment of pharmacy compliance with federal and state pharmacy law	8%
1715.65(a)(2) - Inventory Activities and Inventory Reconciliation reports... (a) Every pharmacy, and every clinic licensed under section 4180 or 4190 of the Business and Professions Code, shall perform	8%	4126.5(a)(5)(c) - A Pharmacy may furnish dangerous drugs only to the following: (5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law. (c) Notwithstanding any other law…	8%	1714(d)(e) - Operational Standards and Security: Each Pharmacist when on duty is responsible...The Pharmacy Owner is responsible...	8%
1715(a) - Self-assessment form of a pharmacy by the pharmacist-in-charge; shall complete a self-assessment of pharmacy compliance with federal and state pharmacy law	8%	4059(a) - Furnishing dangerous drugs without a prescription	8%	1714(d) - Operational Standards and Security; Pharmacist responsible for pharmacy security	8%
1714(d)(e) - Operational Standards and Security: Each Pharmacist when on duty is responsible...The Pharmacy Owner is responsible...	8%	11153(a) - Responsibility for legitimacy of prescription; a prescription for a controlled substance shall only be issued for a legitimate medical purpose...	8%	1714(c)(d) - Operational Standards and Security; pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition/Operational Standards and Security; Pharmacist responsible for	8%
1714(d) - Operational Standards and Security; Pharmacist responsible for pharmacy security	8%	1764/56.10(a) - Unauthorized disclosure of prescription and medical information	7%	1714(c) - Operational Standards and Security; pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition	8%
1714(c)(d) - Operational Standards and Security; pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition/Operational Standards and Security; Pharmacist responsible for	8%	1714(c) - Operational Standards and Security; pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition	5%	1707.2(b)(1)(C) - In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in	8%
1707.2(b)(1)(C) - In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in	8%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	5%	1793.2(b) - Duties of a pharmacy technician - Counting, pouring, or mixing pharmaceuticals;	8%

California State Board of Pharmacy

SB 1441 Uniform Standards

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

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

SB 1441 Uniform Standards

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

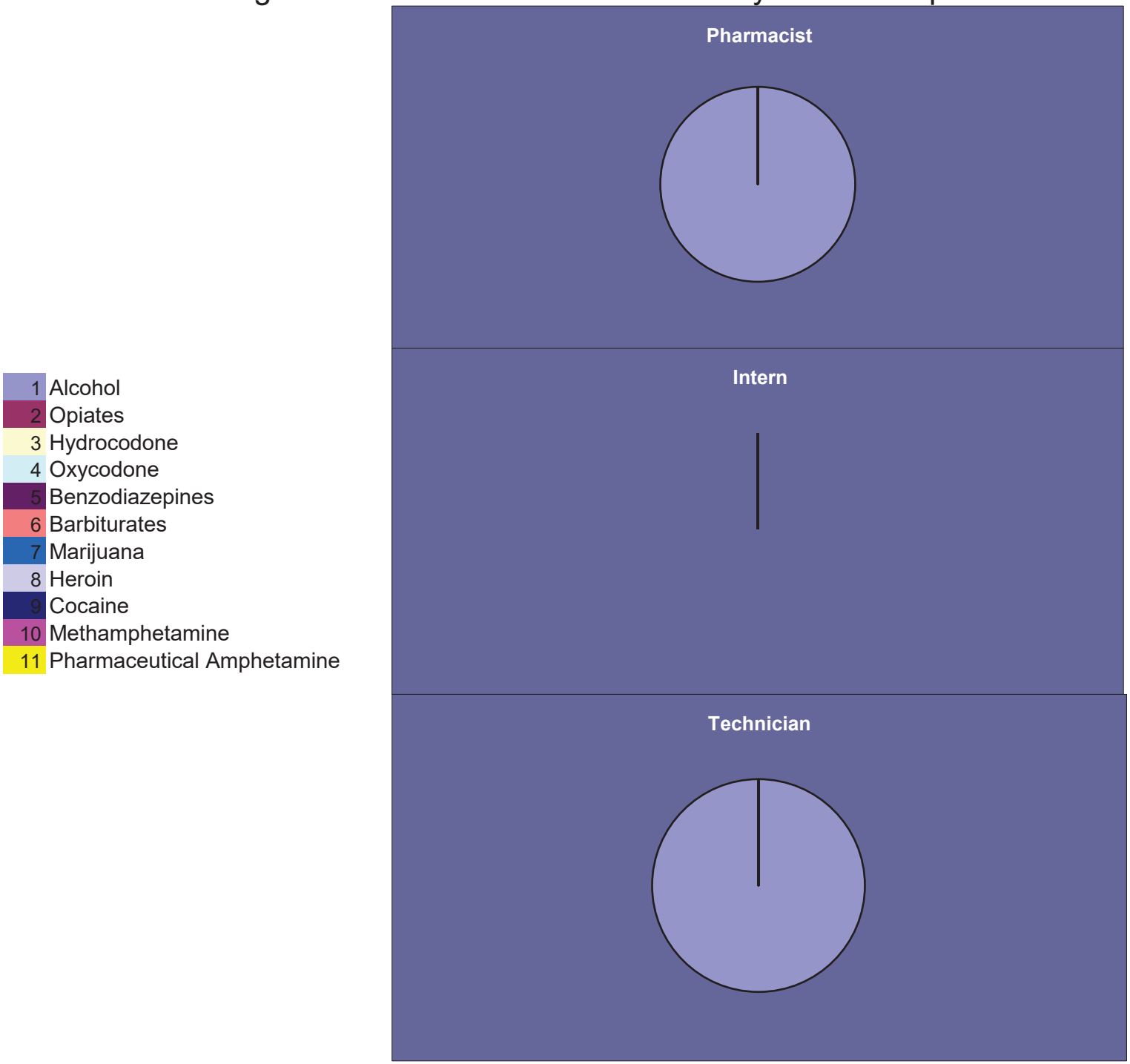
Board of Pharmacy	July -Sep	Oct Dec	Jan Mar	Apr Jun	25/26
Drug of Choice at PRP Intake or Probation					
Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 25/26**
Alcohol	1				1
Ambien					
Opiates					
Hydrocodone					
Oxycodone					
Morphine					
Benzodiazepines					
Barbiturates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

SB 1441 Uniform Standards

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

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

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



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