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
October 19, 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 July 18, 2023, Enforcement and Compounding Committee Meeting

Attachment 1 includes a copy of the draft minutes.

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

a. Assembly Bill 663 (Haney) Pharmacy: Mobile Units

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

b. Assembly Bill 782 (Lackey) Pharmacies: Compounding

Status: Vetoed
Summary: Would exempt from the definition of compounding the adding of a flavoring agent.
Implementation: As the measure was vetoed, implementation activities are not required.

c. Assembly Bill 1286 (Haney) Pharmacy

Status: Signed October 8, 2023
Summary: The measure creates a mandatory requirement that community pharmacies report medication errors that occur in the outpatient setting to an entity approved by the Board. Further, the measure updates minimum staffing requirements and the authority of the pharmacist-in-charge, updates unprofessional conduct codes, establishes authority for the issuance of a cease and desist under specified conditions, expands authority for pharmacy technicians to perform expanded duties under specified conditions, and updates the renewal requirements for surgical clinics.
Implementation: Significant education should be completed through the newsletter and the Changes in Pharmacy Law webinar. Board staff also recommend development of FAQs on specific elements in the measure.

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

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

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

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

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

e. Assembly Bill 1557 (Flora) Pharmacy: Electronic Prescriptions

Signed: September 1, 2023

Summary: Authorizes a pharmacist located and licensed within California to, on behalf of a health care facility, verify medication chart order reviews for appropriateness before administration from a remote location. As the measure included an urgency clause, the provisions became effective upon signature

Implementation: Staff recommend implementation activities focus on education of the provisions including highlighting the changes in the next version of Change in Pharmacy Law webinar and inclusion of the information in a future issue of *the Script*.

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

Status: Signed September 27, 2023

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

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

g. Senate Bill 816 (Roth) Professions and Vocations

Status: Signed October 10, 2023

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

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

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

Relevant Law

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

Background

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

Effective January 1, 2023, the regulation requirements were updated to include

additional inventory reconciliation reports for specified drugs and to establish a minimum threshold for inventory activities for all controlled substances at least once every two years.

For Committee Consideration and Discussion
During the meeting members will have the opportunity to review proposed changes to the frequently asked questions to incorporate the changes made to the regulation.

Attachment 2 includes a copy of the draft updates to the FAQs.

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

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

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

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

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

Attachment 3 includes a copy of the draft updates to the FAQs.

VII. Review and Discussion of Enforcement Statistics

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

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

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

Attachment 4 includes the enforcement statistics for the first quarter of the fiscal year.

VIII. Future Committee Meeting Dates

- January 23, 2024
- April 11, 2024
- July 17, 2024
- October 23, 2024

IX. Adjournment

Attachment 1

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Business, Consumer Services and Housing Agency
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California State Board of Pharmacy
Department of Consumer Affairs
DRAFT Enforcement and Compounding Committee Meeting Minutes

Date: July 18, 2023

Location: OBSERVATION AND PUBLIC COMMENT IN PERSON:
Department of Consumer Affairs
1625 N. Market Blvd, First Floor Hearing Room
Sacramento, CA 95834

PUBLIC PARTICIPATION AND COMMENT FROM A REMOTE LOCATION:
WEBEX

Board Members Present: Maria Serpa, Licensee Member, Chair
Renee Barker, Licensee Member, Vice-Chairperson
Indira Cameron-Banks, Public Member
Seung Oh, Licensee Member
Jignesh Patel, Licensee Member

Staff Present: Anne Sodergren, Executive Officer
Julie Ansel, Assistant Executive Officer
Corinne Gartner, DCA Counsel

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

Chairperson Serpa called the meeting to order at approximately 9:04 a.m. As part of the opening announcements, Chairperson Serpa reminded everyone that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. Department of Consumer Affairs' staff provided instructions for participating in the meeting.

Roll call was taken. Members present: Renee Barker, Licensee Member; Indira Cameron-Banks, Public Member; Seung Oh, Licensee Member; Jignesh Patel, Licensee 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 comment. No public comment was made by meeting participants in the Sacramento location or via WebEx.

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

The April 13, 2023, Enforcement and Compounding Committee Meeting minutes were presented for review and approval.

