California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

Enforcement and Compounding Committee Report

Maria Serpa, Licensee Member, Chair
Renee Barker, Licensee Member, Vice-Chair
Indira Cameron-Banks, Public Member
Seung Oh, Licensee Member, President
Jignesh Patel, Licensee Member

During the meeting members will receive a summary of the committee's work at its July 18, 2023, Enforcement and Compounding Committee Meeting as well as updates for action as necessary.

a. Presentation on the Disciplinary Case Process by the Office of the Attorney General

Background

The formal administrative disciplinary case process is initiated after an investigation is conducted that reveals violations that, based on the egregiousness of the violations identified, result in referral to the Office of the Attorney General (AGO) for discipline. Upon referral to the AGO, the assigned Deputy Attorney General (DAG) will review the investigation and evidence and independently evaluate if violations occurred. Should such a determination be made, the DAG will prepare an accusation for filing before the Board. An accusation is a formal pleading document that details the allegations and charges levied against a licensee Respondent. Respondents are provided the option to refute the allegations and indicate their intention to do so by filing a Notice of Defense. Upon receipt of a Notice of Defense, the assigned DAG will request to set the matter for hearing before the Office of Administrative Hearings (OAH). The DAG and Respondent (or Respondent's counsel) will exchange discovery, which includes the investigative file. If Respondent is interested in settling the case, Respondent will send mitigation evidence, which is evidence showing rehabilitation or corrective measures taken. Examples of mitigation evidence are set forth in the Board's Manual of Disciplinary Guidelines and Model Disciplinary Orders. Typically, the case is resolved in one of two manners: (1) the disciplinary outcome is reached through a settlement agreement (stipulation); or (2) a hearing is conducted at OAH, followed by a proposed decision from the administrative law judge (ALJ) who is assigned to hear the matter on behalf of the Board. In either manner, the Board is ultimate decision maker and votes to either adopt or nonadopt a settlement agreement or proposed decision. Depending on the outcome of the vote, additional steps occur through the

nonadoption process. If the Board decides to adopt it, the proposed settlement agreement or proposed decision will become a final decision of the Board.

Summary of Committee Discussion and Action
During the meeting members received a presentation by Kristina Jarvis and Nicole Trama, Deputy Attorney Generals on the administrative disciplinary case process which is governed by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The presentation included an overview of the process. Members were advised that the disciplinary process ensures due process for licensees. The presentation included information on the standard of proof required for various matters and licensees, stipulated settlements and administrative hearings, and appeal rights

Following the presentation, members received public comment from an individual suggesting that the Board should resume its discussion on the use of pre-filing conferences.

Attachment 1 includes a copy of the presentation slides.

b. Presentation and Discussion on 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.

Summary of Committee Discussion and Action
During the meeting members received a presentation will be provided detailing inspection information focusing primarily on routine inspections. In fiscal year 2022/23, staff conducted 2,837 in person inspections including 889 routine inspections of pharmacies where the sole purpose of the inspection was triggered for routine evaluation. Of the routine inspections completed 415 inspections resulted in correction(s) being issued and 60 pharmacies were issued a notice of violation(s). Further, 94 routine inspections revealed violations of the Board's patient consultation requirements, either failure to provide consultation, failure to provide written notice of consultation on delivered or mail order prescriptions or failure of the written notice of consultation to meet all required elements. Data shows that 69.3% of licensed pharmacies have been inspected in the last 4 years, which is the Board's policy goal. This is an increase from 37.3% two years ago and 53.1% last year. While data also suggests approximately 4% of the Board's licensed pharmacies have never been inspected. It is anticipated that this fiscal year the Board will complete inspections of

these remaining facilities that have never been inspected and will focus on facilities that have not been inspected in the last four years.

Members expressed appreciation for Board staff's efforts to perform routine inspections and the value it provides to licensees. Members discussed efforts to begin performing routine inspections at nonresident pharmacies and was advised that currently staff are focusing on in state pharmacies.

The Committee did not receive any public comment on this presentation.

Attachment 2 includes a copy of the presentation slides. Data reflects July 1, 2022, through June 16, 2023.

c. Presentation on 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 2018/19	FY 2019/20	FY 2020/21	FY 2021/22	FY 2022/23
Citations Issued	1,144	1,426	934	1,274	1.053
Average Days to Complete	381	400	426	341	325
Order of Abatements Issued	224	415	245	269	196
Amount of Fines Assessed	$1,176,450	$1,462,300	$787,100	$2,029,012	$2,358,337*
Amount Collected	$1,210,086	$963,446	$711,729	$1,093,911	$2,021,404

*Reflects final amounts assessed

For Committee Consideration and Discussion

During the meeting members received a presentation on the Boards citation and fine program. The presentation described the various authorities the Board relies upon to issue citations and fines and provisions for orders of abatements. Data presented also include the number of citations issued under the Board's new authority to issue fines pursuant to Business and Professions Code section 4317.5(a)&(b). Members were provided with information regarding the more frequent violations that result in the issuance of a citation and fine.

The committee did not receive any public comment on the presentation.

Attachment 3 includes a copy of the presentation slides. Data reflects July 1, 2022, through June 16, 2023.

d. Presentation and Discussion on Quality Assurance Reports Received Pursuant to California Code of Regulations Section 1711(f) Related to the Use of Automated Drug Delivery Systems

Relevant Law

Business and Professions Code Section 4427.8 requires the Board to report on the regulation of ADDS units as part of the Sunset Evaluation Process.

California Code of Regulation Section 1711(f) establishes a requirement for any quality

assurance record related to the use of an automated drug delivery systems as specified in the section.

For Committee Consideration and Discussion
During the meeting members were provided a presentation describing information related to quality assurance records received. Members discussed the preliminary information and noted there are other elements that could be brought forward for the Board's consideration prior to completing the legislative report. Chairperson Serpa will work with staff in the coming months to ensure members have additional information and recommendations ready in advance of the legislative deadline.

Members also expressed concern with what appears to be a lack of reporting by some hospitals. Members requested that staff look for additional means to remind hospitals of the reporting requirements including potentially adding a statement to the annual renewal application.

Members received public comment from an individual suggesting that following the submission of the legislative report, the Board should remove the quality assurance reporting requirement.

Attachment 4 includes a copy of the presentation slides.

e. Discussion and Consideration of Draft Policy Statement Related to Implementation of USP General Chapters 795 Pharmaceutical Compounding – Nonsterile Preparations; 797 Pharmaceutical Compounding – Sterile Preparations; 800 Hazardous Drugs – Handling in Healthcare Settings; and 825 Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging

Background
Following completions of revisions to USP Compounding General Chapters 795 and 797, USP announced that the USP Compounding Expert Committee voted to extend the date on which the chapters become official to November 1, 2023, to allow for increased flexibility and engagement for adoption. With this extension the official date for Chapter 800 and Chapter 825 were also updated to November 1, 2023.

Following publication of the revised Chapters 795 and 797, and new General Chapters 800 and 825, the Enforcement Compounding Committee convened several public meetings to consider the Board's regulations and determine what if any changes were necessary to implement, clarify, or make more specific requirements related to the respective chapters.

Summary of Committee Discussion and Action
During the meeting members considered a draft statement intended to convey to stakeholders, the Board's policy related to licensees transitioning to the updated USP

General Chapters and actions under consideration by the Board.

Members noted support for the policy statement and recommended revision to the policy statement to include the specific USP chapters covered in the policy statement.

Committee Recommendation: Recommend approval of the proposed policy statement with revisions to include the specific USP General Chapters.

Attachment 5 includes a copy of the revised draft statement.

f. Review and Discussion of Enforcement Statistics

During the last fiscal year, the Board initiated 3,502 investigations and closed 3,180 investigations. The Board has issued 201 Letters of Admonishment, 1,053 Citations and referred 259 cases to the Office of the Attorney General. The Board has revoked 59 licenses, accepted the disciplinary surrender of 67 licenses, and denied 8 applications, and imposed other levels of discipline against 165 licensees and/or applicants.

As of July 1, 2023, the Board had 1,391 field investigations pending. Below is a breakdown providing more detail in the various investigation process:

	Jul. 1, 2022		Oct. 1, 2022		Jan. 1, 2023		Apr. 1, 2023		Jul. 1, 2023	
	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days
Awaiting Assignment	24	6	110	6	80	12	116	6	59	8
Cases Under Investigation	793	118	749	125	853	129	874	138	942	141
Pending Supervisor Review	171	39	223	46	199	85	146	22	163	31
Pending Second Level Review	97	58	205	36	226	55	245	35	79	22
Awaiting Final Closure	127	10	113	42	92	35	8	43	148	12

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

Attachment 1

C A L I F O R N I A

DEPARTMENT OF JUSTICE

THE DISCIPLINARY PROCESS

PRESENTED FOR THE CALIFORNIA STATE BOARD OF PHARMACY

July 18, 2023

THE OFFICE OF THE ATTORNEY GENERAL AND ITS ROLE IN THE DISCIPLINARY PROCESS FOR THE CALIFORNIA STATE BOARD OF PHARMACY

Presented by Deputy Attorneys General
Kristina T. Jarvis and Nicole R. Trama

The Office of the Attorney General:

- Represents state agencies and employees in judicial and other proceedings. (Gov. Code, § 11040)

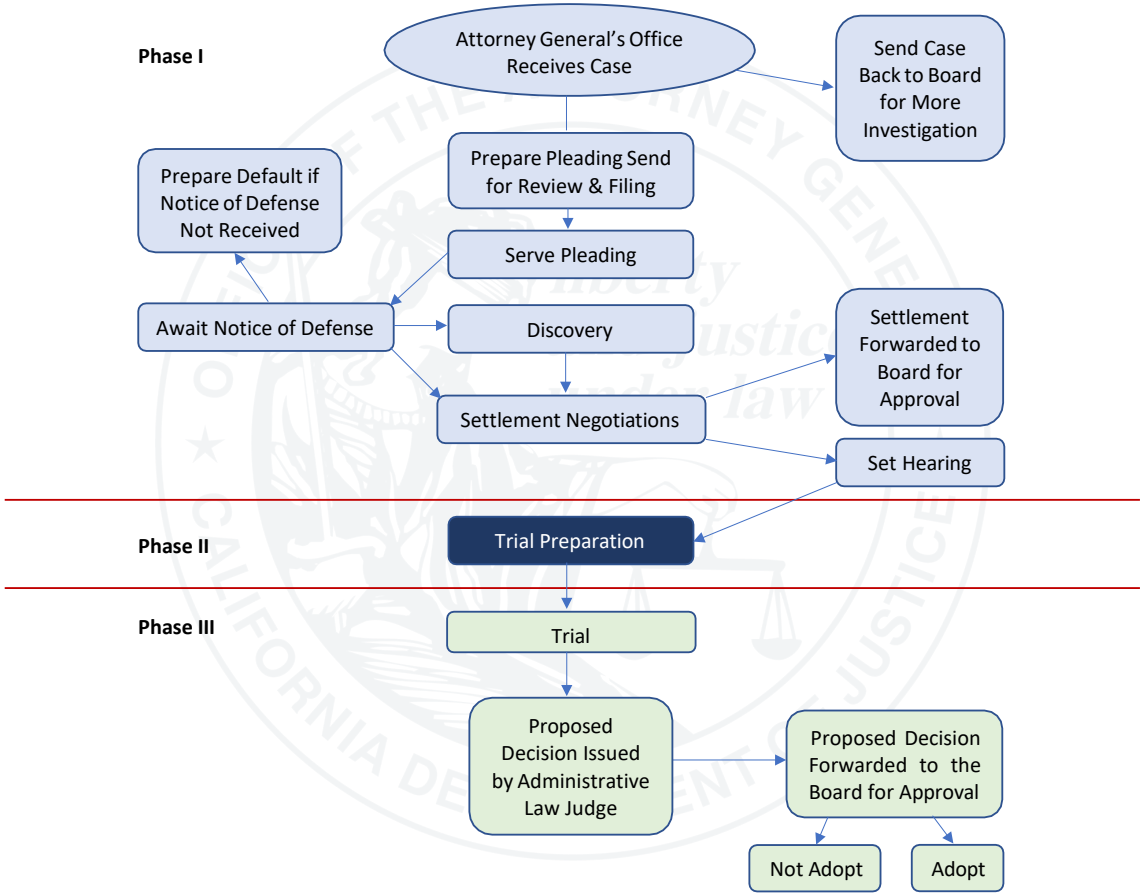
The Office of the Attorney General Mission Statement:

- It is our duty to serve our state and work honorably every day to fulfill California's promise. The Attorney General and Department of Justice employees provide leadership, information and education in partnership with state and local governments and the people of California to:
  - Enforce and apply all of our laws fairly and impartially.
  - Ensure justice, safety and liberty for everyone.
  - Encourage economic prosperity, equal opportunity and tolerance.
  - Safeguard California's human, natural and financial resources for this and future generations.

The Licensing Section helps achieve this mission to protect California consumers by:

- Representing client agencies in the enforcement of licensing laws, and thereby:
  - Remove or discipline licensees who do not meet minimum professional standards.
  - Deter licensees from committing misconduct.
  - Promote public confidence in licensed professionals.
  - Provide due process to accused licensees.

GENERAL CASE PROCESS



Accusations

- Jurisdictional paragraph
- License history
- Relevant statutes and regulations
- Charging paragraphs
- Service
- The accusation is served on the respondent's address of record and sometimes on another address that is identified by the agency or the AGO.
- What's the point?

Due Process

Notice of Defense

- Respondent must file a Notice of Defense (NOD) within 15 days
  - Govt. Code section 11506

- The NOD is also the request for a hearing

- Failure to file a NOD: Default Decision (Govt. Code section 11520)
  - Relief for good cause if requested within 7 days of service of Default Decision

Request to Set for Hearing

- A request to set for hearing is submitted to the Office of Administrative Hearings (OAH)
  Parties are required to meet and confer, or must file explanation
- OAH and Administrative Law Judge (ALJ) availability
- Deputy Attorney General (DAG), Client, Respondent, and Opposing Counsel availability
- Witness availability
- Length of hearing is estimated
  May be required to attend or may request prehearing or settlement conferences.

Discovery and Settlement

- Govt. Code section 11507.6 provides the only right to, and method of, discovery
  - Parties entitled to obtain information upon written request to the other party prior to hearing
    - Within 30 days of service by the agency of the initial pleading or
    - Within 15 days after service of an additional pleading

- Settlement
  - Mitigation or Rehabilitation Information per disciplinary guidelines
  - Agency Offer of Settlement
  - Counter Offer/Negotiations

- Reasons to Settle
  - Risk Avoidance
  - Save Time/Expense
  - Stipulations are Good

Disciplinary Guidelines

- California Code of Regulations, title 16, section 1760
- Vital to the process from start to finish
- Gives direction to Board staff, DAG, and Respondent
- ALJs review and consider disciplinary guidelines when drafting proposed decisions

What is in the Disciplinary Guidelines?

- The Board's primary purpose is to protect the public (Bus. & Prof. Code § 4001.1)
- Factors to be Considered in Determining Penalties
- The Board has four categories of violations, Categories I-IV, in ascending seriousness with Category IV being the most serious
- The categories outline EXAMPLES of violations, but each case must be considered on its own merits
- Sample language for decisions and orders

Category I

- Minimum Penalty: Revocation stayed, two years probation.

- These violations are less serious than Category II-IV, but are still potentially harmful.

Category II

- Minimum Penalty: Revocation stayed, three years probation.

- Five years probation if self-administration or diversion of controlled substances, dangerous drugs or devices, or alcohol.

- These violations have serious potential for harm, involve disregard for public safety, reflect on ethics, competence, or diligence.

Category III

- Minimum Penalty: Revocation stayed, 90 days suspension, three to five years probation.

- Five years probation if self-administration or diversion of controlled substances, dangerous drugs or devices, or alcohol.

- These violations have greater potential for harm, more imminent, or more serious harm than Category II.

Category IV

- ONLY Penalty: Revocation.

- The most serious violations of laws or regulations governing pharmacy or to the illegal dispensing or distributing of dangerous drugs/devices or controlled substances.

- Remember, the categories assume only one violation, so where there are multiple violations (almost always), the category should increase.

Probation Terms and Conditions

- The disciplinary guidelines provide model language for settlements and proposed decisions.
  - Consistency is important, but each case must be decided on its own merits.
- 16 standard terms and conditions to include in all settlements.
- 26 optional terms and conditions that should be selected specific to the violation(s).
- Remember that ALJs will generally ONLY include probation terms from the disciplinary guidelines.
  - Creativity requires settlement!

Due Process

- Due process and the protection of the public are fundamental guiding factors.

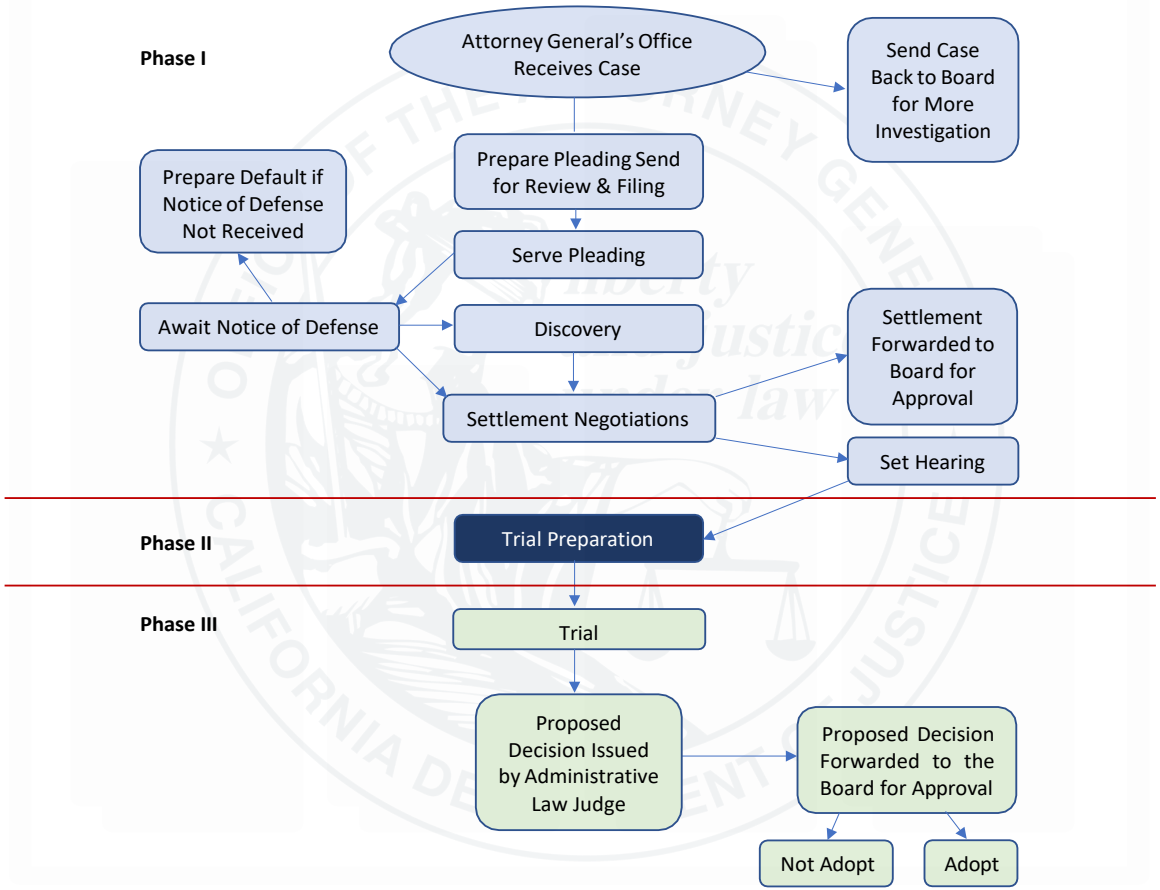
- Protection of the public is the highest priority of the Board, where other interests conflict with the protection of the public, the protection of the public must be paramount (Bus. & Prof. Code § 4001.1).

- Licensees acquire a license, permission from the state to operate, and the state has the right to ensure that licensees are competent and trustworthy.
  - *Shea v. Bd. Med. Exam*. (1978) 81 Cal.App.3d 564.

- The state may not deprive a person of life, liberty, or property without due process of law (US and California Constitutions).

- A licensee has a property interest in their license and therefore is entitled to reasonable notice of the charges, notice of the time and place of a hearing, and a fair hearing on the charges before being deprived of their license.

GENERAL CASE PROCESS



Hearing

- Held in Accordance with the Administrative Procedures Act
- Sequence of Hearing: Presentation of Testimony and Evidence
  - Government Code 11513
- Consequences for Failing to Appear

Burden of Proof – Clear and Convincing Evidence

- Clear and Convincing
  - Proof is clear, explicit, and unequivocal
  - High probability that it occurred

- Accusations against professional licenses, such as pharmacist
  - Professional license = licensee has fulfilled extensive education, training, and testing requirements
  - *Ettinger v. Board of Med. Quality Assurance* (1982) 135 Cal.App.3d 853

- Who has the burden?
  - Accusations = Burden is on Complainant
  - Petition for Reinstatement/Petition for reduction of penalty = licensee

Burden of Proof – Preponderance of Evidence

- Preponderance of Evidence
  - More likely than not that something occurred

- Accusations against occupational/non-professional licenses and premises permits:
  - Occupational license = minimal requirements, holder's investment in training, education, and other qualifications is small
  - *Imports Performance v. Dept. of Consumer Affairs, Bur. Of Automotive Repair* (2011) 201 Cal.App.4th 911
  - *San Benito Foods v. Veneman* (1996) 50 Cal.App.4th 1889

Post Hearing

- Proposed Decision
  - Due to agency within 30 days after submission of case
  - Becomes a public record and is served on parties 30 days after receipt
  - Adoption/Rejection (Non-Adoption)

- Even more Due Process
  - Reconsideration – Final Order
  - Writ of Mandate – Superior Court

THANK YOU!

