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

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

Enforcement and Compounding Committee Report
October 16, 2024

Maria Serpa, Licensee Member, Chair
Renee Barker, Licensee Member, Vice-Chair
Indira Cameron-Banks, Public Member
Jeff Hughes, Public Member
Seung Oh, Licensee Member, President
Nicole Thibeau, Licensee Member

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

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

Note: The Committee may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide whether to place the matter on the agenda of a future meeting. [Government Code sections 11125, 11125.7(a)]

III. Approval of Draft Minutes from the July 17, 2024 Enforcement and Compounding Committee Meeting

Attachment 1 includes a copy of the draft minutes.

IV. Presentation on Distribution of Controlled Substances, Wholesalers Perspective, Provided by Leah Lindahl, Vice President State Government Affairs, Healthcare Distribution Alliance and Sara Watson, CPhT, Manager, State Regulatory Outreach, Cardinal Health

Background

As of the April 2023 Committee Meeting, members received a presentation on drug shortages including information on DEA's response to stimulant shortages. As part of the presentation, members were advised about actions taken by the DEA to change allocation quotas and steps taken to increase manufacturer transparency. During this meeting, as well as in other meetings, members have received public comments from patients and chronic pain advocates about impacts to patients that cannot receive controlled substances medications.

For Committee Consideration and Discussion

During the meeting, members will receive a presentation on controlled substances distribution from the wholesalers' perspective.

V. Discussion and Consideration of Draft Report to the Legislature on Automated Drug Delivery Systems as Required in Business and Professions Code Section 4427.8

Relevant Law
Business and Professions Code (BPC) section 4427.8 requires the Board to report on the regulations of automated drug delivery system (ADDS) units as part of its sunset review process.

Background
To ensure the Board could respond appropriately and fully to the Legislature on the use of ADDS, the Board amended its quality assurance regulations, Title 16, California Code of Regulations Section 1711, to establish mandatory reporting requirements for medications related to the use of an ADDS.

The Committee has previously received presentations on the data and findings from these medication error reports, most recently during its July 2024 meeting. As was noted, the information learned from this reporting, would be included as part of the legislative report required.

For Committee Consideration and Discussion
During the meeting members will have the opportunity to review the draft of the legislative report and provide feedback to staff.

Attachment 2 includes a copy of the draft legislative report.

VI. Discussion and Consideration of Enrolled or Recently Signed Legislation Impacting the Practice of Pharmacy

a. Assembly Bill 1842 (Reyes, Chapter 633, Statutes of 2024) Health Care Coverage: Medication-Assisted Treatment

Summary: Will prohibit a health care service plan or health insurer from requiring prior authorization or step therapy for a naloxone or other opioid antagonist approved by the FDA or a buprenorphine or long-acting injectable naltrexone for detoxification or maintenance treatment of a substance use disorder.
Implementation: Staff recommend 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*.

b. Assembly Bill 1902 (Alanis, Chapter 330, Statutes of 2024) Prescription Drug Labels: Accessibility

Summary: Will require a pharmacy to provide translated directions for use on prescription labels, in the languages made available by the Board and will require a pharmacy to provide a person, at no additional cost, an accessible prescription label affixed to the container that meets specified conditions. Further, the provisions require a dispenser to ensure that a prescription label is compatible with a prescription reader if provided. The measure requires the Board to promulgate regulations necessary to implement this section.

Implementation: Staff recommend implementation activities focus on education on the provisions including highlighting the provisions in the Change in Pharmacy Law webinar, information in the upcoming issue of *the Script,* and updates to the community pharmacy self-assessment form.
Further during the meeting based on discussion and public comment, it may be appropriate to determine if the language of the statute is sufficient for self-execution or if regulations are necessary to provide clarity to the regulated public. For example, does the Board believe a regulation is appropriate to define "large print" or should this be determined on a case-by-case basis. If the Committee and Board believe a regulation is appropriate, staff will work with counsel to draft language for consideration at a future meeting. Consistent with past practice, staff will seek guidance from the Committee Chairperson.

c. Assembly Bill 2115 (Haney, Chapter 634, Statutes of 2024) Controlled Substances

Summary: Will authorize a nonprofit or free clinic to dispense a 72-hour supply of schedule II controlled substance for the purpose of relieving acute withdrawal symptoms while arrangements are being made for referral for treatment. Will allow for the dispensing of a C-II from a hospital pharmacy inventory not to exceed a 72-hour supply for purposes of initiating maintenance treatment and provides that no more than a 3-day supply may be dispensed at one time, while such arrangements are being made.
Implementation: Staff recommend implementation activities focus on education on the provisions including highlighting the provisions in the Change in Pharmacy Law webinar, information in the upcoming issue of *the Script,* and updates to the inpatient pharmacy self-assessment form.

d. Assembly Bill 3063 (McKinnor, 2024) Pharmacies: Compounding

Summary: Would have exempted from the definition of compounding the addition of a "flavoring agent that is inert, nonallergenic, and produces no other effect than the instillations or modification of flavor" if the flavoring agent does not alert the medication's concentration beyond the level of variance accepted in the United States Pharmacopeia. This measure was vetoed by the governor. The veto message is available here.

While the legislation was pending, the Board conveyed amendments that would have facilitated implementation of USP standards related to flavoring. Regrettably the Board's amendments were not accepted. Given the governor's recent action, it may be appropriate for the Committee to consider if it should sponsor legislation to facilitate implementation of the USP standards in line with the amendment sought during the legislative process. Provided below is the amendment language offered.

> *A flavoring agent may be added to a prescribed FDA approved drug in an oral liquid dosage form at the request of a patient or patient's agent without consultation with the prescriber or their authorized agent. A pharmacist performing such action must provide documentation on the prescription*

record.

Should the committee agree such action is appropriate Board staff can work with the Committee Chairperson to refine language for consideration by the Board during the November 2024 Board Meeting. The proposal could be incorporated into the Board's sunset report. The following motion could be used:

> **Possible Motion**: Recommend that the chairperson and staff work together to develop potential statutory language in line with the Board's prior requested amendment related to flavoring agents and prescription requirements.

e. Senate Bill 164 (Committee on Budgets, Chapter 41, Statutes of 2024) State Government

Summary: As related to Board licensees, will increase the CURES fee from $9 annually to $15 annually. These new fees in impact licenses expiring on or after April 1, 2025. Implementation: The Board anticipates that the Department of Justice will begin providing education to impacted licensees about the fee increase. The Board will share education through its listservs as appropriate. In addition, Staff recommend implementation activities focus on education on the provisions including highlighting the provisions in the Change in Pharmacy Law webinar, information in the upcoming issue of *the Script*. The Board's licensing systems will also require programming changes and renewal application forms will require updates.

f. Senate Bill 954 (Menjiva, 2024) Sexual Health

Summary: As related to the Board's jurisdiction, would have included provisions prohibiting a retail establishment from refusing to furnish nonprescription contraception to a person based solely on basis of age. This measure was vetoed by the governor. The veto message is available here.

g. Senate Bill 966 (Wiener, 2024) Pharmacy Benefits

Summary: Would have established the regulation of Pharmacy Benefit Managers (PBMs) within the California Department of Insurance, including actions that are prohibited by a PBM. This measure was vetoed by the governor. The veto message is available here.