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

Motion: Accept the April 13, 2023, Enforcement and Compounding Committee Meeting minutes as presented.

M/S: Oh/Patel

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

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

Board Member	Vote
Barker	Support
Cameron-Banks	Support
Oh	Support
Patel	Support
Serpa	Support

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

Chairperson Serpa advised as part of the actions undertaken by the Board to meet its consumer protection mandate, the Board may refer a completed investigation to the Office of the Attorney General in instances where the investigation identifies egregious violations that warrant removal or restriction of the license. Dr. Serpa noted a review of the annual statistics reveals that the Board referred 259 matters to the Attorney General last fiscal year, which was about 8 percent of all closed investigations. The

data also revealed that 218 disciplinary matters were closed with outcomes including 59 revocations, 74 licenses placed on probation, 67 licenses being surrendered, and the public reproval of 20 licenses.

Chairperson Serpa introduced Kristina Jarvis and Nicole Trama, Deputy Attorneys General (DAGs) who serve as liaisons to the Board, to give the presentation to the Board.

DAG Jarvis and DAG Trama introduced themselves to the Board. Ms. Trama reviewed the Office of the Attorney General's statutory authority and mission statement, and the role of the Licensing Section of the Office of the Attorney General. Ms. Jarvis and Ms. Trama reviewed the general case process. Ms. Jarvis reviewed the elements of an Accusation and explained that they provide respondents with due process. Ms. Trama reviewed the Notice of Defense (NOD). Ms. Jarvis provided a review of the Request to Set for Hearing process. Ms. Trama provided an overview of the Discovery and Settlement process. Ms. Jarvis provided a review of the Board's Disciplinary Guidelines. Ms. Trama reviewed elements included in the Disciplinary Guidelines. Ms. Jarvis and Ms. Trama reviewed the minimum penalties, general probation durations, and types of violations for Categories I-IV. Ms. Jarvis reviewed the Probation Terms and Conditions. Ms. Trama discussed Due Process. Ms. Jarvis provided an overview of the Hearing process. Ms. Trama reviewed the Clear and Convincing Evidence Burden of Proof and Ms. Jarvis reviewed the lower Preponderance of Evidence Burden of Proof. Ms. Trama reviewed the Post Hearing process.

Chairperson Serpa thanked Ms. Jarvis and Ms. Trama for their informative presentation, noting that she believed it served as an important reminder about the due process protections built into the process.

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

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

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

A member of the public commented that the disciplinary process was complex and inefficient. The commenter suggested the process was

expensive and the pharmacist wasn't able to explain their side of the story. The commenter suggested having a pre-enforcement meeting and asked if it would be discussed in the future.

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

V. Presentation and Discussion on Board's Inspection Program

Chairperson Serpa advised that strategic objective 2.3 of the Board's strategic plan calls for completion of routine inspections of all licensed pharmacies at least every four years to proactively assess pharmacy operations and educate licensees. Dr. Serpa recalled that on an annual basis the Committee receives a presentation providing summary information detailing accomplishments towards this objective. Dr. Serpa welcomed the Board's Assistant Executive Officer Julie Ansel to provide the annual presentation.

Ms. Ansel reviewed the Board's Mandate; Inspection Process including observations and items reviewed; What is Inspected; and Education. Ms. Ansel reviewed the total inspections completed from FY 18/19 to FY 22/23. Ms. Ansel reviewed for FY 22/23: Inspections by Visit Type; Routine Pharmacy Inspections Completed; and Routine Inspection Outcomes. Ms. Ansel provided the Top Corrections and Top Violation Notices on Routine Pharmacy Inspections for FY 22/23. Ms. Ansel reviewed the FY 22/23 CCR 1707.2 Duty to Consult inspection findings during pharmacy routine inspections. As a summary, Ms. Ansel explained that 69 percent of 5,966 pharmacies have received a routine inspection within the last four years not including the licenses issued in FY 22/23. Ms. Ansel reviewed the year of the last routine inspection for current pharmacy licensees and percentages for pharmacies receiving routine inspections.

Chairperson Serpa thanked Ms. Ansel for the informative presentation, noting that she is pleased to see the progress being made to achieve the strategic objective, and that she was hopeful that it may be achieved by next year's presentation and ongoing. Dr. Serpa voiced appreciation for all of the efforts of the Board's field staff to perform these inspections, and reminded the Board that the workload was established and performed within existing resources.

