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

# Enforcement and Compounding Committee Report
## July 18, 2023

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

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

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

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

## III. Discussion, Consideration and Approval of Draft Minutes from the April 13, 2023, Enforcement and Compounding Committee Meeting

**Attachment 1** includes a copy of the draft minutes.

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

Background

The formal administrative disciplinary case process is initiated after an investigation is conducted that reveals violations that, based on the egregiousness of the violations identified, result in referral to the Office of the Attorney General (AGO) for discipline. Upon referral to the AGO, the assigned Deputy Attorney General (DAG) will review the investigation and evidence and independently evaluate if violations occurred. Should such a determination be made, the DAG will prepare an accusation for filing before the Board. An accusation is a formal pleading document that details the allegations and charges levied against a licensee Respondent. Respondents are provided the option to refute the allegations and indicate their intention to do so by filing a Notice of Defense. Upon receipt of a Notice of Defense, the assigned DAG will request to set the matter for hearing before the Office of Administrative Hearings (OAH). The DAG and

Respondent (or Respondent's counsel) will exchange discovery, which includes the investigative file. If Respondent is interested in settling the case, Respondent will send mitigation evidence, which is evidence showing rehabilitation or corrective measures taken. Examples of mitigation evidence are set forth in the Board's Manual of Disciplinary Guidelines and Model Disciplinary Orders. Typically, the case is resolved in one of two manners: (1) the disciplinary outcome is reached through a settlement agreement (stipulation); or (2) a hearing is conducted at OAH, followed by a proposed decision from the administrative law judge (ALJ) who is assigned to hear the matter on behalf of the Board. In either manner, the Board is ultimate decision maker and votes to either adopt or nonadopt a settlement agreement or proposed decision. Depending on the outcome of the vote, additional steps occur through the nonadoption process. If the Board decides to adopt it, the proposed settlement agreement or proposed decision will become a final decision of the Board.

For Committee Consideration and Discussion
During the meeting members will receive 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.

**Attachment 2** includes a copy of the presentation slides.

## V. 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.

For Committee Consideration and Discussion
During the meeting a presentation will be provided detailing inspection information focusing primarily on routine inspections. In fiscal year 2022/23, staff conducted 2,837 in person inspections including 889 routine inspections of pharmacies where the sole purpose of the inspection was triggered for routine evaluation. Of the routine inspections completed 415 inspections resulted in correction(s) being issued and 60 pharmacies were issued a notice of violation(s). Further, 94 routine inspections revealed violations of the Board's patient consultation requirements, either failure to provide consultation, failure to provide written notice of consultation on delivered or mail order prescriptions or failure of the written notice of consultation to meet all required elements. Data suggests approximately 4% of the Board's licensed pharmacies have

never been inspected. This is a decrease from 8% last year. 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.

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

## VI. 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 |
|---|---|---|---|---|---|
| | | | | | |
| Average Days to Complete | 381 | 400 | 426 | 341 | 325 |
| | | | | | |
| Amount of Fines Assessed | $1,176,450 | $1,462,300 | $787,100 | $2,029,012 | 2,358,337 |
| | | | | | |

For Committee Consideration and Discussion
During the meeting members will receive a presentation providing updated information on the Boards citation and fine program.

**Attachment 4** includes a copy of the presentation slides. Data reflects July 1, 2022, through June 16, 2023.

## VII. 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 Supervising Inspector Janice Dang presentation will be provided describing information related to quality assurance records received.

**Attachment 5** includes a copy of the presentation slides.

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

**Dispensing, and Repackaging**

Background

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

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

For Committee Consideration and Discussion

During the meeting members will have the opportunity to consider a draft statement intended to convey to stakeholders, the Board's policy related to licensees transitioning to the updated USP General Chapters and actions under consideration by the Board.

**Attachment 6** includes a copy of the draft statement.

## IX. Discussion and Consideration of Committee's Strategic Objectives

Background

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

For Committee Consideration and Discussion

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

**2.1 Evaluate, and take necessary actions, regarding the causes and effects of medication errors to reduce errors.**

July 2022 Status: Medication Error Reduction and Task Force Ad Hoc Committee established and has begun convening public meetings.

July 2023 Status: Board sponsors Assembly Bill 1286 (Haney), a patient-safety measure that includes provisions to establish mandatory reporting of medication errors.

**2.2 Analyze enforcement outcomes to identify trends to educate licensees of common violations and improve patient outcomes.**

July 2022 Status: Annual presentation on the Board's Citation and Fine Program and Board's Inspection Program provided and top violations published in the Board's newsletter.
July 2023 Status: Annual presentation on the Board's Citation and Fine Program and Board's Inspection Program provided. Top violations and corrections discussed with information published in the Board's newsletter.

**2.3 Complete routine inspections of all licensed pharmacies at least every four years to proactively assess pharmacy operations and educate licensees.**
July 2022 Status: In FY 2021/22, Board staff conducted 1,598 routine inspections.
July 2023 Status: In FY 2022/23, Board conducted 1,316 routine inspections

**2.4 Determine and reduce barriers to timely case resolution to improve consumer protection.**
July 2023 Status: Board votes to sponsor legislation to Business Professions Code Section s4081 and 4105, related to providing records for the Board.

**2.5 Assess, and pursue where appropriate, further use of a Standard of Care Enforcement Model to protect consumers.**
July 2022 Status: Standard of Care Ad Hoc Committee established and has begun convening public meetings.
July 2023 Status: Board submits report to the Legislature as required in Business and Professions Code Section 4301.3 related to the Board's assessment of Standard of Care Enforcement Model is the regulation of pharmacy.

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

**2.7 Write a Budget Change Proposal to increase the number of enforcement staff to ensure more regular inspections and investigations, and to improve case processing times.**
July 2023 Status: Board secures one inspector position related to new legislative requirements.
July 2022 Status: New inspector position received to perform inspections and related investigations stemming from new legislative mandates.

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

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

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

July 2023 Status: The Board approves draft regulations related to USP General Chapters 795, 797, 800 and 825.

## X. Review and Discussion of Enforcement Statistics

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

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

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

**Attachment 7** includes the enforcement statistics for the fiscal year and three-year comparison data.

## XI. Future Committee Meeting Dates

- October 19, 2023, in person and via WebEx **XII.**

## Adjournment

# Attachment 1

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# DRAFT ENFORCEMENT AND COMPOUNDING COMMITTEE MEETING MINUTES

**DATE:** April 13, 2023

**LOCATION:** Department of Consumer Affairs
1625 N Market Blvd, 1st Floor Hearing Room
Sacramento, CA 95834

Participation was also through WebEx.

**COMMITTEE MEMBERS PRESENT:** Maria Serpa, Licensee Member, Chair
Renee Barker, Licensee Member
Indira Cameron-Banks, Public Member
Seung Oh, Licensee Member
Ricardo Sanchez, Public Member

**COMMITTEE MEMBERS NOT PRESENT:** Jig Patel, Licensee Member, Vice Chair

**STAFF MEMBERS PRESENT:** Anne Sodergren, Executive Officer
Eileen Smiley, DCA Staff Counsel
Debbie Damoth, Executive Manager Specialist

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

Chairperson Maria Serpa called the meeting to order at approximately 9:00 a.m. Dr. Serpa reminded all present that the Board is a consumer protection agency. Dr. Serpa advised the meeting was being conducted with participation through WebEx and being webcast. The meeting moderator provided updated WebEx instructions.

Chairperson Serpa took roll call. Members present included: Renee Barker, Licensee Member; Indira Cameron-Banks, Public Member; Seung Oh, Licensee Member; Ricardo Sanchez, Public Member; and Maria Serpa; Licensee Member. A quorum was established.

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

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

A member of the public suggested another entity do the inspections for all of the California non-sterile compounding pharmacies and all of the out-of-state 503A compounding pharmacies. The commentor suggested licensees disclose as part of the renewal if they perform nonsterile compounding. If disclosed, an inspection would be required.

Members were surveyed to see if any items should be added to a future agenda; however, no comments were made.

## III. Approval of March 23, 2023, Enforcement and Compounding Committee Meeting Minutes

Chairperson Serpa referenced the draft minutes for the March 23, 2023, Enforcement and Compounding Committee Meeting.

Members were provided an opportunity to provide comments on the draft minutes; however, no comments were made.

Counsel Smiley requested being removed as having attended the meeting as Ms. Smiley was not present.

**Motion:** Approve the March 23, 2023, Committee Meeting Minutes as presented in the meeting materials with the correction of removing Counsel Smiley in attendance at the meeting.

**M/S**: Oh/Barker

Members of the public were provided with an opportunity to provide public comment; however, no comment was provided in Sacramento or via WebEx.

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

| Committee Member | Vote |
|---|---|
| Barker | Support |
| Cameron-Banks | Support |
| Oh | Support |
| Patel | Not Present |
| Sanchez | Not Present |
| Serpa | Support |

## IV. Presentation on USP General Chapter 800, Regarding Hazardous Drugs – Handling in Healthcare Settings

Chairperson Serpa introduced Supervising Inspector Ana Kalantar who provided a presentation on the revised USP Chapter 800 related to Pharmaceutical Compounding – Sterile Preparations which become effective November 1, 2023.

Supervising Inspector Kalantar provided a presentation on USP General Chapter 800, Regarding Pharmaceutical Compounding – Sterile Preparations. Dr. Kalantar provided a disclaimer regarding the opinions expressed in the presentation. Dr. Kalantar provided an overview including Introduction and Scope; List of Hazardous Drugs; Types of Exposure; Responsibilities of Personnel Handling Hazardous Drugs; Facilities and Engineering Controls; Environmental Quality and Control; Personal Protective Equipment; Hazard Communication Program; Personnel Training; Receiving; Labeling, Packaging, Transport, and Disposal; Dispensing Final Dosage Forms; Compounding; Administering; Deactivating, Decontaminating, Cleaning and Disinfecting; Spill Control; Documentation and Standard Operating Procedures; and Medical Surveillance.

The Committee took a break from 9:34 a.m. to 9:40 a.m. Chairperson Serpa took roll call after the break. Members present included: Renee Barker, Licensee Member; Indira Cameron-Banks, Public Member; Seung Oh, Licensee Member; and Maria Serpa; Licensing Member. A quorum was established.

Members were provided the opportunity to comment.

Chairperson Serpa commented under 532 Sterile Compounding when negative pressure was discussed between 0.01 and 0.03 that was -0.01 and -0.03 (negative

values). Dr. Serpa requested the slides be updated for the benefit of people reviewing the slides after the presentation.

