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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 and October 19, 2023, meetings as well as updates for action as needed.

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 the 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 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. 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 were 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 Enrolled or Recently Signed Legislation Impacting the Practice of Pharmacy

i. Assembly Bill 663 (Haney) Pharmacy: Mobile Units
Status: Signed October 8, 2023
Summary: Allows a mobile unit deployed as an extension of a county owned pharmacy, to carry controlled substances approved by the FDA for the treatment of opioid use disorder under specified conditions. Further, would allow for the use of one or more mobile units as determined by the pharmacist-in-charge.
Implementation: Staff recommend implementation activities focus on education of the expansion of the authorities related to the use of mobile units including updates to the Frequently Asked Questions, highlighting the changes in the updates to the Change in Pharmacy Law webinar, and information an upcoming issue of *the Script*.
Summary of Committee Discussion and Action:
Members agreed with the implementation activities identified by staff.

Members did not receive any public comment.

ii. Assembly Bill 782 (Lackey) Pharmacies: Compounding
Status: Vetoed
Summary: Would exempt from the definition of compounding the adding of a flavoring agent.
Implementation: As the measure was vetoed, implementation activities are not required.

Summary of Committee Discussion and Action:
There was no committee discussion as the measure was vetoed.

iii. Assembly Bill 1286 (Haney) Pharmacy

Status: Signed October 8, 2023

Summary: The measure creates a mandatory requirement that community pharmacies report medication errors that occur in the outpatient setting to an entity approved by the Board. Further, the measure updates minimum staffing requirements and the authority of the pharmacist-in-charge, updates unprofessional conduct codes, establishes authority for the issuance of a cease and desist under specified conditions, expands authority for pharmacy technicians to perform expanded duties under specified conditions, and updates the renewal requirements for surgical clinics.

Implementation: Significant education should be completed through a future issue of the Script and the Changes in Pharmacy Law webinar. Board staff also recommend development of FAQs on specific elements in the measure.

Further, updates are appropriate to the Board's community pharmacy self-assessment. As the Board continues to receive complaints regarding prior staffing requirements, it also appears appropriate to update licensee information on this measure and prior Senate Bill 362 related to filing a complaint with the Board.

It is recommended that the development of the Surgical Clinic Self-Assessment be reviewed and approved by the Enforcement and Compounding Committee.

As the Board is required to approve an entity to receive the medication error reports, it may be appropriate to provide staff with guidance on entities that may be appropriate to consider for approval. The Board has previously indicated its preference for reporting to be aggregated by a single entity. The Committee may prefer to convening a stakeholder meeting to solicit public comments before initiating a formal process to approve the entity.

Summary of Committee Discussion and Action:
The Committee discussed the significance of the measure and spoke in support of the implementation activities detailed. During the meeting members requested a draft of the medication error reporting FAQs be prepared for review and consideration at its next Committee Meeting. The Committee noted that it would be helpful to have a presentation from AHRQ and other organizations in addition to understanding the state procedures for contracting with an outside entity. Public comment was also received that referred all to review the information presented at the Medication Error Reduction and Workforce Ad Hoc Committee.

Members requested that the Board develop a presentation that can be given to all interested parties to provide education about all of the provisions contained in the measure particularly regarding staffing levels and PIC authority.

The committee noted the need to send out an alert to licensees about implementation timeframes for medication error reporting including information about a delay in implementation while the Board approves an authorized entity.

Members also received public comment which noted agreement with the implementation strategies discussed including information on a delay in the effective date of the medication error reporting requirement. Public comment also reiterated the significance of the measure and its focus on consumer protection. Public commented suggested that there is concern by some pharmacists serving as a pharmacist-in-charge of potential retaliation by pharmacy owners if the PIC files a complaint.

Public comment also requested information about possible cleanup legislation to clarify the specific technician training needed solely for immunizations and not necessarily for other technician functions. It was also suggested that the board will need to pursue a regulation change to approve an entity.

iv. <u>Assembly Bill 1341 (Berman, Chapter 276, Statutes of 2023) Public Health, COVID-19 Testing and Dispensing Sites: Oral Therapeutics</u>

<u>Signed</u>: September 30, 2023
<u>Summary</u>: Authorizes a pharmacist to furnish COVID-19 oral therapeutics until January 1, 2025. As the measure included an urgency clause, the provisions became effective upon signature.
<u>Implementation</u>: Staff recommend implementation activities focus on education of the provisions including highlighting the changes in the updates to the Change in Pharmacy Law webinar and inclusion of the information in a future issue of *the Script*.
<u>Summary of Committee Discussion and Action:</u>
Members agreed with the implementation activities identified by staff.

Public comment suggested that as part of the Board's education on the measure, the information should highlight the potential for pharmacists to engage in "test to treat" for COVID-19 when this measure is paired with other legislation

v. <u>Assembly Bill 1557 (Flora) Pharmacy: Electronic Prescriptions</u>

<u>Signed</u>: September 1, 2023
<u>Summary</u>: Authorizes a pharmacist located and licensed within California to, on behalf of a health care facility, verify medication chart order reviews for appropriateness before administration from a remote location. As the measure included an urgency clause, the provisions became effective upon signature.
<u>Implementation</u>: Staff recommend implementation activities focus on education of the provisions including highlighting the changes in the next version of Change in Pharmacy Law webinar and inclusion of the information in a future issue of *the Script*.
<u>Summary of Committee Discussion and Action:</u>
Members agreed with the implementation activities identified by staff.

Public comment suggested that the Board will need to release information about the implementation strategy noting that some hospitals may currently be using pharmacists from outside of California to perform the remote chart order verification. Public comment also suggested that the language was unclear and questioned if the provisions were applicable to community pharmacies.

vi. Senate Bill 345 (Skinner, Chapter 260, Statutes of 260) Health Care Services: Legally Protected Health Care Services

Status: Signed September 27, 2023

Summary: Prohibits a healing arts board from denying an application for a license or imposing discipline upon a licensee of health care practitioner on the bases of a civil judgement, criminal conviction, or disciplinary action in another state if that the action would have been lawful if provided in California.

Implementation: Staff recommend implementation activities focus on education of the provisions including highlighting the changes in the version of Change in Pharmacy Law webinar, inclusion of the information in an upcoming issue of *the Script*, and coordination with the Office of the Attorney General.

Summary of Committee Discussion and Action

Members agreed with the implementation activities identified by staff.

vii. Senate Bill 816 (Roth) Professions and Vocations

Status: Signed October 10, 2023

Summary: Recasts the Board's fee structure. Provisions become effective January 1, 2025.

Implementation: Given the delayed effective date**,** Staff recommend implementation activities focus on updating the Board's fee regulation, Title 16, CCR Section 1749 to align with the statute, providing clear guidance to applicants and licensees. Further, education of the provisions should be highlighted in the next version of Change in Pharmacy Law webinar and in a future issue of *the Script*.

Summary of Committee Discussion and Action

Members agreed with the implementation activities identified by staff. The Committee requested that staff begin the rulemaking process to align Title 16, CCR Section 1749 by the effective date of the new fees. Members asked if new fees could be implemented prior to regulation changes if there should be a delay.

The Committee did not receive any public comment.

f. Discussion and Consideration of Proposed Revisions to Frequently Asked Questions Related to Inventory Reconciliation Regulation

Relevant Law

Title 16, California Code of Regulations Section 1715.65 establishes the requirements for inventory reconciliation activities.

Background

In April 2018, the Board established requirements for pharmacies and clinics to perform periodic inventory activities and prepare inventory reconciliation reports to detect and prevent the loss of federal controlled substances. As part of the implementation, the Board developed frequently asked questions.

Effective January 1, 2023, the regulation requirements were updated to include additional inventory reconciliation reports for specified drugs and to establish a minimum threshold for inventory activities for all controlled substances at least once every two years.

Summary of Committee Discussion and Action
Committee members noted support for the FAQs and expressed appreciation to the staff. The Committee requested reworking a portion of the language on question one to emphasize the reconciliation requirements for drug losses. Committee members also requested formatting changes to aid users of the document and requested that a hyperlink- to relevant sections of the law be included in the title,

Public comment spoke in support of the formatting changes.

Update: Following the meeting, DCA counsel expressed concern with the FAQs transitioning to an outline form as users of the document may misinterpret the alphabetical listing a referencing a specific subsection within the regulation section. As a result, these sections remain with bullet points.

Attachment 5 includes a copy of the updated FAQs including counsel's changes. Clarifying changes are highlighted in yellow and substantive changes are illustrated in track changes. Nonsubstantive changes were also incorporated but are not highlighted.

g. Discussion and Consideration of Proposed Revisions to Pharmaceutical and Sharps Waste Stewardship Programs

Relevant Law
Chapter 2 of Division 30 of the Public Resources Code (PRC) in general terms establishes the requirements for pharmaceutical and sharps waste stewardship programs. As included in the provisions, the primary regulator of the program is the California Department of Resources Recycling and Recovery (Cal Recycle).