Members were provided an opportunity to comment.

Member Patel noted the progress made in the inspection data.

President Oh inquired if nonresident pharmacies were included in the inspections as Dr. Oh recalled that was added but not reported. Executive Officer Anne Sodergren provided the focus was on pharmacies in California. Ms. Sodergren advised the nonresident pharmacies being inspected now were linked to nonresident sterile compounding licenses and/or on probation. Looking to the future, Ms. Sodergren noted the cost of the inspections would need to be factored in as there was no ability for the Board to recover the inspection costs.

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

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

The Committee took a break from approximately 10:20 a.m. to 10:35 a.m. Roll call was taken after the break. Members present: Renee Barker, Licensee Member; Indira Cameron-Banks, Public Member; Seung Oh, Licensee Member; Jignesh Patel, Licensee Member; and Maria Serpa, Licensee Member. A quorum was established. Member Patel advised he would be stepping out of the meeting from 11:00 a.m. to 11:30 a.m.

VI. Presentation and Discussion on Board's Citation and Fine Program

Chairperson Serpa advised consistent with strategic objective 2.2, on an annual basis the Committee receives a presentation on the citation and fine program that includes information on common violations. Dr. Serpa noted that the information shared during the annual presentation is also included in the Board's newsletter, providing education to licensees. Dr. Serpa noted approximately 33 percent of all investigations completed by the Board result in the issuance of a citation. Dr. Serpa added that reporting out this information provides valuable information to licensees on areas of operations that can result in citations. Dr. Serpa introduced Executive Officer Anne Sodergren to give the presentation.

Ms. Sodergren provided an overview of the Complaint/Citation Process; Relevant Law; Fine Authority; and Factors Considered in Assessing Administrative Fines. Ms. Sodergren then reviewed data from FY 18/19 – FY 22/23 (through 6/16/23) on citations issued and fines assessed and

collected; Citation Processing Times; and Citations Issued/Orders of Abatement. For FY 22/23, Ms. Sodergren provided an overview of the Citations Issued by License Type and Orders of Abatement. Ms. Sodergren provided an overview of Orders of Abatement; Abatement Types; Abatement Examples; and the Appeal Process. Ms. Sodergren reviewed the Citation Appeal Outcomes for FY 22/23 including total office conferences requested and total appeals referred to the Attorney General's Office.

Ms. Sodergren reviewed data for FY 18/19 – FY 22/23 related to Citations Issued under Business and Professions Code (BPC) section 4314. She then reviewed data for FY 21/22 – FY 22/23 related to Citations Issued under BPC section 4317.5. Ms. Sodergren reviewed data for FY 18/19 – FY 22/23 related to Citations Completed or Appealed under BPC section 4314 as well as FY 22/23 data related to Citations Completed or Appealed under BPC section 4317.5.

Ms. Sodergren identified the Top Ten Violations for Pharmacies, Pharmacists, and Pharmacy Technicians in FY 22/23. Ms. Sodergren reviewed data related to the Duty to Consult under CCR 1707.2/BPC 4314 for FY 19/20 – FY 22/23 as well as the Duty to Consult under CCR 1707.2/BPC 4317.5 for FY 21/22 – FY 22/23. Ms. Sodergren then reviewed Citations Issued under BPC section 4317.5 (a) and (b).

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

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

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

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

Chairperson Serpa noted that as detailed in the meeting materials, the Board is required to submit a report to the Legislature on the regulation of Automated Drug Delivery Systems (ADDS) as part of the upcoming sunset evaluation process. Dr. Serpa advised to allow for time for discussion and

input in advance of the report deadline, Dr. Serpa appreciated staff presenting information, providing an opportunity to provide feedback, and ensuring all of the data needed and recommendations were ready for the Legislature. Dr. Serpa introduced Supervising Inspector Janice Dang.