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

**V. Discussion and Consideration and Possible Action on Proposal to add New Titles and Sections 1737-1738.18 to Article 4.7 of Division 17 of Title 16 of the California Code of Regulations Related to the handling of Hazardous Drugs**

Chairperson Serpa advised as the Committee continued work on reviewing the various USP chapters and review current and proposed regulations that may be necessary to implement, clarify, or make more specific requirements related to those respective chapters, Dr. Serpa believed it was appropriate that any such regulations mirror the structure of the respective chapters. This meant the numbering format and section titles for proposed regulations would mirror the USP chapter. Dr. Serpa clarified the goal was not to re-iterate provisions of federal law or USP language but to clarify or make more specific the requirements. Dr. Serpa noted if no clarification was needed or no additional requirements were necessary for public safety, no additional language was being proposed.

Chairperson Serpa reminded participants that the Board is a consumer protection agency. Dr. Serpa advised during development of regulations, it would be through the lens of the Board's consumer protection mandate as the law makes clear whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. Dr. Serpa recalled it was a dynamic process and individuals would have opportunities to participate throughout the development and rulemaking process.

Chairperson Serpa noted licensees of the Board generally must comply with a myriad of state and federal laws and at times, a licensee may be so focused on a specific section of the law, that they may forget the larger picture and other provisions of law that may be relevant. Dr. Serpa noted this was seen in several areas of pharmacy practice, but it was quite pronounced in compounding.

Chairperson Serpa reminded participants of the excellent overview Counsel Eileen Smiley provided during our January 2023 meeting covering the requirements for authorized individuals to qualify for some exemptions to federal law under provisions of section 503A. Dr. Serpa added the livestream of the meeting and the presentation slides were available on the Board's website. Dr. Serpa encourage individuals interested in this area to watch the livestream recording available from the Board's website. Dr. Serpa reiterated:

- The Committee would not be looking to add to regulations requirements already laid out in the USP chapters or federal law. The Committee was generally focused on detailing additional California state requirements related to the changes to the USP chapters.
- The discussions would be dealing with the standard for compounding pharmacies and compounding pharmacists operating in compliance with the exemption in Section 503A of the federal Food Drug and Cosmetic Act and not with 503B or outsourcing facilities.

Chairperson Serpa noted Section 503A was quite extensive, but felt it was appropriate to highlight that one of the specific conditions a licensee must meet to be eligible for the exemptions provided under 503A is that the drug product is compounded in compliance with USP chapters on pharmacy compounding. It was important that members and stakeholders understand prior to the discussion. Business and Professions Code (BPC) section 4126.8 explicitly states the Board has the authority to enforce any USP Chapters where incorporated by reference in Pharmacy Law and its regulations. Dr. Serpa clarified the Board can also add additional requirements to USP language but cannot promulgate a lesser standard in its regulation.

Chairperson Serpa noted that comments were received and posted on the Board's website; however, comments were appropriate for consideration during the April 2023 Board Meeting as the information was not on the Committee's agenda.

Chairperson Serpa reviewed the process for the meeting. Dr. Serpa requested staff display the language during the portion of the meeting to allow for edits to be made during the meeting where changes were appropriate.

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

Chairperson Serpa referenced proposed section 1737 provides that proposed article 4.7 applies to the handling of hazardous drugs, including the standards established in USP 800. The language also provided a cross reference to other articles relating to nonsterile and sterile compounding. The cross references served as a reminder to licensees that where appropriate consideration of the other requirements may be appropriate depending on the activities being performed.

**Title 16. Board of Pharmacy**
**Proposed Regulation**

**Proposal to Add Article 4.7 and add new titles and section 1737 – 1737.18 to Division 17 or Title 16 of the California Code of Regulations to read as follows:**
**Article 4.7 Hazardous Drugs**

**1737 Handling of Hazardous Drugs**

In addition to the standards established by United States Pharmacopeia (USP) General Chapter 800 (USP Chapter 800), titled *Hazardous Drugs – Handling in Healthcare Setting* shall meet the requirements of this Article.

A licensee performing non-sterile and sterile HD compounding shall comply with this article in addition to Article 4.5 and Article 4.6.

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

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

Chairperson Serpa referenced section 1737.1 Introduction and Scope. Dr. Serpa provided the proposed language in this section established a requirement to ensure that as part of patient consultation information was provided concerning the handling and disposal of the hazardous drugs and related supplies furnished. Dr. Serpa believed the language presented in the materials was appropriate and consistent with the Board's consumer protection mandate.

**1737.1 Introduction and Scope**

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

In addition to providing consultation in compliance with section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning on handling and disposal of an HD or related supplies furnished.

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

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

Chairperson Serpa referenced section 1737.2 List of Hazardous Drugs. Dr. Serpa provided the section established requirements for assessment of risks consistent with the standards of the chapter. The draft language also established a requirement for a review of the facilities hazardous drug must be review and approved. Also, unlike the provisions in the other articles as proposed in this section the draft language specified that the designated representative was a single person approved by the pharmacist-in-charge (PIC). Dr. Serpa reviewed the language

and believed it was appropriate and consistent with the Board's consumer protection mandate.

**1737.2 List of Hazardous Drugs**
The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) If an assessment of risk is performed as allowed in USP Chapter 800, it shall be performed or approved and documented at least every 12 months by the designated person and the pharmacist-in-charge, professional director of a clinic, or designated representative-in-charge, as applicable.

(b) The facility's list of HDs must be reviewed and approved by the designated person and the pharmacist-in-charge, professional director of a clinic, or designated representative-in-charge, as applicable. Approval shall be documented at least every 12 months.

(c) "Designated person" is a single individual approved by the pharmacist-in-charge to be responsible and accountable for the performance and operation of the facility and personnel as related to the handling of hazardous drugs. Nothing in this definition allows for the designated person to exceed the scope of their issued license. When the designated person is not a pharmacist, the Pharmacist-in-Charge (PIC) must review all practices related to the operations of the facility that require professional judgement.

Members were provided an opportunity to comment.

Member Barker recommended adding an "s" to "Drug" in the title.

Members of the public were provided an opportunity to comment.

A representative of UCSD Health had a question about the assessment of risk as written in USP 800 was vague and asked how the Board plans to review the assessments of risk. The representative's understanding from the USP Committee that the alternative containment strategies were to be equivalent in minimizing exposure which could be subjective. Chairperson Serpa referred to the USP FAQs.

A pharmacist representative of Pacific Compounding Pharmacy recommended moving section (c) to (a) because it defines the designated person (DP). As the commentor understands the PIC couldn't be the DP and recommended clarifying the PIC could be the DP too.

A pharmacist Kaiser representative requested empirical data be presented for changes recommended and demonstrate the necessity to protect the public. The

representative stated the statement, "When the designated person is not a pharmacist, the Pharmacist-in-Charge (PIC) must review all practices related to the operations of the facility that require professional judgement." was not clear and requested clarification. The representative recommended the Board specify the nature of the record that was required to document the PIC's review of the practices that require the professional judgement of a pharmacist.

A commenter requested clarification if section (c) allowed for only one DP where USP allows for multiple DPs. Chairperson Serpa clarified this was the intent.

Chairperson Serpa indicated the renumbering of the section could be done offline with staff.

Members were provided to provide comment after public comment was received; however, no comments were made.

Chairperson Serpa referenced section 1737.3 Types of Exposure. Dr. Serpa provided the proposed language would require each entity to ensure that all employees were aware of the types of risks of exposure that may occur. Dr. Serpa agreed with the language and also suggested that an FAQ may be appropriate to include the various types of entities that could be covered.

**1737.3 Types of Exposure**
The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

Each entity shall ensure that all employees are aware of the types of risks of HD exposures that may occur as documented in the Chapter. This shall be documented in SOPs and training documents.

Members were provided an opportunity to comment.

Member Barker asked how entity was being defined for this regulation. Ms. Sodergren clarified the language was for many types of settings. Dr. Serpa noted it included those licensed by the Board.

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

Chairperson Serpa referenced section 1737.4 Responsibilities of Personnel Handling Hazardous Drugs. Dr. Serpa provided the proposed language would specify who was responsible for all of the activities and decisions made or approved by the designated person. This language ensured that the individual responsible for overall operational compliance has a clear understanding that their responsibility extends

to hazardous drug handling. Dr. Serpa believed the language was appropriate and consistent with the Board's mandate.

**1737.4 Responsibilities of Personnel Handling Hazardous Drugs**
The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

The Pharmacist-in-charge, designated representative-in-charge, professional director, as applicable shall be responsible for all activities and decisions made or approved by the designated person.

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

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

Chairperson Serpa referenced section 1737.5 Facilities and Engineering Controls. Dr. Serpa provided there were a number of requirements established in this section. Dr. Serpa noted that provisions were intended to reduce exposure risks, as an example section (a) requires the need to minimize traffic into the sterile compounding language. There were also provisions in (d) to require interlocking pass-through doors by January 1, 2026. This provides time for facilities to make changes to comply. Also, in (e) the proposed language included cross-reference to CETA Guidelines, similar to proposed regulation language for sterile compounding. Dr. Serpa believed the proposed language was appropriate and consistent with the Board's consumer protection mandate.

**1737.5 Facilities and Engineering Controls**
The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) HDs used for nonsterile compounding shall not be stored in areas designated for sterile compounding to minimize traffic into the sterile compounding area.

(b) When a containment primary engineering control (C-PECs), used for nonsterile and sterile HDs is placed in the same room, biannual certification must document that the room can continuously maintain ISO 7 classification throughout the nonsterile compounding activity. Specific standard operating procedures (SOPs) shall be written to address the maintenance of the ISO 7 classification.

(c) Handling volatile HDs:
(1) HEPA filters shall not be the only means of containment used.

(2) for sterile compounding, a biological-safety cabinet (BSC) as defined in USP Chapter 800 Class II Type A1 shall not be used.

(d) Where a pass-through is installed in a containment SEC the doors must be gasketed and interlocking. Effective January 1, 2026, all pass-through doors shall be a HEPA purge type pass-through vented to an unclassified space. A pass-through is not allowed between the containment SEC into an unclassified space.

(e) Facility room pressure monitoring equipment shall be placed consistent with CETA Guidelines CAG-003:2022. SOPs shall address corrective and remedial actions in the event of pressure differentials and air changes per hour excursions.

(f) Containment Supplemental Engineering Controls (CSTDs) shall not be used to extend the in-use time, BUD, or expiration of any manufactured product or HD CSP.

(g) CSTDs shall be used when compounding antineoplastic HDs when the dosage form allows.

Members were provided the opportunity to comment.

Member Barker requested clarification on (c)(1) if the language should specify what shall be included rather than what shall not be included. Supervising Inspector Acosta advised the intent was to drive home what the chapter says is required. Dr. Serpa reminded participants the Board's regulations were on top of USP.

