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

Enforcement and Compounding Committee Report
July 19, 2022

Maria Serpa, Licensee Member, Chair
Jignesh Patel, Licensee Member, Vice-Chair
Renee Barker, Licensee Member
Indira Cameron-Banks, Public Member
Seung Oh, Licensee Member, President
Ricardo Sanchez, Public 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 April 20, 2022, Enforcement and Compounding Committee Meeting Minutes

A draft version of the minutes is provided in **Attachment 1.**

IV. Discussion, Consideration, and Possible Recommendation to the Board to Approve Draft Changes to CCR Section 1715.1 related to Self-Assessment of an Automated Drug Delivery System (ADDS) by the Pharmacist-in-Charge of an Unlicensed AUDS

Relevant Law

Business and Professions Code (BPC) section 4427.2 establishes provisions for the use of automated drug delivery systems (ADDS). Included in the provision is an exemption from licensure for an automated unit dose delivery system (AUDS) under specified conditions, as included in the exemption provisions, the AUDS shall comply with all other requirements for an ADDS. (BPC 4427.2(i))

CCR Section 1715.1 establishes the requirements for a PIC of each ADDS as defined to complete a self-assessment of the pharmacy's compliance with federal and state law. The section currently provides that the assessment shall be performed annually before July 1 of every year.

Background

Part of Assembly Bill 1533 (Chapter 629, Statutes of 2021) amended the statutory requirements related to the frequency with which a PIC must perform a self-assessment of

an ADDS, specifically to align with the same frequency for performing a self-assessment of a pharmacy. Following enactment of the provisions, conforming changes were proposed to CCR 1715.1 seeking to update the self-assessment frequency and the self-assessment form incorporated by reference. The Board has approved that language; however, the formal rulemaking process has not yet been initiated.

As part of the implementation of the specific exemption requirement for AUDS referenced above, it appears appropriate to clarify the Board's policy goal related to the self-assessment for such exempt AUDS systems operated by a hospital pharmacy. It is common for a hospital to use such devices throughout the hospital operated by the same staff and under the same procedures. Where the devices are the same make and model and the same policies and procedures required by BPC 4427.2 are used, it may be appropriate to clarify the Board's expectations related to completion of the self-assessment form.

For Committee Consideration and Discussion
During the meeting the Committee may wish to consider if a self-assessment form is necessary for every AUDS used within the hospital, or if it is more appropriate to allow for the completion of a single self-assessment form under specified conditions.

To assist the committee, **Attachment 2** includes draft language that could be used to facilitate regulation changes to clarify the Board's expectations. This draft also includes proposed amendments for the use of gender-neutral language. As the Board previously approved initiation of a rulemaking in this area possible changes are reflected with double underline for new text and double strikethrough to text recommended to be removed.

V. Discussion and Consideration of Proposed Revisions to Frequently Asked Questions Related to Automated Drug Delivery System (ADDS)

Background
As part of the July 2021 Board meeting, the Board approved draft FAQs related to automated drug delivery systems. Since that time, additional changes in the law have occurred. To ensure the FAQs remain a relevant resource for licensees, updates to the FAQs appear appropriate.

For Committee Consideration and Discussion
During the meeting members will have the opportunity to review proposed changes to the FAQs.

Attachment 3 includes a copy of the proposed updated FAQs.

VI. Discussion and Consideration of Committee's Strategic Objectives

Background
The Board's Strategic Plan 2022-2026 includes nine strategic objectives to guide the work of the Enforcement and Compounding Committee.

For Committee Consideration and Discussion
During the meeting members will have the opportunity to review the strategic objectives and actions taken related to the objectives where applicable. It may be appropriate for the Committee to confirm if the strategic objectives remain appropriate and determine if there is a priority for the remaining objectives and additional actions it wishes to take related to objectives.

2.1 Evaluate, and take necessary actions, regarding the causes and effects of medication errors to reduce errors.
Status: Medication Error Reduction and Task Force Ad Hoc Committee established and has begun convening public meetings.

2.2 Analyze enforcement outcomes to identify trends to educate licensees of common violations and improve patient outcomes.
Status: Annual presentation on the Board's Citation and Fine Program and Board's Inspection Program provided and top violations published in the Board's newsletter.

2.3 Complete routine inspections of all licensed pharmacies at least every four years to proactively assess pharmacy operations and educate licensees.
Status: In FY 2021/22, Board staff conducted 1,598 routine inspections.

2.4 Determine and reduce barriers to timely case resolution to improve consumer protection.

2.5 Assess, and pursue where appropriate, further use of a Standard of Care Enforcement Model to protect consumers.
Status: Standard of Care Ad Hoc Committee established and has begun convening public meetings.

2.6 Establish greater consistency in how inspectors interpret the law and carry our inspections to improve compliance, support licensees, and further patient care.

2.7 Write a Budget Change Proposal to increase the number of enforcement staff to ensure more regular inspections and investigations, and to improve case processing times.
Status: New inspector position received to perform inspections and related investigations stemming from new legislative mandates.

2.8 Educate licensees about enforcement responsibilities to improve compliance and build relationships.

2.9 Assess pharmacist involved in medication handling at locations not regulated by the Board of Pharmacy to increase patient safety and standardize care.

2.10 Evaluate if regulations align with federal regulations and standard governing the practice of compounding and pursue changes, if appropriate, to ensure patient safety and assist licensees with education about standards.

VII. Presentation and Discussion of the Board's Inspection Program

Background

Pharmacy inspections are conducted by Board inspectors and are triggered for a variety of reasons including receipt of consumer complaints, required annual inspections for specific license types or routine inspections to determine if a pharmacy complies with state and federal laws and regulations. This process also involves an educational component, wherein licensees have an opportunity to meet and speak with Board inspectors, ask questions and receive guidance, and pharmacy law updates. The Board's policy is to have all pharmacies inspected at least once every four years.

For Committee Consideration and Discussion

During the meeting a presentation will be provided detailing inspection information focusing primarily on routine inspections. In fiscal year 2021/22, staff conducted 2,938 in person inspections including 1,099 routine inspections of pharmacies where the sole purpose of the inspection was triggered for routine evaluation. Of the routine inspections completed 473 inspections resulted in correction(s) being issued and 148 pharmacies were issued a notice of violation(s). Further, 66 routine inspections revealed violations of the Board's patient consultation requirements, either failure to provide consultation or failure to provide written notice of consultation on delivered or mail order prescriptions. Data suggests about 8% of the Board's licensed pharmacies have never been inspected. This is a decrease from 19% last year. It is anticipated that this fiscal year the Board will complete inspections of these remaining 463 facilities and will focus on facilities that have not been inspected in the last four years.

Attachment 4 includes a copy of the presentation slides.

VIII. Presentation and Discussion of the Board's Citation and Fine Program

Relevant Law

Business and Professions Code section 4314 establishes the authority for the Board to issue citations which may include fines and/or orders of abatement. As included in this section, the order of abatement may include completion of continuing education courses and specifies that any such continuing education courses shall be in addition to those required for license renewal.

Title 16, California Code of Regulations Sections 1775-1775.4 are the Board's regulations governing its citation and fine program. More specifically, Section 1775 includes the authority of the executive officer or designee to issue citations which may contain either or both an administrative fine and an order of abatement and details the types of violation for which a citation may be issued.

Section 1775.2 establishes the factors to be considered in assessing an administrative fine. Such factors include:

1. The gravity of the violation.
2. The good or bad faith of the cited person or entity.
3. The history of previous violations.
4. Evidence that the violation was or was not willful.
5. The extent to which the cited person or entity has cooperated with the Board's investigation.
6. The extent to which the cited person or entity has mitigated or attempted to mitigate

any damage or injury caused by the violations.
7. Other matters as may be appropriate.
8. The number of violations found in the investigation.

Section 1775.3 establishes the order of abatement (OOA) compliance requirements.

BPC section 4317.5 establishes authority for the Board to bring an action for fines for repeated violations under specified conditions of up to $100,000 per violation. Further this section provides authority for the Board to bring an action against a chain community pharmacy of not to exceed $150,000 for violations demonstrated to be the result of a written policy or which is expressly encouraged by the owner or manager.

Background
During the meeting, members will receive an annual report on the program. Provided below is summary information providing comparisons for the past five fiscal years. The data suggests improvement in the average days to complete. Fines assessed is trending up from the past few fiscal years.

Citation and Fine	FY 2017/18	FY 2018/19	FY 2019/20	FY 2020/21	FY 2021/22
Citations Issued	2,168	1,144	1,426	934	1,274
Average Days to Complete	381	381	400	426	341
Order of Abatements Issued	30	224	415	245	269
Amount of Fines Assessed	$2,268,600	$1,176,450	$1,462,300	$787,100	$2,029,012
Amount Collected	$2,027,656	$1,210,086	$963,446	$711,729	$1,093,911

For Committee Consideration and Discussion
During the meeting members will receive a presentation providing updated information. Like last year's review, the most frequent violation for pharmacies and pharmacists is medication error. Also, like last year, the most frequent violation for interns is self-use. The most frequent violation for pharmacy technician during the current reporting period is self-use.

The Board has issued two fines pursuant to the new fine authority established in BPC 4317.5.

Attachment 5 includes a copy of the presentation slides.

IX. Discussion and Consideration of Community Pharmacy Staff Requirements including Business and Professions Code Section 4113.5 and Title 16, California Code of Regulations Section 1714.3

Relevant Law
Business and Professions Code Section 4113.5 generally provides that a pharmacist working in a community pharmacy shall not be required to engage in the practice of pharmacy unless another employee of the pharmacy or an employee of the establishment if made available to assist the pharmacists at all times.

California Code of Regulations Section 1714.3 provides the specific requirements a pharmacy must meet to comply with the provisions of the statute. Requirements include that the pharmacy must designate one or more persons to be available to the pharmacist; designated individuals must at a minimum be able to perform duties of non-licensed personnel, ensure designated individuals have completed necessary background checks. Further, the regulation requires that the individual must be able to assist the pharmacist within five minutes after the pharmacist's request.

Background

Senate Bill 1442 (Chapter 569, Statutes of 2018) established the provisions contained in BPC 4113.5. Following enactment, and a subsequent petition from the UFCW, the Board promulgated regulations in CCR section 1714.3. These regulations became effective September 15, 2020.

Upon implementation of these provisions, Board staff as part of the inspection process will assess for compliance. During the early phases of implementation, inspectors provided education of these requirements to licensees as part of the inspection process. Following a period of education of the provisions, Board staff transitioned to issuing orders of correction to secure compliance. When noncompliance is identified either through inspection or as part of an investigation, violation notices are issued. Upon completion of the investigation, depending on the violations substantiated, Board staff determine the appropriate outcome. To date the Board has issued two citations for such violations. Further, the Board has several investigations currently pending.

Board staff is aware of social media posts and other anecdotal information that suggests that pharmacist staff may not be requesting assistance because "no one is going to come anyway." In such cases, if a complaint is received, it is difficult to substantiate the violation because documentation is not available. In addition, there appears to be some misunderstanding about the law itself. As an example, staff is aware of social media posts that indicate that a pharmacist was scheduled to work alone. Being scheduled to work alone, is not, itself a violation. Rather, a violation occurs if the pharmacy does not have policies in place and fails to help as specified in the regulation.

For Committee Consideration and Discussion

During the meeting, members may wish to provide staff with direction on enforcement efforts, including if violations identified should continue to result in the issuance of a citation and fine generally and if so, if staff should consider assessing higher fine amounts.