Specifically related to the Board, staff note that one such prohibition included would have prohibited a pharmacy benefit manager from unreasonably obstruct or interfere with a patient's right to timely access to prescription drug or device that has been legally prescribed for a patient at a contract pharmacy of their choice. Such practice has been identified during investigations completed by the Board.

Staff note that one of the sunset issues under consideration by the Board is payor

practices that negatively impact patients. It may be appropriate to explore the feasibility of the Board pursuing a statutory change to address this patient care issue.

h. Senate Bill 1067 (Smallwood-Cuevas, 2024) Healing Arts, Expedited Licensure Process: Medically Underserved Area or Population

Summary: Would have required the Board (and other DCA Healing Arts Boards) to develop a process to expedite the licensure process by giving priority review to applications for which the applicant demonstrates that they intend to practice in a medically underserved area or serve a medically underserved population. This measure was vetoed by the governor. The veto message is available here.

i. Senate Bill 1089 (Smallwood-Cuevas, Chapter 625, Statutes of 2024) Addressing Food Injustice: Notice of Grocery and Pharmacy Closures

Summary: As related to the Board's jurisdiction, would require a covered establishment that includes a pharmacy, to provide 45-days advance notice of any closure to the Board.

Implementation: Staff recommend implementation activities focus on education on the provisions including highlighting the provisions in the Change in Pharmacy Law webinar, information in the upcoming issue of *the Script*. Further, staff note that the Board previously voted to pursue amendment to CCR section 1708.2 related to Discontinuance of Business requirements. As included in the proposed regulation text, a pharmacy would be required to provide notice to patients at least 30 days in advance of a proposed closure and provide the Board with a copy of the notice. It may be appropriate to consider if the Board wishes to make changes to the proposed rulemaking text to align the timeframe for notification with the statute. Should the Board believe such action is appropriate, staff can would with counsel to determine the appropriate path to facilitate such change.

j. Senate Bill 1468 (Ochoa Bogh and Roth, Chapter 488, Statutes of 2024) Department of Consumer Affairs

Summary: Will require the Board (and other DCA Healing Arts Boards) that license prescribers, to develop and biannually disseminate to each licensee information and educational materials regard the federal "Three Day Rule."

Implementation: Staff recommend implementation activities focus on education on the provisions including highlighting the provisions in the Change in Pharmacy Law webinar, information in the upcoming issue of *the Script*. Board staff contacted the Department of Consumer Affairs to learn if the Department will be assisting with the development of the requirement materials for use by the various impacted programs.

VII. Discussion and Consideration of FDA Actions Related to Implementation of the Drug Supply Chain Security Act

Relevant Law

21 United States Code Sections 360aaa et. seq, outlines the legal framework for the Drug Supply Chain Security Act, including definitions, requirements for stakeholders and provisions related to enforcement.

Background

The Drug Supply Chain Security Act (DSCSA) enacted as part of the Drug Quality and Security Act, aims to enhance the security of the pharmaceutical supply chain and prevent counterfeit drugs from entering the drug distribution channel. The DSCSA established requirements for drug manufacturers, repackagers, wholesale distributors, and dispensers, focusing on the serialization and traceability of prescription drugs.

The DSCSA provided a phased in approach, with several key milestones already required. Most recently, by November 27, 2032, the DSCSA required all prescription drug packages to be serialized with a unique identifier.

The FDA has published several draft and final guidance documents to assist stakeholders in understanding and implementing the requirements of the DSCSA including topics such as product tracing, verification, and interoperability.

As part of the Board's November 2023 Board Meeting, the Board received a presentation from Josh Bolin, Associate Executive Director, Government Affairs/Innovation on the DSCSA. As part of the presentation, Mr. Bolin shared information about FDA "Stabilization Period" guidance and provided an overview of a "pulse" solution developed by the NABP to facilitate interoperability. A number of important resources were also provided. The presentation slides are available here.

More recently, the FDA released information that it is issuing exemptions to small dispensers (pharmacies), and where applicable their trading partners, until November 27, 2026. This exemption provides small dispensers additional time to stabilize their operations to fully implement some of the requires of the DSCSA. The FDA noted that has information received suggests that small business dispensers have described challenges related to the time, costs, and resources needed to further develop the technologies and processes to enable data exchange with trading partners. Additional information is available here.

For Committee Consideration and Discussion

This information is provided for information only to ensure impacted licensees are apprised of actions taken by the FDA as it works to implement fully the requirements of the DSCSA.

VIII. Discussion and Consideration of Enforcement Statistics

During the first quarter of new fiscal year, July 2024-September 2024, the Board initiated 706 complaints and closed 764 investigations. The Board has issued 44 letters of admonishment, 156 citations and referred 43 cases to the Office of the Attorney General. The Board has revoked 25 licenses, accepted the disciplinary surrender of 8 licenses, formally denied five applications, and imposed other levels of discipline against 36 licensees and/or applicants.

As of October 1, 2024, the Board had 1,918 field investigations pending. Following is a breakdown providing more detail in the various investigation processes:

	Oct. 1, 2023		Jan. 1, 2024		Mar. 1, 2024		July. 1, 2024		Oct. 1, 2024	
	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days
Awaiting Assignment	88	22	152	15	107	7	44	6	63	14
Cases Under Investigation	982	138	1,037	146	1,061	134	1,005	136	908	146
Pending Supervisor Review	183	47	286	77	355	85	223	74	147	74
Pending Second Level Review	82	22	81	21	115	26	99	22	229	26
Awaiting Final Closure	34	13	26	19	24	3	56	8	34	14

Attachment 3 includes the enforcement statistics.

IX. Future Committee Meeting Dates

- January 8, 2025
- April 10, 2025
- June 11, 2025
- October 16, 2025

X. Adjournment

Attachment 1

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

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

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

Date: July 17, 2024

Location: OBSERVATION AND PUBLIC COMMENT IN PERSON:
California State Board of Pharmacy
2720 Gateway Oaks Drive, First Floor Hearing Room
Sacramento, CA 95833

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

PUBLIC PARTICIPATION AND COMMENT FROM REMOTE LOCATIONS VIA WEBEX

Board Members Present:
Maria Serpa, PharmD, Licensee Member, Chair
Renee Barker, PharmD, Licensee Member, Vice Chair
Seung Oh, PharmD, Licensee Member
Nicole Thibeau, PharmD, Licensee Member

Board Members Not Present:
Indira Cameron-Banks, Public Member
Jeff Hughes, Public Member

Staff Present:
Anne Sodergren, Executive Officer
Julie Ansel, Deputy Executive Officer
Corinne Gartner, DCA Counsel
Jennifer Robbins, DCA Counsel
Debbie Damoth, Executive Specialist Manager

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

Chairperson Serpa called the meeting to order at approximately 9:00 a.m. As part of the opening announcements, Chairperson Serpa reminded everyone that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. Department of Consumer Affairs' staff provided instructions for participating in the meeting.