Attachment 2

CA State Board of Pharmacy

Enforcement Committee Meeting

Inspection Presentation

July 18, 2023

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
- Tools for Licensees

TOTAL INSPECTIONS COMPLETED

- 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
- FY 22/23 2,837 (FYTD through June 16, 2023)

INSPECTIONS BY VISIT TYPE – FY22/23

- **Routine Pharmacy Inspections (PHY-PHE): 889**
- **Complaint Inspections: 422**
- **Pharmacist Recovery Program/Probation: 328**
- **Compounding Inspections: 842**
  - New 51
  - Renewal 791

INSPECTIONS BY VISIT TYPE - FY22/23 CONTINUED

- Outsourcing Inspections **27**
  - New 5
  - Renewal 22

- Other Inspections, by License Type:
  - Automated Drug Delivery Systems 285
  - Clinic 19
  - Drug Room 2
  - Hospital 2
  - Hypodermic needle 1
  - Wholesaler 18
  - Unlicensed Inspection 2

Total Inspections Completed: 2,837

Routine Pharmacy Inspections Completed FY 22/23

- Total number of licensed pharmacies: 6,241
- Total number of Routine Pharmacy inspections (PHY/PHE): 1,316
  - 889 Routine Pharmacy Inspections Completed
  - 89 Routine Pharmacy Inspections Completed on a Probation Visit
  - 248 Routine Pharmacy Inspections Completed on a Complaint Investigation
  - 90 Routine Pharmacy Inspections Completed on a Sterile Compounding Visit

Routine Inspection Outcomes FY22/23

- Routine Inspections Completed: 889
  - 470 Pharmacies Were Issued No Violations
  - 415 Pharmacies Were Issued 1,045 Corrections
  - 60 Pharmacies Were Issued 140 Violation Notices

- Routine Inspections Completed Complaint Visit: 248
  - 119 Pharmacies Were Issued No Violations
  - 102 Pharmacies Were Issued 226 Corrections
  - 63 Pharmacies Were Issued 118 Violation Notices

- Routine Inspections Completed Probation Visit: 90
  - 73 Pharmacies Were Issued No Violations
  - 14 Pharmacies Were Issued 20 Corrections
  - 3 Pharmacies Were Issued 5 Violation Notices

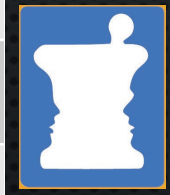
A pharmacy may receive both corrections and violation notices during one inspection.

TOP CORRECTIONS ON ROUTINE PHARMACY INSPECTIONS FY22/23

	Operational Standards and Security
CCR 1707.5	Patient-Centered Labels for Prescription Drug Containers
CCR 1707.2	Duty to Consult
CCR 1715.65	Inventory Reconciliation Reports of Controlled Substances
BPC 4058	License Display
CCR 1746.4	Pharmacists Administering Vaccines
CCR 1715	Self-Assessment of PHY by PIC
CCR 1735.3	Recordkeeping for Compounded Drug Preparations
CFR 1304.11	Inventory Requirements
CCR 1707.6	Notice to Consumers

TOP VIOLATION NOTICES ON ROUTINE PHARMACY INSPECTIONS FY22/23

CCR 1714	**Operational Standards and Security**
BPC 4301	**Unprofessional Conduct**
CCR 1707.2	**Duty to Consult**
CCR 1735.2	**Compounding Limitations/Requirements; Self-Assessment**
CCR 1715	**Self-Assessment of Pharmacy by PIC**
CCR 1715.65	**Inventory Reconciliation Reports of Controlled Substances**
CCR 1735.5	**Compounding Policies and Procedures**
BPC 4115(f)(1)	**Packaging Emergency Supplies**
CCC 56.10(a)	**Unauthorized Disclosure of Medical Information**
CCR 1735.3	**Recordkeeping for Compounded Drug Preparations**



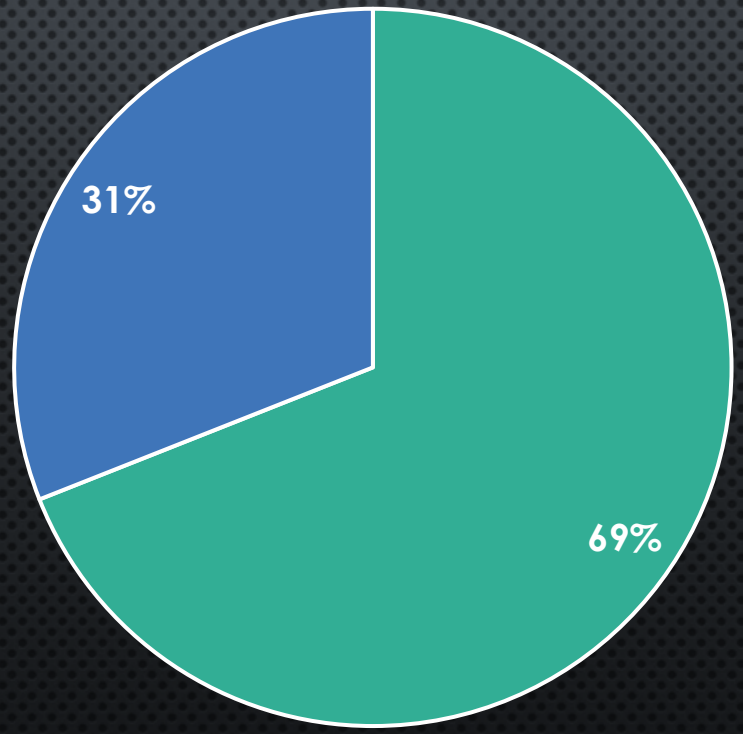
CCR 1707.2 – DUTY TO CONSULT PHARMACY ROUTINE INSPECTIONS

In FY 22/23 94 routine inspections revealed issues with patient consultation

- In 15 of the 94 inspections the inspector observed that consultation was not provided to the patient or pharmacy staff was observed screening for consultation
- In 33 of the 94 inspections the inspector found that the site was not providing written notice of consultation on delivered or mail order prescriptions
- In 46 of 94 Inspections the inspector found that the written notice of consultation did not meet All the requirements of the regulation (lacked one or more required elements)

INSPECTION SUMMARY

69% OF 5,966* PHARMACIES HAVE RECEIVED A ROUTINE INSPECTION WITHIN THE LAST 4 YEARS

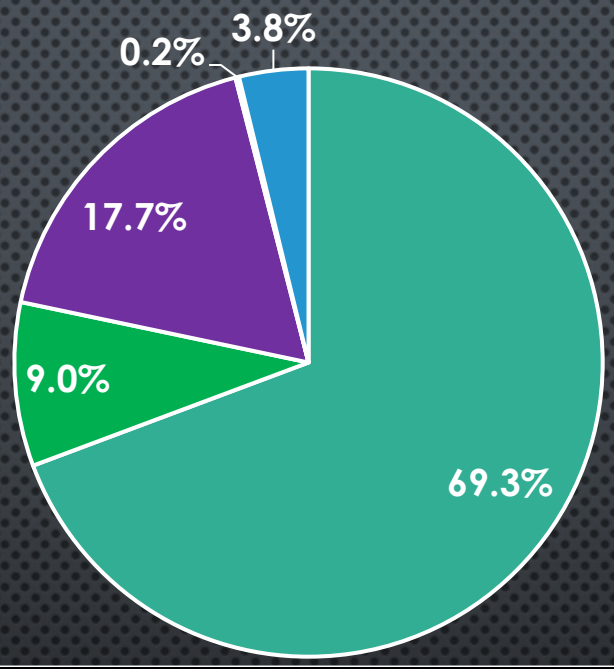


*not including licenses issued in current fiscal year FY 2022/23

YEAR OF LAST ROUTINE INSPECTION FOR CURRENT PHARMACY LICENSEES

	FY 2019/20	FY 2020/21	FY 2021/22	FY 2022/23
Inspected within 1 year	507	1,078	1,011	1,316
Inspected within 2 years	1,233	1,479	2,170	2,395
Inspected within 3 years	1,512	2,093	2,570	3,595
Inspected within 4 years	1,698	2,310	3,194	4,133
Percent Inspected within 4 years	27.4%	37.3%	53.1%	69.3%
Total Pharmacies (Data does not include any new PHY/PHE licenses issued during the fiscal year)	6,200	6,187	6,011	5,966

PHARMACY INSPECTION PERCENTAGES



	FY 2022/23
Received a routine type inspection within the past 4 years	69.3%
Received a routine type inspection within the past 5-10 years	17.7%
Received a non-routine type inspection within the past 10 years	9.0%
Not inspected and have been licensed for less than 4 years	3.8%
Not inspected and have been licensed for 4 or more years	0.2%
TOTAL ISSUED LICENSES (5,966)	100%

QUESTIONS?

