

Attachment A

**July 27-28, 2022,
Board Meeting**



**California State Board of Pharmacy
 Department of Consumer Affairs
 DRAFT Public Board Meeting Minutes**

Date: July 27-28, 2022

Location: Public participation provided via WebEx

Board Members

Present: Seung Oh, Licensee Member, President
 Maria Serpa, Licensee Member, Vice President
 Jignesh Patel, Licensee Member, Treasurer
 Indira Cameron-Banks, Public Member
 Jessi Crowley, Licensee Member
 Jose De La Paz, Public Member
 Kula Koenig, Public Member
 Ricardo Sanchez, Public Member
 Nicole Thibeau, Licensee Member
 Jason Weisz, Public Member

Board Members

Not Present: Renee Baker, Licensee Member

Staff Present: Anne Sodergren, Executive Officer
 Eileen Smiley, DCA Staff Counsel
 Debbie Damoth, Executive Manager Specialist

July 27, 2022

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

President Oh called the Board Meeting to order at 9:02 a.m.

President Oh reminded all individuals present that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. Where protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

President Oh advised all individuals the meeting was being conducted via WebEx. Dr. Oh advised participants watching the webcast they could only observe the meeting. He noted anyone interested in participating in the meeting must join the WebEx meeting using the instructions posted on the Board's website.

Department of Consumer Affairs' staff provided general instructions for the WebEx Board Meeting for members of the public participating in the meeting.

President Oh welcomed Dr. Renee Barker as the newest appointed Board Member in the established compounding position consistent with the provision contained in AB 1533. Dr. Barker was unable to attend the Board Meeting.

President Oh advised he would be working with staff for the Board to resume recognizing pharmacists who have dedicated 40 years of service to the profession in the WebEx platform. Dr. Oh hoped to roll it out as part of the September 2022 Board Meeting.

Roll call was taken. Board Members present included: Maria Serpa, Licensee Member; Jignesh Patel, Licensee Member; Indira Cameron-Banks, Public Member; Jessi Crowley, Licensee Member; Jose De La Paz, Public Member; Ricardo Sanchez, Public Member; Nicole Thibeau, Licensee Member; Jason Weisz, Public Member; and Seung Oh, 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 public comment.

A representative from CPhA requested an agenda item for the October 25, 2022, Standard of Care Ad Hoc Meeting regarding updates and date around pharmacists providing care at top of their license. The issue was deferred to President Oh and Executive Officer Sodergren in developing the agenda for the meeting.

III. Approval of Board Meeting Minutes

a. President Oh referenced the draft minutes from the April 26-27, 2022, meeting.

Members were provided with an opportunity to provide comments. Member Thibeau inquired if a member was not present at the meeting should the member abstain from voting on the minutes. Ms. Smiley advised it is permissible to vote on the minutes if the member wasn't at the meeting.

Motion: Approve the April 26-27, 2022, minutes as presented in the meeting materials.

M/S: Weisz/Thibeau

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

Support: 9 Oppose: 0 Abstain: 0 Not Present: 2

Board Member	Vote
Barker	Not Present
Cameron-Banks	Yes
Crowley	Yes
De La Paz	Yes
Koenig	Not Present
Oh	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes
Thibeau	Yes
Weisz	Yes

- b. President Oh referenced the draft minutes from the May 11, 2022, meeting.

Members were provided with an opportunity to provide comments; however, none were provided.

Motion: Approve the May 11, 2022, minutes as presented in the meeting materials.

M/S: Patel/Sanchez

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

Support: 9 Oppose: 0 Abstain: 0 Not Present: 2

Board Member	Vote
Barker	Not Present
Cameron-Banks	Yes
Crowley	Yes
De La Paz	Yes
Koenig	Not Present
Oh	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes
Thibeau	Yes
Weisz	Yes

c. President Oh referenced the draft minutes from the June 16, 2022, meeting.

Members were provided with an opportunity to provide comments; however, none were provided.

Motion: Approve the June 16, 2022, minutes as presented in the meeting materials.

M/S: Patel/Crowley

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

Support: 9 Oppose: 0 Abstain: Not Present: 2

Board Member	Vote
Barker	Not Present
Cameron-Banks	Yes
Crowley	Yes
De La Paz	Yes
Koenig	Not Present
Oh	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes
Thibeau	Yes
Weisz	Yes

IV. Update from the Department of Consumer Affairs

MaryKate Cruz Jones with Department of Consumer Affairs (DCA) provided an updated to the Board on behalf of the Executive Office.