Member Barker ask for clarification about (d) to see if the two sentences could be combined. Dr. Serpa clarified in (d) there were three components adding that (1) and (3) could be combined but the (2) was a standalone. Dr. Serpa clarified the purge functionality was being added as a standard starting in 2026. Dr. Barker inquired if it applied to a containment SEC, the HEPA filter purge type. Dr. Serpa asked the Supervising Inspectors if language would need to be added to make it clearer that the Board is talking about the HEPA purge filter was only for devices covered under USP 800. Dr. Acosta suggested making (d) into two sections. Dr. Acosta inquired if in 2026 when all pass-through doors shall be HIPAA purge type pass throughs to an unclassified space. Dr. Acosta added by starting by saying containment SEC, it was clear it was for HD only. Dr. Acosta noted the regulations could be reviewed for continuity as was done for USP 795 and USP 797.

Members of the public were provided the opportunity to comment.

A compounding pharmacist commented on (e) as being outdated and not providing location or placement. The compounding pharmacist commented on (g) that "shall" instead of "should" was too strong language.

A pharmacist representative of Sutter Health commented on (c) about the term "handling" as it was already defined in USP and proposed to specified clarification. The pharmacist representative commented on section (f) if an FAQ could provide an example.

A pharmacist representative of Kaiser commented on (a) the requirement around storage of HD used for non-sterile compounding and not storing those in areas designated for sterile compounding. The representative noted that there were some facilities that may infrequently compound non-sterile HD drugs on occasion and didn't agree with the requirement for those who do it on occasion. The representative commented about (c) with a concern about for inspection purposes with the term "volatile" and requested clarification. The representative commented on (d) noting concern that the requirement of a pass through not go from C-SEC to classified space could result in reduce access to public.

A representative from UCSD Health requested clarification about the pass through effective 1/1/26. Dr. Serpa clarified and updated the language so that after 1/1/26 all pass through doors shall be a HEPA purge pass through.

Chairperson Serpa summarized the changes discussed and requested: suggesting that (d) be divided into two sections; changing the word "handling" in (c); suggesting FAQ for (f); and suggesting more discussion on (a) as for environmental and personal safety, it was better to have the non-sterile and sterile be separated.

Member Barker noted it was worth discussing again because if not to be stored in a sterile compounding area but bringing supplies into the area, SOPs would apply. Dr. Barker added it could be tested during environmental testing and understood it creates a hard situation to store a small amount of drugs in the new space. Ms. Sodergren suggested adding to (a) "contamination and" as well as "except as defined in the SOPs."

Chairperson Serpa referenced section 1737.6 Environmental Quality and Control. Dr. Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. The proposed language specified requirements for the standard operation procedures to establish provisions for environmental wipe sampling and clarified the proposed language included the minimum actions that number be taken when actionable contamination is found.

**1737.6 Environmental Quality and Control**

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.
(a) An entity's SOPs shall address environmental wipe sampling for HD surface residue, its frequency, areas of testing, levels of measurable contamination, and actions when those levels are exceeded.
(b)When actionable contamination is found, at minimum the following shall occur:
(1) Reevaluate work practices
(2) Reevaluate the appropriateness of deactivation, decontamination and cleaning agents
(3) Re-train personnel on deactivation, decontamination and cleaning
(4) Re-train personnel on donning and doffing appropriate PPEs

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

Members of the public were provided an opportunity to comment.

A pharmacist representative from Kaiser commented on (a) and (b) reading as a facility selecting the frequency including not doing the wipe sampling at all. The representative asked if that was the case, the regulation believed the appropriate level of flexibility was allowed to determine the frequency and nature of wipe sampling to be perform. Specifically, on (b), proposed text read "when actionable contamination is found" and suggested modifying to say "when contamination that exceeds the level specified in the entity's SOP is found" to be clearer. Dr. Serpa asked Dr. Kalantar if a frequency of none was allowable. Dr. Kalantar commented a frequency was required.

A compounding pharmacist added USP 800 requires every six months sampling but recommended USP 800 to stand on its own in terms of wipe sampling and requested evidence.

Chairperson Serpa addressed the request for (b) to harmonize with "actionable" in USP 797.

The Committee took a break from 10:53 a.m. to 11:05 a.m. Chairperson Serpa took roll call after the break. Members present included: Renee Barker, Licensee Member; Indira Cameron-Banks, Public Member; Seung Oh, Licensee Member; Ricardo Sanchez, Public Member; and Maria Serpa; Licensing Member. A quorum was established.

Chairperson Serpa referred to section 1737.7 Personal Protective Equipment (PPE). Dr. Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. Dr. Serpa noted the use of PPE was

extremely important in protecting staff and there were many provisions in this section that were permissive in Chapter 800 that the proposed language will make as requirements. Dr. Serpa provided as an example (d) makes requirements specifically related the removing of PPE. The proposed language in this subsection provides specific information that PPE worn during compounding must be disposed of in a proper waste container while also establishing that the SOPs must describe where donning and doffing can occur.

**1737.7 Personal Protective Equipment (PPE)**

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) Two pairs of gloves labeled to meet the ASTM D-6978 standard shall be worn for handling HD waste, cleaning HD spills, and performing routine cleaning in HD areas.

(b) The outer pair of gloves labeled to meet the ASTM D-6978 standard chemotherapy gloves shall be changed every 30 minutes during compounding unless otherwise recommended by the manufacturer's documentation. Documentation from the manufacturer shall be readily retrievable. For sterile compounding both pairs of gloves labeled to meet the ASTM D-6978 standard chemotherapy gloves shall be sterile.

(c) Outer gloves used for compounding must be changed between each different type of HD preparation and the standards established in Chapter 800 if continuously compounding a single HD preparation. The facilities SOPs shall define the circumstances under which the gowning and gloves must be changed between HD handling/preparations.

(d) PPE shall be removed cautiously to avoid transferring contamination to skin, the environment, and other surfaces. PPE worn during compounding shall be disposed of in the proper waste container before leaving the C-SEC. SOPS must be in place which describe in detail the donning and doffing of PPE and where it takes place in the C-SEC.

(e) An appropriate full-facepiece, chemical cartridge-type respirator or powered air-purifying respirator (PAPR) shall be worn when there is a risk of respiratory exposure to HDs, including when:

(1) Attending to HD spills larger than what can be contained with a spill kit
(2) Deactivating, decontaminating, and cleaning underneath the work surface of a C-PEC
(3) There is a known or suspected airborne exposure to powders or vapors.

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

Members of the public were provided an opportunity to comment.

A compounding pharmacist representative of Pacific Compounding Pharmacy requested removing "labeled" and change to "two pairs of gloves that meet the ASTM d697 etc. standard" noting meeting the standard was appropriate but not all gloves that meet the standard actually pay to have the labeling. The commenter requested better defining "type."

A pharmacist representative of Kaiser agreed with the prior comment regarding the gloves in (a). The representative commented on (c) to clarify "type" or delete requirement. The representative commented on (d) that "removed cautiously" was a non-specific and subjective term that could lead to unequal application during inspection. The representative commented on (e) (2) requesting data substantiating requirement change and if no data exists, the requirement be removed.

A pharmacist representative of Sutter Health agreed with the Kaiser representative on (e)(2).

The Committee discussed removing the word "labeled" and replace with "meet" but noted the documentation to meet the requirement would need to be stored. Dr. Serpa indicated the language would be refined.

The Committee discussed the change to "type" meaning no cross contamination between two products. The intent was to have no cross contamination of one chemotherapy onto the next product and cross contamination could be on the outside of the container. Dr. Acosta confirmed the intent was the type of HD to ensure no cross contamination. The Committee agreed an FAQ would be helpful.

Chairperson Serpa was concerned with changing (e)(2) as the employee needs to be protected. Dr. Acosta confirmed the language was to take USP language and change "should" to "shall."

Chairperson Serpa referenced section 1737.8 Hazard Communication Program. Dr. Serpa provided the proposed language required that the designated person was required to develop the entity's communication plan. Dr. Serpa believed this was appropriate and consistent with the Board's mandate.

**1737.8 Hazard Communication Program**
The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

The designated person is responsible for developing the entity's hazardous communication program. The program shall be documented in SOPs and training documents.

Members were provided an opportunity to comment.

Member Barker commented on the entity's hazardous communication program that in larger facilities the overarching was usually the environmental health and safety which isn't always the standard. Dr. Barker wondered how the hazardous communication program required by Title XIII CCR General Industry Safety Orders section 5194; Health and Safety Code (HSC) sections 25500 and 25520; and Department of Toxics Substances Control could be harmonized to reduce duplicative efforts.

Chairperson Serpa understood in larger organizations it was usually a team rather than a person and the intent was for the designated person that they be part of the development of the hazardous communication plan.

Member Barker suggested in changing to "developing or participating in the development of the entity's" as well as cross reference other CA law sections (e.g., CalOSHA, etc.).

Members of the public were provided an opportunity to comment.

A pharmacist representative of Kaiser appreciated the discussion and comments from Dr. Barker that in larger entities there are other groups involved.

A pharmacist representative of Sutter Health had similar concern with Dr. Barker's and agreed with the proposed change as well as recommended to include the single designated person is responsible for participating in development or being responsible for what the pharmacy compounding chemicals and hazards are in the pharmacy rather than the broader OSHA communication plan which is a broader team.

Chairperson Serpa referenced section 1737.9 Personnel Training. Dr. Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. The proposed language specified the training requirements and included a cross reference to the documentation portion of the article. The language includes that personnel that fail any aspect of training will be required to successfully pass reevaluation in deficient areas before being involved in handling of hazardous drugs. Dr. Serpa noted language was added to those only who have direct oversight over personnel and HD compounding up to 14-days to pass re-evaluation of deficient areas as a result of public comment.

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

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

Chairperson Serpa referenced section 1737.10 Receiving. Dr. Serpa advised the proposed language in subsection (a) was included as the requirements were necessary to avoid contamination in the event of the spill during the shipping and receiving of an API adding the package needs to be appropriately identifiable as a hazardous product.

**1737.10 Receiving**
The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

All HD API and antineoplastic HD shall be received from the supplier in segregated impervious plastic and labeled as HD on the outside of the delivery container.

Members were provided the opportunity to comment.

Member Barker noted the proposed language stated, "shall be received from the supplier" but added FAQ 57 states suppliers aren't required to ship in impervious plastic" and wasn't under the control of the receiver. Dr. Serpa added the Board had control over wholesalers shipping in the state. Dr. Kalantar agreed this was for the wholesalers to follow in regulation. Dr. Acosta suggested changing the verbiage to "HD shall be shipped" to place the burden on the shipper.

Members of the public were provided the opportunity to comment.

The Committee heard comments from representatives of Kaiser, Pacific Compounding Pharmacy, CSHP, and Sutter Health agreeing the onus should be on the shipper as the receiver cannot guarantee how the materials will be received.

Chairperson Serpa noted wholesalers were also receivers as well as shippers as mentioned by the CSHP representative.

Chairperson Serpa referenced section 1737.11 Labeling, Packing, Transport and Disposal. Dr. Serpa provided the proposed language was incorporating the labeling requirements contained in other sections of pharmacy law to serve as a reminder of the labeling requirements that must be met. Additionally, subsection (b) clarified that the package must be labeled as a hazardous drug on the outside

packaging. Dr. Serpa believed the language was appropriate and consistent with the Board's mandate.