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

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

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

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

Members of the public were provided the opportunity to comment via WebEx.

A civil engineer and pain advocate commented on ongoing controlled substances shortages made worse by the state attorney generals' nation-wide opioid settlement with the three major drug distributors. The commenter requested prioritization of the agenda item to discuss the injunctive threshold issue.

A representative of CSHP and individual pharmacist requested the discussion of enforcement of AB 352 related to the letter from the attorney general's office to CVS Pharmacy.

Members were surveyed to see if they wanted to add any of the suggested items to a future agenda.

Chairperson Serpa noted the issue related to thresholds would be included on a future agenda.

Members discussed adding to a future agenda item enforcement of AB 352 and the letter to CVS Pharmacy. Members were cautioned against providing legal advice at the meetings and the agenda item would be taken under advisement.

III. Approval of Draft Minutes from the April 11, 2024 Enforcement and Compounding Committee Meeting

The draft minutes of the April 11, 2024 Enforcement and Compounding Committee meeting were presented for review and approval.

Motion: Approve April 11, 2024 Enforcement and Compounding Committee meeting minutes as presented

M/S: Oh/Barker

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

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

Board Member	Vote
Barker	Support
Cameron-Banks	Not Present
Hughes	Not Present
Oh	Support
Serpa	Support
Thibeau	Support

IV. Presentation on Board's Inspection Program

Chairperson Serpa recalled strategic objective 2.3 of the Board's strategic plan calls for completion of routine inspections of all licensed pharmacies at least every four years to proactively assess pharmacy operations and educate licensees. On an annual basis, the Committee receives a presentation providing summary information detailing accomplishments towards this objective. Dr. Serpa commended Board staff on their significant efforts to meet the Board's strategic goal without any additional resources.

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

Following the presentation, members were provided the opportunity to comment. Members thought the presentation was informative, were pleased to see the improvement without additional staff, and thanked the staff for their diligent work. A member discussed the decrease in pharmacies from 2020 to current fiscal year trending down approximately 10 percent and expressed interest in learning more about the trending decrease.

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

Members of the public were provided the opportunity to comment via WebEx.

A pharmacists applauded the Board for improving toward the goal of inspecting every pharmacy every four years and thought it would be interesting to compare pre-COVID and post-COVID statistics. The pharmacist asked for the Board to report on how pharmacies are offering telephone service six days a week when pharmacies are often open five days a week. The pharmacist agreed needing to understand why pharmacies are decreasing.

Members were provided the opportunity to comment after having received public comment; however, no comments were received.

V. Presentation on Board's Citation Program

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

Dr. Serpa welcomed Executive Officer Anne Sodergren to provide the annual citation program. Ms. Sodergren reminded members and participants depending on the nature and severity of the violations, the Board has various tools to use ranging from education, issuance of a letter of admonishment, or issuance of a citation, all of which represent non-disciplinary outcomes. She highlighted when the Board takes disciplinary action, it was done through the provisions of the Administrative Procedure Act. Ms. Sodergren reviewed the complaint and citation process; and relevant law including fine authority. Ms.

Sodergren provided an overview of factors considered in assessing administrative fines and reviewed citation statistics including the use of orders of abatement. Ms. Sodergren highlighted the appeal process and appeal outcomes. Ms. Sodergren reviewed top violations by license type as well as related to duty to consult.

Following the presentation, members were provided the opportunity to comment. A member noticed the fines collected were lower than the fines assessed and inquired why this was the case. Ms. Sodergren provided sometimes fines are spread out across fiscal year or were reduced through the appeal process.

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

Members of the public were provided the opportunity to comment via WebEx.

A commentor asked if the medication error was for lack of having a medication error report or if an actual medication error occurred.

A pharmacist commented the report was helpful to share with pharmacy students and requested more information on a term unfamiliar to the commenter as "citation for misuse of pharmacy education or pharmacist education" and requested examples be provided.

Members were provided the opportunity to comment after having received public comment; however, no comments were received.

The Committee took a break from 10:20 a.m. to 10:35 a.m. Roll call was taken. The following members were present via WebEx: Renee Barker, Licensee Member; Seung Oh, Licensee Member; Nicole Thibeau, Licensee Member; and Maria Serpa, Licensee Member. A quorum was established.

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

Chairperson Serpa referenced meeting materials noting the Board was required to submit a report to the Legislature on the regulation of automated drug delivery systems (ADDS) as part of the upcoming sunset evaluation process. At the July 2023 Committee meeting, members received the first presentation related to the findings of the quality assurance (QA) reports received when Dr. Serpa expressed concern about what appeared to be a lack of compliance with reporting requirements. However, based on review of the presentation, Dr. Serpa was pleased to report that the issue appears to have at least in part been addressed. Dr. Serpa thanked everyone submitting reports and the staff for performing additional education about the mandatory reporting.

Dr. Serpa welcomed Supervising Inspector Janice Dang, PharmD, to provide the presentation on the data received through these reports. Dr. Dang provided an overview of the ADDS system and the requirement for the Board to report the public safety concerns related to the ADDS as part of the sunset review process. Dr. Dang provided information about the ADDS Quality Assurance Reporting requirements and ADDS medication error reporting requirements.

Dr. Dang provided an overview of the data collected from July 2023 to April 2024. She reviewed the four types of ADDS related medication errors by ADDS location including inside a pharmacy; under California Department of Public Health's (CDPH) General Acute Care Hospital license; at long-term care and psychiatric health facilities; and at correctional clinics and jails. Dr. Dang provided a summary of work the Board is continuing to complete related to ADDS.

Following the presentation, members were provided the opportunity to comment; however, no comments were made.

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

Members of the public were provided the opportunity to comment via WebEx.

A pharmacist representative of Kaiser Permanente requested with the passage of AB 1286 requiring medication errors in outpatient settings be reported to the Board and CDPH requires robust hospital medication error reduction program that once the report is made to the legislature, the

requirement for ADDS medication errors to be required to the Board was redundant and requested it be deleted.

VII. Discussion on Draft Policy Statement Related to IV Hydration Clinics

Chairperson Serpa referenced relevant sections of federal law that establish the conditions under which compounded human drug products are exempt from three sections of the federal Food, Drug and Cosmetic Act in the meeting materials. Also provided was some background information on the issue of IV hydration clinics, including information about warnings released by the FDA involving instances of drug products being compounded under insanitary conditions. The materials highlighted that many warnings stem from compounding occurring at sites that are not regulated by the Board, including IV hydration clinics.