PRC section 42031 provides reporting requirements to the California Board of Pharmacy, including a list and description of drugs or sharps that are covered or not covered as provided by the manufacturer or other specified covered entity.

Background
As part of the Board's implementation efforts, in January 2022, the Board approved draft Frequently Asked Questions, to assist covered entities and others with an understanding of the requirements. Since that time, staff continue to receive several

questions that appear could be appropriate for incorporation into the Board's FAQs.

Summary of Committee Discussion and Action
Committee members spoke in support of the FAQs and noted a typo in the proposed change to the answer to question one.

Members did not receive any public comment on the FAQs.

Attachment 6 includes a copy of the corrected draft updates to the FAQs.

h. Review and Discussion of Enforcement Statistics

During the first quarter of the fiscal year, the Board received 765 complaints and closed 764 investigations. The Board has issued 47 Letters of Admonishment, 270 Citations and referred 78 cases to the Office of the Attorney General. The Board has revoked 11 licenses, accepted the disciplinary surrender of 4 licenses, formally denied 1 application(s), and imposed other levels of discipline against 25 licensees and/or applicants.

As of October 1, 2023, the Board had 1,369 field investigations pending. On the following page is a breakdown providing more detail in the various investigation process:

	Oct. 1, 2022		Jan. 1, 2023		Apr. 1, 2023		Jul. 1, 2023		Oct. 1, 2023	
	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days
Awaiting Assignment	110	6	80	12	116	6	59	8	88	22
Cases Under Investigation	749	125	853	129	874	138	942	141	982	138
Pending Supervisor Review	223	46	199	85	146	22	164	31	183	47
Pending Second Level Review	205	36	226	55	245	36	79	22	82	22
Awaiting Final Closure	113	42	92	35	8	43	148	12	34	13

Summary of Committee Discussion and Action
Committee members reviewed the statistics.

The committee did not receive public comment on this agenda item.

Attachment 7 includes the enforcement statistics for the first quarter of the fiscal year.

Attachment 1

CALIFORNIA

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)

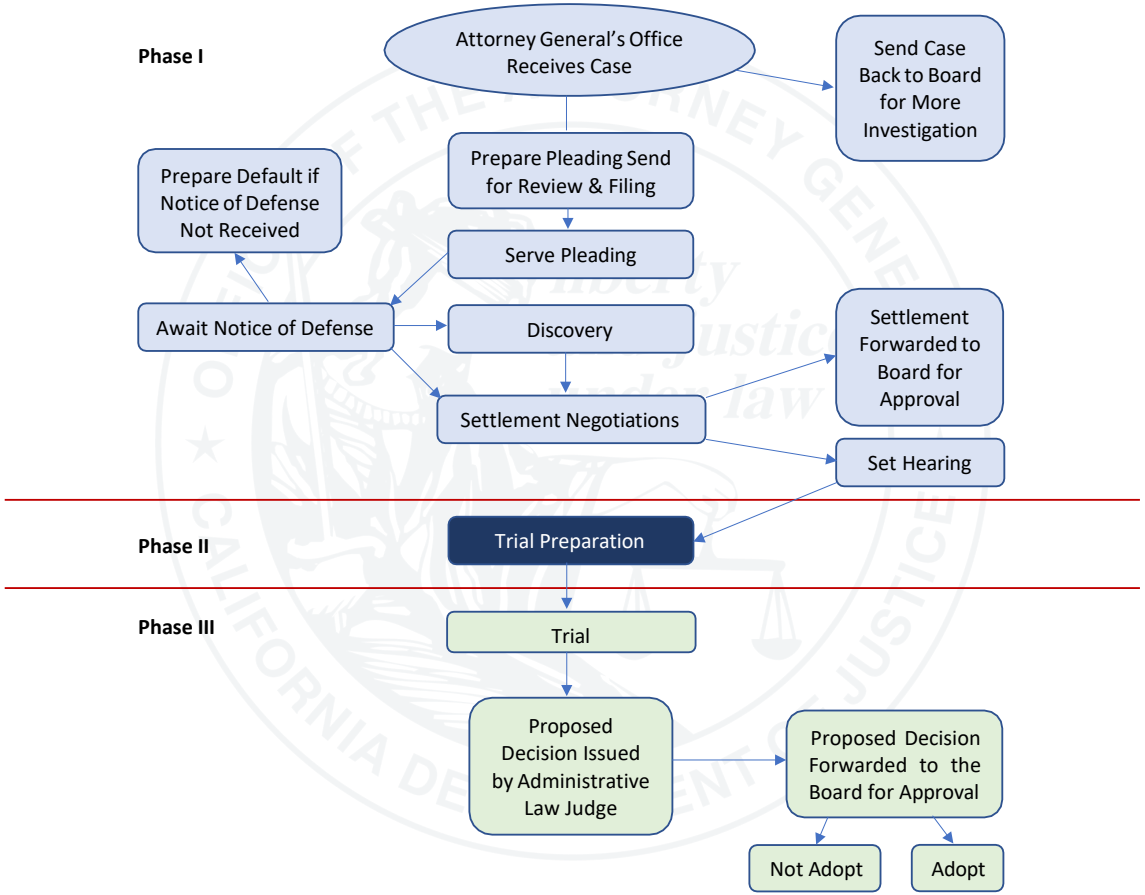
The Office of the Attorney General Mission Statement:

- 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.

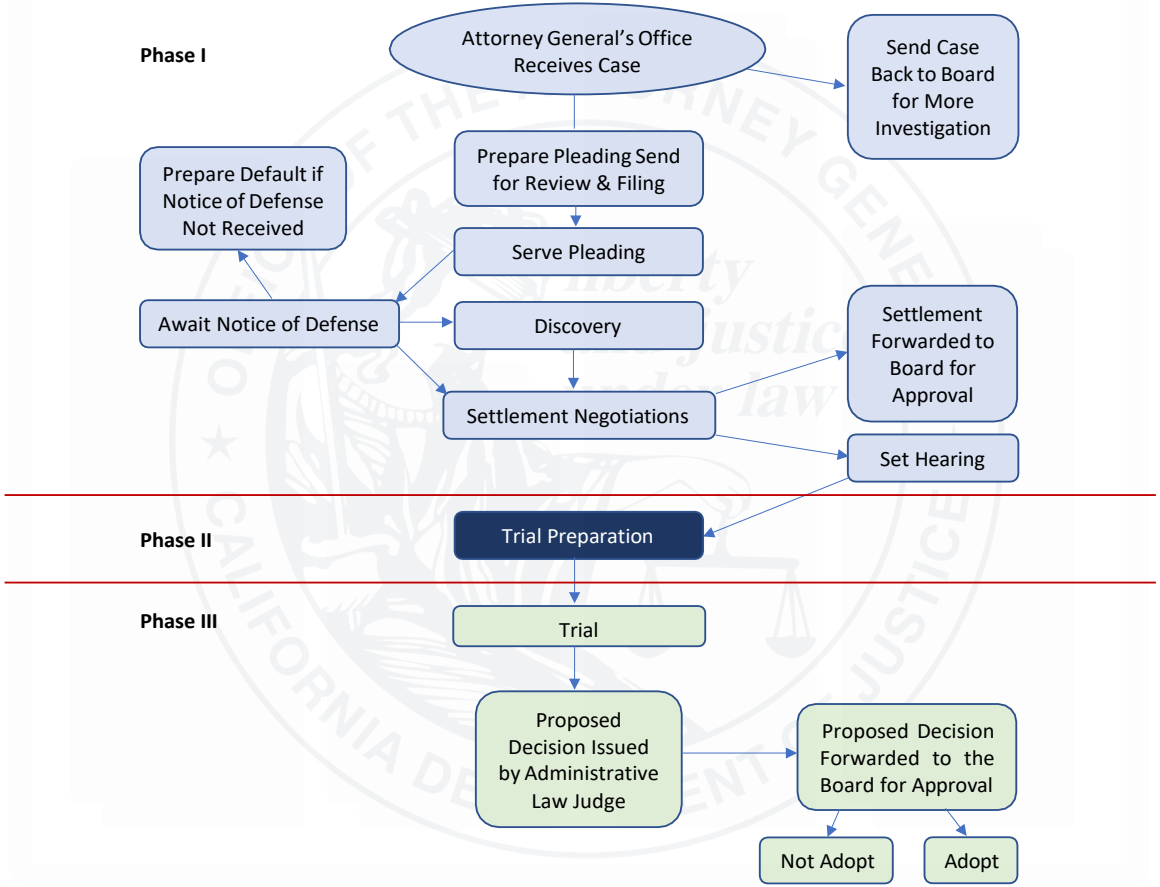
- Protection of the public is the highest priority of the Board, where other interests conflict with the protection of the public, the protection of the public must be paramount (Bus. & Prof. Code § 4001.1).