**1737.11 Labeling, Packing, Transport and Disposal**
The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) Any compounded HD preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5.

(b) All HD API and antineoplastic HDs shall be transported in impervious plastic container and labeled as HD on the outside of the container.

Members were provided the opportunity comment.

Member Barker recommended changing (b) to "in an impervious" to correct the grammar.

Dr. Kalantar suggested changing the title to "Packaging" instead of "Packing."

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

Chairperson Serpa referenced section 1737.12 Dispensing Final Dosage Form. Dr. Serpa provided the proposed language specified that equipment used must be decontaminated after each use. Dr. Serpa noted this was another example where the chapter included this concept as permissive. Dr. Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate.

**1737.12 Dispensing Final Dosage Form**

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

Equipment used in nonsterile compounding shall be dedicated for use with HDs and shall be decontaminated after each use.

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

A compounding pharmacist representative of Pacific Compounding Pharmacy commented with regards to the cleaning there were many pieces of equipment

that do not come in contact with the HD or APIs (e.g., pieces of the electronic mortar and pestle). The representative recommended leaving this up to the SOPs.

Chairperson Serpa referenced section 1737.13 Compounding. Dr. Serpa noted the the language in this section made permissive standards within the Chapter, requirements in the proposed regulation language. Dr. Serpa believed it to be appropriate.

**1737.13 Compounding**
The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) A preparation mat shall be placed on the work surface of the C-PEC when compounding HD preparations. Where the compounding is a sterile preparation, the preparation mat shall be sterile. The preparation mat shall be changed immediately if a spill occurs, after each type of HD and at the end of daily compounding activity.

(b) Only one HD drug may be handled in a C-PEC at one time if making multiple preparations.

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

Members of the public were provided an opportunity to comment.

A pharmacist representative of Sutter Health regarding (a) requesting not using preparation mats as they have found that the use of the mats does not facilitate good decontamination processes of wiping vials or the direct compounding surface and being able to remove gloves/mats during each compound. The representative noted the burden was in some facilities where they could be using a hundred mats or more a day as batches can't always be done due to scheduling. The representative encouraged the use of the preparation mat around spill and to utilize cleaning processes in the direct compounding area routinely so that an organization can assess for use and not be a requirement.

A compounding pharmacist representative from Pacific Compounding Pharmacy commented in agreement with the Sutter Health representative. The representative added if you have to change a mat with every chemo, it would an opportunity for create more hands going in and out of hood noting the SOPs should be appropriate. The representative commented on (b) requesting removal of "if making multiple preparations."

A pharmacist representative from Kaiser commented in agreement with the Sutter Health and Pacific Compounding Pharmacy representatives and agreed with not having to use the preparation mat. The representative was not aware of evidence that indicated the use of the preparation mats and the compounding of hazardous drugs enhancing patient safety resulting but increase in waste and would result in an increase of cost of care. The representative added with regard to (b) that many modern chemo treatment plans include multiple agents that are administered on the same treatment day and believed that establishing a requirement that only one HD drug may be handled in the PEC at a time if making multiple preparations will be at tension with the nature of modern chemotherapy regimens and requested empirical data be provided.

Chairperson Serpa clarified the word "disposable" needed to be added for preparation mats. Dr. Serpa posed the question to the Committee when it should be required and believed it was important to use in the non-sterile environment.

Member Barker shared having experience using mats but shared a concern about supply issues. Dr. Barker supported the use of the mats but had concerns with the sterility on top of the mat noting that the sterility and HD management could be at odds.

Chairperson Serpa thought adding the word "disposable" would help to clarify that a reusable mat couldn't be used. Dr. Serpa agreed with harmonizing (a) with the types of HD drugs used to make it clear. Dr. Serpa explained (b) was written to avoid the unintended consequence of one dose at a time. Dr. Barker indicated it could be made clearer and included in an FAQ.

Chairperson Serpa referenced section 1737.14 Administering. Dr. Serpa noted the proposed language in this section was ensuring that the hazardous drug was placed in an appropriate container and labeled as hazardous. Further, it ensures that patients and/or their agents will have the appropriate gloves to protect themselves when handling the hazardous drug. Dr. Serpa believed the language was appropriate and consistent with the Board's mandate.

**1737.14 Administering**

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) When dispensing an HD to a patient or caregiver for administration, the pharmacy shall attach and prime all tubing, attach a CSTD when appropriate, and place the HD in a decontaminated impervious plastic container with an HD label on the outside of the container.

(b) There shall be a sufficient supply of gloves to allow for appropriate administration, handling, and disposal of HD drugs by the patient or the

patient's agent when dispensing an antineoplastic HD. The gloves shall meet the ASTM D-6978 standard.

Members were provided the opportunity to comment.

Member Barker indicated it might be difficult to control the supply.

Chairperson Serpa understood but noted USP 800 indicates the entity has greater roles and responsibilities so that part of the hazardous communication team would be involved with ensuring there were adequate waste streams that have adequate gowns and linens to protect the staff.

Members of the public were provided the opportunity to comment.

A compounding pharmacist representative of Pacific Compounding Pharmacy commented regarding (a) if a new container would have to decontaminate a new container and requested "cleaned or" be added before "decontaminated." For (b) the representative inquired who determines "sufficient supply" and requested the first sentence to be amended to say, "There shall be a blank supply of ASTM standard meeting gloves" to clarify.

A pharmacist representative of Sutter Health commented on concern with the term "sufficient" supply of ASTM gloves. The representative asked how it would be enforceable and how they should prepare in order to be compliant in alternative settings (e.g., home health, etc.).

A commenter suggested adding "antineoplastic" before "HD" in (a).

Chairperson Serpa confirmed with Dr. Kalantar the intent would be antineoplastic HDs.

The Committee took a break from 12:07 p.m. to 12:50 p.m. Chairperson Serpa took roll call after the break. Members present included: Renee Barker, Licensee Member; Indira Cameron-Banks, Public Member; Seung Oh, Licensee Member; Ricardo Sanchez, Public Member; and Maria Serpa; Licensing Member. A quorum was established.

Chairperson Serpa referenced section 1737.15 Deactivation, Decontamination, Cleaning and Disinfecting. Dr. Serpa noted the proposed language in this section was explicitly stating that agents used must be used in accordance with manufacturer's specification. Dr. Serpa recalled this was similar to language in other articles previously considered. Dr. Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. Dr. Serpa noted included were concepts contained with the Chapter that were

currently permissive but the proposed language would make requirements to protect patients and personnel. Dr. Serpa believed the language was appropriate and consistent with the Board's mandate.

**1737.15 Deactivation, Decontamination, Cleaning, and Disinfecting**
The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.
(a) Deactivating, decontaminating, cleaning, disinfecting and sporicidal agents shall be used in accordance with manufacturers' specifications and shall be surface compatible.

(b) Agents used for deactivation, decontamination, cleaning and disinfecting all areas and equipment involved in HD handling shall be applied through the use of wipes wetted with appropriate solution and shall not delivered by a spray bottle to avoid spreading HD residue.

(c) SOPs for decontamination and deactivation procedures for the final HD product shall be created by the entity in accordance with the entity's SOPs and approved by the pharmacist-in-charge, professional director of a clinic, designated representative-in-charge, as applicable.

Members were provided the opportunity to comment.

Member Barker commented that the USP language requiring wipes only was limiting.

Members of the public were provided the opportunity to comment.

A compounding pharmacist representative of Pacific Compounding Pharmacy commented with concern for (c) with decontaminating deactivating procedures for a final HD product. The representative was not aware if the IV bag was of appropriate material to handle decontamination or deactivation agents without causing problem to the preparation. The representative was also not comfortable working with tubing lines and wiping down, etc. The term "deactivate" was noted as a scientifically imprecise phase.

A pharmacist representative of Sutter Health commented in agreement with Dr. Barker's comments about the wipes and noted (c) was a hard bar to make a must. The final HD product versus preparation was pointed out as a difference in wording.

Chairperson Serpa referred to section 1737.16 Spill Control. Dr. Serpa noted the proposed language in this section was again requiring the entity to address specific items within their SOPs. Dr. Serpa advised the approach ensured an entity has considered the issue and developed the process to protect employees. Dr. Serpa

believed the language as presented is appropriate and consistent with the Board's consumer protection mandate.

**1737.16 Spill Control**
The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) The entity shall have an SOP addressing the use of appropriate full-facepiece, chemical cartridge-type respirators if the capacity of the spill kit is exceeded or if there is known or suspected airborne exposure to vapors or gases.

(b) The entity shall maintain a list of properly trained and qualified personnel able to clean up an HD spill. An SOP shall outline how a qualified personal will be available at all times while HDs are handled.

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

Members of the public were provided the opportunity to comment.

A pharmacist representative of Sutter Health commented in section 1736.7 (a) talked about the use of a full-face piece chemical cartridge type respirator but didn't mention any other type of respirator that could be used and wondered why PAPRS or other type of vapor exposure respirators were allowed. The representative noted as in previous sections, it would be helpful to reference the type of respirator that was potential to the exposure.

Dr. Serpa commented they will look to harmonize about respirators in other sections.

Chairperson Serpa referenced section 1737.17 Documentation and Standard Operating Procedures. Dr. Serpa noted the proposed language in this section explicitly stated that the entity shall follow their SOPs. The proposed language also required SOPs in 16 areas. The identified areas were permissive concepts in the Chapter. Dr. Serpa clarified in the interest of safety, the proposed language was requiring the SOPs to address each of these areas. The proposed language included a requirement for SOPs to be reviewed at least every 12 months and specified that changes in SOPs must be disseminated in writing to appropriate staff prior to implementation. Dr. Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate.

**1737.17 Documentation and Standard Operating Procedures**
The requirements of this section apply to the handling of HDs in addition to the

standards in USP Chapter 800.

(a) Any entity engaged in the compounding or handling of HDs shall maintain and follow written SOPs.

(b) The SOPs for compounding or handling HDs shall include at least the following:

(1) Hazard communication program
(2) Occupational safety program
(3) Designation of HD areas
(4) Receipt
(5) Storage
(6) Compounding, if applicable
(7) Use and maintenance of proper engineering controls (e.g., C-PECs, C-SECs, and CSTDs), if applicable
(8) Hand hygiene and use of PPE based on activity (e.g., receipt, transport, compounding, administration, spill, and disposal), if applicable
(9) Deactivation, decontamination, cleaning, and disinfection
(10) Dispensing, if applicable
(11) Transport
(12) Administering, if applicable
(13) Environmental monitoring (e.g., wipe sampling)
(14) Disposal
(15) Spill control
(16) Medical surveillance

(c) The pharmacist-in-charge, professional director of a clinic, designated representative-in-charge, as applicable, shall work with the entity's designated person to ensure HD handling SOPs are reviewed at least every 12 months and this review is documented.