Dr. Serpa recalled at the April 2024 April Committee meeting, IV hydration clinics appeared to be operating in a number of settings, including beauty salons, mobile vans, and gymnasiums, and appear to lack appropriate oversight, use of appropriate equipment, and proper storage, placing patients at risk. These issues were occurring across the nation, including in California. Dr. Serpa noted Board staff have observed inspections in some IV hydrations clinics and report witnessing alarming practices placing consumers at risk. Staff also report challenges with conducting investigations because even basic patient information (administration information, *etc.)* was not maintained and/or provided to the Board.

Given the risk to patients and the documented harm, Dr. Serpa recalled this issue was brought before the Committee to consider the issue and determine if there were any actions the Board should take to protect patients and was determined the Board should have a greater role in monitoring this practice starting with the development of a policy statement to educate consumers about IV hydration clinics and some potential risks, without creating undue concern for patients that have a medication condition that requires such treatment. Dr. Serpa referenced meeting materials that included a draft policy statement with the approved statement including contact information for the various healing arts boards to aid consumers in understanding more for those programs as well. She reviewed the draft and believed it was appropriate. Dr. Serpa believed it provided education and action steps consumers can take to protect themselves.

Members were provided the opportunity to comment.

Dr. Barker thought it was a great place to start with the draft policy and made suggestions to clarify key words and add examples to other key words. She suggested adding that there can be little or no evidence that these mixtures work. Dr. Barker also recommended moving the caution of risk to the beginning of the document as well as referencing FDA's 2021 statement "FDA Highlights Concerns of Compounding of Drug Products by Medical Offices and Clinics under Insanitary Conditions" as a reference or resource.

Motion: Recommend the approval of the draft policy statement consistent with the committee's discussion and authorizing the executive officer to make changes working with the Enforcement and Compounding Committee Chairperson

M/S: Barker/Oh

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

Members of the public were provided the opportunity to comment via WebEx.

The Board heard comments from the public recommending hearing how other health care professional boards are handling the issue and making sure the tone was appropriate for the seriousness of the issue. Other comments received included asking if this would address all types of infusion.

Dr. Serpa advised the statement would include the other health care professional boards with contact information.

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

Board Member	Vote
Barker	Support
Cameron-Banks	Not Present
Hughes	Not Present
Oh	Support
Serpa	Support
Thibeau	Support

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

Chairperson Serpa recalled as part of the Committee's discussion on implementation of Assembly Bill 1286 and based on the comprehensive nature of the measure, the development of frequently asked questions (FAQs) was deemed appropriate. Dr. Serpa added the FAQs were initially approved during the February 2024 Board meeting and noted that additional questions may need to be added. The Committee considered and approved updates at the April 2024 Committee meeting. Meeting materials include additional updates for consideration including the new questions 8 and 19 and highlighted in yellow.

Members were provided the opportunity to comment. Members discussed the confusion and the unintended consequences of providing the FAQ 19. The Committee agreed to remove the FAQ 19. Staff was directed to schedule discussion for the Board to evaluate the statutory requirement in Business and Professions Code (BPC) section 4115(b)(1). It was noted that the discussion related to the BPC section 4115 (b)(1) telephone transfers would pair well with the discussion of pharmacy technician training and authorization at a differ Committee.

Motion: Recommend approval of the additional FAQs related to Assembly Bill 1286 without question 19

M/S: Oh/Thibeau

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

Members of the public were provided the opportunity to comment via WebEx.

The Board heard comments from the public supporting the removal of question FAQ #19 and appreciated clarification of the statute as well as clarifying training elements in BPC 4115. The Board also heard comments regarding FAQ #8 if nonresident pharmacies only need to report errors regarding California residents.

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

Board Member	Vote
Barker	Support
Cameron-Banks	Not Present
Hughes	Not Present
Oh	Support
Serpa	Support
Thibeau	Support

IX. Discussion and Consideration of Committee's Strategic Objectives

Chairperson Serpa referenced meeting materials containing the Enforcement and Compounding Committee's ten strategic objectives as well as updates on the objectives, highlighting efforts over the past year. Dr. Serpa was proud of the Committee's accomplishments towards its strategic objectives and was looking forward to continued efforts, including activities related to reducing medication errors which is core to the Board's consumer protection mandate.

Dr. Serpa also acknowledged the progress staff made to meeting the strategic objective in 2.3 and believed great strides were made to reach the four-year benchmark. Currently, 79.7% of pharmacies have been inspected within the 4-year period. She highlighted that only 0.3% of licensed pharmacies have never been inspected and presumed those facilities would be prioritized in the coming year and looked forward to continued pursuit of this strategic objective.

Dr. Serpa highlighted that while the Committee's work was complete in strategic goal 2.5 specifically related to consideration of further use of a Standard of Care Enforcement Model, with submission of the legislative report, work in this general area continues through the Licensing Committee who was considering provisions related to a more robust standard of care practice model for pharmacists.

Dr. Serpa believes as the Committee continued work related to strategic objective 2.8, it may be appropriate to focus some efforts on education of nonresident pharmacies. This would serve as a nice complement to the work being undertaken by the Licensing Committee related to the regulation of nonresident pharmacies.

Dr. Serpa added the work related to strategic objective 2.10 resulted in the initiation of the formal rulemaking process to update the Board's

compounding regulations and was proud of the work completed as a Committee. Dr. Serpa appreciated all of the engagement received from interested parties and looked forward to discussing the regulations during the July 31-August 1, 2024 Board meeting.

Dr. Serpa believed it may be appropriate to add a new strategic objective aimed at evaluating the barriers to patient consultation. Appropriate patient consultation would reduce medication errors and also improve patient understanding of medication adherence and safety and address challenges with low medication health literacy rates.

Members were provided the opportunity to comment. Members congratulated staff for their hard work resulting in progress. Members discussed adding a strategic goal to enhance patient consultation compliance by evaluating barriers to consultation to provide patient education and reduce medication errors. Members discussed working with the Communication and Public Education Committee to ensure consumers know and understand the importance of consultation.

Motion: To add Strategic Goal 2.11 – enhance patient consultation compliance by evaluating barriers to consultation to provide patient education and reduce medication errors.

M/S: Oh/Thibeau

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

Members of the public were provided the opportunity to comment via WebEx.

The Board heard comments from the public supporting the progress of the Committee and supporting the consultation goal. Comment was received in support of a study for the value of pharmacist consultation.

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

Board Member	Vote
Barker	Support
Cameron-Banks	Not Present
Hughes	Not Present
Oh	Support
Serpa	Support
Thibeau	Support

X. Review and Discussion of Enforcement Statistics

Chairperson Serpa referenced meeting materials that included a summary of enforcement statistics for fiscal year 2023/24 as well as three-year comparison data. The Board has initiated 3,183 complaints and closed 3,237 investigations. As of July 1, 2024, the Board has 1,662 field investigations pending. The materials provide a breakdown of the average timeframe for the various stages of the field investigation process. Dr. Serpa noted improvement in the average time for cases pending supervisor review and thanked everyone that contributed to reduce that review time.