- 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

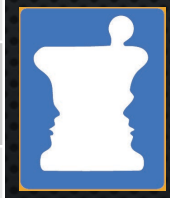
- Routine Inspections Completed Complaint Visit: 248
  - 119 Pharmacies Were Issued No Violations
  - 102 Pharmacies Were Issued 226 Corrections
  - 63 Pharmacies Were Issued 118 Violation Notices

- 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.

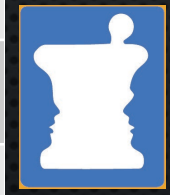
TOP CORRECTIONS ON ROUTINE PHARMACY INSPECTIONS FY22/23

CCR 1714	**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**



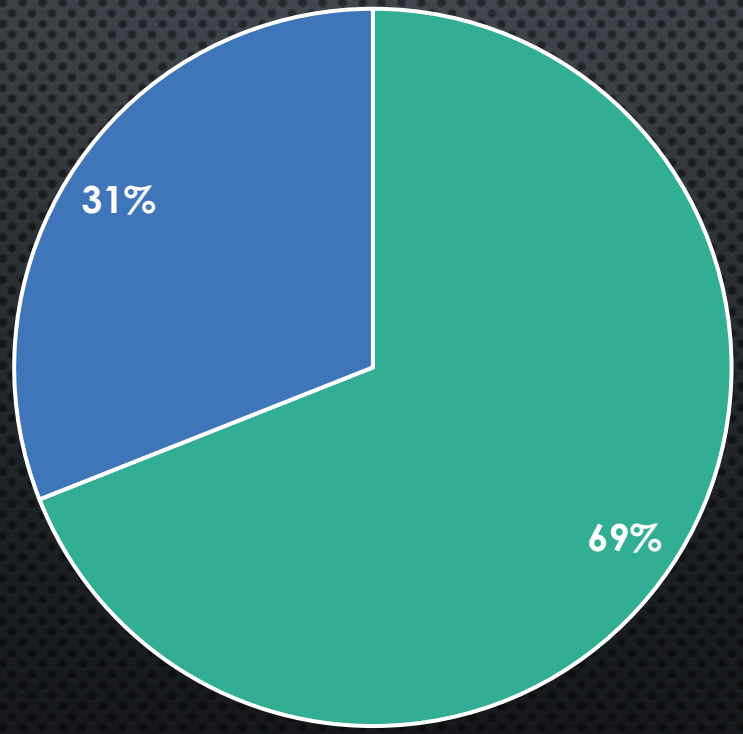
CCR 1707.2 – DUTY TO CONSULT PHARMACY ROUTINE INSPECTIONS

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

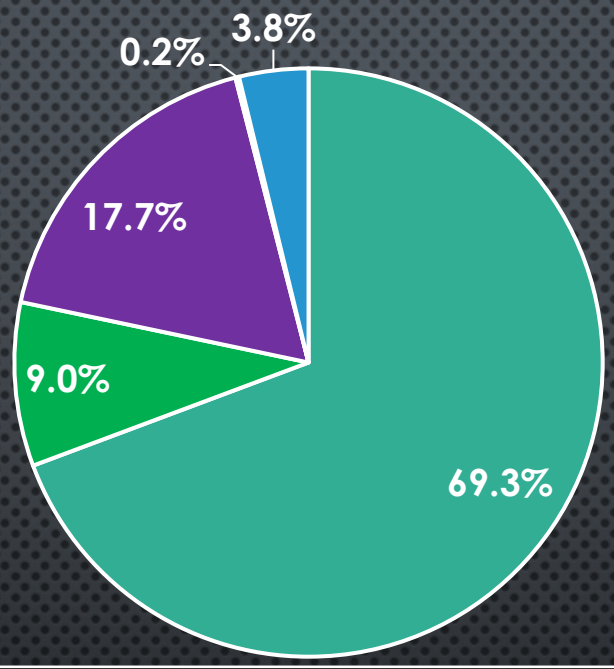


*not including licenses issued in current fiscal year FY 2022/23

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

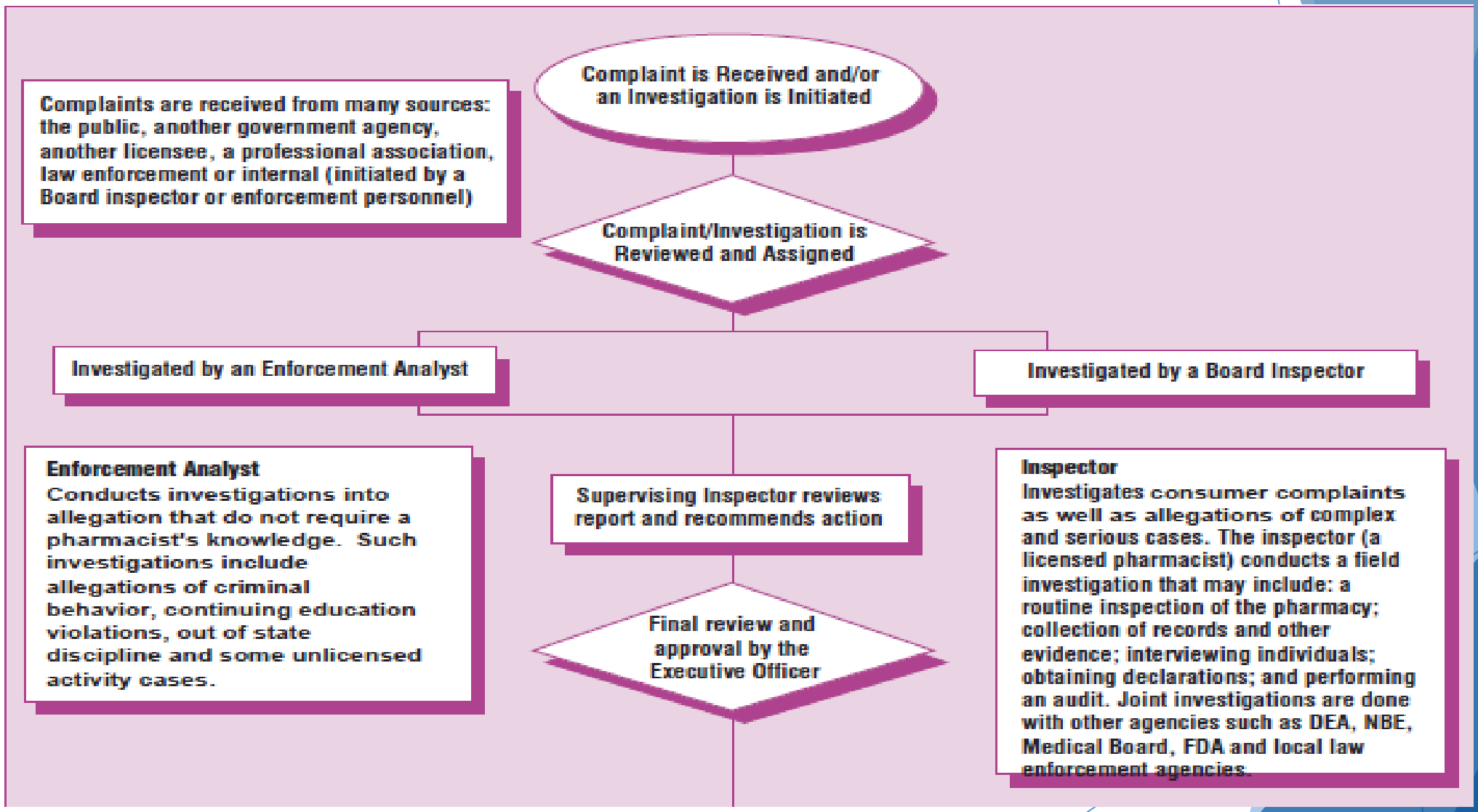
California State Board of Pharmacy

Enforcement and Compound Committee Meeting

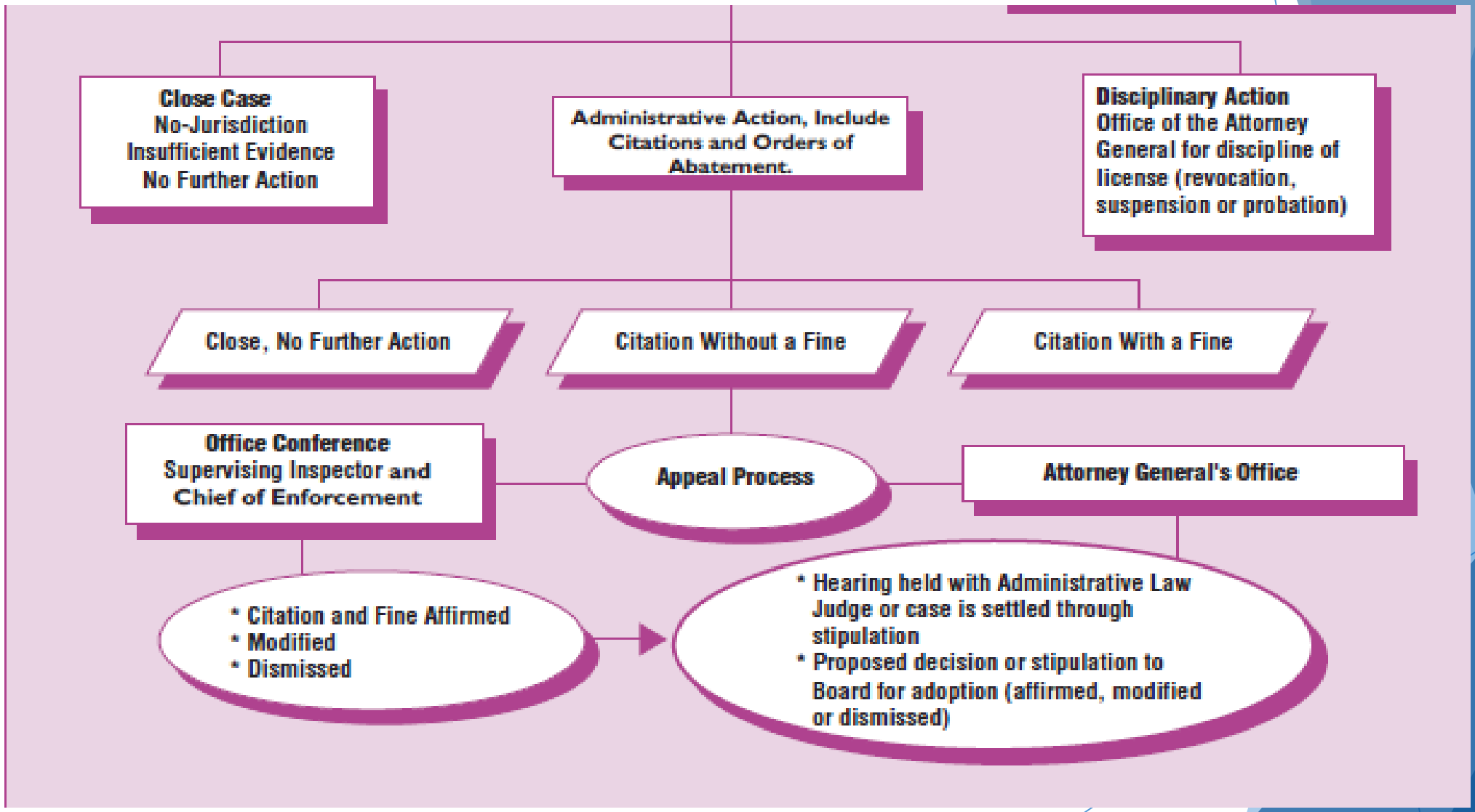
Citation Presentation

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

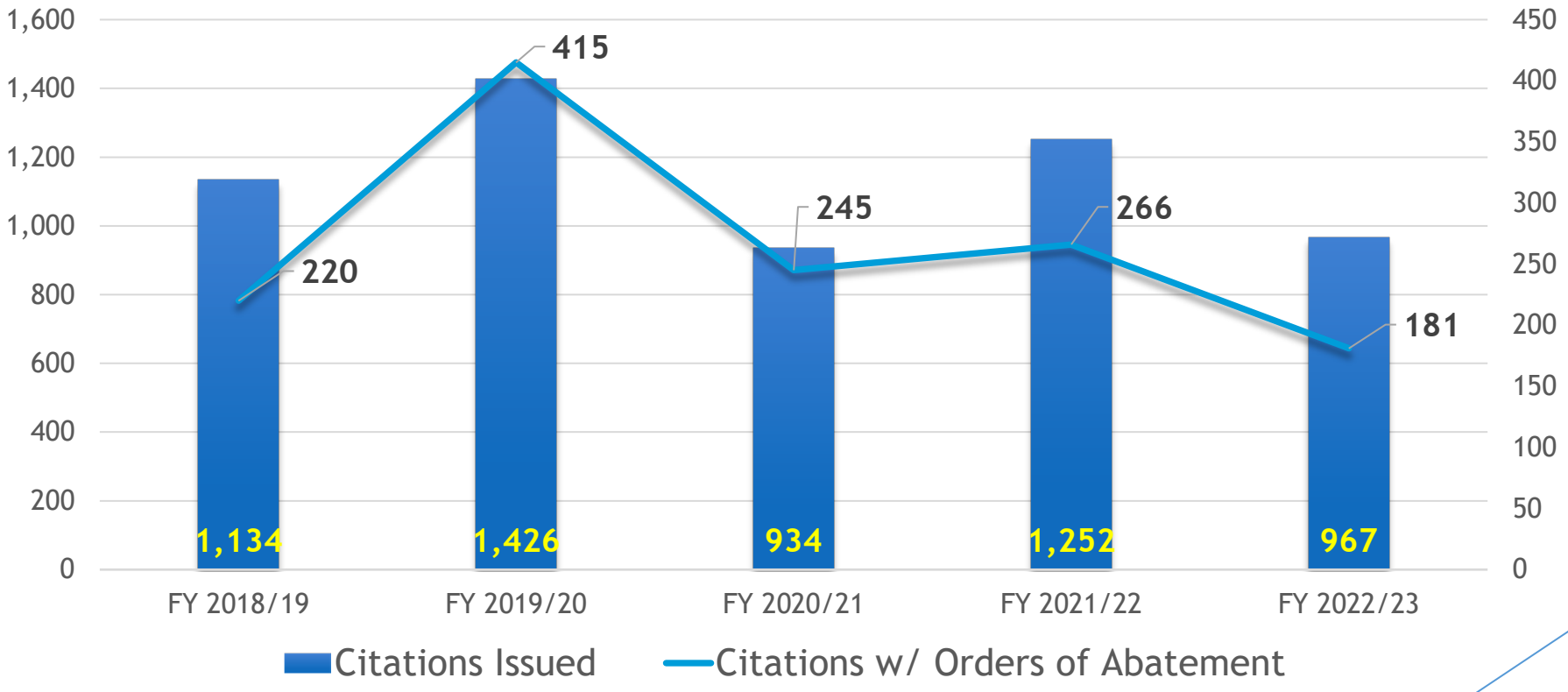
Citations Issued by License Type

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

FAQs for the Revisions to Inventory Reconciliation (Revised 10/20/2023)

The revisions to California Code of Regulations (CCR), Title 16, section 1715.65, Inventory Reconciliation Reports of Controlled Substances took effect January 1, 2023. The regulation text is available here.

Below are questions frequently asked regarding the revisions to CCR §1715.65.

General:

1. With CCR §1715.65 revised, what inventory activities and inventory reconciliation reports are now required for controlled substances?