Supervising Inspector Janice Dang presented a Review of ADDS: Quality Assurance Programs. Dr. Dang reviewed ADDS Licensure Requirements; and ADDS Quality Assurance Program requirements. Dr. Dang reviewed ADDS data for FY 18/19 – FY 22/23 including ADDS Licensing Statistics; ADDS Medication Errors Reported; Medication Errors Reported Based on Location of ADDS; and Type of Medication Errors Reported. Dr. Dang also reviewed Causes for Errors and Challenges in Reporting ADDS Medication Errors. Dr. Dang provided Recommendations for Pharmacies and for the Board.

Chairperson Serpa thanked Dr. Dang for the comprehensive presentation including offering some recommendations. Dr. Serpa believed this was a great starting point for the beginning of the Board's assessment. Dr. Serpa noted as this was the first opportunity to review the ADDS program with some time before the report was due to the Legislature if the Committee would be agreeable to the Chairperson working with staff on some other elements that should be brought forward for consideration. Dr. Serpa added there may be some other data points as well that maybe helpful. If the Committee was agreeable, another presentation could be made in six months which should allow time to further refine as necessary to ensure the Board was well positioned to meet the deadline.

Chairperson Serpa noted concern about what appears to be a lack of reporting by some hospitals using unlicensed ADDS and would like to encourage staff to consider if there were additional means that could be used to remind of the reporting requirements, either through incorporation on the renewal form or some other means.

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

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

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

A pharmacist representative of Kaiser commented that based on the rulemaking package that modified CCR section 1711 in accordance with these requirements, the Board's justification for establishing the requirement was to provide a report to the Legislature. Because the requirement was for a single report with no reporting in the future, the commenter suggested the Board consider amending in the future CCR section 1711 to eliminate the reporting requirement after the report was submitted to the Legislature.

VIII. Discussion and Consideration of Draft Proposed Policy Statement Related to Implementation of USP 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

Chairperson Serpa reminded members that, as included in the meeting materials, as of November 1, 2023, changes to USP Chapters 795 and 797, and new Chapters 800 and 825, become compendial. For the past several years, as changes have occurred with the process to establish new USP Chapters and revise existing Chapters, the Board has released statements providing licensees with information on the Board's policy during the transition period. Dr. Serpa referenced Attachment 6 to the meeting materials containing a draft policy statement for the Committee's consideration. Dr. Serpa noted that she has reviewed the policy statement and believes it is appropriate.

Members were provided an opportunity to comment.

Member Barker agreed with the statement and commented that, for clarity, it would help to add references to the specific USP General Chapters that are being revised or added. Dr. Serpa agreed and noted that these clarifying changes could be made before the statement was presented to the Board.

Motion: Approve the Draft Compounding Policy Statement with clarifying modifications to add references to the specific USP General Chapters being revised or added.

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.

M/S: Oh/Barker

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

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

A registered pharmacist with Kaiser commented in appreciation of the policy statement and encouraged the Committee to use the statement to provide more definitive guidance to the regulated public on how the Board intends to approach situations in which a pharmacy was in compliance with the applicable USP Chapters but did not comply with the provision of the current compounding regulations that directly conflict with the USP Chapters.

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

Board Member	Vote
Barker	Support
Cameron-Banks	Support
Oh	Support
Patel	Support
Serpa	Support

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

Chairperson Serpa noted that the Enforcement and Compounding Committee has nine strategic objectives. The meeting materials included updates on the objectives, highlighting the Committee's efforts over the past year. Dr. Serpa suggested some additional updates to the strategic objectives specifically related to objective 2.3. Dr. Serpa appreciated the update but thought the Board should further elaborate. Dr. Serpa noted as the presentation highlighted, Board staff were making good progress towards the goal and believed the Board should include the percentage of licensees that meet the established criteria and perhaps a comment that staff would continue to prioritize inspections of pharmacies that have been licensed over a year.

Chairperson Serpa added that specific to objective 2.6, the Committee should note the post-inspection surveys that were performed as a means to receive feedback from licensees. Dr. Serpa believed management staff review cases together as a team to achieve consistency where appropriate.

Chairperson Serpa also added that specific to objective 2.8, Dr. Serpa believed it was appropriate to highlight the presentations that were given by Board staff including presentations via WebEx as well as in person. Dr.

Serpa attended a few such presentations and noted they always appeared to be well received. Additionally, the Board also develops FAQs to assist licensees.

Chairperson Serpa generally believed the objectives remained appropriate and didn't believe any changes to the strategic objectives were appropriate.