X. Review and Discussion of Enforcement Statistics

During the las fiscal year the Board initiate 3,037 investigations and closed 2,947 investigations. The Board has issued 266 Letters of Admonishment, 1,274 Citations and referred 166 cases to the Office of the Attorney General. The Board has revoked 60 licenses, accepted the disciplinary surrender of 84 licenses, and issued public reproval on 50 licenses.

As of July 1, 2022, the Board had 1,212 field investigations pending. Below is a breakdown providing more detail in the various investigation process:

	October 1, 2021		January 3, 2021		April 1, 2022		July 1, 2022	
	Volume	Average Days	Volume	Average Days	Volume	Average Days	Volume	Average Days
Awaiting Assignment	71	14	43	29	43	6	24	6
Cases Under Investigation	560	146	626	136	738	122	793	118
Pending Supervisor Review	134	40	135	41	173	30	171	39
Pending Second Level Review	42	47	135	41	94	56	97	58
Awaiting Final Closure	167	75	66	60	50	15	127	10

The Board has experienced a 15% increase in the number of cases initiated. Pending investigations by team indicate that the prescription drug abuse team, probation team and criminal conviction unit appear to have the largest increases in pending cases. The Board experienced an increase in the number of investigations that are non-jurisdictional or where insufficient evidence exists to substantiate violations.

Applications denied has increased slightly over the three-year period. Data suggests a decrease in cases pending at the Office of the Attorney General and disciplinary outcomes, with the exception of Letters of Public Reproval, which show overall increases, primarily in outcomes for pharmacists, pharmacies and pharmacy technicians.

Attachment 6 includes the past fiscal year and three-year comparison enforcement statistics.

XI. Future Committee Meeting Dates

- August 25, 2022
- October 4, 2022
- October 19, 2022

Attachment 1

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Business, Consumer Services and Housing Agency
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ENFORCEMENT AND COMPOUNDING COMMITTEE
Draft MEETING MINUTES

DATE:	April 20, 2022
LOCATION:	Board of Pharmacy 2720 Gateway Oaks Drive Sacramento, CA 95833 Via WebEx
COMMITTEE MEMBERS PRESENT:	Maria Serpa, Licensee Member, Chair Jig Patel, Licensee Member, Vice Chair Indira Cameron-Banks, Public Member Seung Oh, Licensee Member Ricardo Sanchez, Public Member Debbie Veale, Licensee Member
STAFF MEMBERS PRESENT:	Anne Sodergren, Executive Officer Eileen Smiley, DCA Staff Counsel Debbie Damoth, Executive Manager Specialist

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

Chairperson Maria Serpa called the meeting to order at 9:02 a.m. Dr. Serpa reminded all present that the Board is a consumer protection agency. Dr. Serpa advised the meeting was being conducted as a hybrid meeting in person and with participation through WebEx and being webcast.

The meeting moderator provided updated WebEx instructions.

Chairperson Serpa welcomed Board Member Indira Cameron-Banks to the Board and Committee.

Chairperson Serpa took roll call. Members present included: Jignesh Patel, Indira Cameron-Banks, Seung Oh, Ricardo Sanchez, Debbie Veale, and Maria Serpa. A quorum was established.

Chairperson Serpa advised the public Agenda Item VI would not be discussed and would be deferred to another meeting.

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

Members of the public were provided the opportunity to provide comments for items not on the agenda.

No members of the public were present at the Sacramento location.

Members of public attending via WebEx were also provided with the opportunity to provide public comment.

The Committee heard public comment from a representative from Walgreens requesting reconsideration of the definition of compounding within or create an exception to the quality assurance requirements for items such as magic mouthwash. Public comment referenced action taken by Mississippi related to this issue.

Chairperson Serpa advised the Committee would be discussing compounding in depth about the implementation of USP standards.

III. Approval of January 18, 2022, Enforcement and Compounding Committee Meeting Minutes

Members were provided an opportunity to provide comments on the draft minutes.

Motion: Approve the January 18, 2022, Committee Meeting minutes as presented.

M/S: Oh/Sanchez

Members of the public were provided with an opportunity to provide public comment at the Sacramento location and via WebEx; however, none were provided.

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

Committee Member	Vote
Cameron-Banks	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support

IV. Presentation, Discussion and Consideration of Hospital at Home Programs

Member Serpa provided an overview of Hospital at Home (HaH) programs noting that these programs were established under a waiver program established by CMS that provides flexibility for certain health care services that can be provided outside of a traditional hospital setting and within a patient's home. As part of the program requirements, patient can only be admitted into a program from an emergency department or inpatient hospital bed and an in-person physician evaluation is required prior to starting the services. The meeting materials include the link to the CMS Hospital at Home Pharmacy FAQs.

Chairperson Serpa advised in December 2020, the California Department of Public Health released an all facilities letter (AFL) related to general acute care hospitals and its flexibility requirements for hospital at home programs. A link to the AFL was also included in the meeting materials. A review of the California Department of Health Care Services website reveals that a few hospitals within California have received approval to operate these programs.

Chairperson Serpa noted as part of the Committee's education on this topic, the Committee would receive two presentations today.

Chairperson Serpa introduced Pat Blaisdell, Vice President of Policy, with the California Hospital Association.

Ms. Blaisdell provided an over of the HaH program noting that it is a new and unique service and indicated that this is not the same as other services such as home health, case management, chronic care management, skilled nursing, remote patient monitoring or admission prevention.

Ms. Blaisdell reviewed during COVID-19, CMS noted hospital capacity was challenged by COVID surges and previous at-home hospital care models were successful. In May 2020, CMS issued a blanket Hospital Without Walls waiver and in November 2020 developed the Acute Hospital Care at Home (AHCaH) provider waiver.

Ms. Blaisdell reviewed the required services that must be provided as part of the AHCaH, including pharmacy services. Ms. Blaisdell indicated that seven hospitals have been approved by CMS. Members were advised that one hospital has received approval from CDPH to provide services and three are going through the process.

Ms. Blaisdell discussed some of the pharmacy related areas including patient self-administration of medication, bedside storage of medication, monitoring of medication temperature and the stocking and re-stocking of medication "kit."

Members were advised, that for the right patient, there is data that suggests the model is beneficial. CMS notes that the 7.14% of escalations trends lower than previously published results. CMS data suggests there is value in this type of program moving forward.

Members were advised that federal legislation has been introduced to extend the current CMS waiver, AHCaH program for an additional two years to allow for more additional data collection to evaluate the safety of the program. Legislation is also pending to allow for this at the state level.

Members were provided the opportunity to provide comments. However, no comments were provided.

Chairperson Serpa introduced Dr. Kyle Robb, American Society of Health System Pharmacists (ASHP) State Policy and Advocacy Associate. Dr. Robb provided history of the model at John Hopkins in 1995 and noted that initial trials were conducted between 1996 – 2002 that concluded HaH was feasible, safe, cost-effective, and met disease-specific quality standards at rates similar to acute hospital.

Dr. Robb provided an overview of the patient HaH experience which starts with the patient being identified in the emergency department, inpatient hospital bed or ambulatory clinic site. A patient must provide consent to transition to this program. Dr. Robb noted should tests be required that cannot be provided at home, a patient would be transported via medical transport. Members were advised that the most common acute conditions managed through HaH programs include heart failure, pneumonia, COPD exacerbation and soft tissue infections.

Dr. Robb advised ASHP released a report in November 2021 on HaH related to pharmacy services. Pharmacy considerations include medication handling, technology and patient information management, medication storage and waste disposal, workforce, and access to provisions of clinical services.

Dr. Robb reviewed medication storage and administration questions including ideal timing and quantify for delivery of medications; handling of missing medications; administration of medications; available emergency medications; securing and storing controlled substances; handling hazardous drug waste; and disposal of discontinued or unused medications.

Dr. Robb provided technology and information management issues include integration of information into the EHR, documentation of medication administration, and impact of patients with limited broadband internet access connecting to the care team.

Dr. Robb explained the provisions of clinical pharmacy services includes process to teach patients and validate medications were taken; completion of medication reconciliation; provision of medication management services; and 24/7 pharmacy coverage.

Dr. Rob provided ASHP HaH pharmacy future considerations included pharmacists involved in the planning, implementation and maintenance; legislative and regulatory framework to promote safe and effective medication use; education, training and resource to empower pharmacy workforce; and research additional HAH care models.

Member Veale asked about actions taken by other state jurisdictions. Dr. Robb provided the two states he spoke with about it were concerned with discouraging the practice by being too prescriptive and developing regulations too soon. They were making sure the hospitals participating were adhering to labeling requirements for outpatient prescriptions and being informed based on existing home infusion regulations. Dr. Robb reported none of the boards he spoke with felt is necessary to have comprehensive set of regulatory guidelines on currently regarding HaH, although it is early in the process.

Dr. Serpa noted that the program provides great opportunities, but there are concerns that may need to be addressed including some patient safety issues for medications in the first dose kits which would be administered prior to a pharmacist review; consideration of security of transportation and storage issues; controlled substances security; and documentation of administration as well as monitoring.

Member Veale agreed the concept could be a very positive idea and wanted to ensure the Board doesn't get in the way by overregulating.

Member Patel added closed door facilities currently provide prescription e-kits to skilled nursing facilities and this program mimics with the skilled nursing facilities. He noted there are current labeling and record keeping requirements for e-kits in place. If it is kept as is, they can operate within the current Medical Board requirements to operate a hospital.

Dr. Serpa noted these areas need to be reviewed and ensured they are there because it is a different license category. She noted there are differences in regulations between acute care and long-term care pharmacies. Dr. Serpa added there are opportunities to discuss to make sure the process is consistent and safe.

Members of the public were provided with an opportunity to provide public comment at the Sacramento location.

A representative of CVS Health commented in Idaho allow hospice e-kits listing the drugs that could be contained in it however it has now been removed from the regulations.

Members of the public were provided with an opportunity to provide public comment via WebEx participants; however, no comments were provided.

Dr. Serpa provided the Legislation and Regulation Committee was reviewing pending legislation in this area and the information learned today may help shape the Board's actions when considering this legislation. Dr. Serpa added at this time any further action may be premature until the Board's policy specific to these programs is understood. She added if these programs continue to operate, it will be very important to consider how pharmacy related care is provided in this type of patient care model to ensure patients receive appropriate care.

Member Veale inquired about a policy statement. Dr. Serpa indicated it might be premature as it is operating under a waiver. Ms. Sodergren indicated positions taken on pending legislation will indicate the Board's policy.

IV. Discussion and Consideration of Compounding by Board Licensees Outside of a Pharmacy

Chairperson Serpa referred to the meeting materials that provide some of the relevant sections of pharmacy law. Dr. Serpa noted Members have received comments about pharmacy personnel compounding outside of licensed pharmacies and Board staff have observed this practice as well. Dr. Serpa referred to the meeting materials where staff are familiar with some investigations and patient care issues that have been identified regarding some compounding practices in some locations.

Chairperson Serpa clarified the Committee considered if it would be appropriate to regulate locations where compounding is happening outside of a board licensed pharmacy. Dr. Serpa noted that related to pharmacy technicians it may be more of a licensure issue for pharmacy technician.

Chairperson Serpa indicated her concern included:
• Board licensed technicians ordering drugs under a physician's license, compounding, and overseeing compounding in physician offices and/or licensed clinics with no pharmacist present.
• Board licensed technician working at an oncology medical practice, preparing cancer treatments for injection or infusion with no pharmacist present.
• Board licensed pharmacists compounding, overseeing compounding and providing additional pharmacy services in physician offices and/or licensed clinics following lower standards because they are not in a pharmacy.
• Board licensed pharmacists compounding and overseeing technicians at an unlicensed infusion center.