Effective January 1, 2023, every pharmacy and every clinic licensed under Business and Professions Code (BPC) §§ 4180 and 4190 must conduct inventory activities and prepare inventory reconciliation reports on the following ongoing basis:

- All federal Schedule II controlled substances, at least once every three months;
- For products containing the following substances in the following strengths per tablet, capsule, other unit, or specified volume, at least once every 12 months, the following controlled substances: alprazolam 1mg/unit, alprazolam 2mg/unit, tramadol 50mg/unit, and promethazine with codeine 6.25mg promethazine/10mg codeine/5mls drug product;
- For any controlled substances not listed above, an inventory reconciliation report must also be prepared when a controlled substance loss is identified, no later than three months after discovery of the **reportable loss** of the controlled substance in addition to the timely report of the loss as required;
- For any controlled substance not listed above, inventory activities must be performed at least once every two years from the performance of the last inventory activities.

CCR §§1715.65(a)(1), (a)(2), (a)(3)

However, if you are an inpatient hospital pharmacy, the inventory reconciliation for all federal Schedule II controlled substances, and alprazolam 1mg/unit, alprazolam 2mg/unit, tramadol 50mg/unit, and promethazine with codeine 6.25mg promethazine/10mg codeine/5mls drug product, must be performed quarterly. CCR §1715.65(a)(1), (a)(2), (a)(3)

2. While reviewing the pharmacy's wholesale invoices, I noticed extra bottles of diazepam 5mg were being ordered when no prescriptions for diazepam 5mg was dispensed in the past 3 months. What time period am I required to audit to determine if there was any loss of diazepam 5mg and am I required to report any losses to the board?