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

www.pharmacy.ca.gov

Attachment 3

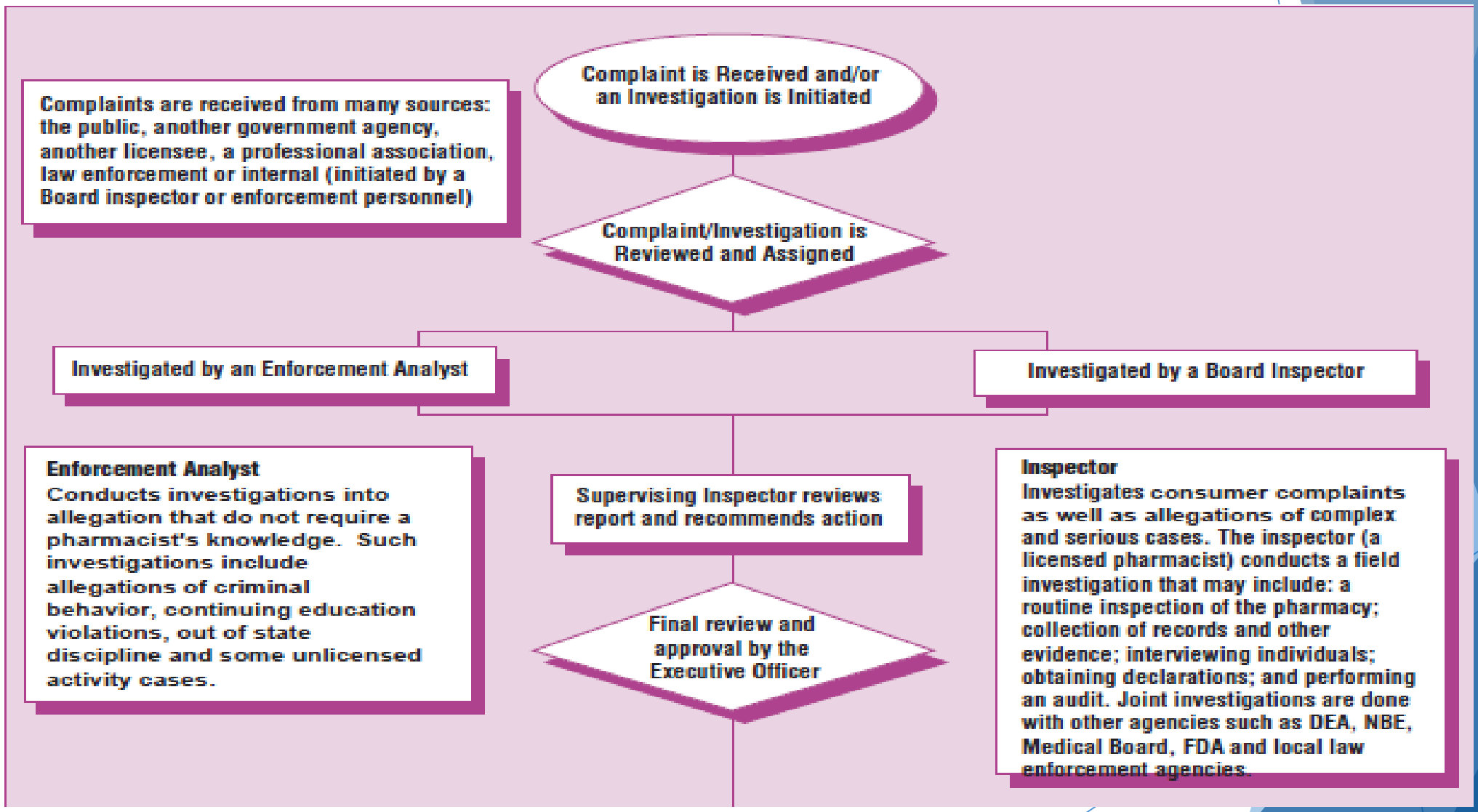
California State Board of Pharmacy

Enforcement and Compound Committee Meeting

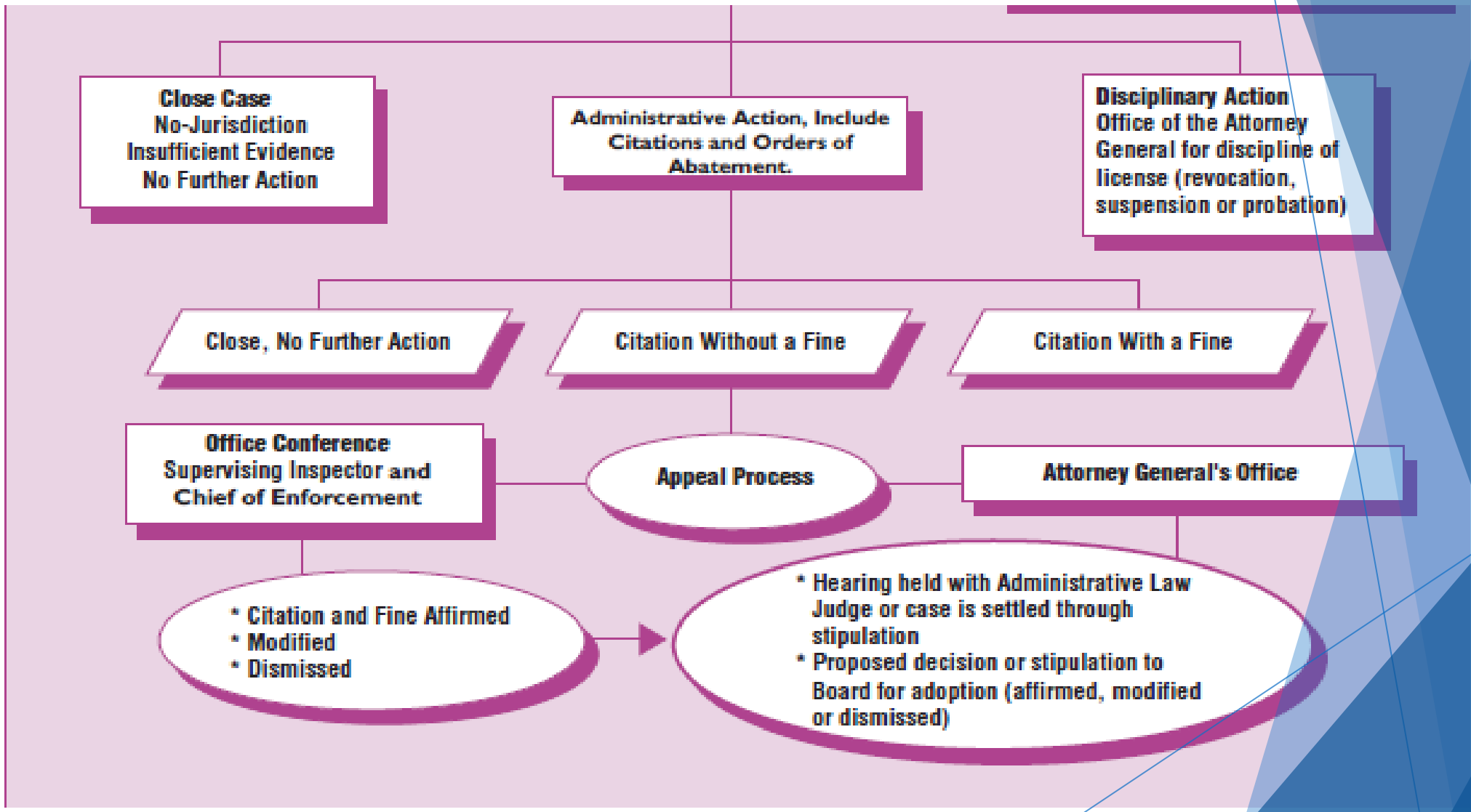
Citation Presentation

July 2023

Complaint/Citation Process



Complaint/Citation Process



Relevant Law

Business and Professions Code (BPC) Section 4314 establishes the authority for the board to issue citations

BPC Section 4317.5(a) establishes the authority for the board to issue citations for similar repeat violations occurring within five years by three or more pharmacies within a chain pharmacy for a fine not to exceed $100,000 per violation.

BPC Section 4317.5(b) establishes the authority for the board to issue citations for violations demonstrated to be the result of a written policy or which was expressly encouraged by a common owner or manager of a chain pharmacy for a fine not to exceed $150,000.

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

Fine Authority

- BPC 125.9 Fine of up to $5,000 per investigation
- BPC 4067 Fine of $25,000 per prescription for internet sales of drugs where no underlying appropriate examination occurred
- BPC 4126.5 Fine of up to $5,000 per occurrence
- BPC 4317.5 (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(b) 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

Factors Considered in Assessing Administrative Fines

- 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 they have 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

	FY 2018/19	FY 2019/20	FY 2020/21	FY 2021/22	FY 2022/23*
CITATIONS ISSUED	1,134	1,426	934	1,274	967
CITATIONS ISSUED WITHOUT FINE	339	535	401	451	351
CITATIONS ISSUED WITH FINE	795	891	533	823	616
FINES ASSESSED	$1,166,700	$1,462,300	$787,100	$2,029,012	$3,124,750
FINES COLLECTED	$1,212,077	$963,446	$711,729	$1,093,911	$1,704,459

Citations Issued
BPC 4314 and 4317.5

*Data through June 16, 2023

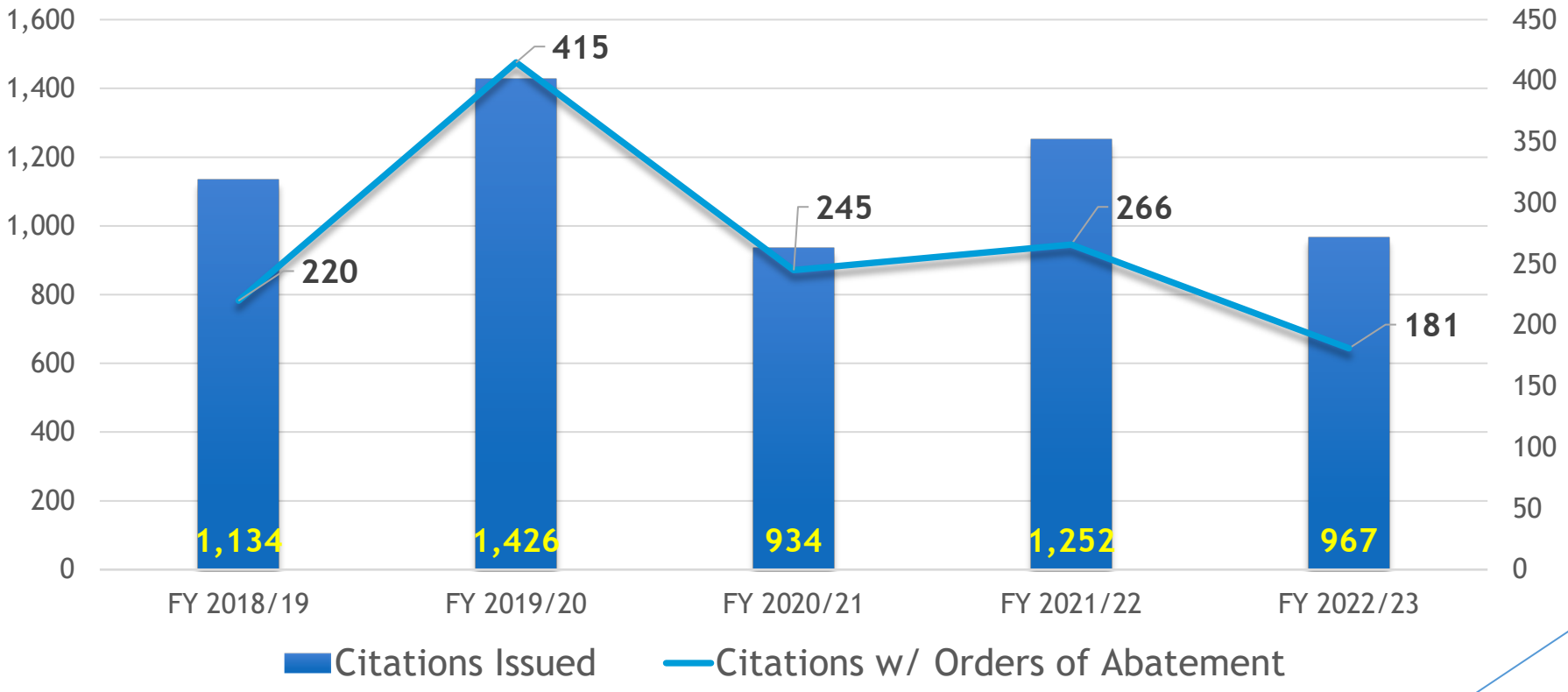
Citations Issued by License Type

License Type	Count of Citations
PHY	478
RPH	346
TCH	30
HSP	19
LSC	17
OSD	12
NRP	12
WLS	11
NSF	11
PHE	3
HPE	3
OTHER	25

Citation Processing Time Receipt to Issuance

FISCAL YEAR	AVERAGE DAYS
FY 2018/19	333
FY 2019/20	400
FY 2020/21	426
FY 2021/22	341
FY 2022/23	325

Citations Issued/Orders of Abatement



Orders of Abatement

Total Abatements Issued:	181
Abatements Satisfied:	158

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
- May result in either a reduction or forgiveness of the fine