(d) SOPs shall be updated whenever changes are implemented. Such changes shall be disseminated in writing to the staff responsible for handling HDs prior to implementation. All notifications of such changes and the changes shall be documented in SOPs and training documents.

(e) Failure to follow written SOPs shall constitute a basis for enforcement action.

Members were provided the opportunity to comment.

Member Barker asked if "providing in writing" would allow electronic versions. Ms. Sodergren provided if the intent was to be written or electronic communication but not orally or verbal communication but could work with counsel on the language.

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

Chairperson Serpa referenced to the final section 1737.18 Medical Surveillance. Dr. Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. The Chapter included this concept as permissive. Dr. Serpa agreed it should be a requirement to protect employees handling hazardous drugs and believed the proposed language was appropriate.

**1737.18 Medical Surveillance**

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

Elements of a medical surveillance program shall be consistent with the entity's Human Resource policies and employees handling HDs must be aware of the program.

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

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

Chairperson Serpa thanked participants for the discussion. Dr. Serpa stated in addition to changes discussed with the Committee's agreement, Dr. Serpa would work with staff to finalize language. Similar to the regulation text considered in prior meetings, the Committee will work to ensure consistency between these proposed requirements and those in the proposed requirements for the compounding of nonsterile and preparations and radiopharmaceuticals where appropriate. These changes would be completed prior to the Board's consideration of all of proposed regulations during the April 2023 Board Meeting.

Chairperson Serpa thanked Supervising Inspectors Acosta, Kalantar, and Panella-Spangler who dedicated significant time preparing for and attending the meetings, providing education us on the USP Chapters and working very diligently to develop the regulation text considered during the meetings. Dr. Serpa noted the Board was extremely fortunate to have subject matter experts that were truly committed to consumer protection.

Chairperson Serpa thanked all of the stakeholders that attended and participated in the process noting it was vital to ensure that all aspects of an issue as part of the decision-making process were considered.

Chairperson Serpa looked forward to the discussion at the Board Meeting and hoped the Board would be in a position to move regulation text to initiate the formal rulemaking process as November 1, 2023, was around the corner and licensees benefit greatly from clarity to understand requirements.

## VII. Discussion and Consideration of Proposal to Amend Title 16, California Code of Regulations Sections Related to Compounding of Nonsterile and Sterile Preparations for Dispensing by Veterinarians for Animal Patients

Chairperson Serpa recalled at the February 2023 discussion on requirements for nonsterile compounding, the Committee received public comment regarding compounding for animal patients and a request to expand current provisions. During the discussion at that time, the Committee determined it appropriate to leave the language as it was currently provided in the law which specified that a pharmacy may compound a reasonable quantity sufficient for administration or application to a patient solely in prescriber's office or furnishing of not more than a 120-hour supply for veterinary medical practices.

Chairperson Serpa advised subsequent to that discussion, the Committee received further comments from the California Veterinary Medical Association (CVMA) requesting reconsideration. Dr. Serpa noted a copy of the letter was included in the meeting materials. Dr. Serpa believed it was possible to extend the provisions for non-sterile preparations to a seven-day supply after reviewing the letter and having an opportunity to confer with staff and receive information from the Board's expert on veterinary compounding. Dr. Serpa believed the Board could establish provisions to allow for a 28-day supply for sterile ophthalmic preparations under specified conditions, including a requirement that such sterile preparations meet the requirements of USP Chapter 797 Section 14.5.

Chairperson Serpa added the area of veterinary compounding was challenging because the requirements vary from human compounding under federal law. In additional there were many national manufacturing drug shortages. Dr. Serpa added many of the drugs listed in the comment letter that were found to be difficult to obtain were not compounded drugs but as a result of the national manufacturing shortages. Dr. Serpa believed the comment letter highlighted the need for additional education in this area where perhaps the use of compounded products was contrary to federal law.

Chairperson Serpa noted the meeting materials included the two areas where believed it may be appropriate to update language. Dr. Serpa added if there was agreement with the Committee, Dr. Serpa would work with staff the draft language to incorporate the changes for the Board to consider the language at the April 2023 Board Meeting.

Members were provided the opportunity to comment.

President Oh and Member Barker spoke in support of the proposed changes to pharmacy services to veterinarians.

Members of the public were provided the opportunity to comment.

A representative of CVMA commented in disagreement with the statement about drug products but CVMA supported the recommended changes and appreciated the Committee's consideration of the comment letter in making the recommendations.

A pharmacist representative of Pacific Compounding Pharmacy commented in support.

## VIII. Discussion and Consideration of Draft Statutory Proposal to Amend Business and Professions Code Sections 4081 and 4105

Chairperson Serpa recalled at the January 2023 Meeting, the Committee considered a recommendation from staff to amended Business and Professions Code sections 4081 and 4105 to address challenges staff were experiencing in obtaining records necessary to evaluate pharmacy operations for compliance with Pharmacy Law. During prior discussions, the Committee requested staff develop statutory language for consideration. The meeting materials included the draft language. Dr. Serpa reviewed the language and believed the language was appropriate. If the Committee similarly agreed, Dr. Serpa believed the Committee could offer a recommendation to the Board for consideration at the April 2023 Board Meeting..

Members were provided the opportunity to comment.

President Oh asked for the reason for the strike out in BPC section 4105 (a). Ms. Sodergren clarified the language was updated to reflect as required by the chapters. Dr. Oh requested the acquisition and disposition of dangerous drugs and dangerous devices be added to the meeting materials so that it was covered.

**Motion:** Sponsor statutory language as presented.

> **Proposal to Amend Business and Professions Code section 4081**
> (a) All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every

manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility, physician, dentist, podiatrist, veterinarian, laboratory, licensed correctional clinic, as defined in Section 4187, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge, responsible manager, or designated representative-in-charge, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge, responsible manager, or designated representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge, responsible manager, or designated representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

(d) Pharmacies that dispense nonprescription diabetes test devices pursuant to prescriptions shall retain records of acquisition and sale of those nonprescription diabetes test devices for at least three years from the date of making. The records shall be at all times during business hours open to inspection by authorized officers of the law.

(e) In addition to the records described in subdivision (a) records that must be maintained include staffing schedules, pharmacy personnel job duty statements, consultant reports, and policies and procedures related to pharmacy personnel and pharmacy operations.

**Proposal to amend BPC 4105**

(a) All records or other documentation required by this Chapter ~~of the acquisition and disposition of dangerous drugs and dangerous devices~~ to be maintained by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.

(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.

(d) (1) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hardcopy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(2) In the case of a veterinary food-animal drug retailer, wholesaler, or third-party logistics provider, any records that are maintained electronically shall be maintained so that the designated representative-in-charge or the responsible manager, or the designated representative on duty or the designated representative-3PL on duty if the designated representative-in-charge or responsible manager is not on duty, shall, at all times during which the licensed place of business is open for business, be able to produce a hardcopy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(e) (1) Notwithstanding subdivisions (a), (b), and (c), the board may, upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.

(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter.

(f) When requested by an authorized officer of the law or by an authorized representative of the board, the owner, corporate officer, or manager of an entity licensed by the board shall provide the board with the requested records within three business days of the time the request was made. The entity may request in writing an extension of this timeframe for a period not to exceed 14 calendar days from the date the records were requested. A request for an extension of time is subject to the approval of the board. An extension shall be deemed approved if the board fails to deny the extension request within two business days of the time the extension request was made directly to the board.

**M/S:** Oh/Barker

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

A pharmacist representative of Kaiser recommended allowing for records to be maintained solely in an electronic format regardless of the format they were made if maintained consistent with provisions of the BPC section 470(c) and California Evidence Code sections 1550 and 1552 to help facilities struggling to maintain records in paper format that may otherwise be able to be maintained in a non-alterable electronic format.

President Oh requested incorporating the comment if allowable. Ms. Sodergren requested discussing with the AG's Office before incorporating the change. Dr. Oh kept the motion as stated and requested it to be discussed at the April 2023 Board Meeting.

**Support: 5 Oppose: 0 Abstain: 0 Not Present: 1**

| **Committee Member** | **Vote** |
|---|---|
| Barker | Support |
| Cameron-Banks | Support |
| Oh | Support |
| Patel | Not Present |
| Sanchez | Support |
| Serpa | Support |

## IX. Review and Discussion of Enforcement Statistics

Chairperson Serpa referred to the enforcement statistics included in the meeting materials. The Board initiated 2,686 investigations and closed 2,376 investigations. Outcomes varied and included the issuance of 141 letters of admonishment, 766 citations and referral of 181 cases to the AG's Office. Dr. Serpa highlighted the last statistic of 181 cases have been referred to the AG's Office. Dr. Serpa believed there was a misconception about the Board's disciplinary activities with some suggesting that the Board is always seeking to discipline a license. The data tells otherwise as referrals to the AG's Office was about 7.6 percent.

Chairperson Serpa highlighted that the Board secured six interim suspension orders and has been granted eight Penal Code 23 restrictions. In both instances the Board was successful in securing immediate public protection through these actions while the disciplinary case process continues. Such actions were core to the Board's mandate. Investigation timeframes were also included. Dr. Serpa thanked Supervising Inspectors who have worked to reduce supervisor review time with two vacancies. Dr. Serpa noted it was commendable and appreciated. Dr. Serpa reminded Members at the July 2023 meeting, the Committee will receive a three-year comparison data to help evaluate trends.

Chairperson Serpa asked about the statistics for awaiting final closure where the April 2023 showed the average days going up to 75 days which wasn't consistent with the previous reports. Ms. Sodergren provided staff was looking into the data as one identified bottleneck and continue to validate and provide updates at the April 2023 Board Meeting.

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

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

## X. Future Committee Meeting Dates

Chairperson Serpa reminded the next meeting was scheduled July 18, 2023. Dr. Serpa advised the meeting will be held in person with the option for members of the public to participate via WebEx.

## XI. Adjournment

Chairperson Serpa and President Oh thanked all participants. The meeting adjourned at 1:25 p.m.