Yes. When a controlled substance loss is identified, an inventory reconciliation report must be completed. The audit period must cover the period from the last physical count of the

controlled substance before the loss was discovered through the date of discovery. CCR §1715.65(a)(3)(A)

Losses of controlled substances must be reported no later than 30 days after the date of discovery in accordance with CCR 1715.6. If the cause of the losses is related to theft, diversion, or self-use the loss must be reported to the board within 14 days of discovery.

Controlled substance losses can be either mailed to the address of the board or emailed to DEA106@dca.ca.gov. CCR §1715.65(d), CCR §1715.6, BPC §4104(c)

3. With the new revisions for inventory reconciliation reports and inventory activities, what is now required to be in the report?

An inventory reconciliation report must include the following:

- A physical count, not an estimate, of all quantities of each federal controlled substance covered by the report that the pharmacy or clinic licensed by the board has in inventory, pursuant to BPC §§ 4180 or 4190. If an inpatient hospital pharmacy or licensed correctional pharmacy uses an ADDS to stock the controlled substances, the inventory in the ADDS may be accounted for by using a means other than a physical count.
- The individual(s) who performed the inventory must sign and date the inventory or the report.
- A review of all acquisitions and disposition of each federal controlled substance covered by the report since the last inventory reconciliation report covering that controlled substance.
- A comparison of the physical counts in inventory to all acquisitions and dispositions (since the last inventory reconciliation report) of each federal controlled substance covered by the report.
- Identification of all records used to compile the report, which must be maintained in the pharmacy or clinic.
- The identification of each individual involved in preparing the report.
- The possible causes of overages.
- Identify to the Board, in writing, the losses and known causes. Reportable losses defined in CCR §1715.6, must be reported to the board within 30 days of discovery, unless the cause of the loss is theft, diversion, or self-use in which case the board must be notified within 14 days of discovery.
- The inventory reconciliation report must be dated and signed by the PIC or the professional director of the clinic licensed pursuant to BPC §§4180 or 4190.
- The report and all records used to compile the report must be readily retrievable in the pharmacy or clinic for three years.

CCR §1715.65(c), (d), (e)

4. What type of "inventory activities" does the board require a pharmacy to perform for all other controlled substances that are not mandated to be physically counted quarterly or every 12 months?

"Inventory activities" are required for each controlled substances that is not already required to be physically counted quarterly or at least every twelve months. Inventory activities for these controlled substances must be performed at least once every two years from the performance of the last inventory activities. "Inventory activities" means inventory and all other functions sufficient to identify loss of controlled substances. The functions that are sufficient to identify loss outside of the inventory reconciliation process must be identified within the pharmacy's policies and procedures.

CCR §1715.65(a)(1), (a)(2), (a)(3)(B)

5. Can I delegate a staff pharmacist to do the physical count and prepare the inventory reconciliation report for the pharmacy?

Yes. Any individual involved in preparing the report must be identified in the report. Any individuals who perform the physical count of each federal scheduled controlled substance must sign and date the inventory or the report.

The pharmacist-in-charge of a pharmacy or the consulting pharmacist for a clinic licensed by the board pursuant to BPC §§ 4180 or 4190, must review all inventory activities performed and inventory reconciliation reports prepared and establish and maintain secure methods to prevent losses of federal controlled substances, including written policies and procedures for performing the inventory activities and preparing the inventory reconciliation reports.

In addition, the inventory reconciliation report must be dated and signed by the pharmacist-in-charge or the professional director for a clinic licensed by the board pursuant to BPC §§ 4180 or 4190. An individual may use a digital or electronic signature or biometric identifier in lieu of a physical signature for this report if, in addition, the individual physically signs a printed statement confirming the accuracy of the inventory or report. The signature must be dated, and the signed and dated statement must be retained on file in the pharmacy or clinic for three years.

CCR §§1715.65(b), (e)(1), (e)(2)

6. How long is the pharmacy required to maintain its inventory reconciliation reports?

All inventory reconciliation reports, and all records used to compile the reports, are required to be readily retrievable in the pharmacy or clinic for three years. CCR §1715.65(e)(2)

7. I am new PIC and this is my first time doing an inventory reconciliation report. What is required to be included in an inventory reconciliation report?

As a new PIC of a pharmacy, the PIC must complete an inventory reconciliation report for all federal Schedule II controlled substances, and alprazolam 1mg/unit, alprazolam 2mg/unit, tramadol 50mg/unit, and promethazine with codeine 6.25mg/10mg/5mls drug product within 30 days of becoming the PIC. CCR §1715.65(f)

8. I notified my employer that I will be resigning as the PIC at the end of the month. Am I required to complete an inventory reconciliation before I leave?

Whenever possible, the outgoing PIC should complete an inventory reconciliation report for all federal Schedule II controlled substances, and alprazolam 1mg/unit, alprazolam 2mg/unit, tramadol 50mg/unit, and promethazine with codeine 6.25mg/10mg/5mls drug product. CCR §1715.65(f)

Whenever possible, it is also recommended (though not required) the outgoing PIC perform an inventory count of all controlled substances prior to their disassociation as the PIC.

Hospital Pharmacies and Drug Rooms:

9. Are drug rooms required to complete an inventory reconciliation report?

Yes. Under 22 CCR §70263(a), hospitals having fewer than 100 licensed beds (informally referred to as drug rooms) are required to have a license pursuant to BPC 4029 and 4056, and must comply with CCR §1715.65.

10. Does a hospital pharmacy need to include the controlled substances stored in the automated drug delivery system (ADDS), if the controlled substances were already removed from the stock inside the hospital pharmacy's narcotic locker?

Yes. The hospital pharmacy must account for all controlled substances subjected to inventory reconciliation stored inside the licensed pharmacy premise and stored in all the ADDS throughout the hospital, including locations listed on the general acute care hospital license, provided the ADDS were stocked by the hospital pharmacy.

However, if any inpatient hospital pharmacy, or licensed correctional pharmacy, uses an ADDS, only the inventory in the ADDS may be accounted for by using a means other than a physical count. CCR §1715.65(h)

11. Are the controlled substance removed from the main hospital pharmacy inventory then transferred to the satellite pharmacies, nursing stations, surgical units, clinics, and other locations listed on the general acute care hospital license required to be included in the hospital pharmacy's inventory reconciliation report?

Yes. The inventory reconciliation reports for an inpatient hospital pharmacy must include controlled substances stored within the pharmacy, within each pharmacy satellite location, and within each drug storage area in the hospital under the pharmacy's control. A physical count of the controlled substances (all federal Schedule II controlled substances, and alprazolam 1mg/unit,

alprazolam 2mg/unit, tramadol 50mg/unit, and promethazine with codeine 6.25mg promethazine/10mg codeine/5mls drug product) is required. If the inpatient hospital pharmacy uses an ADDS to stock the controlled substances, the inventory in the ADDS may be accounted for by using a means other than a physical count.

CCR §§1715.65(a), (g), (h)

12. For federal Schedule II controlled substances stored in an ADDS, are they required to be physically counted?

No. If the inpatient hospital pharmacy uses an ADDS to stock the controlled substances, the inventory in the ADDS may be accounted for by using a means other than a physical count. CCR §1715.65(h)

13. The inpatient hospital pharmacy operates various ADDS throughout the hospital which includes controlled substances. We plan to generate audit reports through the ADDS report module. Are these reports sufficient to account for the controlled substance since the law allows the inpatient hospital pharmacy to use means other than physical counts for controlled substances stored in an ADDS?

It depends. Yes, the inpatient hospital pharmacy may use the ADDS audit report programs. However, when using these audit programs, the board recommends the pharmacy should also consider the following:

- A review of the records of acquisition for the controlled substances being audited.
- A review of the records of disposition for the controlled substances being audited, include expired drugs removed, drugs removed due to breakage, etc.
- Review of discrepancy reports and adjustments made for shortages and overages, including all discrepancy reports opened and closed, and unaccounted-for losses.
- The total loss of each controlled substance during the audit period, resulting from shortages, especially when the count is adjusted. If the total loss causes the aggregated amount to equal or exceed the thresholds listed in CCR §1715.6, the losses must be reported to the board.
- All shortages were investigated to determine the cause.
- When there is a shortage, the policies and procedures were reviewed to determine if any changes were needed to prevent the shortage from reoccurring.

CCR §§1715.65(b), (c), (h), 1715.6

<u>Clinics licensed pursuant to BPC 4180 and 4190</u>:

14. Our surgical center maintains a perpetual inventory for controlled substances. Can we use the counts from the perpetual inventory for the inventory reconciliation report?

No. The surgical clinic is required to take a physical count, not an estimate, of all quantities of each federal controlled substance covered by the inventory reconciliation report. If the inpatient hospital pharmacy uses an ADDS to stock the controlled substances, the inventory in the ADDS may be accounted for by using a means other than a physical count.