Orders of Abatement

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

Abatement Examples

- 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

Office Conference: allows the licensee the opportunity to present additional or mitigating information

Formal Appeal: Conducted pursuant to the Administrative Procedures Act by an administrative law judge who renders a decision for the board to adopt or reject

Citation Appeal Outcomes FY22/23

Total Office Conferences (OC) requested*	**155***
Office conference outcomes:	
➢ Modified	37
➢ Reduced to Letter of Admonishment	11
➢ Dismissed	14*
➢ Upheld	123
Total Appeals Referred to AG	**49**
➢ Pending Appeals	36**

*One office conference resulted in dismissal of multiple citations for one issue at one corporate entity across multiple licensed pharmacies

**May be from a prior fiscal year

Citations Issued
BPC 4314

	FY 2018/19	FY 2019/20	FY 2020/21	FY 2021/22	FY 2022/23
CITATIONS ISSUED	1,134	1,426	934	1,273	895
CITATIONS ISSUED WITHOUT FINE	339	535	401	451	351
CITATIONS ISSUED WITH FINE	795	891	533	822	544
FINES ASSESSED	$1,166,700	$1,462,300	$787,100	$1,954,012	$1,657,250
FINES COLLECTED	$1,212,077	$963,446	$711,729	$1,093,911	$1,634,459

Citations Issued
BPC 4317.5

	FY 2021/22	FY 2022/23
CITATIONS ISSUED	1	72
FINES ASSESSED	$75,000	$1,467,500
FINES COLLECTED	$0	$70,000

Citations Issued
BPC 4317.5

Fine Amounts	Count
$1 - $5,000	0
$5001 - $10,000	40
$10,001 - $15,000	12
$15,001 - $20,000	5
$20,001 - $30,000	7
$30,001 - $50,000	1
$50,001 - $75,000	4
$75,001 - $99,999	0
$100,000 - $125,000	2
$125,001 - $150,000	1

Citations Completed or Appealed
BPC 4314

Status	FY 2018/19	FY 2019/20	FY 2020/21	FY 2021/22	FY 2022/23
CITATIONS COMPLETED	1,116	1,210	992	1,088	954
CITATIONS CONTESTED AT OFFICE CONFERENCE	148	216	154	229	192
CITATIONS CONTESTED AT THE ATTORNEY GENERAL'S OFFICE	29	20	29	34	40

Citations Completed or Appealed
BPC 4317.5

Status	FY 2022/23
CITATIONS COMPLETED	8
CITATIONS CONTESTED AT OFFICE CONFERENCE	58
CITATIONS CONTESTED AT THE ATTORNEY GENERAL'S OFFICE	9

Violation Code	Description	Number of Violations
4113	Notify Board of PIC Change (30 days)	133
1716	Medication Error	86
4301	Unprofessional Conduct	82
1714	Duty of Care – Facility Maintenance	48
733	Prescription Obstruction	31
4115	Pharmacy Technician; Tasks, Ratios, Supervision	27
1715	Pharmacy Self-assessment	27
1707.2	Duty to Consult	26
1764	Unauthorized Disclosure of Medical Information	23
4305	Notify Board of No PIC (30 days)	22

Pharmacies Top Ten Violations FY22/23

Violation Code	Description	Number of Violations
1716	Medication Error	83
4301	Unprofessional Conduct	77
1707.2	Duty to Consult	32
4306.5	Misuse of Education	27
1715	PIC Self-assessment	26
4115	Pharmacy Technician; Tasks, Ratios, Supervision	26
1714	Duty of Care – Facility Maintenance	23
1761	Prescription Error	22
4081	Records Maintained	20
1735.3	Compounding Record Requirements	18

Pharmacist Top Ten Violations FY22/23

Violation Code	Description	Number of Violations
4301(h)	Self Administer Drugs or Alcohol	23
4301(l)	Conviction of a Crime Substantially Related to Pharmacy	21
4301(f)	Moral Turpitude, Dishonesty, Fraud, Deceit or Corruption	4
4301(o)	Violation of State or Federal Pharmacy Law	3
4301(b)	Incompetence	1
4301(g)	False Representation	1
4301(q)	Subversion of an Investigation	1

Technician Top Violations FY22/23

	FY 2019/20	FY 2020/21	FY 2021/22	FY 2022/23
Total Duty to Consult Violations (Pharmacists and Pharmacies)	64	60	49	58
Pharmacy Violations	**30 Total** 23 with fine 7 no fine	**28 Total** 21 with fine 7 no fine	**21 Total** 18 with fine 3 no fine	**26 Total** 23 with fine 3 no fine
Average Violation Amount (PHY)	$3,117	$3,798	$3,416	$3,462
Pharmacist Violations	**34 Total** 12 with fine 22 no fine	**32 Total** 19 with fine 13 no fine	**28 Total** 11 with fine 17 no fine	**32** Total 8 with fine 24 no fine
Average Violation Amount (RPH)	$654	$974	$1,272	$844

Duty to Consult CCR 1707.2
BPC 4314

	FY 2021/22	FY 2022/23
Total Duty to Consult Violations (Pharmacists and Pharmacies)	0	7
Pharmacy Violations	**0 Total**	**7 Total** 7 with fine 0 no fine
Average Violation Amount (PHY)	N/A	$7,500
Pharmacist Violations	**0 Total**	**0** Total
Average Violation Amount (RPH)	N/A	N/A

Duty to Consult CCR 1707.2
BPC 4317.5

Citations Issued
BPC 4317.5

Violations issued under the authority of 4317.5(a)

Violation Code	Description	Count of Violations	Average Fine Amount
1707.2	Duty to consult	7	$7,500
1716	Variation from prescriptions	14	$13,143
1714(c)	Operational standards and security; equipment and facilities are clean and function properly	1	$25,000
4113(a)	Notify Board of PIC Change within 30 days	28	$4,161
4113(d)	Notify Board of PIC termination and proposal of new PIC	42	$4,655
4113(e)	Notify Board of Interim PIC	3	$5,000
4301(g)	Providing false documents	7	$5,714
4305(b)	Operation of Pharmacy without a PIC for more than 30 days	17	$7,000

Violations issued under the authority of 4317.5(b)

Violation code	Description	Count of Violations	Average Fine Amount
4113.7	Quotas Related to RPH or TCH Duties	4	$62,000

Thank You

Attachment 4

Review of ADDS: Quality Assurance Programs

California State Board of Pharmacy
Enforcement Committee Meeting
July 18, 2023

ADDS Licensure requirement:

- **AB 1447 – Effective 1/1/2019; Operative 7/1/2019 (ADD)**
  - BPC 4427.2 required an ADDS installed/leased/owned/operated in CA to be licensed by the Board and renewed annually.
    - Adjacent to the secured pharmacy area of the pharmacy holding the ADDS license.
    - A health facility licensed pursuant to HSC 1250 that complies with HSC 1261.6.
    - A clinic licensed pursuant to HSC 1204 or 1204.1
    - A correctional clinic pursuant to BPC 4187.1
    - An APDS located in a medical office or other location where patients are regularly seen for purposes of diagnosis/treatment and only used to dispense to patients of the practice.

ADDS Licensure requirement: (continue)

- AB 1447 (Licensure not required):
  - AUDS operated by a licensed hospital pharmacy, used solely for administration to patients while in the licensed general acute care hospital facility/licensed acute psychiatric hospital facility, owns the drugs in the AUDS and owns/leases the AUDS are **exempt from licensure only. Must comply with all other requirements for an ADDS.**

    Note: If a hospital pharmacy used the ADDS for dispensing, the exemption did not apply and the ADDS was required to be licensed. These were ADDS used for dispensing pursuant to BPC 4056 (Drug Rooms) and BPC 4068 (ER).

  - **ADDS licensure is NOT required** for ADDS used for technology (to select/ count/ package/label) and installed within the secured licensed premises area of a pharmacy.

ADDS Licensure requirement: (continue)

- **AB 1812 – Effective 6/27/2018; Operative 7/1/2019 (ADC)**
  - Required a correctional clinic to be licensed by the Board.
  - Required ADDS located in a correctional clinic be licensed by the Board.
- **AB 2037 – Effective 9/21/2018**
  - Allowed a pharmacy to operate an APDS on the premise of a “covered entity” or on the premises of a medical professional practice under contract to provide medical services to “covered entity” patients.
  - Required the APDS to be licensed by the Board

ADDS Licensure requirement: (continue)

- **AB 1533 – Effective 1/1/2022**
  - Expanded the locations where a pharmacy may operate an ADDS
    - A facility licensed by CA with the statutory authority to provide pharmaceutical services.
      - Examples: Psychiatric Health Facilities (PHF), Crisis Stabilization Units
    - Jails/Youth Detention Facilities/Other Correctional Facilities where drugs are administered within the facility under the authority of a medical director.

ADDS Quality Assurance Program

- **BPC 4427.7**
  - Requires a pharmacy to comply with quality assurance requirements established in pharmacy law and regulation and shall maintain those records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records.
- **CCR 1711(f)**
  - Quality assurance records must be immediately retrievable in the pharmacy for at least one year from the date the record was created.
  - The QA record related to the use of a licensed ADDS must submit to the Board within 30 days of completion of the QA review.
  - Any facility with an **unlicensed ADDS** must report the QA review to the Board at the time of annual renewal of the facility license.
    - Includes acute care hospital pharmacies, acute psychiatric hospital pharmacies and pharmacies using an ADDS within a pharmacy.
- **BPC 4427.4(d)**
  - Drugs/devices stored in an ADDS is deemed part of the pharmacy's inventory and responsibility.
  - Drugs/devices dispensed from the ADDS **shall be considered to have been dispensed** by that pharmacy.

ADDS Quality Assurance Program (continue)

FAQ posted on the Board's website:

- **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 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.

ADDS Quality Assurance Program (continue)

FAQ posted on Board's website:

- **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 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.

ADDS Quality Assurance Program (continue)

FAQ posted on Board's website:

- **Question #8: What information is required to be reported as part of the Quality Assurance Review?**
  - Answer: 16 CCR section 1711(e) states, the record shall contain at least the following:
    - The date, location of the ADDS, ADDS license number, pharmacy license number and participants in the quality assurance review;
    - The pertinent data and other information related to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);
    - The findings and determinations generated by the quality assurance review; and
    - Recommended changes to pharmacy policy, procedures, systems, or processes, if any.

ADDS Quality Assurance Program (continue)

FAQ posted on Board's website:

- **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
  - Answer: 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.