# Attachment 2


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)

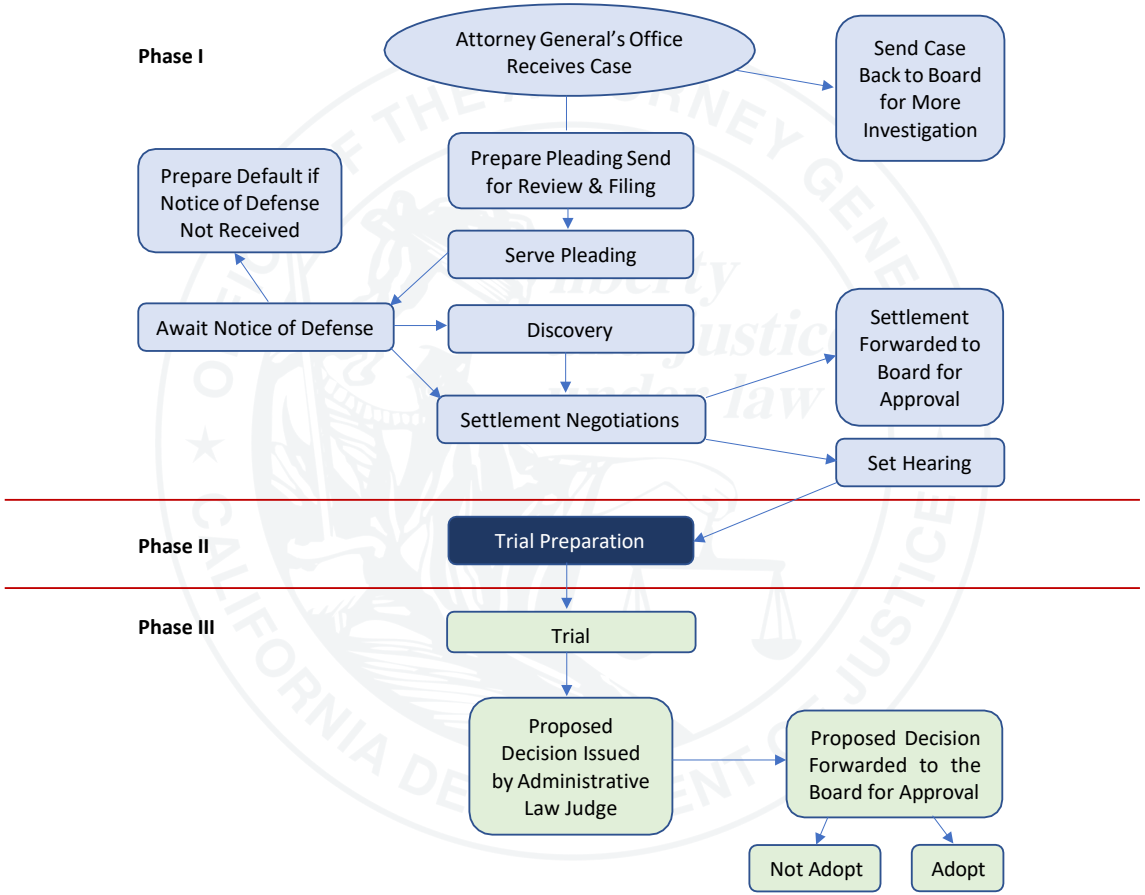
The Office of the Attorney General Mission Statement:

- 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.

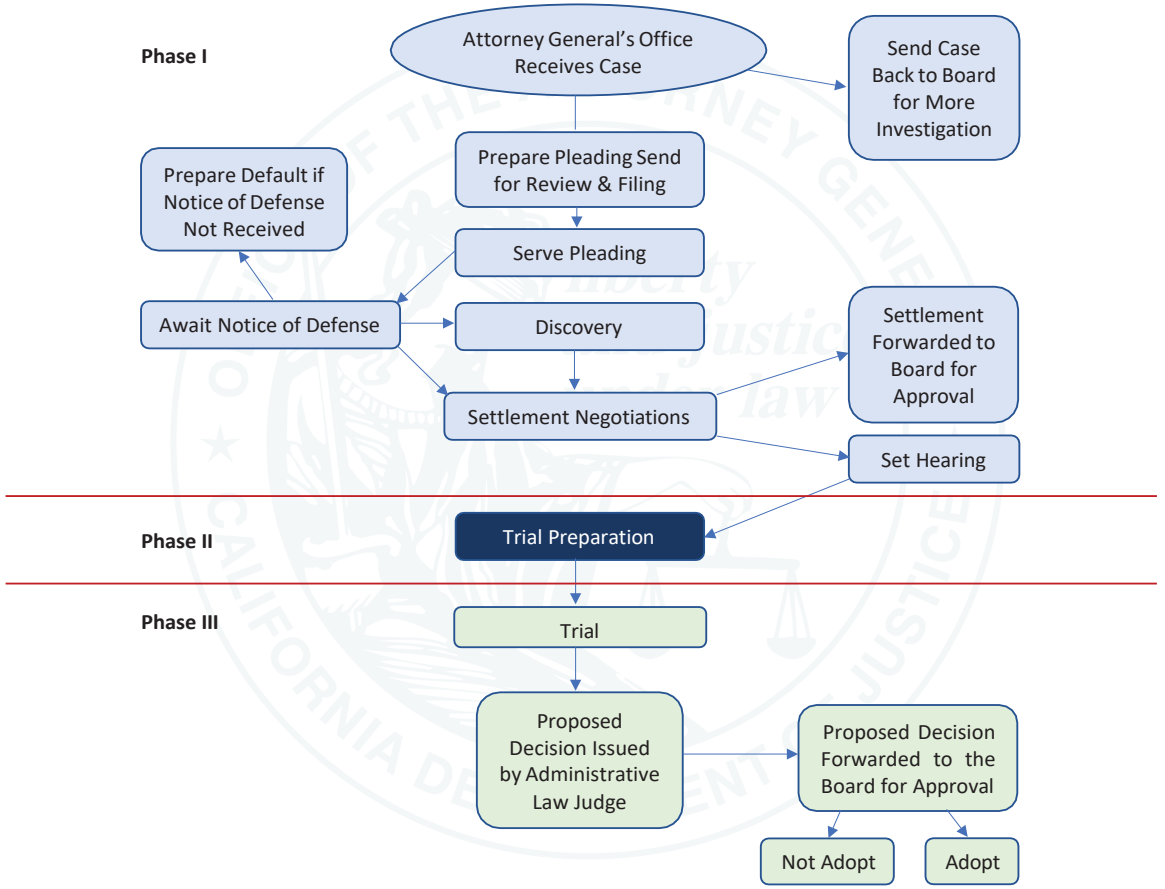
- Protection of the public is the highest priority of the Board, where other interests conflict with the protection of the public, the protection of the public must be paramount (Bus. & Prof. Code § 4001.1).

- 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 3

# CA State Board of Pharmacy

## Enforcement Committee Meeting

## Inspection Presentation

## July 18, 2023

# MANDATE

## Consumer Protection

# Inspection Process - Observations

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

# INSPECTION PROCESS – ITEMS REVIEWED

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

# WHAT IS INSPECTED

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

# EDUCATION

- Questions from Licensee
- Standard education Topics
- Tools for Licensees

# TOTAL INSPECTIONS COMPLETED

- FY 18/19 3,462
- FY 19/20 2,545
- FY 20/21 2,963
  - In Person Inspections 2817
  - Desk Audits 146
- FY 21/22 2,938
  - In Person Inspections 2,862
  - Desk Audits 76
- FY 22/23 2,837 (FYTD through June 16, 2023)

# INSPECTIONS BY VISIT TYPE – FY22/23

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

# Inspections by Visit Type - FY22/23 Continued

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

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

**Total Inspections Completed: 2,837**

# Routine Pharmacy Inspections Completed FY 22/23

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

# Routine Inspection Outcomes FY22/23

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

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

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

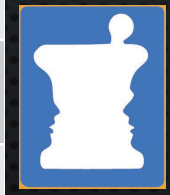
A pharmacy may receive both corrections and violation notices during one inspection.

# TOP CORRECTIONS ON ROUTINE PHARMACY INSPECTIONS FY22/23

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

# TOP VIOLATION NOTICES ON ROUTINE PHARMACY INSPECTIONS FY22/23

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



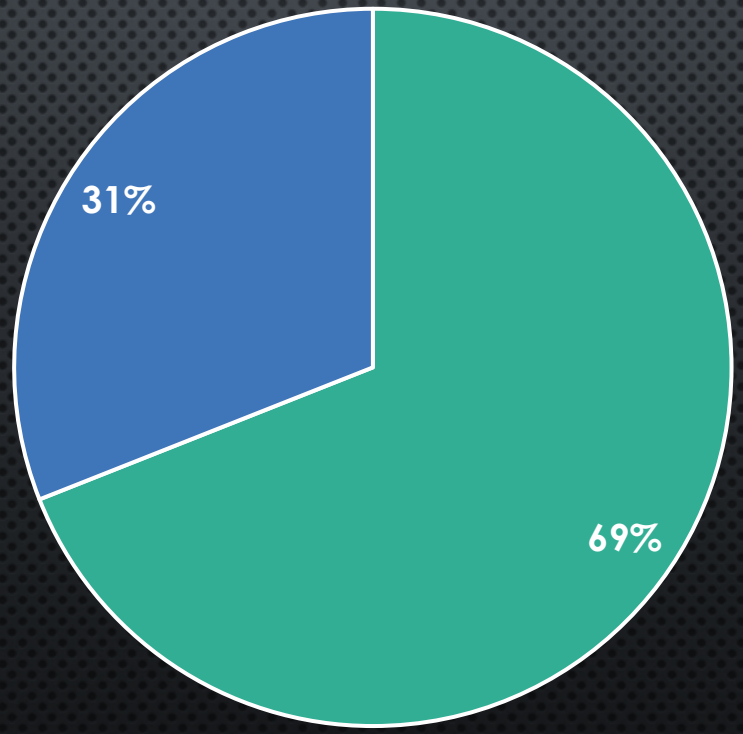
# CCR 1707.2 – DUTY TO CONSULT PHARMACY ROUTINE INSPECTIONS

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

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

# INSPECTION SUMMARY

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

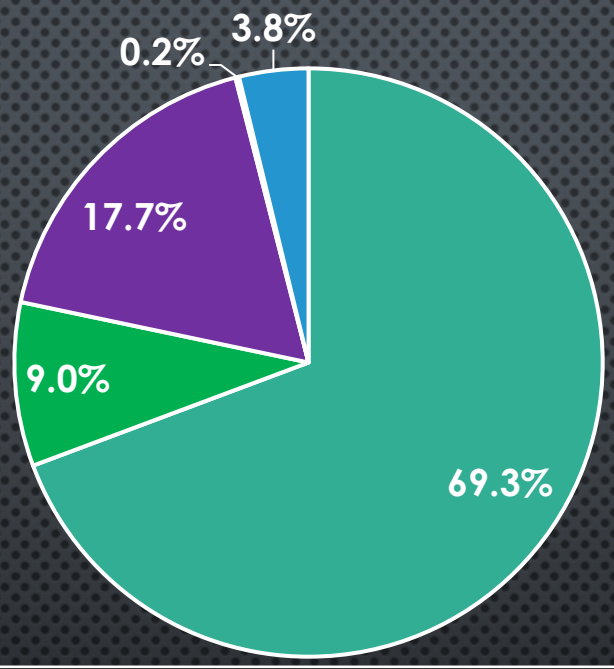



*not including licenses issued in current fiscal year FY 2022/23

# YEAR OF LAST ROUTINE INSPECTION FOR CURRENT PHARMACY LICENSEES

| | FY 2019/20 | FY 2020/21 | FY 2021/22 | FY 2022/23 |
|---|---|---|---|---|
| Inspected within 1 year | 507 | 1,078 | 1,011 | 1,316 |
| Inspected within 2 years | 1,233 | 1,479 | 2,170 | 2,395 |
| Inspected within 3 years | 1,512 | 2,093 | 2,570 | 3,595 |
| Inspected within 4 years | 1,698 | 2,310 | 3,194 | 4,133 |
| Percent Inspected within 4 years | 27.4% | 37.3% | 53.1% | 69.3% |
| Total Pharmacies<br>(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 4