CCR §§1715.65(c)(1), (h)

15. We are a surgical clinic that is listed on the general acute care license as an approved service. We do not have a separate clinic license pursuant to BPC 4180 or BPC 4190. The hospital pharmacy provides the medications for the surgical clinic used for administration only in an ADDS. Does the board require the surgical clinic to conduct a separate inventory reconciliation?

No. If the controlled substance in the ADDS is stocked by the inpatient hospital pharmacy, the controlled substances in the ADDS will need to be included in the inpatient hospital pharmacy inventory reconciliation report. CCR §1715.65(a)

16. I am a consulting pharmacist at an ambulatory surgical center (ASC) that is not licensed with the board pursuant to BPC 4190. Based on the Capen decision in 2013, does an ASC that is not licensed with the board required to perform inventory reconciliation reports?

No. ASC who are not licensed by the board are not required to comply with CCR §1715.65, since it is not licensed as a pharmacy nor a clinic with the board. The controlled substance acquired for the ASC would be acquired by the licensed prescriber authorized to purchase controlled substances. BPC §§4170, 4059(b)

17. At a surgical clinic licensed by the board, can a registered nurse perform the physical count of the federal Schedule II controlled substances?

Yes. CCR §1715.65 does not specify who is required to perform the physical count. However, any individual who performs the required inventory must be authorized to access controlled substances and sign and date the inventory or inventory reconciliation report. CCR §§1715.65(c)(1), (e)(1)

18. Our surgical clinic verifies the inventory count twice each day. Are we required to do inventory reconciliation quarterly for the federal Schedule II controlled substances?

Yes. Every clinic licensed with the board must perform periodic inventory activities and prepare inventory reconciliation reports. CCR § 1715.65(a)

Correctional Clinics – BPC §4187:

19. Our pharmacy stocks federal Schedule II controlled substance in ADDS at each of the correctional clinics at the prison. Are we required to perform a physical count of these controlled substances in the ADDS for the inventory reconciliation?

No. If the correctional clinic, operated by the California Department of Corrections and Rehabilitation, uses an ADDS to stock the controlled substances, the controlled substance inventory in the ADDS may be accounted by using a means other than a physical count. CCR §1715.65(h)

20. The county outpatient pharmacy operates ADDS at the county jail. Are we required to perform a physical count of the controlled substances in the ADDS for the inventory reconciliation and inventory activities?

Yes. A county jail is operated by the county where it is located and not by the California Department of Corrections and Rehabilitation. Therefore, every pharmacy licensed with the board must perform periodic inventory activities and prepare inventory reconciliation reports. CCR § 1715.65(a)

Compounding Pharmacies:

21. We have hydromorphone powder used for compounding. We are concerned, each time the powder is weighed, drug loss may occur with each transfer in and out of the bottle. Is the pharmacy required to physically count the powder by weighing out the powder by emptying the contents and recording the weight of the powder?

No. The board recommends that when the pharmacy receives a new bottle of a powder for a federal Schedule II controlled substance and when a physical count is required for the inventory reconciliation, the pharmacy records the weight of the bottle with the powder remaining in the bottle. CCR §1715.65(c)(1)

Long Term Care (LTC) Pharmacies:

22. We are a LTC pharmacy and provide the long-term care facilities with emergency kits stored in secured containers which contain federal Schedule II controlled substances. Are the federal Schedule II controlled substances in the emergency kits required to be physically counted for the inventory reconciliation?

Yes. A physical count is required. CCR §1715.65(c)(1)

23. Our LTC pharmacy operates ADDS at various long term care facilities, and these ADDS include federal Schedule II controlled substances. Are the federal Schedule II controlled substances stored in the ADDS required to be physically counted for the inventory reconciliation?

Yes. Only inpatient hospital pharmacies and licensed correctional pharmacies that uses an ADDS may account for the inventory in the ADDS using means other than a physical count. CCR §§1715.65(c)(1), (h).

Attachment 6

Proposed Revisions to Frequently Asked Questions: Pharmaceutical and Sharps Waste Stewardship Programs

Note: proposed revisions are highlighted in yellow.

Senate Bill 212 (Jackson, Chap. 1004, Statutes of 2018) was signed by Governor Newsom on September 30, 2018. This bill was codified in the California Public Resources Code, Chapter 2, sections 42030-42036.4. This bill leveraged existing law regarding drug-take back provisions established under pharmacy law and federal law and medical waste management provisions administered by the California Department of Public Health to create a new stewardship program to ensure that a "covered entity" pays for the proper disposal of "covered products" shipped into California. This Board was given certain enumerated responsibilities under the bill. The bill requires the following with respect to the Board of Pharmacy:

- "Covered entities" had to report to the Board by April 1, 2021 a list of the "covered products" and a list of drugs or sharps that are not covered products that it sells or offers for sale in California. **Pub. Resources Code section 42031(a)(1).**
- By January 15 each year, a "covered entity" or the stewardship program to which it belongs must update its list of "covered products" and uncovered products with Board. **Pub. Resources Code section 42031(a)(2).**
- Retail pharmacies that sell a covered product under its own store label were required to notify the Board of the "covered entity" that supplied the retail pharmacy with its store label covered products. **Pub. Resources Code section 42031(b).**
- The Board must verify the information received from covered entities regarding its covered products and from retail pharmacies identifying the supplier of any store label covered products. **Pub. Resources Code section 42031(c).**
- The Board also must review proposed stewardship plans for compliance with pharmacy law and make a determination whether the plan complies with pharmacy law. **Pub. Resources Code section 42032(b).**

The Board has other authorized duties under this law. However, primary oversight over the implementation of this new program lies with the California Department of Resources Recycling and Recovery (CalRecycle), including final approval of stewardship plans and enforcement of these new provisions.

1. How does a covered entity submit a list of products?
   You can email the list of covered and non-covered products to BOPStewardship@dca.ca.gov. The Board provides a template to facilitate the submission and its review. Pursuant to Public Resources Code

(PRC) section 42031(a)(1), a covered entity must submit both a list of covered products, and a "a list and description of any drugs or sharps that are not covered products", **that is sells or offers for sale in California,** to the Board. A covered entity is responsible for the accuracy and completeness of the list.
Reference: PRC 42031(a)(1)

2. How often shall a covered entity submit the list of products?
   Public Resources Code section 42031(a)(2) specifies that a covered entity or a stewardship organization on behalf of a group of covered entities shall submit an updated list with highlighted changes to the Board on or before January 15 of each year or upon request.
   Reference: PRC 42031(a)(2)

3. Are auto-injectors and pre-filled syringes "covered products"?
   Yes. Pursuant to Public Resource Code section 42030 (g), "covered product" means a covered drug or home-generated sharps waste. **Auto-injectors and pre-filled syringes are "covered products" unless they meet the exclusion criteria set forth in PRC 422030(e)(2) or PRC 42030(l)(2).**
   Reference: PRC 42030(g)

4. Are intramuscular injection needles used by ultimate users at home "covered products"?
   Yes. Intramuscular injection needles, such as the ones for testosterone injection, are used to penetrate skin for the delivery of medication. They are "home-generated sharps waste" pursuant to Health & Safety Code (HSC) Section 117671, and thus "covered products" pursuant to Public Resource Code section 42030 (g).
   Reference: PRC 42030(g); HSC 117671

5. Can an ultimate user bring sharps waste to a pharmacy or deposit sharps waste into a drug take-back kiosk?

   Pursuant to California Code of Regulations (CCR), tit. 16 section 1776.1(e), medical sharps and needles shall not be deposited into a drug take-back kiosk. Under Business and Professions Code (BPC) section 4146, a pharmacy is permitted but not required to accept sharps containers. Please check https://www.calrecycle.ca.gov/epr/pharmasharps/sharps/ for more information about sharps waste stewardship.
   Reference: CCR 1776.1(e); BPC 4146

6. Some drugs are only being used in clinical settings. Are they "covered drugs"?

   Pursuant to Public Resource Code section 42030(e)(1), a "covered drug" means a drug sold, offered for sale, or dispensed in or into the State of

California. Additionally, Business and Professions Code sections 4024 and 4016 defines "dispense" and "administer", respectively.
Based on the relevant sections of the law, a drug that is SOLELY administered in clinical settings within the definition of BPC section 4016, and not offered, sold or dispensed to a patient in California, would not be considered a "covered drug". Public Resources Code section 42031(a)(1) requires that "covered entities" submit a list of covered and uncovered products, and the Board prefers that potential covered entities submit to the Board a statement why its drugs should not be considered "covered drugs" based on any such statutory interpretation. The potential covered entity is responsible for the truthfulness of such statement.
Reference: PRC 42030(e)(1); BPC 4016, 4024

7. Are APIs (Active Pharmaceutical Ingredients) "covered drugs"?
   APIs are not finished drugs, thus not "covered drugs" pursuant to Public Resource Code section 42030(e).
   Reference: PRC 42030(e)

8. How do I know if I am a "covered entity"?
   Please refer to Public Resource Code section 42030(f) for the definition of "covered entity". Please contact CalRecycle at pharmasharpsenforcement@calrecycle.ca.gov for interpretive questions regarding a "covered entity".
   Reference: PRC 42030(f)

9. Where can I find the list of "covered products" and "covered entities"?
   Pursuant to California Public Resource Code 42035(a)(1), on or before June 30, 2022, CalRecycle will post on its Internet Web site (https://www.calrecycle.ca.gov/epr/pharmasharps) a list of stewardship organizations, including entities with an approved stewardship plan, and covered entities, authorized collection sites, retail pharmacies, and retail pharmacy chains provided in the stewardship plans that are in compliance with this chapter. The law does not require posting of a list of "covered products".
   Reference: PRC 42035(a)(1)

10. Where can I find information regarding stewardship organizations and stewardship plans?
    You can find information about potential stewardship organizations at https://www.calrecycle.ca.gov/epr/pharmasharps/coveredentities You can find information about Pharmaceutical Stewardship Plans at https://www.calrecycle.ca.gov/epr/pharmasharps/pharma/plan, and Home-Generated Sharps Waste Plans at https://www.calrecycle.ca.gov/epr/pharmasharps/sharps/plan.