The Committee discussed managing the current jurisdiction and in the future additional jurisdictions as well as considering laws related to name tag requirements and licensees. The Committee agreed the Licensing Committee would be an appropriate avenue to discuss the issue about pharmacy technician licensure and name tags. The Committee agreed to add a new agenda item to discuss compounding in other practices outside of licensed pharmacies.

Chairperson Serpa continued for pharmacists compounding outside of a licensed pharmacy and not following compounding regulations, it was her understanding that as a pharmacist, the pharmacist is still required to follow all of the compounding regulations. Ms. Sodergren offered at the staff level to research the issue and see how other jurisdictions are addressing the issue as well as provide additional education on federal requirements. She reminded the Committee that the Standard of Care Ad Hoc Committee's work may impact how pharmacists are performing compounding.

Members of the public were provided with an opportunity to provide public comment at the Sacramento location.

A representative from CVS Health commented on consequences and suggested that going to a standard of care model may address issues.

Members of the public were provided with an opportunity to provide public comment through WebEx.

A representative from Kaiser encouraged the Board to remove statutory provisions that limit where a technician can work.

A representative from California Councill for the Advancement of Pharmacy agreed with the Kaiser representative and asked if pharmacy technicians can perform clerk duties.

Chairperson Serpa suggested that issues regarding pharmacy technicians be discussed under the Licensing Committee. The Committee agreed with the suggestion.

Chairperson Serpa summarized the Committee will continue to investigate with staff researching actions at the national level and compounding outside of pharmacy and request the Standard of Care Ad Hoc Committee address the issue.

Chairperson Serpa added the issue of unlicensed locations that do compounding by non-Board licensed personnel will be added to a future agenda regarding compounding.

VII. Review and Discussion of Enforcement Statistics

Chairperson Serpa advised enforcement statistics were included in the meeting materials with a summary provided in the chair report. Dr. Serpa noted this fiscal year the Board has received 2,336 complaints and has closed 2,360 complaints. The Board has issued 230 Letters of Admonishment, 949 Citations and referred 120 cases to the Office of the Attorney General. The Board has revoked 44 licenses and accepted 67 disciplinary surrenders.

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

Members of the public were provided with an opportunity to provide public comment at the Sacramento location and through WebEx; however, no comment was provided.

VIII. Future Committee Meeting Dates

Chairperson Serpa advised the next Enforcement and Compounding Committee will be July 19, 2022. Dr. Serpa advised to watch for updates as the Enforcement and Compounding Committee was hoping to add an additional meeting date in August to discuss compounding.

IX. Adjournment

The meeting adjourned at 10:49 a.m.

Attachment 2

Proposed Amendment to § 1715.1. Self-Assessment of an Automated Drug Delivery System by the Pharmacist-in-Charge. Changes in ~~double strike~~ through and double underline are possible changes for the Committee's consideration.

(a) The pharmacist-in-charge of each automated drug delivery system as defined under section 4119.11, 4187.5 or section 4427.3 of the Business and Professions Code (BPC) shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed ~~annually~~ before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:
(1) A new automated drug delivery system license has been issued.
(2) There is a change in the pharmacist-in-charge~~, and he or she becomes the new pharmacist-in-charge of an automated drug delivery system~~.
(3) There is a change in the licensed location of an automated drug delivery system to a new address.

(c) A pharmacist-in-charge of an automated drug delivery system shall assess the system's compliance with current laws and regulations by using the components of Form 17M-112 (Rev 1~~2~~/~~18~~ 22) entitled "Automated Drug Delivery System Self-Assessment". Form 17M-112 shall be used for all automated drug delivery systems and is hereby incorporated by reference.
(1) The pharmacist-in-charge shall provide identifying information about the underlying operating pharmacy including:
(A) Name and any license number(s) of the underlying pharmacy and their expiration date(s);
(B) Address, phone number, and website address, if applicable, of the underlying pharmacy;
(C) DEA registration number, expiration date, and date of most recent DEA inventory;
(D) Hours of operation of the pharmacy; and
(E) ADDS license number, address, and hours of operation.
(2) The pharmacist-in-charge shall respond "yes", "no", or "not applicable" (N/A) about whether the automated drug delivery system is, at the time of the self-assessment, in compliance with laws and regulations that apply to that pharmacy setting.
(3) For each "no" response, the pharmacist-in-charge shall provide a written corrective action or action plan to come into compliance with the law.
(4) The pharmacist-in-charge shall initial each page of the self-assessment with original handwritten initials in ink or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form.
(5) The pharmacist-in-charge shall certify on the last page of the self-assessment that they have ~~he or she has~~ completed the self-assessment of the automated drug delivery system of which they are ~~he or she is~~ the pharmacist-in-charge.

The pharmacist-in-charge shall also certify a timeframe within which any deficiency identified within the self-assessment will be corrected and acknowledge that all responses are subject to verification by the Board of Pharmacy. The certification shall be made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct with an original handwritten signature in ink or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form.

(6) The automated drug delivery system owner shall certify on the final page of the self-assessment that they have ~~he or she has~~ read and reviewed the completed self-assessment and acknowledges that failure to correct any deficiency identified in the self-assessment could result in the revocation of the automated dispensing system's license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California with an original handwritten signature in ink or digitally signed in compliance Civil Code Section 1633.2(h) on the self-assessment form.

(d) Each self-assessment shall be completed in its entirety and kept on file in the underlying pharmacy for three years after it is performed. The completed, initialed, and signed original must be readily available for review during any inspection by the board.

(e) Any identified areas of noncompliance shall be corrected as specified in the assessment.

(f) The pharmacist-in-charge of a hospital using more than one unlicensed automated drug delivery system as authorized in BPC section 4427.2(i) may complete a single self-assessment of the hospital's compliance with federal and state pharmacy law for all automated drug delivery systems under the following conditions:

(1) The mechanical devices used as part of the ADDS to store, dispense or distribute dangerous drugs are of the same vendor and controlled by the same software system on a single server; and

(2) The same policies and procedures required by Section 4427.2 of BPC are used.

Note: Authority cited: Sections 4119.11 and 4427.7, Business and Professions Code. Reference: Sections 4001.1, 4008, 4017.3, 4021, 4022, 4036, 4037, 4038, 4040, 4050, 4051, 4052, 4059, 4070, 4076, 4081, 4101, 4105, 4107, 4113, 4119.11, 4125, 4126, 4180, 4186, 4305, 4330, 4332, 4333, 4400, 4427, 4427.1, 4427.2, 4427.3, 4427.4 and 4427.5, Business and Professions Code; and Section 16.5, Government Code.

Attachment 3

ADDS FREQUENTLY ASKED QUESTIONS – Updated 7/2022

Question #1: My pharmacy provides pharmacy services to a psychiatric health facility (PHF) and utilizes an AUDS at the nursing units. Are we exempt from licensure if the AUDS is used for administration only?

Answer: No. Effective January 1, 2022, the Legislature amended BPC section 4427.3 and added BPC section 4427.65 that expanded the permissible locations at which AUDS can be located to include a facility licensed by the State of California to provide pharmaceutical services. The exemptions from licensure of an ADDS are contained in BPC section 4427.2. Section 4427.2(i) exempts from licensure an AUDS operated by a licensed hospital pharmacy, as defined in BPC section 4029, and used solely to provide doses administered to patients in a licensed general acute care hospital or a licensed acute psychiatric hospital facility if the licensed hospital pharmacy owns the dangerous drugs and devices in the AUDS. A psychiatric health facility does not meet the requirements for licensure exemption unless it is a licensed acute psychiatric hospital facility as detailed in Section 4427.2(i). If a psychiatric health facility does not meet the licensure exemption criteria in BPC section 4427.2(i), it may use an AUDS, but that AUDS must be licensed with the Board and it must follow all the other requirements for an ADDS.

Note: A psychiatric health facility, as defined in Health and Safety Code § 1250.2, is required to provide pharmaceutical services pursuant to Welfare and Institution Code § 4080(e)(1)(J).

References: Business and Professions Code (BPC) section 4427.65, Welfare and Institution Code section 4080(e)(1)(J), Health and Safety Code section 1250(a), 1250(b), 1250.2.

Question #2: My pharmacy provides pharmacy services to a county youth detention facility and utilize an AUDS to administer medications to the youth inmates. Are we required to obtain licensure for the AUDS?

Answer: Yes. Effective January 1, 2022, the Legislature amended BPC section 4427.3 and added BPC section 4427.65(a)(2) that expanded the permissible locations at which AUDS can be located to include a jail or youth detention facility where drugs are administered within the facility under the authority of the medical director. However, the exemptions from the licensure requirements for an ADDS are contained in BPC section 4427.2(i) and AUDS in youth facilities are not exempt from licensure.

References: BPC section 4427.2(i), 4427.3, 4427.65(a)(2).

Question #3: My pharmacy has multiple licensed ADDS, do I have to complete a self-assessment for each licensed ADDS?

Answer: Yes, per BPC section 4427.2(c), defines when a separate application and license is required for each ADDS. Also, per BPC section 4427.7(a), a pharmacy holding an ADDS license shall complete a self-assessment performed pursuant to section 1715 of Title 16 of the California Code of Regulations (CCR), before July 1 of every odd-numbered year. Prior to January 1, 2022, BPC section 4427.7(a) required an annual self- assessment whereas 16 CCR section 1715 requires a self-assessment to be performed before July 1 of every odd-numbered year. (Effective January 1, 2022, a self-assessment must only be performed before July 1 of every odd-numbered year.) The pharmacy must maintain those records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records.

References: BPC sections 4427.2(i), 4427.7(a), 4427.2(c), 16 CCR section 1715

Question #4: Do I have to complete a new self-assessment for each ADDS if my pharmacy received a new permit, had a change in pharmacist-in-charge, or the pharmacy had a change in address?

Answer: Yes, per 16 CCR section 1715(b), the pharmacist-in-charge of the pharmacy shall complete a self-assessment within 30 days whenever a new pharmacy permit has been issued, or change in PIC, or change in the licensed location of the pharmacy to a new address.

References: BPC section 4427.7; 16 CCR section 1715(b)

Question #5: My pharmacy uses an ADDS located in the pharmacy dispensing area to help with the dispensing of prescription drugs. The ADDS counts the number of tablets or capsules to be dispensed and labels the prescription container. A pharmacist is required to do the final product verification prior to the prescription medication being bagged and placed in the will call area for the patient to pick up their prescription medication at the pharmacy. As the pharmacist-in-charge, will I need to complete an ADDS Self-Assessment?

Answer: No. An ADDS or other technology installed within a licensed pharmacy that is used to select, count, package and label dangerous drugs but then requires the pharmacist to do the product verification and dispensing to a patient is not required to be licensed as an ADDS. BPC 4427.2(j). Such an ADDS or other technology also does not require the pharmacy to comply with all other requirements for an ADDS in Article 25, including the specific self-assessment for an ADDS, but is required to comply with all other pharmacy laws. In these cases, pursuant to 16 CCR section 1714(b), pharmacies are required to maintain its equipment so that drugs are safely and properly prepared, maintained, secured and distributed. Any misfiling of a prescription resulting from the use of such an ADDS or other technology should be evaluated to assure the ADDS or other technology is operating appropriately. Pursuant to 16 CCR section 1714(c), the pharmacy is also required to maintain all equipment in a clean and orderly condition. This would include such ADDS or other technology used in the dispensing process.