Members were provided an opportunity to comment.

President Oh thanked the staff for their hard work and reported for 2.9 the Licensing Committee was looking into any opportunities.

Member Barker commented regarding 2.6 to add proactive education and information to licensees.

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

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

Chairperson Serpa noted since no changes to the objectives were being proposed, there was no need for a vote.

X. Discussion and Consideration of Enforcement Statistics

Chairperson Serpa referred to the meeting materials including a summary of enforcement statistics for the last fiscal year along with a three-year comparison. Dr. Serpa noted the Board initiated over 3,500 investigations which was about a 50 percent increase from FY 2020/21. Dr. Serpa added the Board experienced about a 25 percent increase in cases closed over the three-year period. Dr. Serpa noted that although growth and declines vary across the various data points, she wanted to highlight the overall increase in citations issued and matters referred to the AG's Office. Dr. Serpa advised some of the largest increases of investigations pending include probation, PRP monitoring, and criminal convictions.

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

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

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

XI. Future Committee Meeting Dates

Chairperson Serpa thanked everyone for their time and participation, noting the next meeting was currently scheduled for October 19, 2023. Dr. Serpa added the meeting would be conducted in person with stakeholders again having the option to participate in person or via Webex. Dr. Serpa asked that stakeholders monitor the Board's website for updates.

XII. Adjournment

The meeting adjourned at 12:06 p.m.

Attachment 2

FAQs for the Revisions to Inventory Reconciliation (Revised 10/12/2023)

The revisions to California Code of Regulations, title 16, section 1715.65, Inventory Reconciliation Reports of Controlled Substances took effect January 1, 2023.

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

General:

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

Effective January 1, 2023, every pharmacy and every clinic licensed under Business and Professions Code §§ 4180 and 4190 must prepare on the following ongoing basis:

- All federal Schedule II controlled substances, at least once every three months;
- For products containing the following substances in the following strengths per tablet, capsule, other unit, or specified volume, at least once every 12 months, the following controlled substances: alprazolam 1mg/unit, alprazolam 2mg/unit, tramadol 50mg/unit, and promethazine with codeine 6.25mg promethazine/10mg codeine/5mls;
- For any controlled substances not listed above, an inventory reconciliation report must also be prepared when a controlled substance loss is identified, no later than three months after discovery of the reportable loss of the controlled substance in addition to the timely report of the loss as required;
- For any controlled substance not listed above, inventory activities must be performed at least once every two years from the performance of the last inventory activities. CCR §1715.65(a)(1)(2)(3).

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

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

Yes. When a controlled substance loss is identified, an inventory reconciliation report must be completed. The audit period must cover the period from the last physical count of the controlled substance before the loss was discovered through the date of discovery. CCR §1715.65(a)(3)(A).

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

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

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

An inventory reconciliation report must include the following:

- A physical count, not an estimate, of all quantities of each federal controlled substance covered by the report that the pharmacy or clinic licensed by the board pursuant to BPC §§ 4180 or 4190.
- The individual(s) who performed the inventory must sign and date the inventory or the report.
- A review of all acquisitions and disposition of each federal controlled substance covered by the report since the last inventory reconciliation report covering that controlled substance.
- A comparison of the physical counts to the acquisitions and disposition of each federal controlled substance covered by the report.
- Identification of all records used to compile the report, which must be maintained in the pharmacy or clinic.
- The identification of each individual involved in preparing the report.
- The possible causes of overages.
- In writing, identify the losses and known causes. Reportable losses defined in CCR §1715.6, must be reported to the board within 30 days of discovery, unless the cause of the loss is theft, diversion, or self-use in which case the board must be notified within 14 days of discovery.
- The inventory reconciliation report must be dated and signed by the PIC or the professional director of the clinic licensed pursuant to BPC §§4180 or 4190.
- The report and all records used to compile the report must be readily retrievable in the pharmacy or clinic for three years. CCR §1715.65(c)(d)

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

"Inventory activities" are required for each controlled substances that is not already required to be physically counted quarterly or at least every twelve months. Inventory activities for these controlled substances must be performed at least once every two years from the performance of the last inventory activities. "Inventory activities" means inventory and all other functions

sufficient to identify loss of controlled substances. The functions must be sufficient to identify loss outside of the inventory reconciliation process and must be identified with the pharmacy's policies and procedures. CCR §1715.65(a)(3)(B).