11. What are the responsibilities of a wholesaler in compliance with SB212?
A wholesaler may be considered a "covered entity" per the tiered definition under Public Resource Code 42030(f). Wholesalers should coordinate with appropriate entities in their supply chains to determine how statutory and regulatory requirements will be met.
In addition, a wholesaler has the reporting responsibility pursuant to Public Resource Code 42035(c). A wholesaler shall determine if covered products are in compliance with the law, by verifying that the covered entities providing the covered products are in compliance with the law and shall notify CalRecycle if it determines that the covered entity is not listed on CalRecycle's Internet Web site.
Reference: PRC 42030(f), Reference: PRC 42035(c)

12. How can a pharmacy participate in a stewardship plan for pharmaceutical or home- generated sharps waste?

A pharmacy can contact approved stewardship plan operators for participating in the program. Please check https://www.calrecycle.ca.gov/epr/pharmasharps/coveredentities/for approved stewardship plans and their contact information.

13. Are compounded medications "covered drugs"?
Compounded medications are exempted from section 505 of the Federal Food, Drug and Cosmetics Act (21 U. S.C. 355). Therefore, compounded medications are not "covered drugs" under the stewardship program.
Reference: PRC 42030(e)(1)

14. Can a covered entity include non-covered drugs to the covered drug list?
The intent of the SB212 is to ensure the safe disposal of pharmaceutical and home- generated sharps wastes. In the spirit of the law, the Board does not view it as a violation of law if a covered entity voluntarily elects non-covered drugs to be covered under a stewardship plan.

15. Where can I get more information if needed?
You can find more information at CalRecycle's web site: https://www.calrecycle.ca.gov/epr/pharmasharps. Questions regarding "covered drugs" or "covered products" should be directed to bopstewardship@dca.ca.gov. Questions regarding "covered entity" and other provision of SB212 should be directed to pharmasharpsenforcement@calrecycle.ca.gov

16. How do I know if an over-the-counter drug is a "covered drug"?
Public Resource Code 42030(e)(1)(B) states a drug marketed under an over-the-counter drug monograph is a "covered drug". Pursuant to Public Resource Code 42030(e)(1)(A), non-prescription drugs (over-the-

counter drugs) marketed under NDA or ANDA pursuant to Section 505 of the Federal Food, Drug and Cosmetic Act or Section 351 of the Federal Public Health Service Act are also "covered drugs". There are some exclusions pursuant to Public Resource Code 42030(e)(2)(C). Please note whether a product is a cosmetic or/and a drug under the law is determined by a product's intended use. Different laws and regulations apply to each type of product. The Board recommends potential covered entities examine their over-the-counter drugs for their intended uses and contact appropriate agents, including potentially a lawyer, for guidance of whether their particular product is a covered drug. Reference: PRC 42030(e)(1)(A); 42030(e)(1)(B); 42030(e)(2)(C); FDA Is It a Cosmetic, or a Drug, or Both?

17. **If a covered entity does not currently offer a drug for sale, could that drug still be considered a "covered drug"?**
Yes. Pursuant to PRC 42030(e)(1), "covered drug" includes drugs that were sold, offered for sale, or dispensed in the State of California. If the drug is no longer produced or no longer offered for sale, it could still be considered a "covered drug" under this law.

18. **If a covered entity does not currently offer a "covered drug" for sale, does the covered entity still need to report the covered drug?**
No. PRC 42031(a) states a covered entity shall provide a list of covered products and a list of any drugs or sharps that are not covered products, that it sells or offers for sale in the state to the Board. While a drug may still be covered, the covered entity does not need to report it if the drug is no longer for sale in the State of California.

Attachment 7

Board of Pharmacy

Enforcement Workload Statistics FY 2023/24

Complaint Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	765	0	0	0	765
Closed	764	0	0	0	764
					Quarter Ending
Pending	1,932	0	0	0	1,932
Average Days for Investigation	213	0	0	0	213

Cases Under Investigation (By Team)	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Compliance / Routine	745	0	0	0	745
Drug Diversion / Fraud	241	0	0	0	241
Prescription Drug Abuse	221	0	0	0	221
Compounding	40	0	0	0	40
Outsourcing	16	0	0	0	16
Probation / PRP	42	0	0	0	42
Enforcement	53	0	0	0	53
Criminal Conviction	571	0	0	0	571

Application Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	64	0	0	0	64
Closed					
Approved	28	0	0	0	28
Denied	7	0	0	0	7
Total Closed (includes withdrawn)	***38***	***0***	***0***	***0***	***38***
Pending	102	0	0	0	102

Complaint Closure Outcomes Not Resulting in Further Action	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Insufficient Evidence	229	0	0	0	229
Non-Jurisdictional	115	0	0	0	115
No Violation	51	0	0	0	51
No Further Action	33	0	0	0	33
Other - Non-Substantiated	59	0	0	0	59
Subject Educated	21	0	0	0	21

Letter of Admonishments / Citations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
LOA Issued	47	0	0	0	47
Citations Issued	270	0	0	0	270
Proof of Abatement Requested	36	0	0	0	36
Appeals Referred to AG's Office	42	0	0	0	42
Dismissed	3	0	0	0	3
Total Fines Collected	***$702,692***	***$0***	***$0***	***$0***	***$702,692***

Administrative Cases	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Referred to the AG's Office	78	0	0	0	78
Pleadings Filed	75	0	0	0	75
Total Closed	46	0	0	0	46
Pending					Quarter Ending
Pre-Accusation	144	0	0	0	144
Post-Accusation	169	0	0	0	169
Total Pending	**313**	**0**	**0**	**0**	**313**

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation					
Pharmacist	2	0	0	0	2
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	8	0	0	0	8
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	***11***	***0***	***0***	***0***	***11***

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

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation, stayed, probation					
Pharmacist	8	0	0	0	8
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	4	0	0	0	4
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	2	0	0	0	2
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***14***	***0***	***0***	***0***	***14***

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

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Public Reproval / Reprimand					
Pharmacist	6	0	0	0	6
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	1	0	0	0	1
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	1	0	0	0	1
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***8***	***0***	***0***	***0***	***8***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Granted (with or w/o conditions)					
Pharmacist	0	0	0	0	0
Intern Pharmacist	1	0	0	0	1
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	1	0	0	0	1
Total	***2***	***0***	***0***	***0***	***2***

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

Administrative Case Cost Recovery Efforts	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Cost Recovery Requested	***$361,102***	***$0***	***$0***	***$0***	***$361,102***
Cost Recovery Collected	***$254,704***	***$0***	***$0***	***$0***	***$254,704***

Immediate Public Protection Sanctions	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Interim Suspension Orders	1	0	0	0	1
Automatic Suspension Orders	1	0	0	0	1
Penal Code 23 Restrictions	2	0	0	0	2
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	164	0	0	0	164
Intern Pharmacist	2	0	0	0	2
Pharmacy Technician	20	0	0	0	20
Designated Representative	1	0	0	0	1
Wholesaler / 3PL	2	0	0	0	2
Pharmacy	52	0	0	0	52
Sterile Compounding	9	0	0	0	9
Outsourcing	0	0	0	0	0
Total	***250***	***0***	***0***	***0***	***250***
Probation Compliance Measures					Total
Probation Office Conferences	18	0	0	0	18
Probation Interviews / Site Inspections	141	0	0	0	141
Probation Terminated / Completed	25	0	0	0	25
Referred to AG for Non-Compliance	0	0	0	0	0

As of 9/30/2023

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 2023 through June 2024.