Reference: BPC sections 4427.2(j), 4017.3, 16 CCR section 1714(b), 1714(c)

Question #6: A medication error was made, and a quality assurance review was completed related to

the licensed ADDS, do I have to report to the Board?

Answer: Yes, per 16 CCR section 1711(f), any quality assurance record related to the use of a licensed automated drug delivery system must also be submitted to the board within 30 days of completion of the quality assurance review. A "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716.

NOTE: Examples of medication errors related to the use of an ADDS, include, but are not limited to, the following:

- A drug removed from the ADDS that is the wrong drug, strength, quantity or contains incorrect directions for use.
- The nurse removes the wrong drug from the ADDS.
- An ADDS that packages the drug in plastic pouches containing 2 tablets and should only contain one tablet as prescribed.
- An ADDS with an open matrix configuration and the nurse selects the wrong drug.
- An APDS dispenses a prescription container labeled and intended for another patient.

References: 16 CCR section 1711(f), 1716; BPC section 4427.8

Question #7: My pharmacy is located in an acute care hospital and exempt from the licensing requirements for ADDS, do I have to report ALL quality assurance records related to the use of the ADDS to the Board at the time of renewal, including quality assurance records related to near-misses, or errors caught by nursing staff?

Answer: Yes, per 16 CCR section 1711(f), any facility with an unlicensed automated drug delivery system must report the quality assurance review to the Board annually at the time of annual renewal of the facility license.

16 CCR section 1711(b) defines "medication error" as any variation from a prescription or drug order not authorized by the prescriber, as described in 16 CCR section 1716. Section 1711(b), however, expressly excludes from the definition of a medication error any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.

NOTE: Only, quality assurance records related to the use of the ADDS that caused the medication error, as defined by the section, are required to be reported to the Board at the time of renewal.

NOTE: Drugs dispensed from the ADDS are considered to have been dispensed by the pharmacy. Therefore, if a medication error occurred that resulted from an incorrect dispensing by the ADDS, the medication error is required to be reported to the Board.

References: 16 CCR sections 1711(b), 1716; BPC sections 4427.8, 4427.4(d).

Question #8: What information is required to be reported as part of the Quality Assurance Review?

Answer: 1 6 CCR section 1711(e) states, the record shall contain at least the following:

1. The date, location of the ADDS, ADDS license number, pharmacy license number and participants in the quality assurance review;
2. The pertinent data and other information related to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);
3. The findings and determinations generated by the quality assurance review; and
4. Recommended changes to pharmacy policy, procedure, systems, or processes, if any.

References: 16 CCR sections 1711(e), 1716; BPC section 4427.8

Question #9: Where do I submit my quality assurance reports to the Board?

Answer: Pharmacies with a licensed ADDS may submit their quality assurance reports within 30 days of completion of the quality assurance review either: 1) by mail to the address of the California State Board of Pharmacy at 2720 Gateway Oaks Drive Suite 100, Sacramento, CA 95833; or 2) by email to ADDS@dca.ca.gov.

Pharmacies operating an unlicensed ADDS must report the quality assurance review to the Board at the time of annual renewal of the facility license. Such reports may be submitted via email to ADDS@dca.ca.gov or included with the renewal application.

References: 16 CCR section 1711(f).

Question #10: What personnel are authorized to restock the ADDS (e.g., nurses and other personnel)?

Answer: This depends on the location of the ADDS. The stocking and restocking of an ADDS shall be performed by a pharmacist, or by a pharmacy technician or intern pharmacist under the supervision of a pharmacist, except for an ADDS located in a health facility licensed pursuant to Section 1250 of the Health and Safety Code, where the stocking and restocking of the ADDS may be performed in compliance with Section 1261.6 of the Health and Safety Code.

Pursuant to Health and Safety Code section 1261.6 (g) if the ADDS utilizes removable pockets, cards, drawers, or similar technology, or unit of use, or single dose containers, and the facility, in conjunction with the pharmacy, has developed policies and procedures to ensure the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS, then the facility and contracted personnel authorized by law to administer drugs may also restock the ADDS.

References: June 2017 Script Newsletter, , BPC sections 4427.3, 4427.4,4186, 4187.5, 4119.11, Health and Safety Code section 1261.6 (g)

Question #11: Are drugs required to be restocked immediately into the ADDS?

Answer: Per BPC section 4427.4(f), if drugs are not immediately transferred into an ADDS upon arrival at the ADDS location, the drugs may be stored for no longer than 48 hours in a secured room within the ADDS location. Upon retrieval of these drugs from secured storage, an inventory must be taken to detect any losses or overages.

References: BPC section 4427.4

Question #12: The pharmacy uses an ADDS device with an open-matrix design allowing the user to access multiple drugs, what are the requirements for the facility?

Answer: Facilities using automated drug delivery system with an open-matrix design shall contact the California Department of Public Health for a clear understanding of the requirements for such use.

References: Health and Safety Code section 1261.6

Question #13: Does my pharmacy have to review the ADDS on a monthly basis?

Answer: Yes, if the pharmacy is operating an ADDS located in: 1) a health facility pursuant to Health and Safety Code 1250 that complies with Health and Safety Code 1261.6; 2) a clinic pursuant to BPC section 4119.11; 3) a correctional clinic pursuant to BPC section 4187.5(e); 4) a facility licensed by the State of California with the statutory authority to provide pharmaceutical services; or 5) a jail, youth detention facility, or other correctional facility where drugs are administered within the facility under the authority of the medical director. A review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system

NOTE: A clinic that operates an ADDS, pursuant to BPC section 4186, is responsible for reviewing the drugs contained in the ADDS, the operations and the maintenance of the ADDS. The review must be conducted on a monthly basis by a pharmacist which includes a physical inspection of the drugs in the ADDS, an inspection of the ADDS for cleanliness, and a review of all transaction records in order to verify the security and accountability of the drugs in the ADDS.

References: Health and Safety Code (HSC) 1261.6(h); BPC sections 4186(d), 4187.5(e), 4119.11(h), 4427.3(b)(2)(3)(4), 4427.65(c)(7)

Question #14: Is the pharmacy required to obtain a separate Drug Enforcement Administration (DEA) registration for each licensed ADDS if the device contains controlled substances?

Answer: Pharmacies should consult the federal regulations to ensure compliance with DEA requirements and contact the DEA for any necessary clarifications regarding federal rules regarding controlled substances. Cited below are some authorities from the DEA regarding ADDS.

Reference: Code of Federal Regulations (CFR) section 1301.27, ADDS FAQ, Dispensing of Controlled Substances to Residents at Long Term Care Facilities

Question #15: Our pharmacy offers an APDS to dispense to patients, what is required for patient consultation?

Answer: The APDS shall only be used for patients who have signed a written consent form

demonstrating their informed consent to receive drugs from an APDS and the APDS has a means to identify each patient and only release the drugs to the patient or the patient's agent.

All prescribed drugs and devices dispensed from the APDS ***for the first time*** must be accompanied by a consultation conducted by a pharmacist licensed by the board via a telecommunications link that has two-way audio and video.

References: BPC sections 4119.11(d)(6), 4427.6(f)

Question #16: Can the pharmacist provide consultation via telephone for new prescriptions prior to placing the medication in the APDS?

Answer: No, all prescribed drugs and devices dispensed from the APDS ***for the first time*** shall be accompanied by a consultation conducted by a pharmacist licensed by the board via a telecommunications link that has two-way audio and video.

References: BPC section 4427.6(f)

Question #17: Who can provide the consultation for patients using the APDS?

Answer: A pharmacist licensed by the board shall perform all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation.

References: BPC section 4427.6(d)

Question #18: What drugs can be placed in the APDS?

Answer: The pharmacy should have policies and procedures to determine which drugs and devices are appropriate for placement in the automated patient dispensing system.

References: BPC sections 4119.11(d)((1)(B), 4427.6(a)(2)

Question #19: What shall a pharmacy do if a patient cannot use the APDS due to the drug not being in stock or the APDS is not in service?

Answer: The pharmacy must develop policies and procedures orienting participating patients on the use of the APDS, notifying patients when expected prescription medications are not available in the APDS, and ensuring that patient use of the APDS does not interfere with delivery of drugs and devices. The pharmacy shall ensure the delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.

References: BPC section 4427.6(a)

Question #20: We are a hospital with less than 100-beds and have a licensed drug room. When patients are discharged from the hospital, the physician sometimes writes an order for the patient to be discharged with a 72-hour supply which is taken from the ADDS. The physician will remove the drugs from the ADDS and dispense the drugs to the patient that is properly labeled and meets the patient centered labeling requirements. Is the drug room exempt from licensing the ADDS located at the nursing station if the ADDS is primarily used to administer doses to patients in the hospital, but occasionally used for dispensing no more than a 72-hour supply of discharge medications to the

patient?

Answer: No, the drug room is not exempt from licensing the ADDS if the location is dispensing medications to discharge patients. The drug room will be required to license the ADDS location. The drug room is only exempt if the drugs in the ADDS are solely used for administration to patients while in the acute care hospital. When drugs from the ADDS is used for dispensing, not solely for administration, the exemption no longer applies.

Should your hospital provide discharge medication from the drug stock contained within an ADDS, your facility must secure ADDS licensure to be compliant withthese requirements.

References: BPC sections 4427.2(i), 4056

Question #21: Can the facility start using the ADDS device as soon as the ADDS application is submitted or do I need to wait until the Board issues the ADDS permit?

Answer: The ADDS device cannot be used until the Board issues the ADDS permit.

Reference: BPC sections 4427.1, 4427.2(a), 4119.11(a)(1), 4119.01(a)

Question #22: We are a hospital with a 24-hour pharmacy. Can we utilize an ADDS to dispense a 72-hour supply of medication from our ER, if we request a license from the board for the ADDS.

Answer: No. A prescriber may only dispense a prescription medication to an emergency room patient, if the pharmacy is closed and there is no pharmacist available.

Reference: BPC section 4068(a)(1)

Question #23. In the emergency room, when the pharmacy is not open, the physician will remove from the ADDS and dispense no more than a 72-hour supply of drugs to a patient to ensure a drug regimen is immediately commenced and continued pursuant to Business and Professions Code section 4068. Is the hospital pharmacy required to license the ADDS in the emergency room if the ADDS is primarily used for the administration of doses to patients in the emergency room but occasionally used to dispense a 72-hour supply of drugs to a patient discharged from the emergency room for doses removed from the ADDS by the physician?

Answer: Yes, the ADDS will be required to be licensed. The hospital pharmacy is only exempt from licensing the ADDS when the acute care hospital pharmacy solely uses the ADDS to administer drugs. When an ADDS is used to dispense drugs to a patient, the exemption no longer applies. While the ADDS must be licensed, as long as the physician removes the dangerous drug or device from the ADDS to dispense to the patient, the ADDS is not considered to be an APDS and need not follow the APDS requirements found in BPC section 4427.6.

Should your hospital provide discharge medication from the drug stock contained within an ADDS, your facility must secure ADDS licensure to be compliant with these requirements.

NOTE: As a reminder, under provisions of BPC section 4068, medications can only be dispensed from the emergency room if the hospital pharmacy is closed and there is no

pharmacist available in the hospital.

Reference: BPC sections 4017.3, 4068, 4427.2(i), 4427.6.

Question #24. I submitted my application for an ADDS and have completed the pre-licensure inspection. How will I know my application has been approved before I receive the physical license to be posted?