Dr. Serpa noticed the Board has realized a 5% growth in investigations received as well as an increase in the number of cases closed with insufficient evidence. Staff have advised that this trend in part can be explained by an increase in consumer complaints received that are non-jurisdictional such as customer service issues.

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

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

XI. Future meeting dates and adjournment

Chairperson Serpa thanked everyone for their time and participation, noting the next meeting was currently scheduled for October 16, 2024.

X. Adjournment

The meeting adjourned at 12:10 p.m.

Attachment 2

Automated Drug Delivery Systems

CALIFORNIA STATE
BOARD OF PHARMACY

CALIFORNIA STATE BOARD OF PHARMACY

Members

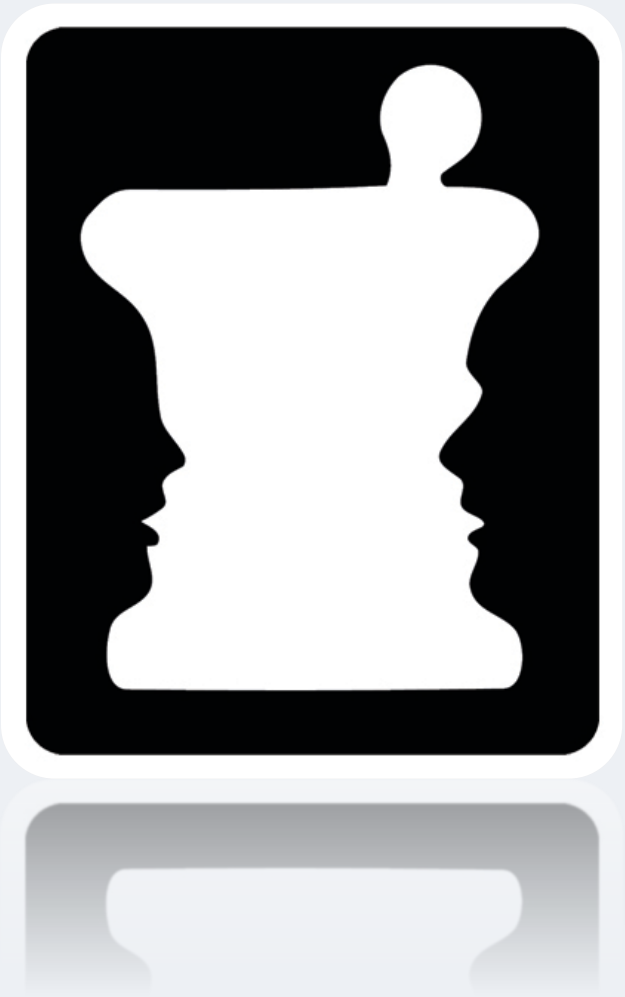
Seung Oh, PharmD, President
Jessica Crowley, PharmD, Vice President
Trevor Chandler, Treasurer
Renee Armendariz Barker, PharmD
Indira J. Cameron-Banks
Jeff Hughes
Kartikeya Jha, RPh
Jason Newell, MSW
Satinder Sandhu, PharmD
Maria D. Serpa, PharmD
Nicole Thibeau, PharmD
Jason Weisz

Vision

Healthy Californians through quality pharmacist's care.

Mission

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



January 6, 2025

Summary

As required in Business and Professions Code section 4427.8, the California State Board of Pharmacy (Board) is pleased to report to the Legislature its efforts in regulating Automated Drug Delivery System (ADDS) units. This report will

- Summarize the specified information and recommendations offered at the conclusion of the report,
- Describe the use and dispersion of ADDS throughout the health care system,
- Highlight the number of ADDS prelicensure inspections conducted by the Board and its findings from these inspections,
- Discuss public safety concerns related to the use of ADDS.

Background

A pilot study conducted by the University of California, San Diego (UCSD) and Sharp Memorial Hospital in San Diego sought to evaluate the use of an ADDS for the dispensing of the hospital employee's prescriptions and their dependents. The study results presented to Board concluded that the ADDS was a convenient and safe extension of the hospital's pharmacy, with similar prescription pick up and consultation patterns at the regular pharmacy counter.

Given the results, the Board sponsored legislation to expand the use of automated drug delivery systems to include provisions to allow patients who choose to do so, to pick up their prescriptions from an ADDS, as well as, to develop licensing requirements for such devices while also expanding the settings where ADDS may be utilized. Many of the current statutory requirements were included in Senate Bill 1447 (Chapter 666, Statutes of 2018) and Assembly Bill 1533 (Chapter 629, Statutes of 2021).

Types of Technology

Business and Professions Code section 4017.3 defines an ADDS as a mechanical system that performs operations or activities, other than compounding or administration, related to the storage, dispensing, or distribution of drugs. As required by law, the ADDS shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability. Further, the law defines two subcategories of ADDS including "automated unit dose system" (AUDS) and "automated patient dispensing system" (APDS).

An AUDS is an ADDS for storage and retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions, such as a nurse within a hospital or skilled nursing facility. An APDS is an ADDS used for storage and dispensing of prescribed drugs directly to patients pursuant to a prior authorization by a pharmacist, such as at a pharmacy, medical office or clinic. The provisions for licensure and legal requirements vary based on the specific type of ADDS.

The law establishes provisions for licensure of ADDS operated by pharmacies while also allowing for use of unlicensed ADDS operated by pharmacies under specific conditions.

Further, the law allows for the use of ADDS by an Emergency Medical Services (EMS) provider agency for the restocking of secured emergency pharmaceutical supplies containers.

Licensed locations where the ADDS is operated by a pharmacy include:

- Adjacent to a pharmacy
- A health care facility licensure pursuant to Health and Safety Code 1250
- Clinics, including primary care and specialty clinics, free clinics, surgical clinics and correctional clinics
- Medical offices
- Locations where patients are regularly seen for purposes of diagnosis and treatment and patients of the practice
- Licensed facilities with the statutory authority to provided pharmaceutical services such as psychiatric health facilities.
- Jails, youth detention facilities and other correctional facilities
- "Covered entities" or affiliated sites as established in 42 United States Code 256b
- On the premises of a fire department headquarters, fire station or EMS provider agency location.

Unlicensed locations where licensure is not required include:

- Licensed hospitals used solely to provide doses administered to patients in an acute care hospital or licensed acute psychiatric hospital facility.
- ADDS used within the secured licensed premises of a pharmacy, used for the selecting, counting, packaging, and labeling of dangerous drugs and dangerous devices.