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

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

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

In addition, the inventory reconciliation report must be dated and signed by the pharmacist-in-charge or the professional director for a clinic licensed by the board pursuant to BPC §§ 4180 or 4190. An individual may use a digital or electronic signature or biometric identifier in lieu of a physical signature if, in addition, the individual physically signs a printed statement confirming the accuracy of the inventory or report. The signature must be dated, and the signed and dated statement must be retained on file. CCR §1715.65(b), CCR §1715.65(e)(1)(2).

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

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

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

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

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

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

Whenever possible, it is also recommended the outgoing PIC perform an inventory count of all controlled substances prior to their disassociation as the PIC.

Hospital Pharmacies and Drug Rooms:

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

Yes. 22 CCR §70263(a) requires hospitals having fewer than 100 licensed beds must have a pharmacy license issued by the board pursuant to BPC 4029 and 4056. Therefore, a drug room is considered a pharmacy licensed by the board and must comply with CCR §1715.65.

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

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

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

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

Yes. The inventory reconciliation reports for an inpatient hospital pharmacy must include controlled substances stored within the pharmacy, within each pharmacy satellite location, and within each drug storage area in the hospital under the pharmacy's control. A physical count of the controlled substances is required. If the inpatient hospital pharmacy uses an ADDS to stock the controlled substances, the inventory in the ADDS may be accounted by using a means other than a physical count. CCR §§1715.65(g), CCR §§1715.65(h).

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

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

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

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

- A review of the records of acquisition for the controlled substances being audited.
- A review of the records of disposition for the controlled substances being audited, include expired drugs removed, drugs removed due to breakage, etc.
- Review of discrepancy reports and adjustments made for shortages and overages, including all discrepancy reports opened and closed, and unaccounted losses.
- The total loss of each controlled substance during the audit period, resulting from shortages, especially when the count is adjusted. If the total loss causes the aggregated amount to equal or exceed the thresholds listed in CCR §1715.6, the losses must be reported to the board.
- All shortages were investigated to determine the cause.
- When there is a shortage, the policies and procedures were reviewed to determine if any changes were needed to prevent the shortage from reoccurring. CCR §1715.65(b),(c),(h), CCR 1715.6.

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

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

No. The surgical clinic is required to take a physical count, not an estimate, of all quantities of each federal controlled substance covered by the inventory reconciliation report. If the inpatient hospital pharmacy uses an ADDS to stock the controlled substances, the inventory in the ADDS may be accounted by using a means other than a physical count. CCR §1715.65(c)(1).

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

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

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

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

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

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

18. Can the Director of Nurses sign the inventory reconciliation report?

It depends. If the Director of Nurses performed the physical count of the controlled substance, then the Director of Nurses must sign and date the inventory or inventory reconciliation report.

However, if the Director of Nurses did not perform the physical count, the Director of Nurses can sign the inventory reconciliation report, if the Director of Nurses is also listed with the board as the professional director responsible for the safe, orderly, and lawful provision of pharmacy services. CCR § 1715.65(e)(1), BPC §4192.

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

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

<u>Correctional Clinics – BPC §4187</u>:

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

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

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

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

Compounding Pharmacies:

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

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

Long Term Care (LTC) Pharmacies:

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

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

24. Our LTC pharmacy operates ADDS at various long term care facilities which include federal schedule II controlled substances. Are the federal schedule II controlled substances stored in the ADDS require to be physically counted for the inventory reconciliation?