Answer: Once the application is approved, an email will be sent to the pharmacist-in-charge (PIC). The email will notify the pharmacy the application was approved and will include the ADDS license number, type of ADDS, the primary pharmacy license, the status, the name and address of the ADDS location, and expiration date. The board requests that you print and attach a copy of the email to the location of the ADDS and replace when the original is received. Allow 4 to 6 weeks to receive the physical license in the mail at the pharmacy.

Note: To inquire about the status of your ADDS application, please email ADDS@dca.ca.gov.

Note: All references to BPC refer to the Business and Professions Code and all references to CCR refers to Title 16 of the California Code of Regulations unless otherwise specified.

Rev 7.10.2022

Attachment 4

CA State Board of Pharmacy

Enforcement Committee Meeting

Inspection Presentation

July 19, 2022

MANDATE

Consumer Protection

Inspection Process - Observations

- Consultation procedure
- Notice to Consumer poster, language sign, pharmacy permit
- Security features
- Name tags
- Privacy (audio and visual)
- Staffing ratio and duties being performed
- Professional interactions

INSPECTION PROCESS – ITEMS REVIEWED

- SELF-ASSESSMENT
- TRANSMITTING TO CURES
- ENROLLMENT IN THE SUBSCRIBER ALERT SYSTEM
- QUALITY ASSURANCE POLICY AND MEDICATION ERRORS REPORTS
- POLICIES AND PROCEDURES

WHAT IS INSPECTED

- PHYSICAL FACILITY
- SECURITY
- CLEANLINESS, ORDERLINESS
- EXPIRATION DATES, INCLUDING ON LABELS

EDUCATION

- Questions from Licensee
- Standard education Topics

TOTAL INSPECTIONS COMPLETED

- FY 17/18 2,366
- FY 18/19 3,462
- FY 19/20 2,545
- FY 20/21 2,963
  - In Person Inspections 2817
  - Desk Audits 146
- FY 21/22 2,938
  - In Person Inspections 2,862
  - Desk Audits 76

Inspections by Visit Type – FY21/22

- Routine Pharmacy Inspections (PHY-PHE): 1099
- Complaint Inspections: 313
- Pharmacist Recovery Program/Probation: 331
- Compounding Inspections: 935
  - New 64
  - Renewal 871
    - In Person Inspections 799
    - Desk Audit 72

INSPECTIONS BY VISIT TYPE - FY21/22 CONTINUED

- Outsourcing Inspections **30**
  - New In Person Inspections 6
  - Renewal
    - In Person Inspections 19
    - Desk Audit 3
  - Probation
    - In Person Inspections 1
    - Desk Audit 1

- Other Routine Inspections, by License Type: **230**
  - Automated Drug Delivery Systems 185
  - Clinic 3
  - Drug Room 1
  - Hospital 23
  - Third Party Logistics Provider 1
  - Unlicensed Inspection 2
  - Wholesaler 15

Total Inspections Completed: 2,938

Routine Pharmacy Inspections Completed FY 21/22

- Total number of licensed pharmacies: 6,392
- Total number of Routine Pharmacy inspections (PHY/PHE): 1,598
  - 1,099 Routine Pharmacy Inspections Completed
  - 79 Routine Pharmacy Inspections Completed Probation Visit
  - 222 Routine Pharmacy Inspections Completed on Complaint Investigation
  - 198 Routine Pharmacy Inspections Completed During Sterile Compounding Visit

Routine Inspection Outcomes FY21/22

- Routine Inspections Completed: 1099
  - 507 Pharmacies Were Issued No Violations
  - 473 Pharmacies Were Issued 1128 Corrections
  - 148 Pharmacies Issued 229 Violation Notices
- Routine Inspections Completed Complaint Visit: 222
  - 76 Pharmacies Were Issued No Violations
  - 84 Pharmacies Were Issued 206 Corrections
  - 62 Pharmacies Issued 126 Violation Notices
- Routine Inspections Competed Probation Visit: 79
  - 69 Pharmacies Were Issued No Violations
  - 10 Pharmacies Were Issued 43 Corrections
  - 1 Pharmacy Issued 1 Violation Notice

A pharmacy may receive both corrections and violation notices during one inspection.

TOP CORRECTIONS ON ROUTINE PHARMACY INSPECTIONS FY21/22

Violation Code	Description
CCR 1714(c)	Pharmacy Clean and Orderly
CCR1714(b)	Safe and Secure Pharmacy - Maintain Facility
CCR 1707.5(a)(1)	Prescription Labeling Requirements - Patient Centered 12 Pt. Font
CCR 1707.2(b)(1)	Written Notice of Right to Consultation when Patient or Agent is not Present (including drugs shipped by mail)
BPC 4058	License Display
CCR 1715(a)	Self Assessment
CCR 1735.3(a)(2)	Compounding Log Requirements
BPC 4126.8	Compounding Consistent with United States Pharmacopeia – National Formulary

TOP VIOLATION NOTICES ON ROUTINE PHARMACY INSPECTIONS FY21/22

Violation Code	Description
CCR 1714(c)	Pharmacy Clean and Orderly
CCR 1761(a)	Erroneous or Uncertain Prescription
CCR 1715(a)	Self-Assessment
CCR 1764	Unauthorized Disclosure of Prescription
BPC 4301(o)	Unprofessional Conduct

CCR 1707.2 – DUTY TO CONSULT PHARMACY ROUTINE INSPECTIONS

In FY 21/22 66 routine inspections revealed issues with patient consultation

- In 9 of the 66 inspections the inspector observed that consultation was not provided to the patient

- In 57 of the 66 inspections the inspector found that the site was not providing written notice of consultation on delivered or mail order prescriptions

Current Pharmacy Licensees Year of Last Routine Inspection	As of FY 19/20	As of FY 20/21	As of FY 21/22
Inspected Within 1 Year	507	1078	1011
Inspeted Within 2 Years	1233	1479	2170
Inspected Within 3 Years	1512	2093	2570
Inspected Within 4 Years	1698	2310	3194
Inspected Within 5 Years	1807	2440	3433
Inspected Within 6 Years	1970	2518	3594
Inspected Within 7 Years	2134	2637	3688
Inspected Within 8 Years	**N/A**	**2702**	**3819**
Inspected within 9.5 Years	**N/A**	**N/A**	**3912**
Inspected or Visited for Other Reasons After January 1, 2013 (COMPLAINT OR PROBATION VISIT)	**1986**	**2292**	**1636**
Inspected Before January 1, 2013 OR Never Inspected	**2080**	**1193**	**463**
Total Pharmacies (DOES NOT INCLUDE NEW PHY-PPHE LICENSES ISSUED IN CURRENT FY)	**6200**	**6187**	**6011**

INSPECTION SUMMARY

THE BOARD VISITED 92% OF THE CURRENT PHARMACY POPULATION SINCE JANUARY 2013

QUESTIONS?

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

www.pharmacy.ca.gov

Attachment 5

Board of Pharmacy

Enforcement Committee Meeting

Citation Presentation

July 19, 2022

CITATION PROGRAM RELEVANT LAW

- Business and Professions Code Section 4314 establishes the authority for the board to issue citations, which may include fines and/or orders of abatement.
- Orders of abatement may include completion of continuing education courses and specifies that any such continuing education courses shall be in addition to those required for license renewal.
- Title 16, California Code of Regulations(CCR) Sections 1775-1775.4, provide the board's regulations governing its citation and fine program.
- CCR Section 1775 includes the authority of the executive officer or designee to issue citations
- A citation may contain no fine, an administrative fine or a fine and an order of abatement

CITATION PROGRAM OVERVIEW

- The board uses its authority to issue citations to deal with important violations that warrant the licensee's attention, thought and correction, but do not rise to the level where sanctions such as probation, suspension or revocation are appropriate.
- Consistent with the board's direction, the highest fines for the most serious violations
- In most cases, The board has the authority to issue citations of up to $5,000 per license (BPC 125.9).
- The board has specific statutory authority to issue fines of $25,000 per prescription for internet sales of drugs where no underlying appropriate examination occurred (BPC 4067).
- The board has specific statutory authority to issue fines up to $25,000 per prescription for internet sales of drugs where no underlying appropriate examination occurred (BPC 4067).
- the board may assess a fine for up to $100,000 for repeated violations for pharmacies operating under common ownership or management within a chain community pharmacy (BPC 4317.5).
- The board may assess a fine for up to $150,000 for violations that are a result of a written policy or which was expressly encouraged by a common manager or owner (BPC 4317.5).

Factors to Consider in Assessing Administrative Fines – CCR 1775.2

- Gravity of the violation
- Good or bad faith of the cited person or entity
- History of previous violations
- Evidence that the violation was or was not willful
- Extent to which the cited person or entity has cooperated with the Board's investigation
- Extent to which the cited person or entity has mitigated or attempted to mitigate any damage or injury caused by the violations
- Other matters as may be appropriate
- Number of violations found in the investigation

Citation Process

1. Investigation is completed
2. Supervising Inspector Review
3. Second level review
4. Citation issued without fine & with/without abatement
5. Citation completed with fine or abatement accepted
6. Appeal - - Office Conference and/or AG's Office

CITATIONS ISSUED

	FY2015/16	FY2016/17	FY2017/18	FY2018/19	FY2019/20	FY2020/21	FY2021/22
CITATIONS ISSUED	1,975	1,936	2,168	1,134	1,426	934	1,274
CITATIONS ISSUED WITHOUT FINE	376	439	504	339	535	401	451
CITATIONS ISSUED WITH FINE	1,599	1,497	1,664	795	891	533	823
FINES ASSESSED	$2,264,650	$2,354,525	$2,268,625	$1,166,700	$1,462,300	$787, 100	$2,029,012
FINES COLLECTED	$2,145,398	$2,071,478	$2,079,806	$1,212,077	$963,446	$711,729	$1,093,911

CITATION PROCESSING TIMES FROM RECEIPT TO ISSUANCE

FISCAL YEAR	AVERAGE DAYS
2015/16	280
2016/17	319
2017/18	354
2018/19	333
2019/20	400
2020/21	426
2021/22	341

CITATION WITH ORDER OF ABATEMENT

- THE BOARD MAY ISSUE CITATIONS WITH ORDERS OF ABATEMENT
- THE BOARD HAS BEEN USING ORDERS OF ABATEMENT ROUTINELY SINCE 2018
- THE ABATEMENT ORDER MAY REQUIRE:
  - THE LICENSEE TO TAKE CONTINUING EDUCATION COURSES/ TRAINING
  - THE LICENSEE TO PROVIDE SPECIFIC DOCUMENTATION
  - THE LICENSEE TO DETAIL A PLAN TO COMPLY WITH PHARMACY LAW
- COMPLIANCE WITH THE ORDER OF ABATEMENT TYPICALLY RESULTS IN EITHER A REDUCTION OR FORGIVENESS OF THE FINE