Licensing and Inspection Activities:
Following enacted of Senate Bill 1447 and related measures, the Board undertook a number of implementation activities including education on the requirements. Although the provisions for licensure became effective July 1, 2019, the Board implemented its application and inspection process in advance of the July 1, 2019, effective date to ensure those entities interested in using the technology were positioned to do so immediately. As of July 1, 2024, the Board has licensed 1,832 ADDS in California. This includes:

- 376 automated unit dose devices operated by the California Department of Corrections and Rehabilitation.[1]
- 735 automated unit does devices used in other health care facilities including hospitals, skilled nursing facilities, jails, etc.[2]
- 15 automated patient dispensing devices[3].
- 1 automated delivery device used to restock ambulances[4].
- 1 automated patient dispensing device used in a 340B clinic[5].

[1] Business and Professions Code section 4187.5
[2] Business and Professions Code sections 4427.2 & 4427.3
[3] Business and Professions Code section 4427.6
[4] Business and Professions Code section 4119.01
[5] Business and Professions Code section 4119.11

The Board has performed 2,004 pre-licensure inspections. These pre-licensure inspections provide a better window in to understanding the unique issues facing various settings. As the Board learned about some of these challenges, it sought changes in Assembly Bill 1533 expanding authority for use of ADDS.

Board inspector staff have provided significant education based on the various settings and unique challenges. As examples.

1. The use of an ADDS in an emergency department of a hospital requires licensure by the Board, while ADDS used within the hospital for administration to patients is exempt from licensure. This has led to some confusion. In such an instance, the Board provides education about labeling requirements for medications that are dispensed from the ADDS for patients discharged from the emergency department and well as the requirements to report to CURES if the prescription is for a controlled substance.
2. The placement of ADDS is important as some of the dispensing devices are in the waiting area of a medical office, creating challenges in maintaining patient confidentiality. Inspector staff offered recommendations such as reposition devices or utilization of privacy screens.
3. In some instances, the ADDS was placed in a closet which lacked ventilation and temperature control. Inspector staff offered recommendations to modify the room or closet to allow better circulation to ensure appropriate storage of medications that must be maintained within specific temperature ranges.
4. Some facilities were not familiar with DEA requirements for controlled substances in an ADDS. In addition to providing education, at times, reinspection was necessary to ensure compliance was achieved.
5. Many inspections revealed either insufficient policies and procedures or failure to adhere to policies.

Quality Assurance Requirements

To ensure the Board was positioned to respond to the questions posed by the Legislature, the Board amended its Quality Assurance Regulations, to require reporting of medication errors stemming from the use of ADDS. Although the regulations became effective July 1, 2021, the Board did not receive reports from many of the entities as required. The Board undertook significant educational activities to try to gain compliance with the reporting requirements including as part of the Board's FAQs and newsletters, in licensure renewals and self-assessments, education through the inspection process and through phone calls. The significant increase in reporting as noted in the tables below for FY 2023/24 demonstrates the impact of the Board's educational efforts.

Medication Errors Reported by Type of ADDS FY 2023/2024

Type of Device	Number of reports
ADDS (used inside a pharmacy for counting, etc.)	280
AUD (used for unit dose administration)	1,929

APD (patient-dispensing device)	0
Unknown	3

ADDS Medication Error Reports Received

Operated By	FY 20/21	FY 21/22	FY 22/23	FY 23/24*
Pharmacies	252	305	53	770
Hospitals	0	0	151	294
Exempt Hospitals	0	0	0	101
Licensed Correctional Facilities	1	11	66	1047
Total	253	316	270	2,212

*Includes reports submitted through March 1, 2024.

ADDS Medication Errors Reported by Location Type

Operated By	FY 20/21	FY 21/22	FY 22/23	FY 23/24*
Adjacent to Pharmacy	0	0	0	0
Medical Office	0	0	0	0
Clinic	0	0	0	2
Correctional Clinic	1	11	63	1,034
Skilled Nursing Facility	0	0	0	340
Intermediate Care Facility	0	0	3	0
Inside the Pharmacy	252	305	49	281
Other	0	0	155	555, including 395 at hospitals
Total	253	316	270	

Types of ADDS Medication Errors Reported

	FY 20/21	FY 21/22	FY 22/23	FY 23/24*
Wrong Drug	28	39	37	200
Wrong Strength	0	6	21	141
Wrong Quantity	210	258	55	583
Wrong Patient	0	1	8	321
Labeling Error	15	4	1	4
Duplicate Therapy	0	0	6	24
Expired Drug	0	0	1	6

Unauthorized Dispensing	0	0	139	924
Unknown	0	8	2	598
Total	253	316	270	2,801**

** a medication error report may have into more than one category

Based on reports received, the data suggests that access to medications directly from an APDS device as allowed under the law, does not appear to create additional patient safety concerns from ADDS medication errors. This is consistent with the findings of the initial study of APDS conducted by UCSD. However, the data does reveal a concerning number of errors, some with the potential of causing patient harm or death stemming from the use of AUDS.

The data reveals that unauthorized dispensing accounts for the greatest number of ADDS medication errors reported. This occurred most frequently with the use of AUDS devices in hospitals, skilled nursing facilities and correctional clinics where authorized individuals (registered nurses, licensed vocational nurses, etc.) accessed a medication that was not ordered for a patient or removed medication without authorization by utilizing the device's override function. Further, almost 25% of the errors reported were patients receiving the wrong medication or a medication intended for another patient. ADDS medication errors involving duplicate therapy and the wrong medication strength also have the potential of causing patient harm or death depending on the type of medication.

ADDS medication errors related to the quantity dispensed into a prescription can, but generally would not, result in potential patient harm. Quantity errors can lead to interruptions in therapy when a patient receives less than their full quantity and runs out medication. Such errors are typically related to the use of an ADDS located inside a pharmacy used for purposes of selecting, counting, packaging, and labeling prescriptions.

The Board further notes that, over 25% of the ADDS medication error reports received did not provide sufficient data for evaluation and to understand the type of error.

Conclusions:
The use of ADDS for medication distribution is found throughout a variety of health care settings. ADDS offer medication security and the opportunity to improved patient care. Risks exist with the use of technology that is not appropriately implemented and utilized. After review and discussion of the data, the Board finds ADDS have many technological safeguards available, but some facilities elect not to use some features or allow staff to override the safeguards. Further, review of the ADDS medication error reports suggests that failure to follow a facility's established policies and procedures related to the use of an ADDS can lead to medication errors.

The Board has presented these findings during a public meeting and intends to release further education materials and best practices on the use of ADDS. Since ADDS medication error reporting to the Board has been limited and to ensure there is data necessary to perform ongoing assessment of ADDS medication errors, it is anticipated the Board will continue to require ongoing submission of reports for the foreseeable future. The Board may consider developing a standardized report template to assure sufficient information is included in the ADDS medication error report for evaluation.