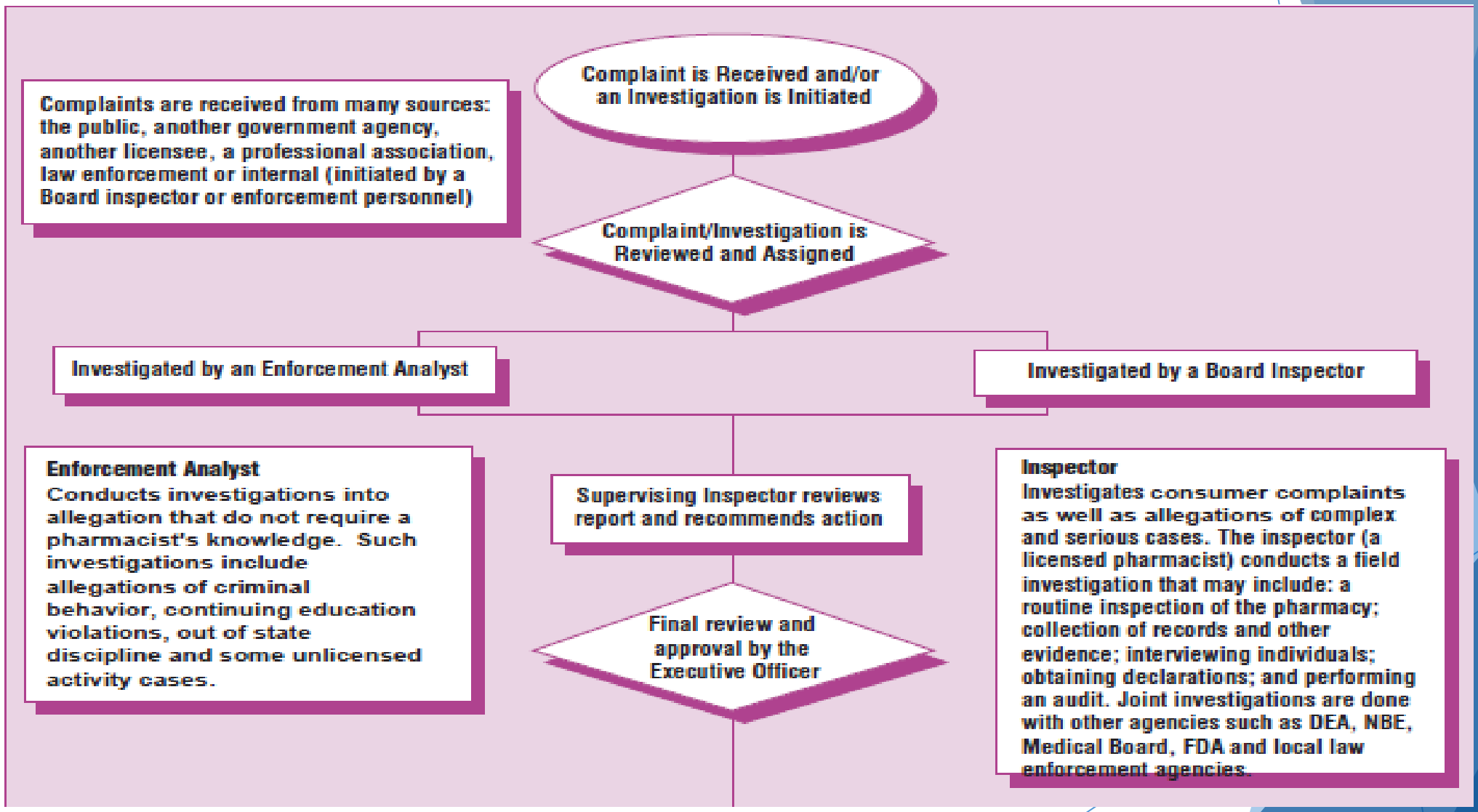
# California State Board of Pharmacy

# Enforcement and Compound Committee Meeting

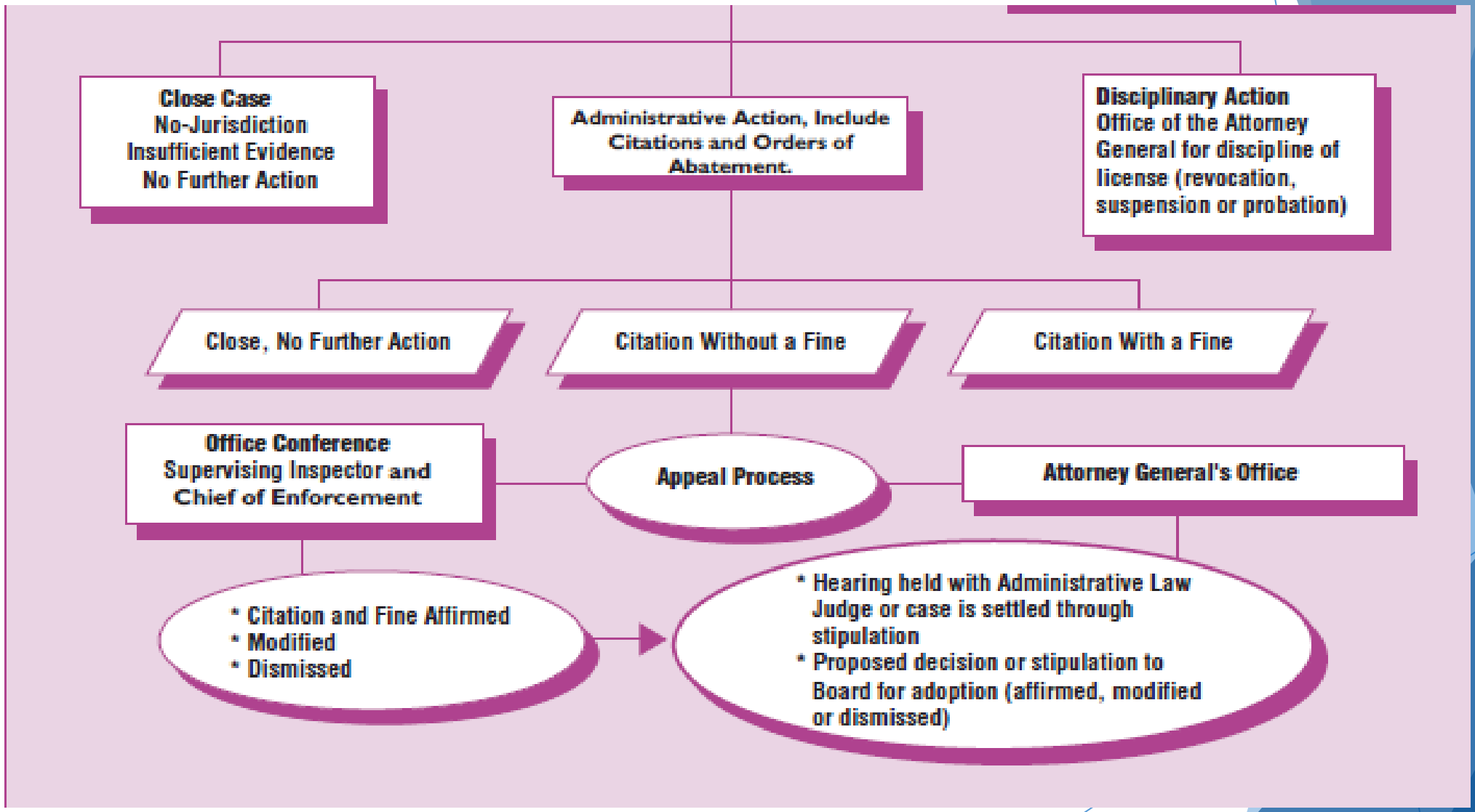
# Citation Presentation

# 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

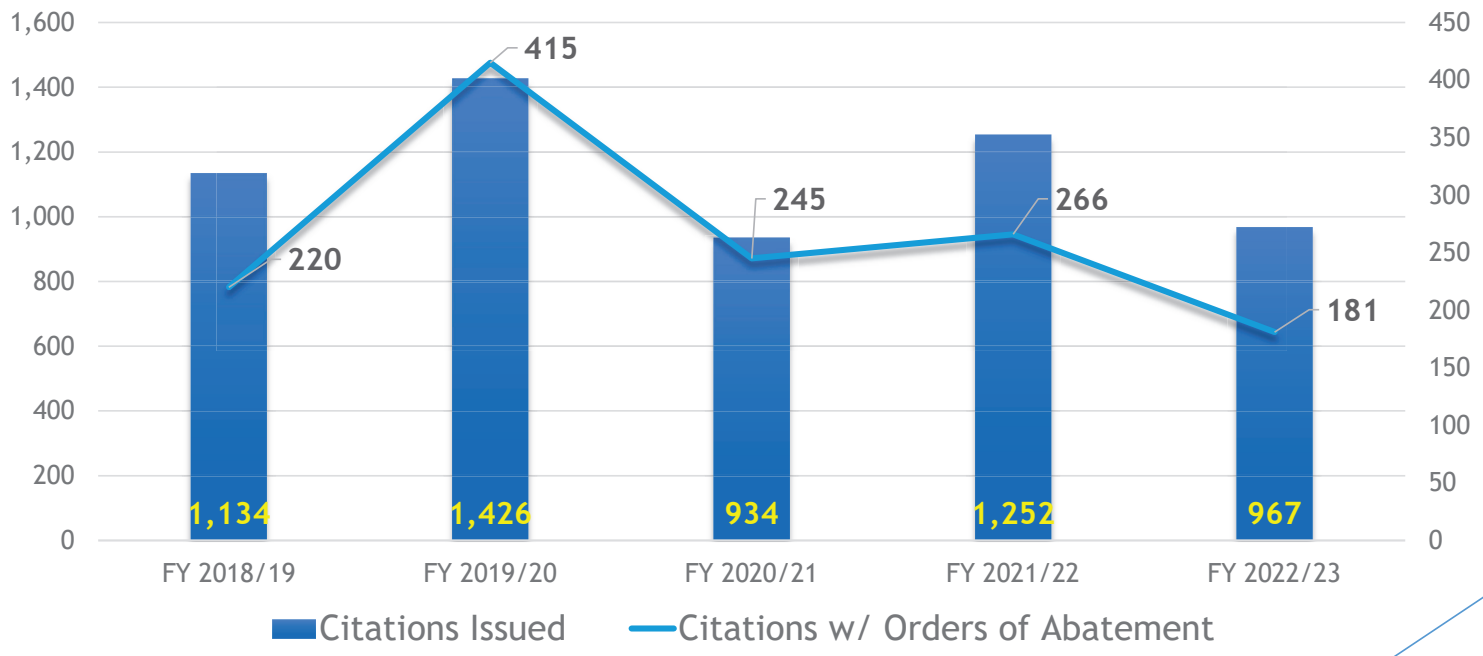
# Citations Issued by License Type

| 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**<br>23 with fine<br>7 no fine | **28 Total**<br>21 with fine<br>7 no fine | **21 Total**<br>18 with fine<br>3 no fine | **26 Total**<br>23 with fine<br>3 no fine |
| Average Violation Amount (PHY) | $3,117 | $3,798 | $3,416 | $3,462 |
| Pharmacist Violations | **34 Total**<br>12 with fine<br>22 no fine | **32 Total**<br>19 with fine<br>13 no fine | **28 Total**<br>11 with fine<br>17 no fine | **32** Total<br>8 with fine<br>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**<br>7 with fine<br>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 5

# 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 6

**Draft Compounding Policy Statement**

In light of the November 1, 2023, compendial date for several USP General Chapters, the California State Board of Pharmacy (Board) wishes to update its stakeholders on its policy related to licensees transitioning to the updated USP General Chapters as well as actions under consideration by the Board.