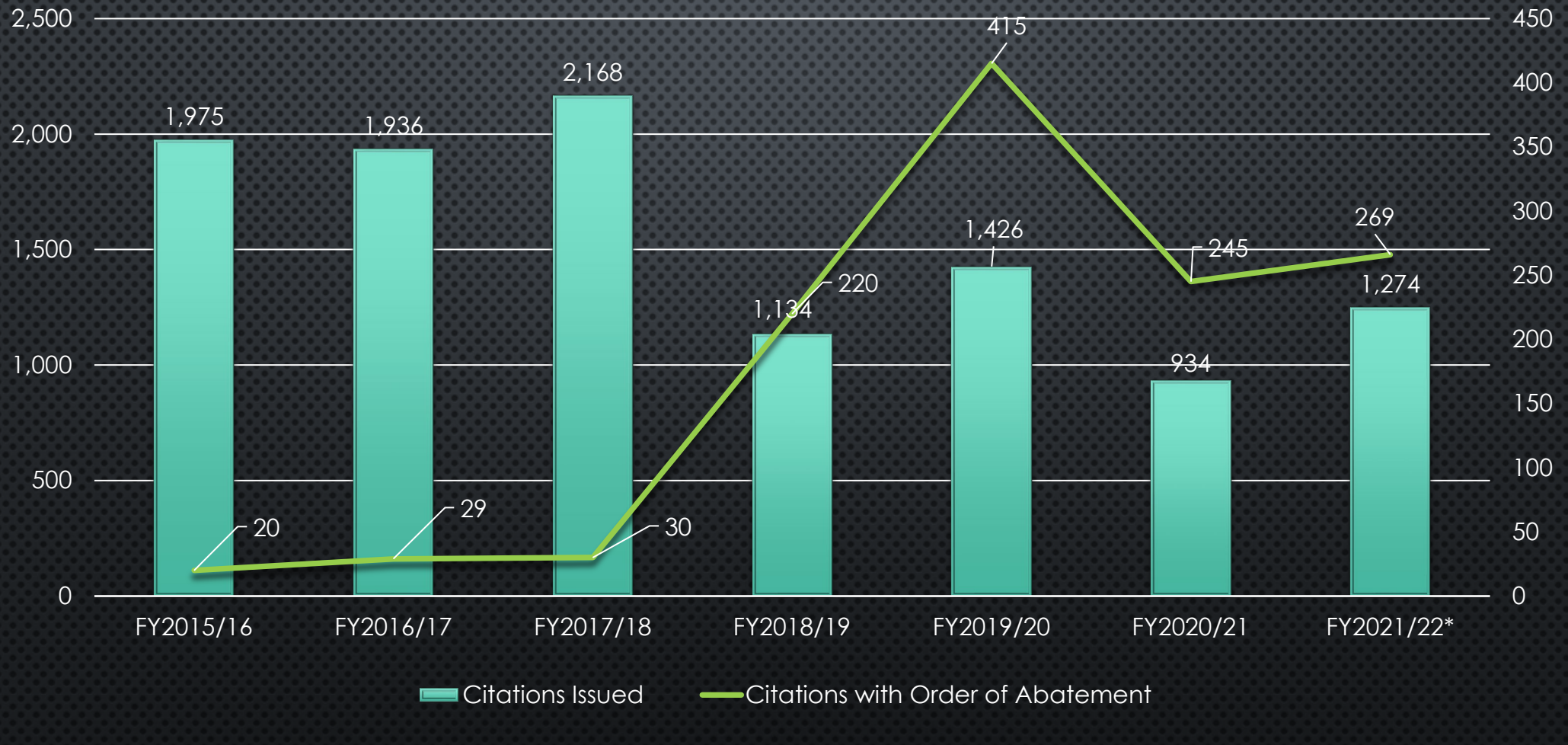
ABATEMENT TYPES

- Requested Continuing Education (CE) to be Completed by Licensee (Typically 2-6 hours)
  - Board Provided Rx Drug Abuse Course
  - Ethics Course (Pursuant to CCR 1773.5)
  - Immunization Training
  - Compounding Training
  - Pharmacy Operations
  - Pharmacy Law & Ethics
  - Role of the Pharmacist in Charge (PIC)
  - Medication error reduction strategies

ABATEMENT TYPES

- Other abatements that may be requested by the board:
  - Internal policy training for pharmacy staff
  - In service trainings for staff
  - Updated Self Assessment
  - Updated policies and procedures

CITATIONS ISSUED/ ORDERS OF ABATEMENT



PROOF OF CITATION ABATEMENTS FY21/22

- TOTAL ABATEMENTS ISSUED: 269
  - ABATEMENTS SATISFIED: 168

VIOLATIONS THAT LEND THEMSELVES TO ABATEMENTS

- 1714(c) PHARMACY SHALL BE CLEAN AND ORDERLY – ABATE WITH PHOTOS OF CLEANLINESS AND ORDER
- CCR 1714(d): PHARMACY SECURITY – ABATE WITH CE IN PHARMACY LAW AND OPERATIONS
- CC1716: MEDICATION ERROR – ABATE WITH CE IN MEDICATION ERROR REDUCTION STRATEGIES (MAJORITY OF ABATEMENTS FALL INTO THIS CATEGORY)
- CCR 1746.4: VACCINES AND IMMUNIZATIONS – ABATE WITH CE IN IMMUNIZATION TRAINING
- CCR 1735.1 TO 1735.8: COMPOUNDING VIOLATIONS – ABATE WITH CE IN COMPOUNDING TRAINING

APPEAL PROCESS

- Licensees who are issued a fine may request an informal office conference
- Office conference allows the licensee the opportunity to present additional or mitigating information to the board's executive officer or designee and a supervising inspector
- In addition, a licensee may submit a formal appeal to the board within 30 days of issuance of the citation
  - appeals are conducted pursuant to the Administrative Procedures Act by an administrative law judge who renders a decision for the board to adopt or reject

CITATIONS COMPLETED OR CONTESTED

	FY 2015/16	FY 2016/17	FY 2017/18	FY 2018/19	FY 2019/20	FY 2020/21	FY 2021/22
CITATIONS COMPLETED	1,753	1,855	2,112	1,116	1,210	992	1,088
CITATIONS CONTESTED AT OFFICE CONFERENCE	201	191	140	148	216	154	229
CITATIONS CONTESTED AT THE ATTORNEY GENERAL'S OFFICE	54	61	50	29	20	29	34

CITATION APPEAL OUTCOMES FY21/22

- **TOTAL OFFICE CONFERENCES (OC) REQUESTED** **229**
- OFFICE CONFERENCE OUTCOMES
  - MODIFIED 31
  - REDUCED TO LETTER OF ADMONISHMENT 16
  - DISMISSED 27
  - UPHELD 85
- **TOTAL APPEALS REFERRED TO AG** **34**
  - WITHDRAWN 9
  - STIPULATED AGREEMENT 1
  - STILL PENDING 24

PHARMACIES TOP TEN VIOLATIONS FY21/22

Violation Code	Description	Number of Violations
CCR 1716	Medication Error	141
BPC 4113(d)	Pharmacy Shall Notify Board in Writing within 30 days when a Pharmacist in Charge Disassociates	66
BPC 4113(a)	Pharmacy Shall Designate a Pharmacist in Charge in Writing within 30 Days	46
CCR 1764/56.10	Unauthorized Disclosure of Prescription and Medical Information	41
CCR 1714(b)	Safe and Secure Pharmacy - Maintain Facility	39
BPC 4305	Pharmacist Notify Board They are no Longer Acting as Pharmacist in Charge within 30 Days	26
CCR 1707.3	Duty to Review Drug Therapy	25
BPC 4081(a)	Records Kept Open for Inspection for 3 Years	22
CCR 1718	Controlled Substances Inventory Available for 3 Years	19
CCR 1761(a)	Erroneous or Uncertain Prescription	18

PHARMACIST TOP TEN VIOLATIONS FY21/22

Violation Code	Description	Number of Violations
CCR 1716	Medication Error	139
CCR 1714(b)	Safe and Secure Pharmacy - Maintain Facility	33
BPC 4306.5	Misuse of Education by a Pharmacist	24
CCR 1735.2	Compounding Limitations and Requirements	24
CCR 1764/56.10	Unauthorized Disclosure of Prescription and Medical Information	22
CCR 1707.3	Duty to Review Drug Therapy	19
CCR 1761(a)	Erroneous or Uncertain Prescription	17
CCR 1718	Controlled Substances Inventory Available for 3 Years	16
BPC 4301(h)	Unprofessional Conduct - Self Administer Drugs or Alcohol	16
BPC 4081(a)	Records Kept Open for Inspection for 3 Years	15

INTERN TOP TEN VIOLATIONS FY21/22

Violation Code	Description	Number of Violations
BPC 4301(h)	Unprofessional Conduct - Self Administer Drugs or Alcohol	3
BPC 4301()	Conviction Involving Drugs or Alcohol	3
BPC 4306.5	Misuse of Education	1
CCR 1746	Emergency Contraception	1
CCR 1716	Medication Error	1
BPC 4169(a)	Prohibited Acts Involving Dangerous Drugs or Devices	1

TECHNICIAN TOP TEN VIOLATIONS FY21/22

Violation Code	Description	Number of Violations
BPC 4301(h)	Self Administer Drugs or Alcohol	91
BPC 4301(l)	Conviction of a Crime Substantially Related to Pharmacy	88
BPC 4301(f)	Moral Turpitude, Dishonesty, Fraud, Deceit or Corruption	18
BPC 4301(k)	Convictions Involving Drugs or Alcohol	12
CCR 4301(g)	False Representation	9
CCR 4301(j)	Violation of any Statute Regulating Controlled Substances and Dangerous Drugs	4
CCR 4301(q)	Subversion of an Investigation	4
CCR 1708.2	Discontinuation of Business	3
BPC 4115(a)	Technician Supervision	2
BPC 4115(e)	Technician Licensure	2

DUTY TO CONSULT CCR 1707.2 FY21/22

	FY 19/20	FY 20/21	FY 21/22
Total Duty to Consult Citations (Pharmacists and Pharmacies)	64	60	49
Pharmacy Citations	30 (23 with fine, 7 without)	28 (21 with fine, 7 without)	21 (18 with fine, 3 without)
Average Citation Amount for Pharmacies	$3,117	$3,798	$3,416
Pharmacist Citations	34 (12 with fine, 22 without)	32 (19 with fine, 13 without)	28 (11 with fine, 17 without)
Average citation Amount for Pharmacists	$654	$974	$1,272

CITATIONS ON COMMUNITY PHARMACIES UNDER COMMON OWNERSHIP OR MANAGEMENT BPC 4317.5 FY21/22

Total Citations Issued 2

THANK YOU

QUESTIONS?