Further, the Board notes that while recently enacted legislation requires the reporting of medication errors that occur in specified community pharmacies, that reporting requirement does not extend to all environments where ADDS are in use.

State of California

Governor Gavin Newsom
Kimberly Kirchmeyer, Director, Department of Consumer Affairs

California State Board of Pharmacy Executive Staff

Anne Sodergren, Executive Officer
Julie Ansel, Deputy Executive Officer

Additional Copies of this report can be obtained from
www.pharmacy.ca.gov

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
(916) 518-3100

Attachment 3

Board of Pharmacy

Enforcement Workload Statistics FY 2024/25

Complaint Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	706	0	0	0	706
Closed	764	0	0	0	764
					Quarter Ending
Pending	1,918	0	0	0	1,918
Average Days for Investigation	237	0	0	0	237

Cases Under Investigation (By Team)	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Compliance / Routine	830	0	0	0	830
Drug Diversion / Fraud	242	0	0	0	242
Prescription Drug Abuse	178	0	0	0	178
Compounding	56	0	0	0	56
Outsourcing	7	0	0	0	7
Probation / PRP	36	0	0	0	36
Enforcement	59	0	0	0	59
Criminal Conviction	510	0	0	0	510

Application Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	41	0	0	0	41
Closed					
Approved	29	0	0	0	29
Denied	17	0	0	0	17
Total Closed (includes withdrawn)	***49***	***0***	***0***	***0***	***49***
Pending	90	0	0	0	90

Complaint Closure Outcomes Not Resulting in Further Action	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Insufficient Evidence	356	0	0	0	356
Non-Jurisdictional	86	0	0	0	86
No Violation	37	0	0	0	37
No Further Action	47	0	0	0	47
Other / Non-Substantiated	40	0	0	0	40
Subject Educated	19	0	0	0	19

Letter of Admonishments / Citations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
LOA Issued	44	0	0	0	44
Citations Issued	156	0	0	0	156
Proof of Abatement Requested	12	0	0	0	12
Appeals Referred to AG's Office	63	0	0	0	63
Dismissed	7	0	0	0	7
Total Fines Collected	***$612,872***	***$0***	***$0***	***$0***	***$612,872***

Administrative Cases	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Referred to the AG's Office	43	0	0	0	43
Pleadings Filed	65	0	0	0	65
Total Closed	68	0	0	0	68
Pending					Quarter Ending
Pre-Accusation	123	0	0	0	123
Post-Accusation	181	0	0	0	181
Total Pending	**304**	**0**	**0**	**0**	**304**

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation					
Pharmacist	4	0	0	0	4
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	20	0	0	0	20
Designated Representative	1	0	0	0	1
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	***25***	***0***	***0***	***0***	***25***

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	11	0	0	0	11
Intern Pharmacist	1	0	0	0	1
Pharmacy Technician	3	0	0	0	3
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	5	0	0	0	5
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***20***	***0***	***0***	***0***	***20***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Surrender / Voluntary Surrender					
Pharmacist	0	0	0	0	0
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	5	0	0	0	5
Designated Representative	0	0	0	0	0
Wholesaler	2	0	0	0	2
Pharmacy	1	0	0	0	1
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***8***	***0***	***0***	***0***	***8***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Public Reproval / Reprimand					
Pharmacist	7	0	0	0	7
Intern Pharmacist	1	0	0	0	1
Pharmacy Technician	1	0	0	0	1
Designated Representative	1	0	0	0	1
Wholesaler	0	0	0	0	0
Pharmacy	3	0	0	0	3
Sterile Compounding	1	0	0	0	1
Outsourcing	0	0	0	0	0
Total	***14***	***0***	***0***	***0***	***14***

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	2	0	0	0	2
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	***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	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 Cost Recovery Efforts	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Cost Recovery Requested	***$281,598***	***$0***	***$0***	***$0***	***$281,598***
Cost Recovery Collected	***$198,145***	***$0***	***$0***	***$0***	***$198,145***

Immediate Public Protection Sanctions	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Interim Suspension Orders	5	0	0	0	5
Automatic Suspension Orders	0	0	0	0	0
Penal Code 23 Restrictions	1	0	0	0	1
Cease and Desist - Outsourcing	0	0	0	0	0
Cease and Desist - Unlicensed Activity	0	0	0	0	0
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	166	0	0	0	166
Intern Pharmacist	4	0	0	0	4
Pharmacy Technician	29	0	0	0	29
Designated Representative	1	0	0	0	1
Wholesaler / 3PL	3	0	0	0	3
Pharmacy	54	0	0	0	54
Sterile Compounding	9	0	0	0	9
Outsourcing	0	0	0	0	0
Total	***266***	***0***	***0***	***0***	***266***
Probation Compliance Measures					Total
Probation Office Conferences	21	0	0	0	21
Probation Interviews / Site Inspections	183	0	0	0	183
Probation Terminated / Completed	16	0	0	0	16
Referred to AG for Non-Compliance	0	0	0	0	0

As of 9/30/2024

Board of Pharmacy

Citation and Fine Statistics FY 2024/25

Citation Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Pharmacist with Fine	15	0	0	0	15
Pharmacist-in-Charge with Fine*	9	0	0	0	9
Pharmacist no Fine	24	0	0	0	24
Pharmacist-in-Charge no Fine*	24	0	0	0	24
Pharmacy with Fine	56	0	0	0	56
Pharmacy no Fine	29	0	0	0	29
Pharmacy Technician with Fine	9	0	0	0	9
Pharmacy Technician no Fine	11	0	0	0	11
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	2	0	0	0	2
Miscellaneous**	20	0	0	0	20
Unlicensed Premises	1	0	0	0	1
Unlicensed Person	0	0	0	0	0

