California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

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

California State Board of Pharmacy
Department of Consumer Affairs
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.