Attachment 6

Board of Pharmacy

Enforcement Workload Statistics FY 2021/22

Complaint Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	661	718	803	855	3,037
Closed	755	740	703	749	2,947
Pending	1,308	1,294	1,417	1,602	1,602
Average Days for Investigation	246	194	175	145	190

Cases Under Investigation (By Team)	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Compliance / Routine	484	541	611	564	564
Drug Diversion / Fraud	144	178	197	208	208
Prescription Drug Abuse	107	92	168	167	167
Compounding	38	43	50	46	46
Outsourcing	15	15	22	25	25
Probation / PRP	19	25	50	73	73
Enforcement	235	93	4	136	136
Criminal Conviction	266	307	315	383	383

Application Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	54	42	58	63	217
Closed					
Approved	36	44	31	23	134
Denied	16	11	15	13	55
Total Closed (includes withdrawn)	***54***	***61***	***52***	***41***	***208***
Pending	74	53	63	89	89

Complaint Closure Outcomes Not Resulting in Further Action	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Insufficient Evidence	189	149	171	157	666
Non-Jurisdictional	119	122	153	148	542
No Violation	92	108	53	71	324
No Further Action	59	68	56	27	210
Other - Non-Substantiated	7	4	11	26	48
Subject Educated	20	17	12	15	64

Letter of Admonishment / Citations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
LOA Issued	92	73	65	36	266
Citations Issued	360	332	258	324	1,274
Proof of Abatement Requested	89	84	45	51	269
Appeals Received	27	22	7	1	57
Dismissed	5	14	3	4	26
Total Fines Collected	***$212,256***	***$235,844***	***$312,425***	***$333,387***	***$1,093,911***

Administrative Cases	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Referred to the AG's Office	44	21	55	46	166
Pleadings Filed	51	50	30	40	171
Pending					Quarter Ending
Pre-Accusation	85	58	78	79	78
Post-Accusation	153	167	147	146	146
Total Pending	**242**	**225**	**225**	**225**	**225**
Total Closed	50	45	62	45	202

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation					
Pharmacist	2	1	3	3	9
Intern Pharmacist	0	0	0	1	1
Pharmacy Technician	5	1	17	7	30
Designated Representative	1	0	0	0	1
Wholesaler	0	0	0	0	0
Pharmacy	10	1	2	4	17
Sterile Compounding	1	0	0	1	2
Outsourcing	0	0	0	0	0
Total	***19***	***3***	***22***	***16***	***60***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation; stayed suspension/probation					
Pharmacist	0	0	1	0	1
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***	***1***	***0***	***1***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation; stayed; probation					
Pharmacist	10	16	12	14	52
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	1	2	0	1	4
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	6	6	1	5	18
Sterile Compounding	2	1	0	0	3
Outsourcing	0	1	0	0	1
Total	***19***	***26***	***13***	***20***	***78***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Surrender / Voluntary Surrender					
Pharmacist	4	7	9	6	26
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	3	3	7	3	16
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	11	9	13	7	40
Sterile Compounding	0	0	1	1	2
Outsourcing	0	0	0	0	0
Total	***18***	***19***	***30***	***17***	***84***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Public Reproval / Reprimand					
Pharmacist	3	3	10	3	19
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	1	0	1	0	2
Designated Representative	0	0	1	1	2
Wholesaler	0	0	1	2	3
Pharmacy	5	9	5	1	20
Sterile Compounding	1	0	1	2	4
Outsourcing	0	0	0	0	0
Total	***10***	***12***	***19***	***9***	***50***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Granted					
Pharmacist	1	0	0	0	1
Intern Pharmacist	1	0	0	0	1
Pharmacy Technician	0	0	2	0	2
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	0	1	0	0	1
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***2***	***1***	***2***	***0***	***5***

Administrative Case Outcome	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	1	0	2
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	0	3	0	1	4
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***1***	***3***	***1***	***1***	***6***

Administrative Case Cost Recovery Efforts	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Cost Recovery Requested	***$348,542***	***$1,128,139***	***$734,380***	***$633,939***	***$2,845,000***
Cost Recovery Collected	***$262,261***	***$1,082,219***	***$289,705***	***$649,519***	***$2,283,704***

Immediate Public Protection Sanctions	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Interim Suspension Orders	0	1	0	1	2
Automatic Suspension Orders	1	0	0	3	4
Penal Code 23 Restrictions	0	0	0	0	0
Cease and Desist - Outsourcing	1	0	0	0	1
Cease and Desist - Unlicensed Activity	0	1	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	223	226	215	217	217
Intern Pharmacist	3	3	3	1	1
Pharmacy Technician	29	27	24	22	22
Designated Representative	2	2	2	2	2
Wholesaler / 3PL	3	3	3	3	3
Pharmacy	68	65	64	60	60
Sterile Compounding	10	11	11	11	11
Outsourcing	0	0	1	1	1
Total	***338***	***337***	***323***	***317***	***317***

Probation Statistics	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Probation Office Conferences	18	23	16	17	74
Probation Site Inspections	127	96	50	107	380
Probation Terminated / Completed	30	24	30	5	89
Referred to AG for Non-Compliance	6	1	0	1	8

As of 6/30/2022

Board of Pharmacy

Citation and Fine Statistics FY 2021/22

Citation Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Pharmacist with Fine	88	75	52	32	247
Pharmacist no Fine	61	48	49	49	207
Pharmacy with Fine	74	75	70	193	412
Pharmacy no Fine	66	56	41	21	184
Pharmacist-in-Charge with Fine*	44	53	24	22	143
Pharmacist-in-Charge no Fine	70	52	37	38	197
Pharmacy Technician with Fine	20	32	10	11	73
Pharmacy Technician no Fine	0	0	6	1	7
Wholesalers	2	4	1	0	7
Designated Representative	4	1	1	0	6
Clinics	0	1	0	0	1
Drug Room	0	0	0	0	0
Exempt Hospital	2	0	0	0	2
Hospital Pharmacy	4	7	5	2	18
Miscellaneous**	36	30	22	14	102
Unlicensed Premises	2	5	4	2	13
Unlicensed Person	1	0	1	0	2

*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

Pharmacists	%	Pharmacies	%	Pharmacists In Charge	%
1716 - Variation from prescription	36%	4301/1793.7(a) - Unprofessional Conduct…/Requirements for pharmacies employing pharmacy technicians - any pharmacy employing pharmacy technicians	27%	1716 - Variation from prescription	25%
1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	14%	4301/1714(d) - Unprofessional Conduct…/Operational Standards and Security; Pharmacist responsible for pharmacy security	27%	1764/56.10(a) - Unauthorized disclosure of prescription and medical information	13%
11153(a) - Responsibility for legitimacy of prescription; a prescription for a controlled substance shall only be issued for a legitimate medical purpose...	13%	4113(D) - Every pharmacy shall notify the board in writing within 30 days of the date of a change in pharmacist-in-charge	16%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	13%
1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	9%	4113(a) - Pharmacist-in-Charge: Notification to Board; Responsibilities; Every pharmacy shall designate a pharmacist-in-charge within 30 days in writing of the identity and license number of that phar	9%	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%
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%	4305(b) - Operation of a pharmacy for more than 30 days without supervision or management by a pharmacist-in-charge shall constitute grounds for disciplinary action	8%	1714(c) - Operational Standards and Security; pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition	8%
1714(c) - Operational Standards and Security; pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition	5%	1716 - Variation from prescription	7%	1707.3 - Duty to review drug therapy	8%
1764/56.10(a) - Unauthorized disclosure of prescription and medical information	5%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	2%	4301(o)/111335/111440 - Unprofessional Conduct - Assist in violation/ Any drug or device is misbranded if its labeling or packaging does not conform to the requirement of Chapter 4/It is unlawful for	8%
1714(b)(d) - Operational Standards and Security; pharmacy responsible for pharmacy security/Each pharmacist when on duty is responsible for security	4%	4301(g) - Unprofessional Conduct - Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts	2%	1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	8%
1707.3 - Duty to review drug therapy	4%	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	1%	4081(a) - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory	5%
1707.3/1707.1(a)(1)(c) - Duty to review drug therapy/ Duty to maintain medication profiles on all patients…including; patient allergies, idiosyncrasies, current medications and relevant prior medication	4%	1764/56.10(a) - Unauthorized disclosure of prescription and medical information	1%	1714(b)(d) - Operational Standards and Security; pharmacy responsible for pharmacy security/Each pharmacist when on duty is responsible for security	5%

California State Board of Pharmacy
SB 1441 Uniform Standards

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

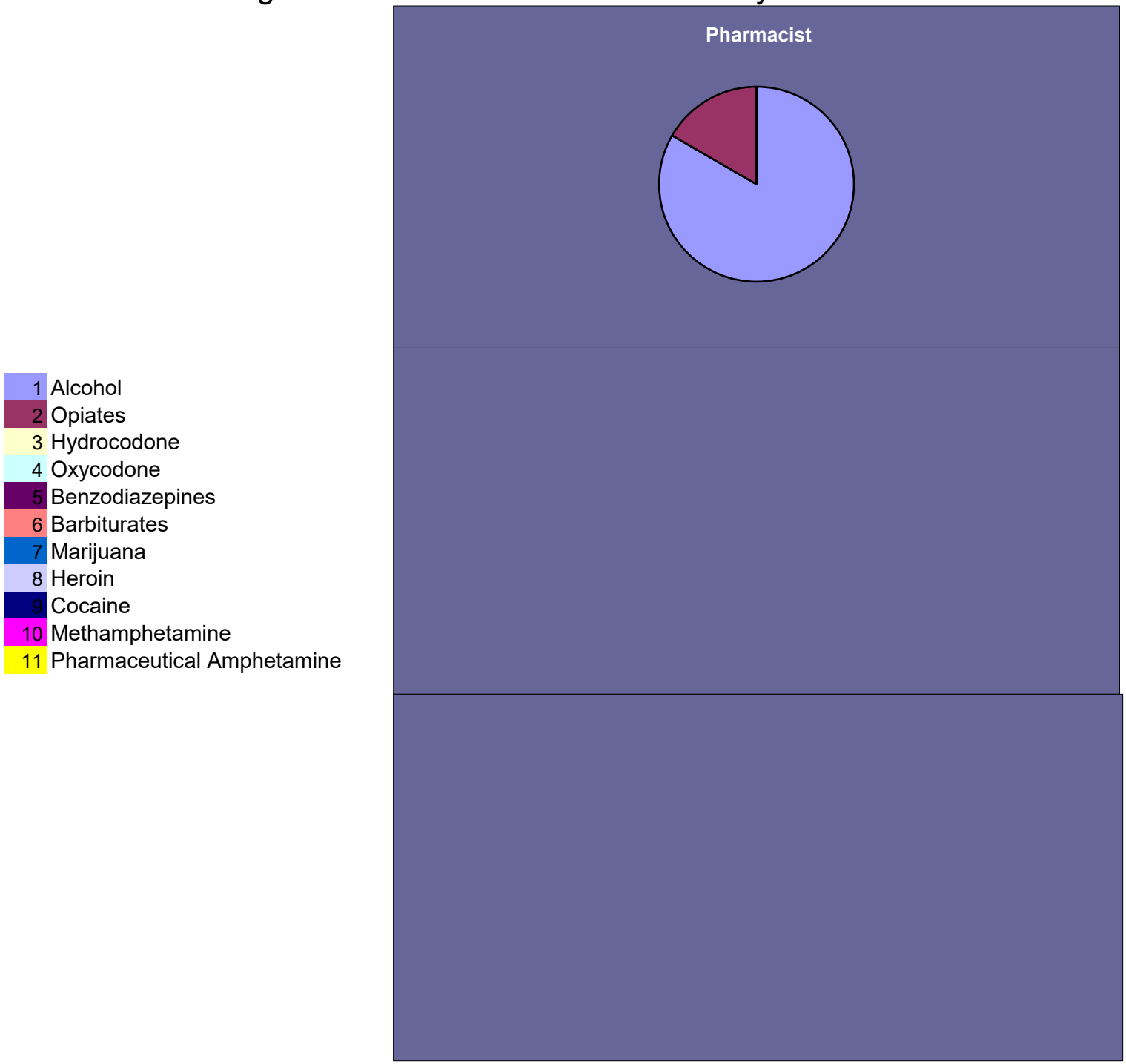
Board of Pharmacy	July Sep	Oct – Dec	Jan-Mar	Apr Jun	Total 21/22
PRP Intakes					
PRP Self-Referrals			1	1	2
PRP Probation Referrals			2		2
PRP Under Investigation	1			1	2
PRP In Lieu Of (investigation conducted)					
Total Number of PRP Intakes	1		3	2	6
New Probationers					
Pharmacists	1	1	2		4
Intern Pharmacists					
Pharmacy Technicians	1	1	1		3
Total New Probationers	2	2	3		7
PRP Participants and Recovery Agreements					
Total PRP Participants	52	47	45	45	N/A
Recovery Agreements Reviewed	40	43	35	43	161
Probationers and Inspections					
Total Probationers	70	69	65	56	N/A
Inspections Completed	44	41	43	23	151
Referrals to Treatment					
Referrals to Treatment (PRP and Probationers)	1	2	1	1	5
Drug Tests					
Drug Test Ordered (PRP and Probationers)	694	689	624	610	2617
Drug Tests Conducted (PRP and Probationers)	661	663	625	598	2547
Relapses (Break in Sobriety)					
Relapsed (PRP and Probationers)		2		1	3
Major Violation Actions					
Cease Practice/Suspension (PRP and Probationers)	3	3	6	9	21
Termination from PRP	1				1
Probationers Referred for Discipline	3				3
Closure					
Successful Completion (PRP and Probationers)	4	6	5	13	28
Termination (Probation)			2	1	3
Voluntary Surrender (Probation)	2	2	1	1	6
Surrender as a result of PTR (Probation)					
Closed Public Risk (PRP)	1				1
Non-compliance (PRP and Probationers)	51	38	43	32	164
Other (PRP)			1	3	4
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.