ADDS Licensing Statistics:

ADD = Pharmacy licensed ADDS pursuant to BPC 4427.3 and 4427.65

ADD	FY 18/19	FY 19/20	FY 20/21	FY 21/22	FY 22/23
Applications received	595	325	233	199	NA*
Applications withdraw	NA	100	21	39	NA*
Licenses issued	NA	1012	150	172	294
Licenses discontinued	NA	57	98	57	NA*
License renewed	NA	604	790	983	NA*
Current license populations	NA	910	946	1004	1052**

* NA = Not Available
** AUD = 576
APDS= 21
COR= 455

ADDS Licensing Statistics:

ADC = Pharmacy licensed ADDS located at "covered entity" pursuant to BPC 4119.11

ADC	FY 18/19	FY 19/20	FY 20/21	FY 21/22	FY 22/23
Applications received	1	0	0	2	0
Applications withdraw	0	0	0	0	0
Licenses issued	1	0	0	0	0
Licenses discontinued	NA	0	1	0	0
License renewed	NA	1	0	0	0
Current license population	1	1	0	0	1

ADDS Licensing Statistics:

ADE = ADDS operated by emergency medical services licensed pharmacy or wholesaler used to restock ADDS at fire department headquarters/fire stations/emergency medical services provider agency's locations pursuant to BPC 4119.01

ADE	FY 18/19	FY 19/20	FY 20/21	FY 21/22	FY22/23
Applications received	0	1	0	0	0
Applications withdraw	0	0	0	0	0
Licenses issued	0	1	0	0	0
Licenses discontinued	NA	0	0	0	0
License renewed	NA	0	1	1	0
Current license population	0	1	1	1	1

ADDS Medication Errors Reported

Number of medication error reports received based on date error occurred

Operated by:	FY 18/19*	FY 19/20*	FY 20/21*	FY 21/22	FY 22/23
PHY	0	0	252	305	53
HSP	0	0	0	0	151
LCF	0	0	1	11	66
Total:	**0**	**0**	**253**	**316**	**270**

Number of pharmacies submitted medication error reports

Operated by:	FY 18/19*	FY 19/20*	FY 20/21	FY 21/22	FY 22/23
PHY	0	0	8	8	4
HSP	0	0	0	0	1
LCF	0	0	3	3	12
Total # of pharmacies reporting:	**0**	**0**	**11**	**11**	**17**

* CCR 1711(f) – Effective 7/1/2021

Med Errors Reported Based on Location of ADDS

Location of ADDS	FY 18/19	FY 19/20	FY 20/21	FY 21/22	FY 22/23
Adjacent to Pharmacy	NA	NA	0	0	0
Medical Office	NA	NA	0	0	0
Clinic	NA	NA	0	0	0
Correctional Clinic	**NA**	**NA**	**1**	**11**	**63**
Skilled Nursing Facility	NA	NA	0	0	0
Intermediate Care Facility	**NA**	**NA**	**0**	**0**	**3**
Inside the Pharmacy	**NA**	**NA**	**252**	**305**	**49**
Other	**NA**	**NA**	**0**	**0**	**155**
Totals for FY:	NA	NA	253	316	270

Type of Med Errors Reported

Type of Med Errors	FY 18/19	FY 19/20	FY 20/21	FY 21/22	FY 22/23	Totals:
Wrong Drug	NA	NA	28	39	37	104
Wrong Strength	NA	NA	0	6	21	27
Wrong Quantity	NA	NA	210	258	55	523
Wrong Patient	NA	NA	0	1	8	9
Labeling Error	NA	NA	15	4	1	10
Duplicate Therapy	NA	NA	0	0	6	6
Expired Drug	NA	NA	0	0	1	1
Unauthorized Dispensing	NA	NA	0	0	139	139
Not enough info provided	NA	NA	0	8	2	10
Totals # of med errors	**NA**	**NA**	**253**	**316**	**270**	829

Causes for errors

- Misuse of the override transaction function
- ADDS allowed the use of the same code for multiple pulls
- Storing different salts of the same drug (HCl vs pamoate)
- ADDS allowed the same dose for same patient to be removed more than once without approval resulting in duplicate administration.
- Failure to send an alert for duplicate administration.
- ADDS allowed medications pulled under wrong patient names or similar name.
- ADDS allowed nurses to removed the wrong dose not on a patient's profile
- ADDS allowed nurses to remove the wrong quantity
- ADDS allowed nurses to remove the wrong strength
- ADDS allowed nurse to remove a drug without the order reviewed by the pharmacist.

Challenges in reporting ADDS med errors

- Non-compliance with reporting ADDS related medication errors.
  - Between 2021 to 2023 pharmacies who submitted med error reports:
    - 1 - licensed hospital pharmacies submitted reports*
    - 12 - licensed correctional pharmacies submitted reports**
    - 8 - licensed retail pharmacies with licensed ADDS***
- Inconsistent reporting of information or lack of information reported.
  - Details of the cause of the medication error not reported.
  - Information listed in FAQ not provided
  - Consider a standardized form

Challenges (continue)

- Unable to determine the type and model of the ADDS causing the med error for unlicensed ADDS in hospitals and ADDS used in the pharmacy for counting/packaging/labeling.
- Misunderstanding of what type of errors are required to be submitted
  - Example: When a drug is removed from the ADDS but the nurse catches the error prior to administering to the patient, some hospitals will consider this a near miss and not required to be reported.
- Nursing not notifying the pharmacy when an error occurs.

Challenges (continue)

- Misunderstanding that hospital pharmacies are exempt from reporting medication errors because they are exempt from licensure.
- SNF misunderstanding that errors are only reported to CDPH.
  - Due to gap in training when installing an ADDS and annual training.
  - Nursing misunderstanding that an error related to the ADDS is considered a near miss and only med errors administered to the patient is considered a med error.
- SNF/ICF/Prison has high nursing turn over in staffing or Director of Nursing contributing to inconsistencies.

Challenges (continue):

- Pharmacies operating ADDS inside a pharmacy that results in a med error due to wrong drug/wrong quantities are not always considered a med error required to be reported to the board.
  - Example: Rx is dispensed by an ADDS and is checked by a pharmacist then picked up by the patient and stray and different looking tablet is found in the prescription container. The pharmacist determines it's a med error, but does not identify the error is related to the use of an ADDS that require to be reported to the board.

Recommendations

- Pharmacies:
  - To incorporate in the training for nurses what is considered a med error related to an ADDS, during initial and annual training.
  - To work with the ADDS manufacturer to provide continuous training to help improve pharmacy's processes.
  - To restrict the use of the override transaction function
  - Reassess and limit which drugs can be removed using the override transaction function.
  - Encourage use of ADDS that limit access to one drug versus an open matrix configuration.
  - Consider requiring different passcodes for transaction overrides.

Recommendations (continue)

- Board:
  - To continue to educate licensee during pre-licensure of ADDS and to provide a copy of the FAQ.
  - To consider a SCRIPT article on what is a reportable ADDS med error.
  - Issue a follow up Subscriber alert to submit ADDS med errors
  - Include reporting of ADDS med errors as a Topic to Educate during routine inspections and LSC renewal inspections, especially for non-licensed ADDS.
  - Conduct random inspections of pharmacies operating ADDS.
  - Work with CDPH to notify BOP when a med error occurs related to the dispensing by an ADDS.
  - Update community pharmacy self-assessment to address reporting of med errors related to unlicensed ADDS used in the pharmacy for technology to assist with counting/package/labeling.

Thank You

Attachment 5

Draft Compounding Policy Statement

In light of the November 1, 2023, compendial date for several USP General Chapters, included General Chapter 795 Pharmaceutical Compounding – Nonsterile Preparations, 797 Pharmaceutical Compounding – Sterile Preparations, 800 Hazardous Drugs – Handling in Healthcare Settings and 825 Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging, the California State Board of Pharmacy (Board) wishes to update its stakeholders on its policy related to licensees transitioning to the updated USP General Chapters as well as actions under consideration by the Board.

There are several provisions of state and federal law governing the practice of pharmacy. Most notably related to compounding are provisions in the Federal Food, Drug and Cosmetic Act including exemptions provided under Section 503A; California Sherman Food, Drug, and Cosmetic Act; and several provisions within the Business and Professions Code including Sections 4126.8 and 4342.

As required by law, the Board has undertaken a review of its compounding regulations and identified changes necessary to clarify or make more specific requirements of Federal Law and USP General Chapters. These efforts resulted in the Board voting, as part of its April 2023 Board Meeting, to promulgate new regulations that are in addition to USP Standards. Additional information is available here. The effective date of the newly updated state regulations is yet to be determined.

During this intervening period, the Board encourages licensees to begin transitioning to the new standards established in USP to ensure compliance with state and federal law. It is the Board's expectation that as compounding practices transition to new requirements, including provisions related to establishing beyond use dates (BUDs), that standard operating procedures must be updated and staff appropriately trained prior to implementing new practices and BUDs.

Attachment 6

Board of Pharmacy

Enforcement Workload Statistics FY 2022/23

Complaint Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	928	914	885	775	3,502
Closed	638	822	919	801	3,180
					Quarter Ending
Pending	1,875	1,999	1,955	2,004	2,004
Average Days for Investigation	174	165	185	223	223

Cases Under Investigation (By Team)	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Compliance / Routine	716	732	704	715	715
Drug Diversion / Fraud	251	269	231	244	244
Prescription Drug Abuse	273	319	276	255	255
Compounding	62	48	28	43	43
Outsourcing	20	18	15	16	16
Probation / PRP	87	81	51	58	58
Enforcement	14	10	30	26	26
Criminal Conviction	452	522	529	572	572

Application Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	60	43	44	58	205
Closed					
Approved	30	25	41	29	125
Denied	20	16	23	15	74
Total Closed (includes withdrawn)	***50***	***46***	***67***	***51***	***214***
Pending	100	97	67	79	79

Complaint Closure Outcomes Not Resulting in Further Action	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Insufficient Evidence	135	190	344	259	928
Non-Jurisdictional	135	169	140	116	560
No Violation	67	85	52	35	239
No Further Action	29	111	41	53	234
Other - Non-Substantiated	34	52	47	42	128
Subject Educated	20	36	19	23	98

Letter of Admonishment / Citations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
LOA Issued	44	48	49	60	201
Citations Issued	281	218	266	288	1,053
Proof of Abatement Requested	68	55	36	37	196
Appeals Referred to AG's Office	6	20	11	11	48
Dismissed	1	3	5	9	18
Total Fines Collected	***$448,797***	***$643,100***	***$523,984***	***$405,523***	***$2,021,404***

Administrative Cases	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Referred to the AG's Office	51	53	77	78	259
Pleadings Filed	34	34	38	50	156
Total Closed	46	46	51	75	218
Pending					Quarter Ending
Pre-Accusation	94	105	129	138	138
Post-Accusation	140	138	141	140	140
Total Pending	**234**	**215**	**271**	**278**	**278**