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

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

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

# Attachment 7

**Board of Pharmacy**

**Enforcement Workload Statistics FY 2022/23**

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

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

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

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

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

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

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

| **Administrative Case Outcomes** | July - Sept | Oct - Dec | Jan - March | Apr - Jun | Total |
|---|---|---|---|---|---|
| ***Revocation; stayed suspension/probation*** | | | | | |
| Pharmacist | 1 | 1 | 1 | 1 | 4 |
| Intern Pharmacist | 0 | 0 | 0 | 0 | 0 |
| Pharmacy Technician | 0 | 0 | 0 | 0 | 0 |
| Designated Representative | 0 | 0 | 0 | 0 | 0 |
| Wholesaler | 0 | 0 | 0 | 0 | 0 |
| Pharmacy | 0 | 0 | 0 | 0 | 0 |
| Sterile Compounding | 0 | 0 | 0 | 0 | 0 |
| Outsourcing | 0 | 0 | 0 | 0 | 0 |
| ***Total*** | ***1*** | ***1*** | ***1*** | ***1*** | ***4*** |

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

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

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

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

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

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

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

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

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

*As of 6/30/2023*

**Board of Pharmacy**

**Citation and Fine Statistics FY 2022/23**

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

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

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

# Top Ten Violations by License Type

| Pharmacists | % | Pharmacies | % | Pharmacists In Charge | % |
|---|---|---|---|---|---|
| 1716 - Variation from prescription | 33% | 4113(d) - Every pharmacy shall notify the board in writing within 30 days of the date of a change in pharmacist-in- charge | 28% | 733(a) - Dispensing prescription drugs and devices- No licentiate shall obstruct a patient in obtaining a prescription | 21% |
| 1764/56.10(a) - Unauthorized disclosure of prescription and medical information | 12% | 1716 - Variation from prescription | 17% | 1715(a) - Self-assessment form of a pharmacy by the pharmacist-in-charge; shall complete a self-assessment of pharmacy compliance with federal and state pharmacy law | 14% |
| 1707.2(a)(3) - Duty to consult: (a) A pharmacist shall provide oral consultation to his or her patient or the agent of patient in all care settings: (3) Whenever the prescription drug has not previously been dispensed to a patient | 10% | 4113(a) - Pharmacist-in-Charge: Notification to Board; Responsibilities; Every pharmacy shall designate a pharmacist-in-charge within 30 days in writing of the identity and license number of that pharmacy | 14% | 1764/56.10(a) - Unauthorized disclosure of prescription and medical information | 11% |
| 1715(a) - Self-assessment form of a pharmacy by the pharmacist-in-charge; shall complete a self-assessment of pharmacy compliance with federal and state pharmacy law | 7% | 4305(b) - Operation of a pharmacy for more than 30 days without supervision or management by a pharmacist-in- charge shall constitute grounds for disciplinary action | 12% | 4306.5(a) - Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist | 11% |
| 733(a) - Dispensing prescription drugs and devices- No licentiate shall obstruct a patient in obtaining a prescription | 7% | 1764/56.10(a) - Unauthorized disclosure of prescription and medical information | 8% | 1715.65 - Inventory Reconciliation Report of Controlled Substances | 7% |
| 1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission… | 7% | 4301(g) - Unprofessional Conduct - Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts | 5% | 1714(d)/4301(o)/4081(a) - Operational Standards and Security; Pharmacist responsible for pharmacy security/Unprofessional conduct; assist in violation/Records of Dangerous Drugs and Devices Kept Open | 7% |
| 4306.5(a) - Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist | 7% | 1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission… | 5% | 1707.2(a)(3) - Duty to consult: (a) A pharmacist shall provide oral consultation to his or her patient or the agent of patient in all care settings: (3) Whenever the prescription drug has not previously been dispensed to a patient | 7% |
| 4301(g) - Unprofessional Conduct - Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts | 6% | 733(a) - Dispensing prescription drugs and devices- No licentiate shall obstruct a patient in obtaining a prescription | 5% | 1716 - Variation from prescription | 7% |
| 1715(b)(2) - Self-Assessment of a pharmacy by the pharmacist-in-charge; shall complete a self-assessment within 30 days whenever: there is a change in pharmacist- in-charge | 4% | 1707.2(a)(3) - Duty to consult: (a) A pharmacist shall provide oral consultation to his or her patient or the agent of patient in all care settings: (3) Whenever the prescription drug has not previously been dispensed to a patient | 3% | 1716/4306.5(a) - Variation from prescription/Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist | 7% |
| 4301(o) - Unprofessional conduct; assist in violation | 4% | 4113(e) - Pharmacist-in-Charge: Notification to Board; Responsibilities; If a pharmacy is unable, in the exercise of reasonable diligence, to identify within 30 days a permanent replacement pharmacist | 3% | 4081(a)/1718 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory/Current Inventory Defined | 7% |

# California State Board of Pharmacy
# SB 1441 Uniform Standards

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

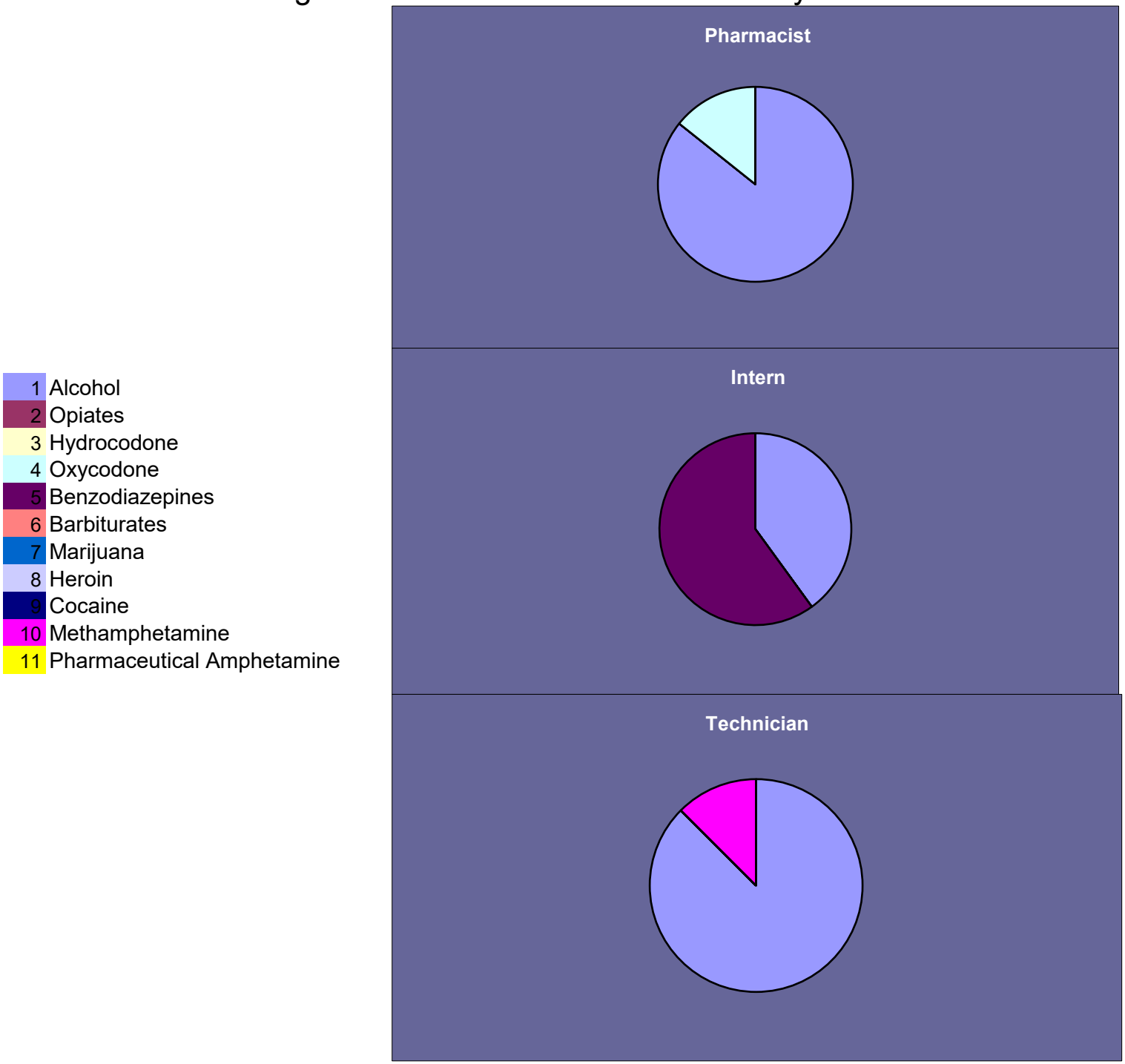
| Board of Pharmacy | July -Sep | Oct – Dec | Jan-Mar | Apr-Jun | 22/23 |
|---|---|---|---|---|---|
| **PRP Intakes** | | | | | |
| PRP Self-Referrals | | | | 1 | 1 |
| PRP Probation Referrals | | | 1 | | 1 |
| PRP Under Investigation | 3 | | | 2 | 5 |
| PRP In Lieu Of (investigation conducted) | | |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

# SB 1441 Uniform Standards

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

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

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




Printed on 7/7/2023

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

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

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

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

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

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

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