Board of Pharmacy	July Sep	Oct – Dec	Jan-Mar	Apr Jun	Total 21/22
Drug of Choice at PRP Intake or Probation					
Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 20/21**
Alcohol	1	1	3		5
Ambien	1				1
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 20/21**
Alcohol			1		1
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana			1		1
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 20/21**
Alcohol	1	1			2
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine			1		1
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					

Drug Of Choice - Data entered from July 2021 to December 2021



Printed on 7/11/2022

Workload Statistics	Total FY 19/20	Total FY 20/21	Total FY 21/22	% Change
Complaint Investigations				
Received	2,647	2,293	3,037	15%
Closed	2,910	2,549	2,947	1%
Pending	1,600	1,582	1,602	0%
Average Days for Investigation	232	233	190	-18%
Cases Under Investigation (By Team)				
Compliance/Routine	837	514	564	-33%
Drug Diversion/Fraud	191	144	208	9%
Rx Abuse	78	126	167	114%
Compounding	67	42	46	-31%
Outsourcing	23	11	25	9%
Probation/PRP	26	14	73	181%
Enforcement	115	449	136	18%
Criminal Conviction	262	282	383	46%
Complaint Closure Outcomes Not Resulting in Further Action				
Insufficient Evidence	635	644	666	5%
Non-Jurisdictional	402	369	542	35%
No Violation	365	346	324	-11%
No Further Action	253	213	210	-17%
Other - Non-Substantiated	32	34	48	50%
Subject Educated	151	89	64	-58%
Application Investigations				
Received	374	240	217	-42%
Closed				
Approved	247	208	134	-46%
Denied	48	33	55	15%
Total Closed (includes withdrawn)	***341***	***271***	***208***	***-39%***
Pending	78	72	63	-19%
Letter of Admonmishment / Citations				
LOA Issued	327	452	266	-19%
Citations Issued	1,428	936	1,274	-11%
Proof of Abatement Requested	414	248	269	-35%
Appeals Received	103	93	57	-45%
Dismissed	21	22	26	24%
Total Fines Collected	***$963,445***	***$785,755***	***$1,093,911***	***14%***
Administrative Cases				
Referred to the AG's Office	230	188	166	-28%
Pleadings Filed	248	194	171	-31%
Pending				
Pre Accusation	128	108	78	-39%
Post Accusation	192	153	147	-23%
Total Pending	***322***	***261***	***225***	***-30%***
Total Closed	***320***	***291***	***202***	***-37%***
Revocation				
Pharmacist	19	12	9	-53%
Intern Pharmacist	2	1	1	-50%
Pharmacy Technician	77	66	30	-61%
Designated Representative	1	1	1	0%
Wholesaler	2	0	0	-100%
Clinic	0	0	0	0%
Pharmacy	9	12	17	89%
Sterile Compounding	1	0	2	100%
Outsourcing	0	0	0	0%
Total	***111***	***92***	***60***	***-46%***

Revocation; stayed suspension/probation				
Pharmacist	0	1	1	0%
Intern Pharmacist	0	1	0	0%
Pharmacy Technician	0	0	0	0%
Designated Representative	0	0	0	0%
Wholesaler	0	0	0	0%
Clinic	0	0	0	0%
Pharmacy	0	0	0	0%
Sterile Compounding	0	0	0	0%
Outsourcing	0	0	0	0%
Total	***0***	***2***	***1***	***0%***
Revocation; stayed; probation				
Pharmacist	60	63	52	-13%
Intern Pharmacist	5	3	0	-100%
Pharmacy Technician	14	15	4	-71%
Designated Representative	1	0	0	-100%
Wholesaler	1	1	0	-100%
Clinic	0	0	0	0%
Pharmacy	15	19	18	20%
Sterile Compounding	2	5	3	50%
Outsourcing	1	0	1	0%
Total	***99***	***106***	***78***	***-21%***
Surrender/Voluntary Surrender				
Pharmacist	28	20	26	-7%
Intern Pharmacist	1	1	0	-100%
Pharmacy Technician	35	18	16	-54%
Designated Representative	4	3	0	-100%
Wholesaler	1	2	0	-100%
Clinic	0	0	0	0%
Pharmacy	31	38	40	29%
Sterile Compounding	1	2	2	100%
Outsourcing	0	2	0	0%
Total	***101***	***86***	***84***	***-17%***
Public Reproval/Reprimand				
Pharmacist	4	38	19	375%
Intern Pharmacist	0	0	0	0%
Pharmacy Technician	1	6	2	100%
Designated Representative	0	1	2	0%
Wholesaler	0	1	3	0%
Clinic	0	2	0	0%
Pharmacy	6	44	20	233%
Sterile Compounding	0	5	4	0%
Outsourcing	0	2	0	0%
Total	***11***	***99***	***50***	***355%***
Licenses Granted				
Pharmacist	2	2	1	-50%
Intern Pharmacist	1	0	1	0%
Pharmacy Technician	6	3	2	-67%
Designated Representative	0	0	0	0%
Wholesaler	0	0	0	0%
Clinic	0	0	0	0%
Pharmacy	0	0	1	0%
Sterile Compounding	0	0	0	0%
Outsourcing	1	0	0	-100%
Total	***10***	***5***	***5***	***-50%***
Licenses Denied				
Pharmacist	4	1	0	-100%
Intern Pharmacist	2	0	0	-100%
Pharmacy Technician	5	3	2	-60%
Designated Representative	0	0	0	0%
Wholesaler	0	0	0	0%
Clinic	0	0	0	0%
Pharmacy	0	1	4	0%
Sterile Compounding	0	0	0	0%
Outsourcing	0	1	0	0%
Total	***11***	***6***	***6***	***-45%***
Cost Recovery Requested	***$2,184,365***	***$2,475,038***	***$2,845,000***	***30%***
Cost Recovery Collected	***$1,072,751***	***$1,578,428***	***$2,283,704***	***113%***

Immediate Public Protection Sanctions				
Interim Suspension Order	8	13	2	-75%
Automatic Suspensions	2	0	4	100%
Penal Code 23 Restrictions	5	2	0	-100%
Cease and Desist - Outsourcing	n/a	n/a	1	0%
Cease and Desist - Unlicensed	1	0	1	0%
Cease and Desist - Sterile Compounding	0	0	0	0%
Probation Statistics				
Licenses on Probation				
Pharmacist	229	232	217	-5%
Intern Pharmacist	12	5	1	-92%
Pharmacy Technician	26	28	22	-15%
Designated Representative	2	2	2	0%
Wholesaler	3	3	3	0%
Pharmacy	72	69	60	-17%
Sterile Compounding	2	8	11	450%
Outsourcing	0	0	1	0%
Total Probationers	***346***	***347***	***317***	***-8%***
Probation Office Conferences	115	79	74	-36%
Probation Site Inspections	442	533	380	-14%
Probation Terminated / Completed	99	96	89	-10%
Referred to AG for Non-Compliance	6	3	8	33%

California State Board of Pharmacy
SB 1441 Uniform Standards
Three Year Comparison

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

Board of Pharmacy	FY19/20	FY20/21	FY21/22
PRP Intakes			
PRP Self-Referrals	1	0	2
PRP Probation Referrals	10	6	2
PRP Under Investigation	6	2	2
PRP In Lieu Of (investigation conducted)	0	1	0
Total Number of PRP Intakes	17	9	6
New Probationers			
Pharmacists	9	7	4
Interns	2	3	0
Pharmacy Technicians	10	8	3
Total New Probationers	21	18	7
PRP Participants and Recovery Agreements			
Total PRP Participants	59	51	45
Total Participant Recovery Agreements Reviewed	221	207	161
Probationers and Inspections			
Total Probationers	95	73	56
Inspections Completed (This information is not available)	226	236	151
Referrals to Treatment			
Referrals to Treatment (PRP and Probationers)	16	6	5
Drug Tests			
Drug Test Ordered (PRP and Probationers)	2947	2912	2617
Drug Tests Conducted (PRP and Probationers)	2884	2780	2547
Relapses			
Relapsed (PRP and Probationers)	11	4	3
Major Violation Actions			
Cease Practice/Suspension (PRP and Probationers)	34	25	21
Terminated from PRP	3	10	1
Probationers Referred for Discipline	0	4	3
Closure			
Successful Completion (PRP and Probationers)	13	12	28
Termination (Probation)	0	1	3
Voluntary Surrender (Probation)	7	11	6
Surrender as a result of PTR (Probation)	0	0	0
Closed Public Risk (PRP)	3	1	1
Non-compliance (PRP and Probationers)	23	4	164
Other (PRP)	4	4	4
Patients Harmed			
Number of Patients Harmed (PRP and Probationers)	None	None	None

Drug of Choice at PRP Intake or Probation			
Pharmacists	**FY19/20**	**FY20/21**	**FY21/22**
Alcohol	13	4	5
Ambien			1
Opiates	2	1	
Hydrocodone	2		
Oxycodone	2	1	
Morphine		1	
Benzodiazepines			
Barbiturates			
Marijuana	1		
Heroin			
Cocaine	1		
Methamphetamine			
Pharmaceutical Amphetamine			
Phentermine			
Methadone			
Zolpidem Tartrate			
Hydromorphone			
Clonazepam			
Tramadol			
Carisprodol			
Phendimetrazine			
Promethazine w/Codeine			
Intern Pharmacists	**FY19/20**	**FY20/21**	**FY21/22**
Alcohol	4	2	1
Opiates			
Hydrocodone			
Oxycodone			
Benzodiazepines			
Barbiturates			
Marijuana			1
Heroin			
Cocaine	1	1	
Methamphetamine			
Pharmaceutical Amphetamine			
Phentermine			
Methadone			
Zolpidem Tartrate			
Hydromorphone	1		
Clonazepam			
Tramadol	1		
Carisprodol			
Phendimetrazine			
Promethazine w/Codeine			
Pharmacy Technicians	**FY19/20**	**FY20/21**	**FY21/22**
Alcohol	6	7	2
Opiates			
Hydrocodone			
Oxycodone			
Benzodiazepines	1		
Barbiturates			
Marijuana			
Heroin			
Cocaine	1		1
Methamphetamine	2	1	
Pharmaceutical Amphetamine			
Phentermine			
Methadone			
Zolpidem Tartrate			
Hydromorphone			
Clonazepam			
Tramadol			
Carisprodol			
Phendimetrazine			
Promethazine w/Codeine			