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation					
Pharmacist	1	3	5	3	12
Intern Pharmacist	0	0	1	1	2
Pharmacy Technician	7	7	8	13	35
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	2	2	2	1	7
Sterile Compounding	0	1	1	1	3
Outsourcing	0	0	0	0	0
Total	***10***	***13***	***17***	***19***	***59***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation; stayed suspension/probation					
Pharmacist	1	1	1	1	4
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	***1***	***1***	***1***	***1***	***4***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation; stayed; probation					
Pharmacist	11	5	8	18	42
Intern Pharmacist	1	0	1	1	3
Pharmacy Technician	1	2	0	5	8
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	4	5	3	3	15
Sterile Compounding	0	1	1	0	2
Outsourcing	0	0	0	0	0
Total	***17***	***13***	***13***	***27***	***70***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Surrender / Voluntary Surrender					
Pharmacist	5	4	7	9	25
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	3	1	1	5	10
Designated Representative	0	0	1	0	1
Wholesaler	0	0	0	0	0
Pharmacy	7	6	9	8	30
Sterile Compounding	0	0	1	0	1
Outsourcing	0	0	0	0	0
Total	***15***	***11***	***19***	***22***	***67***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Public Reproval / Reprimand					
Pharmacist	4	2	2	5	13
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	0	0	1	0	1
Designated Representative	0	0	0	0	0
Wholesaler	0	1	0	0	1
Pharmacy	1	1	2	1	5
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***5***	***4***	***5***	***6***	***20***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Granted					
Pharmacist	0	2	0	0	2
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	0	1	3	1	5
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	1	0	0	0	1
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***1***	***3***	***3***	***1***	***8***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Denied					
Pharmacist	0	0	0	1	1
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	0	0	2	1	3
Designated Representative	0	0	0	0	0
Wholesaler	1	0	0	0	1
Pharmacy	2	0	1	0	3
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***3***	***0***	***3***	***2***	***8***

Administrative Case Cost Recovery Efforts	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Cost Recovery Requested	***$340,239***	***$476,654***	***$538,651***	***$578,807***	***$1,934,351***
Cost Recovery Collected	***$154,930***	***$484,154***	***$446,176***	***$274,020***	***$1,359,280***

Immediate Public Protection Sanctions	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Interim Suspension Orders	2	1	3	1	7
Automatic Suspension Orders	2	0	1	1	4
Penal Code 23 Restrictions	2	2	4	5	13
Cease and Desist - Outsourcing	0	0	0	0	0
Cease and Desist - Unlicensed Activity	0	0	0	0	0
Cease and Desist - Sterile Compounding	0	0	0	0	0

Probation Statistics	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Licenses on Probation					
Pharmacist	208	190	178	177	177
Intern Pharmacist	1	1	2	2	2
Pharmacy Technician	17	16	13	17	17
Designated Representative	2	1	1	1	1
Wholesaler / 3PL	3	3	3	3	3
Pharmacy	57	54	53	48	48
Sterile Compounding	8	8	8	8	8
Outsourcing	1	1	1	0	0
Total	***297***	***274***	***259***	***256***	***256***

Probation Statistics	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Probation Office Conferences	16	10	15	28	69
Probation Interviews / Site Inspections	97	56	150	136	439
Probation Terminated / Completed	35	37	32	31	135
Referred to AG for Non-Compliance	2	2	2	1	7

As of 6/30/2023

Board of Pharmacy

Citation and Fine Statistics FY 2022/23

Citation Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Pharmacist with Fine	41	24	30	32	127
Pharmacist-in-Charge with Fine*	30	18	13	20	81
Pharmacist no Fine	67	69	61	69	266
Pharmacist-in-Charge no Fine*	44	32	33	35	144
Pharmacy with Fine	110	69	126	122	427
Pharmacy no Fine	30	19	15	25	89
Pharmacy Technician with Fine	5	5	4	12	26
Pharmacy Technician no Fine	1	7	6	10	24
Wholesalers	5	3	1	3	12
Designated Representative	0	1	0	2	3
Clinics	0	0	0	0	0
Drug Room	0	0	0	0	0
Exempt Hospital	1	0	2	0	3
Hospital Pharmacy	6	5	5	0	16
Miscellaneous**	16	19	26	19	80
Unlicensed Premises	1	0	0	3	4
Unlicensed Person	1	1	1	0	3

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

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

Top Ten Violations by License Type

Pharmacists	%	Pharmacies	%	Pharmacists In Charge	%
1716 - Variation from prescription	33%	4113(d) - Every pharmacy shall notify the board in writing within 30 days of the date of a change in pharmacist-in- charge	28%	733(a) - Dispensing prescription drugs and devices- No licentiate shall obstruct a patient in obtaining a prescription	21%
1764/56.10(a) - Unauthorized disclosure of prescription and medical information	12%	1716 - Variation from prescription	17%	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	14%
1707.2(a)(3) - Duty to consult: (a) A pharmacist shall provide oral consultation to his or her patient or the agent of patient in all care settings: (3) Whenever the prescription drug has not previously been dispensed to a patient	10%	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 pharmacy	14%	1764/56.10(a) - Unauthorized disclosure of prescription and medical information	11%
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	12%	4306.5(a) - Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist	11%
733(a) - Dispensing prescription drugs and devices- No licentiate shall obstruct a patient in obtaining a prescription	7%	1764/56.10(a) - Unauthorized disclosure of prescription and medical information	8%	1715.65 - Inventory Reconciliation Report of Controlled Substances	7%
1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	7%	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	5%	1714(d)/4301(o)/4081(a) - Operational Standards and Security; Pharmacist responsible for pharmacy security/Unprofessional conduct; assist in violation/Records of Dangerous Drugs and Devices Kept Open	7%
4306.5(a) - Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist	7%	1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	5%	1707.2(a)(3) - Duty to consult: (a) A pharmacist shall provide oral consultation to his or her patient or the agent of patient in all care settings: (3) Whenever the prescription drug has not previously been dispensed to a patient	7%
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	6%	733(a) - Dispensing prescription drugs and devices- No licentiate shall obstruct a patient in obtaining a prescription	5%	1716 - Variation from prescription	7%
1715(b)(2) - Self-Assessment of a pharmacy by the pharmacist-in-charge; shall complete a self-assessment within 30 days whenever: there is a change in pharmacist- in-charge	4%	1707.2(a)(3) - Duty to consult: (a) A pharmacist shall provide oral consultation to his or her patient or the agent of patient in all care settings: (3) Whenever the prescription drug has not previously been dispensed to a patient	3%	1716/4306.5(a) - Variation from prescription/Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist	7%
4301(o) - Unprofessional conduct; assist in violation	4%	4113(e) - Pharmacist-in-Charge: Notification to Board; Responsibilities; If a pharmacy is unable, in the exercise of reasonable diligence, to identify within 30 days a permanent replacement pharmacist	3%	4081(a)/1718 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory/Current Inventory Defined	7%

California State Board of Pharmacy
SB 1441 Uniform Standards

The data includes licensees participating in the Pharmacist Recovery Program (PRP) and licensees on probation with substance use disorders. This data includes July 2022 through June 2023.

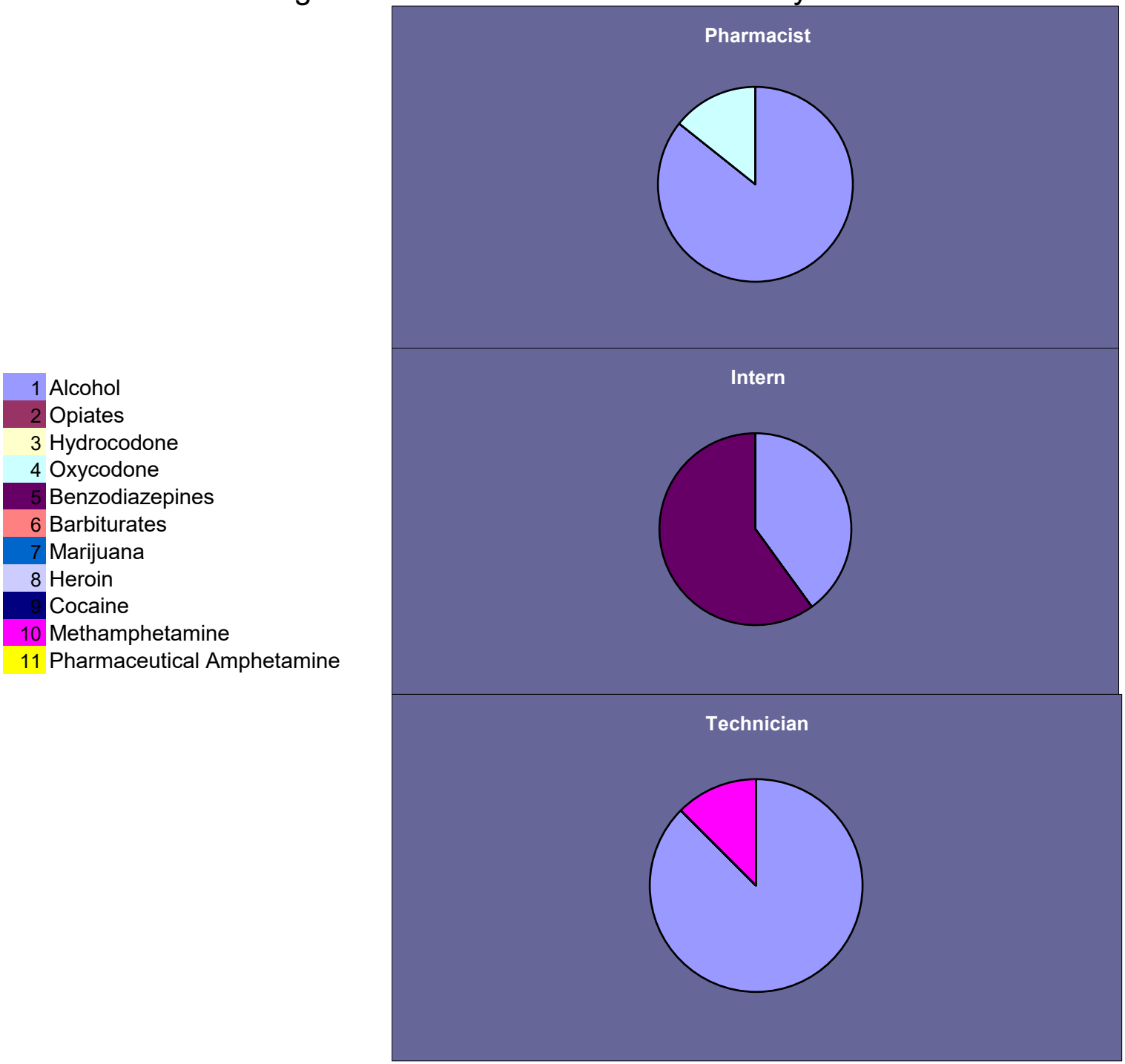
Board of Pharmacy	July -Sep	Oct – Dec	Jan-Mar	Apr-Jun	22/23
PRP Intakes					
PRP Self-Referrals				1	1
PRP Probation Referrals			1		1
PRP Under Investigation	3			2	5
PRP In Lieu Of (investigation conducted)					
Total Number of PRP Intakes	3		1	3	7
New Probationers					
Pharmacists	2	1	3		6
Intern Pharmacists			1		1
Pharmacy Technicians		1	2	3	6
Total New Probationers	2	2	6	3	13
PRP Participants and Recovery Agreements					
Total PRP Participants	39	34	30	30	30
Recovery Agreements Reviewed	26	34	26	28	114
Probationers and Inspections					
Total Probationers	48	45	33	36	36
Inspections Completed	31	33	24	20	108
Referrals to Treatment					
Referrals to Treatment (PRP and Probationers)	2		2	1	5
Drug Tests					
Drug Test Ordered (PRP and Probationers)	435	511	456	450	1852
Drug Tests Conducted (PRP and Probationers)	431	489	450	432	1802
Relapses (Break in Sobriety)					
Relapsed (PRP and Probationers)		1	1	2	4
Major Violation Actions					
Cease Practice/Suspension (PRP and Probationers)	3	3	4	3	13
Termination from PRP			1		1
Probationers Referred for Discipline			2	1	3
Closure					
Successful Completion (PRP and Probationers)	10	5	4	5	24
Termination (Probation)	1		2		3
Voluntary Surrender (Probation)			2	1	3
Surrender as a result of PTR (Probation)				1	1
Closed Public Risk (PRP)			1		1
Non-compliance (PRP and Probationers)	46	49	13	7	115
Other (PRP)	1	2	1	3	7
Patients Harmed					
Number of Patients Harmed (PRP and Probationers)					Zero
Drug of Choice at PRP Intake or Probation					
Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 22/23**
Alcohol	2		2	2	6
Ambien					
Opiates					
Hydrocodone	1				1
Oxycodone					
Morphine					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					

SB 1441 Uniform Standards

The data includes licensees participating in the Pharmacist Recovery Program (PRP) and licensees on probation with substance use disorders. This data includes July 2022 through June 2023.