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

Attachment 3

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

Note: proposed revisions are highlighted in yellow.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Attachment 4

Board of Pharmacy

Enforcement Workload Statistics FY 2023/24

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

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

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

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

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

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

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation					
Pharmacist	2	0	0	0	2
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	8	0	0	0	8
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	1	0	0	0	1
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***11***	***0***	***0***	***0***	***11***

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

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

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

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

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Granted (with or w/o conditions)					
Pharmacist	0	0	0	0	0
Intern Pharmacist	1	0	0	0	1
Pharmacy Technician	0	0	0	0	0
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	0	0	0	0	0
Sterile Compounding	0	0	0	0	0
Outsourcing	1	0	0	0	1
Total	***2***	***0***	***0***	***0***	***2***

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

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

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

Probation Statistics	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Licenses on Probation					
Pharmacist	164	0	0	0	164
Intern Pharmacist	2	0	0	0	2
Pharmacy Technician	20	0	0	0	20
Designated Representative	1	0	0	0	1
Wholesaler / 3PL	2	0	0	0	2
Pharmacy	52	0	0	0	52
Sterile Compounding	9	0	0	0	9
Outsourcing	0	0	0	0	0
Total	***250***	***0***	***0***	***0***	***250***
Probation Compliance Measures					Total
Probation Office Conferences	18	0	0	0	18
Probation Interviews / Site Inspections	141	0	0	0	141
Probation Terminated / Completed	25	0	0	0	25
Referred to AG for Non-Compliance	0	0	0	0	0

As of 9/30/2023

California State Board of Pharmacy
SB 1441 Uniform Standards

The data includes licensees participating in the Pharmacist Recovery Program (PRP) and licensees on probation with substance use disorders. This data includes July 2023 through June 2024.

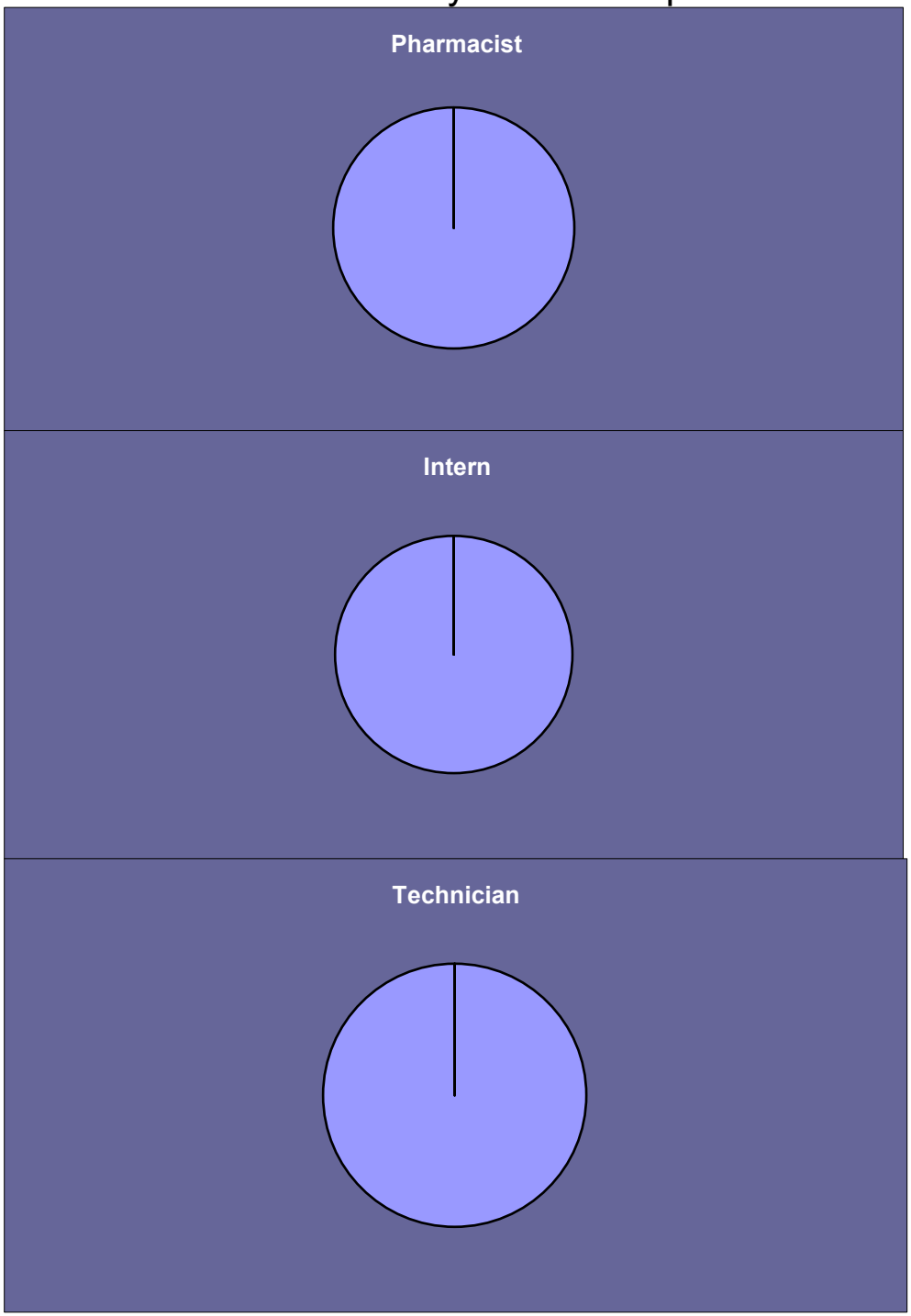
Board of Pharmacy	July -Sep	Oct – Dec	Jan Mar	Apr Jun	23/24
PRP Intakes					
PRP Self-Referrals					
PRP Probation Referrals	1				1
PRP Under Investigation	2				2
PRP In Lieu Of (investigation conducted)	2				2
Total Number of PRP Intakes	5				5
New Probationers					
Pharmacists					
Intern Pharmacists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