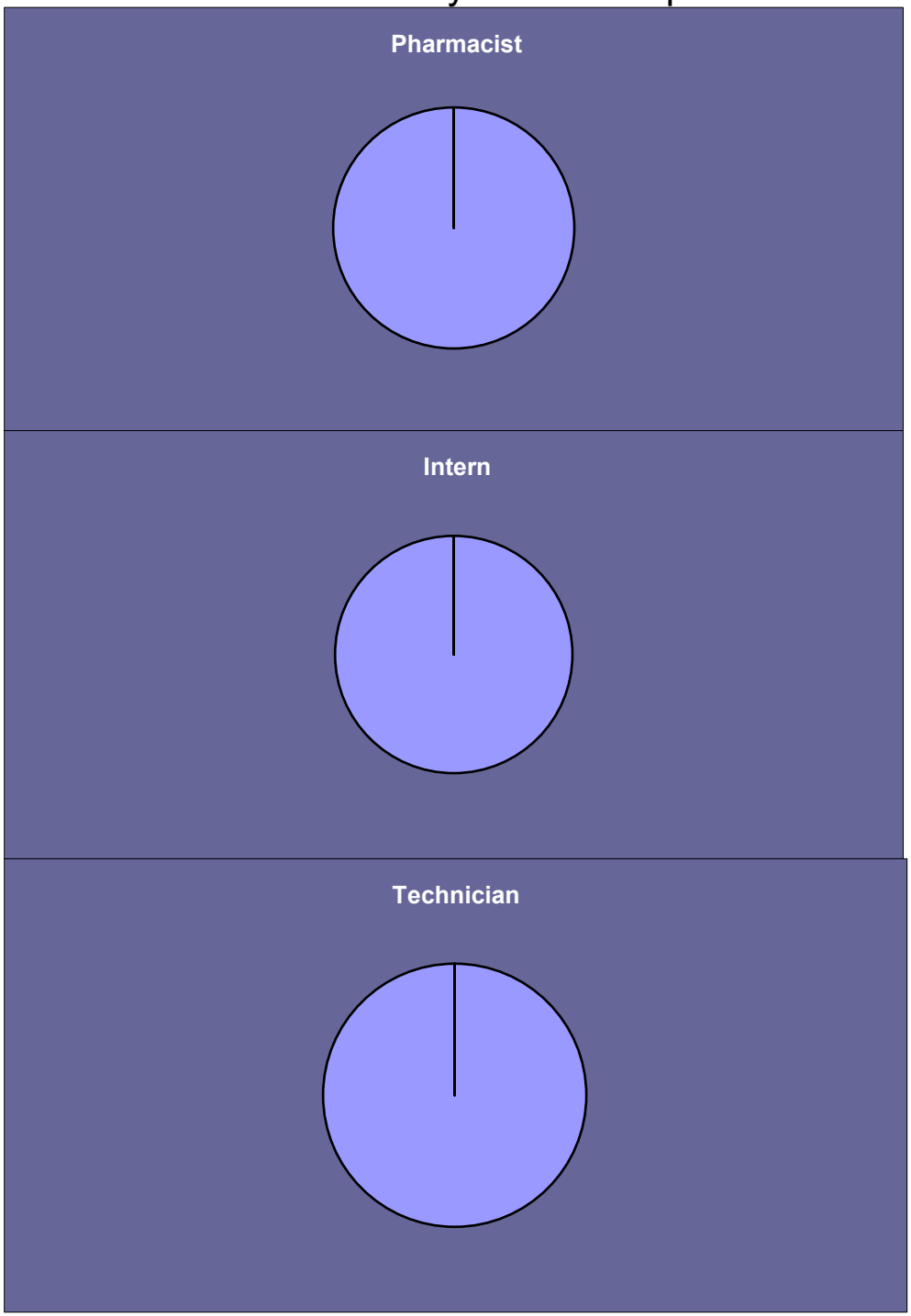
Board of Pharmacy	July -Sep	Oct – Dec	Jan Mar	Apr Jun	23/24
PRP Intakes					
PRP Self-Referrals					
PRP Probation Referrals	1				1
PRP Under Investigation	2				2
PRP In Lieu Of (investigation conducted)	2				2
Total Number of PRP Intakes	5				5
New Probationers					
Pharmacists					
Intern Pharmacists	1				1
Pharmacy Technicians	4				4
Total New Probationers	5				5
PRP Participants and Recovery Agreements					
Total PRP Participants	28				N/A
Recovery Agreements Reviewed	23				23
Probationers and Inspections					
Total Probationers	40				N/A
Inspections Completed	20				20
Referrals to Treatment					
Referrals to Treatment (PRP and Probationers)	1				1
Drug Tests					
Drug Test Ordered (PRP and Probationers)	404				404
Drug Tests Conducted (PRP and Probationers)	389				389
Relapses (Break in Sobriety)					
Relapsed (PRP and Probationers)	3				3
Major Violation Actions					
Cease Practice/Suspension (PRP and Probationers	7				7
Termination from PRP	2				2
Probationers Referred for Discipline	1				1
Closure					
Successful Completion (PRP and Probationers)	3				3
Termination (Probation)	1				1
Voluntary Surrender (Probation)	1				1
Surrender as a result of PTR (Probation)	1				1
Closed Public Risk (PRP)	2				2
Non-compliance (PRP and Probationers)	6				6
Other (PRP)	2				2
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 23/24**
Alcohol	2				2
Ambien					
Opiates					
Hydrocodone					
Oxycodone					
Morphine					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					

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 2023 through June 2024.

Board of Pharmacy	July -Sep	Oct – Dec	Jan Mar	Apr Jun	23/24
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 23/24**
Alcohol	2				2
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Pharmacy Technicians	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 23/24**
Alcohol	4				4
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					

Drug Of Choice - Data entered from July 2023 to September 2023



1 Alcohol
2 Opiates
3 Hydrocodone
4 Oxycodone
5 Benzodiazepines
6 Barbiturates
7 Marijuana
8 Heroin
9 Cocaine
10 Methamphetamine
11 Pharmaceutical Amphetamine

Printed on 10/6/2023

Board of Pharmacy

Citation and Fine Statistics FY 2023/24

Citation Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Pharmacist with Fine	24	0	0	0	24
Pharmacist-in-Charge with Fine*	13	0	0	0	13
Pharmacist no Fine	78	0	0	0	78
Pharmacist-in-Charge no Fine*	48	0	0	0	48
Pharmacy with Fine	134	0	0	0	134
Pharmacy no Fine	22	0	0	0	22
Pharmacy Technician with Fine	4	0	0	0	4
Pharmacy Technician no Fine	7	0	0	0	7
Wholesalers	0	0	0	0	0
Designated Representative	1	0	0	0	1
Clinics	0	0	0	0	0
Drug Room	0	0	0	0	0
Exempt Hospital	1	0	0	0	1
Hospital Pharmacy	2	0	0	0	2
Miscellaneous**	17	0	0	0	17
Unlicensed Premises	2	0	0	0	2
Unlicensed Person	0	0	0	0	0

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

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

Top Ten Violations by License Type

Pharmacists	%	Pharmacies	%	Pharmacists In Charge	%
1716 - Variation from prescription	48%	4113(d) - Every pharmacy shall notify the board in writing within 30 days of the date of a change in pharmacist-in- charge	23%	1716 - Variation from prescription	24%
1764/56.10(a) - Unauthorized disclosure of prescription and medical information	11%	1716 - Variation from prescription	23%	1714(c) - Operational Standards and Security; pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition	15%
1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	6%	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%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	9%
733(a) - Dispensing prescription drugs and devices- No licentiate shall obstruct a patient in obtaining a prescription	6%	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	12%	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	9%
1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	5%	733(a) - Dispensing prescription drugs and devices- No licentiate shall obstruct a patient in obtaining a prescription	8%	1707.2(a) - Duty to consult: A pharmacist shall provide oral consultation to his or her patient or the agent of patient in all care settings	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	5%	1764/56.10(a) - Unauthorized disclosure of prescription and medical information	5%	733(a) - Dispensing prescription drugs and devices- No licentiate shall obstruct a patient in obtaining a prescription	9%
1707.2(a) - Duty to consult: A pharmacist shall provide oral consultation to his or her patient or the agent of patient in all care settings	5%	1714(c) - Operational Standards and Security; pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition	5%	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	9%
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	5%	1714.3(c) - All impacted pharmacy employees and designated persons must read and sign a copy of the policies and procedures required by this section. For purposes of this section, “impacted pharmacy	4%	1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	6%
1707.3 - Duty to review drug therapy	5%	1708.2 - Discontinuance of business	4%	1735.2(k) - Compounding Limitations and Requirements; Self-Assessment - Prior to allowing any drug product preparation to be compounded in a pharmacy….	6%