Board of Pharmacy	July -Sep	Oct – Dec	Jan-Mar	Apr-Jun	22/23
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Intern Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 22/23**
Alcohol			1	1	2
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines			3		3
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Pharmacy Technicians	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 22/23**
Alcohol		1	2	4	7
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine			1		1
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					

Drug Of Choice - Data entered from July 2022 to June 2023



Printed on 7/7/2023

Workload Statistics	Total FY 20/21	Total FY 21/22	Total FY 22/23	% Change
Complaint Investigations				
Received	2,293	3,037	3,502	53%
Closed	2,549	2,947	3,179	25%
	blank	blank	blank	Year Ending
Pending	1,582	1,602	2,005	27%
Average Days for Investigation	233	190	223	-4%
Cases Under Investigation (By Team)				
Compliance/Routine	514	564	715	39%
Drug Diversion/Fraud	144	208	244	69%
Rx Abuse	126	167	255	102%
Compounding	42	46	43	2%
Outsourcing	11	25	16	45%
Probation/PRP	14	73	58	314%
Enforcement	449	136	26	-94%
Criminal Conviction	282	383	572	103%
Complaint Closure Outcomes Not Resulting in Further Action				
Insufficient Evidence	644	666	584	-9%
Non-Jurisdictional	369	542	560	52%
No Violation	346	324	239	-31%
No Further Action	213	210	234	10%
Other - Non-Substantiated	34	48	128	276%
Subject Educated	89	64	98	10%
Application Investigations				
Received	240	217	205	-15%
Closed				
Approved	208	134	125	-40%
Denied	33	55	74	124%
Total Closed (includes withdrawn)	***271***	***208***	***214***	***-21%***
Pending	72	63	79	10%
Letter of Admonmishment / Citations				
LOA Issued	452	266	201	-56%
Citations Issued	936	1,274	1,053	13%
Proof of Abatement Requested	248	269	196	-21%
Appeals Received	93	57	48	-48%
Dismissed	22	26	18	-18%
Total Fines Collected	***$785,755***	***$1,093,911***	***$2,021,404***	***157%***
Administrative Cases				
Referred to the AG's Office	188	166	259	38%
Pleadings Filed	194	171	156	-20%
Pending				
Pre Accusation	108	78	138	28%
Post Accusation	153	147	140	-8%
Total Pending	***261***	***225***	***278***	***7%***
Total Closed	***291***	***202***	***218***	***-25%***
Revocation				
Pharmacist	12	9	12	0%
Intern Pharmacist	1	1	2	100%
Pharmacy Technician	66	30	35	-47%
Designated Representative	1	1	0	-100%
Wholesaler	0	0	0	0%
Clinic	0	0	0	0%
Pharmacy	12	17	7	-42%
Sterile Compounding	0	2	3	0%
Outsourcing	0	0	0	0%
Total	***92***	***60***	***59***	***-36%***

Revocation; stayed suspension/probation				
Pharmacist	1	1	4	300%
Intern Pharmacist	1	0	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	***2***	***1***	***4***	***100%***
Revocation; stayed; probation				
Pharmacist	63	52	42	-33%
Intern Pharmacist	3	0	3	0%
Pharmacy Technician	15	4	8	-47%
Designated Representative	0	0	0	0%
Wholesaler	1	0	0	-100%
Clinic	0	0	0	0%
Pharmacy	19	18	15	-21%
Sterile Compounding	5	3	2	-60%
Outsourcing	0	1	0	0%
Total	***106***	***78***	***70***	***-34%***
Surrender/Voluntary Surrender				
Pharmacist	20	26	25	25%
Intern Pharmacist	1	0	0	-100%
Pharmacy Technician	18	16	10	-44%
Designated Representative	3	0	1	-67%
Wholesaler	2	0	0	-100%
Clinic	0	0	0	0%
Pharmacy	38	40	30	-21%
Sterile Compounding	2	2	1	-50%
Outsourcing	2	0	0	-100%
Total	***86***	***84***	***67***	***-22%***
Public Reproval/Reprimand				
Pharmacist	38	19	13	-66%
Intern Pharmacist	0	0	0	0%
Pharmacy Technician	6	2	1	-83%
Designated Representative	1	2	0	-100%
Wholesaler	1	3	1	0%
Clinic	2	0	0	-100%
Pharmacy	44	20	5	-89%
Sterile Compounding	5	4	0	-100%
Outsourcing	2	0	0	-100%
Total	***99***	***50***	***20***	***-80%***
Licenses Granted				
Pharmacist	2	1	2	0%
Intern Pharmacist	0	1	0	0%
Pharmacy Technician	3	2	5	67%
Designated Representative	0	0	0	0%
Wholesaler	0	0	0	0%
Clinic	0	0	0	0%
Pharmacy	0	1	1	0%
Sterile Compounding	0	0	0	0%
Outsourcing	0	0	0	0%
Total	***5***	***5***	***8***	***60%***
Licenses Denied				
Pharmacist	1	0	1	0%
Intern Pharmacist	0	0	0	0%
Pharmacy Technician	3	2	1	-67%
Designated Representative	0	0	0	0%
Wholesaler	0	0	0	0%
Clinic	0	0	0	0%
Pharmacy	1	4	0	-100%
Sterile Compounding	0	0	0	0%
Outsourcing	1	0	0	-100%
Total	***6***	***6***	***2***	***-67%***
Cost Recovery Requested	***$2,475,038***	***$2,845,000***	***$1,934,351***	***-22%***
Cost Recovery Collected	***$1,578,428***	***$2,283,704***	***$1,359,280***	***-14%***

Immediate Public Protection Sanctions				
Interim Suspension Order	13	2	7	-46%
Automatic Suspensions	0	4	4	0%
Penal Code 23 Restrictions	2	0	13	550%
Cease and Desist - Outsourcing	n/a	1	0	0%
Cease and Desist - Unlicensed	0	1	0	0%
Cease and Desist - Sterile Compounding	0	0	0	0%
Probation Statistics				
Licenses on Probation				
Pharmacist	232	217	177	-24%
Intern Pharmacist	5	1	2	-60%
Pharmacy Technician	28	22	17	-39%
Designated Representative	2	2	1	-50%
Wholesaler	3	3	3	0%
Pharmacy	69	60	48	-30%
Sterile Compounding	8	11	8	0%
Outsourcing	0	1	0	0%
Total Probationers	***347***	***317***	***256***	***-26%***
Probation Office Conferences	79	74	69	-13%
Probation Site Inspections	533	380	439	-18%
Probation Terminated / Completed	96	89	135	41%
Referred to AG for Non-Compliance	3	8	7	133%

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	FY20/21	FY21/22	FY22/23
PRP Intakes			
PRP Self-Referrals	0	2	1
PRP Probation Referrals	6	2	1
PRP Under Investigation	2	2	5
PRP In Lieu Of (investigation conducted)	1	0	0
Total Number of PRP Intakes	9	6	7
New Probationers			
Pharmacists	7	4	6
Interns	3	0	1
Pharmacy Technicians	8	3	6
Total New Probationers	18	7	13
PRP Participants and Recovery Agreements			
Total PRP Participants	51	45	30
Total Participant Recovery Agreements Reviewed	207	161	114
Probationers and Inspections			
Total Probationers	73	56	36
Inspections Completed (This information is not available)	236	151	108
Referrals to Treatment			
Referrals to Treatment (PRP and Probationers)	6	5	5
Drug Tests			
Drug Test Ordered (PRP and Probationers)	2912	2617	1852
Drug Tests Conducted (PRP and Probationers)	2780	2547	1802
Relapses			
Relapsed (PRP and Probationers)	4	3	4
Major Violation Actions			
Cease Practice/Suspension (PRP and Probationers)	25	21	13
Terminated from PRP	10	1	1
Probationers Referred for Discipline	4	3	3
Closure			
Successful Completion (PRP and Probationers)	12	28	24
Termination (Probation)	1	3	3
Voluntary Surrender (Probation)	11	6	3
Surrender as a result of PTR (Probation)	0	0	1
Closed Public Risk (PRP)	1	1	1
Non-compliance (PRP and Probationers)	4	164	115
Other (PRP)	4	4	7
Patients Harmed			
Number of Patients Harmed (PRP and Probationers)	None	None	None

Drug of Choice at PRP Intake or Probation			
Pharmacists	**FY20/21**	**FY21/22**	**FY22/23**
Alcohol	4	5	6
Ambien		1	
Opiates	1		
Hydrocodone			1
Oxycodone	1		
Morphine	1		
Benzodiazepines			
Barbiturates			
Marijuana			
Heroin			
Cocaine			
Methamphetamine			
Pharmaceutical Amphetamine			
Phentermine			
Methadone			
Zolpidem Tartrate			
Hydromorphone			
Clonazepam			
Tramadol			
Carisprodol			
Phendimetrazine			
Promethazine w/Codeine			
Intern Pharmacists	**FY20/21**	**FY21/22**	**FY22/23**
Alcohol	2	1	2
Opiates			
Hydrocodone			
Oxycodone			
Benzodiazepines			3
Barbiturates			
Marijuana		1	
Heroin			
Cocaine	1		
Methamphetamine			
Pharmaceutical Amphetamine			
Phentermine			
Methadone			
Zolpidem Tartrate			
Hydromorphone			
Clonazepam			
Tramadol			
Carisprodol			
Phendimetrazine			
Promethazine w/Codeine			
Pharmacy Technicians	**FY20/21**	**FY21/22**	**FY22/23**
Alcohol	7	2	7
Opiates			
Hydrocodone			
Oxycodone			
Benzodiazepines			
Barbiturates			
Marijuana			
Heroin			
Cocaine		1	
Methamphetamine	1		1
Pharmaceutical Amphetamine			
Phentermine			
Methadone			
Zolpidem Tartrate			
Hydromorphone			
Clonazepam			
Tramadol			
Carisprodol			
Phendimetrazine			
Promethazine w/Codeine			