SB 1441 Uniform Standards

The data includes licensees participating in the Pharmacist Recovery Program (PRP) and licensees on probation with substance use disorders. This data includes July 2023 through June 2024.

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

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



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

Printed on 10/6/2023

Board of Pharmacy

Citation and Fine Statistics FY 2023/24

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

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

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

Top Ten Violations by License Type

Pharmacists	%	Pharmacies	%	Pharmacists In Charge	%
1716 - Variation from prescription	48%	4113(d) - Every pharmacy shall notify the board in writing within 30 days of the date of a change in pharmacist-in- charge	23%	1716 - Variation from prescription	24%
1764/56.10(a) - Unauthorized disclosure of prescription and medical information	11%	1716 - Variation from prescription	23%	1714(c) - Operational Standards and Security; pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition	15%
1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	6%	4305(b) - Operation of a pharmacy for more than 30 days without supervision or management by a pharmacist-in-charge shall constitute grounds for disciplinary action	12%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	9%
733(a) - Dispensing prescription drugs and devices- No licentiate shall obstruct a patient in obtaining a prescription	6%	4113(a) - Pharmacist-in-Charge: Notification to Board; Responsibilities; Every pharmacy shall designate a pharmacist-in-charge within 30 days in writing of the identity and license number of that pharmacy	12%	1715(b)(2) - Self-Assessment of a pharmacy by the pharmacist-in-charge; shall complete a self-assessment within 30 days whenever: there is a change in pharmacist- in-charge	9%
1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	5%	733(a) - Dispensing prescription drugs and devices- No licentiate shall obstruct a patient in obtaining a prescription	8%	1707.2(a) - Duty to consult: A pharmacist shall provide oral consultation to his or her patient or the agent of patient in all care settings	9%
1715(a) - Self-assessment form of a pharmacy by the pharmacist-in-charge; shall complete a self-assessment of pharmacy compliance with federal and state pharmacy law	5%	1764/56.10(a) - Unauthorized disclosure of prescription and medical information	5%	733(a) - Dispensing prescription drugs and devices- No licentiate shall obstruct a patient in obtaining a prescription	9%
1707.2(a) - Duty to consult: A pharmacist shall provide oral consultation to his or her patient or the agent of patient in all care settings	5%	1714(c) - Operational Standards and Security; pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition	5%	1715(a) - Self-assessment form of a pharmacy by the pharmacist-in-charge; shall complete a self-assessment of pharmacy compliance with federal and state pharmacy law	9%
4306.5(a) - Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist	5%	1714.3(c) - All impacted pharmacy employees and designated persons must read and sign a copy of the policies and procedures required by this section. For purposes of this section, “impacted pharmacy	4%	1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	6%
1707.3 - Duty to review drug therapy	5%	1708.2 - Discontinuance of business	4%	1735.2(k) - Compounding Limitations and Requirements; Self-Assessment - Prior to allowing any drug product preparation to be compounded in a pharmacy….	6%