*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	%
1761(a)/4306.5(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…/Acts or omissions that involve, in whole or in part, the inappropriate	13%	1716 - Variation from prescription	38%	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	17%
4059(a) - Furnishing dangerous drugs without a prescription	13%	1764/56.10(a) - Unauthorized disclosure of prescription and medical information	18%	4059(a) - Furnishing dangerous drugs without a prescription	13%
11153(a) - Responsibility for legitimacy of prescription; a prescription for a controlled substance shall only be issued for a legitimate medical purpose...	13%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	11%	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) Nothwithstanding any other law…	13%
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) Nothwithstanding any other law…	13%	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	7%	11153(a) - Responsibility for legitimacy of prescription; a prescription for a controlled substance shall only be issued for a legitimate medical purpose...	13%
4301(f) - Unprofessional Conduct - Acts of moral turpitude, dishonesty, fraud, deceit or corruption	10%	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	5%	1715(b)(2) - Self-Assessment of a pharmacy by the pharmacist-in-charge; shall complete a self-assessment within 30 days whenever: there is a change in pharmacist-in-charge	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	10%	733(a) - Dispensing prescription drugs and devices- No licentiate shall obstruct a patient in obtaining a prescription	5%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	8%
1714(b)(d) - Operational Standards and Security; pharmacy responsible for pharmacy security/Each pharmacist when on duty is responsible for security	7%	1714(c) - Operational Standards and Security; pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition	5%	1714(b)(d) - Operational Standards and Security; pharmacy responsible for pharmacy security/Each pharmacist when on duty is responsible for security	8%
1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	7%	1717.5(a) - (a) A pharmacy may offer a program to automatically refill prescriptions provided the pharmacy complies with this section….	4%	733(a) - Dispensing prescription drugs and devices- No licentiate shall obstruct a patient in obtaining a prescription	8%
1716 - Variation from prescription	7%	1714(b)(d) - Operational Standards and Security; pharmacy responsible for pharmacy security/Each pharmacist when on duty is responsible for security	4%	1776.1(a)(g) - (a) Pharmacies may provide Take-back services to the public. Retail pharmacies and hospital/clinics with onsite pharmacies may maintain collection receptacles in their facilities….(g)	8%
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	7%	4078(a)(1) - False or Misleading Label on Prescription; No person shall place a false or misleading label on a prescription	4%	1714(d) - Operational Standards and Security; Pharmacist responsible for pharmacy security	4%

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 2024 through September 2024.

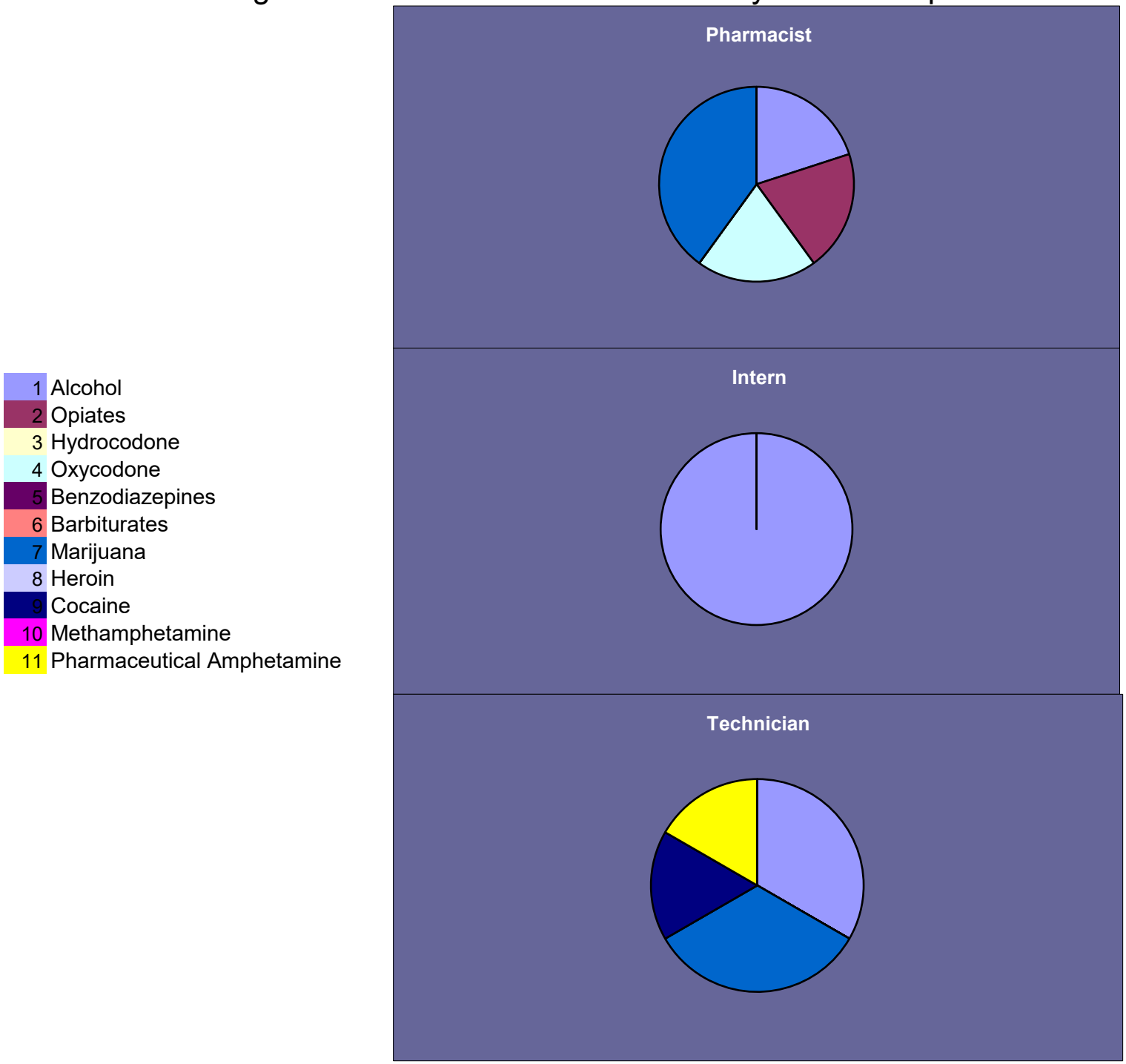
PRP Self-Referrals					
PRP Probation Referrals	3				
PRP Under Investigation	1				
PRP In Lieu Of (investigation conducted)					
Total Number of PRP Intakes	4				
Pharmacists	5				
Intern Pharmacists					
Pharmacy Technicians	4				
Total New Probationers	9				
Total PRP Participants	29				
Recovery Agreements Reviewed	26				
Total Probationers	54				
Inspections Completed	28				
Referrals to Treatment (PRP and Probationers)	1				
Drug Test Ordered (PRP and Probationers)	433				
Drug Tests Conducted (PRP and Probationers)	421				
Relapsed (PRP and Probationers)					
Cease Practice/Suspension (PRP and Probationer	6				
Termination from PRP	1				
Probationers Referred for Discipline					
Successful Completion (PRP and Probationers)	1				
Termination (Probation)					
Voluntary Surrender (Probation)					
Surrender as a result of PTR (Probation)					
Closed Public Risk (PRP)	1				1
Non-compliance in PRP or Probation	19				19
Other (PRP)					
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 2024 through September 2024.

Board of Pharmacy	July -Sep	Oct Dec	Jan Mar	Apr Jun	24/25
Drug of Choice at PRP Intake or Probation					
Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 24/25**
Alcohol	1				1
Ambien	1				1
Opiates					
Hydrocodone	1				1
Oxycodone					
Morphine					
Benzodiazepines	2				2
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 24/25**
Alcohol	1				1
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 24/25**
Alcohol	2				2
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana	2				2
Heroin					
Cocaine	1				1
Methamphetamine					
Pharmaceutical Amphetamine	1				1
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					

Drug Of Choice - Data entered from July 2024 to September 2024



Printed on 10/10/2024