Ms. Cruz Jones advised SB 189 was signed by the Governor on 6/30/22 which reinstates through 7/1/23 remote meeting provision of the Bagley-Keene Open Meeting Act in place during the pandemic. Ms. Cruz Jones stated DCA encourages having the right meeting for the business of the Board while still taking into consideration both costs and public participation. She noted DCA is requesting Boards/Bureaus track the costs for meetings and use WebEx as much as possible to allow the public to attend remotely. Ms. Cruz Jones noted DCA requests Boards/Bureaus to complete surveys to compare costs for in-person and WebEx meetings.

Ms. Cruz Jones provided Board Members and staff are expected to comply with all state and local public health guidelines that apply where the meetings are held. Face coverings are strongly recommended for all Board Members and staff at meetings. The California Department of Public Health (CDPH) strongly recommends individuals continue to mask when in-doors. Ms. Cruz Jones recommended posting face covering guidance signage at meeting check in/entrance. She reminded all Board Members are required to submit vaccination verification or be subject to COVID-19 testing.

Ms. Cruz Jones announced the inaugural report of the Enlightened Licensing Project was now available and distributed to Boards/Bureaus on 5/13/22. Ms. Cruz Jones noted the innovative and collaborative project was started to streamline and enhance licensing processes by utilizing the knowledge and expertise of subject matter experts (SMEs). In partnership with the BRN, the project chairs introduced new ideas and implemented best practices for critical licensing activities. Brown bag meetings were held to discuss the recommendations and future review of the Enforcement process.

Ms. Cruz Jones provided changes to DCA's regulation development and approval processes were presented to Board executive officers and bureau leaders. The changes were discussed and approved by DCA's executive officer cabinet.

Ms. Cruz Jones provided DCA staffing changes. Ms. Cruz Jones announced Nicole Le was hired as the Deputy Director of DCA's Office of Administrative Services (OAS). Ms. Le possess more than 20 years' experience with 10 years at DCA and most recently served as the Acting Deputy Director of DCA OAS. Ms. Cruz Jones advised Ms. Carrie

Holmes and Ms. Brianna Miller left DCA. Both Ms. Holmes and Ms. Miller were a huge asset to DCA. Ms. Cruz Jones advised DCA's Board and Bureau Relations (BBR) will strive to have no changes in the continuity of services. Members were encouraged to contact BBR or Executive Offices directly.

Ms. Cruz Jones reported DCA was advised there would be a delay in processing and approving travel expense claims until the new fiscal year can be established in FISCAL.

Ms. Cruz Jones reminded Board Members are required to complete Board Member Orientation Training (BMOT) within one year of appointment or reappointment. The final BMOT training for 2022 will be held on 10/12/22.

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

Members of the public were provided the opportunity to provide comment. A member of the public commented about a previous report provided by DCA/OPES and communication with NABP.

V. Discussion and Consideration of Board's Strategic Plan

President Oh advised the Board's strategic planning session occurred as part of the Board's September 2021 meeting. Following adoption of the new plan, on an annual basis the Board reviews its strategic plan to confirm the established strategic objectives for each committee remain appropriate or if changes should be considered. This annual review also serves as an opportunity for the Board to evaluate progress in the respective areas. Dr. Oh advised as a precursor to the review, except for the Organizational Development Committee, Committee's completed a review in their respective goal areas.

President Oh stated Chairs from the respective committees to provide the Board with an update on its discussion noting no committees appear to be offering recommendations to change any of their respective objectives.

As the Licensing Committee Chairperson, President Oh reported the status of the various objectives established for the committee noting efforts are underway for many of the objectives. Dr. Oh advised some objectives will be multi-year activities and looked forward to the continued momentum in several of the objectives already underway.

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

Enforcement and Compounding Chairperson Serpa reported Committee belief that the established strategic objectives were deemed appropriate and were not recommending any changes. Dr. Serpa noted in the coming year, the Committee anticipates significant activity related to strategic objective 2.10 as USP completes its work to revise and release chapters related to compounding.

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

Legislative and Regulation Committee Chairperson Crowley reported the Committee was not offering any changes as the Committee felt the current strategic objectives were still appropriate. Dr. Crowley noted several of the objectives will be ongoing as the Committee and Board continue to monitor and respond to legislation for example.

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

Communication and Public Education Committee Chairperson Sanchez reported no changes were recommended as objectives are in line with the overall Board's strategic plan. Committee Members discussed at the last Committee Meeting the frequency of emails being sent from the Board's subscriber alert system. Board staff agreed to review frequency and possibly add to a future agenda.

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

As Chairperson of the Organizational Development Committee, President Oh advised the Organization Development Committee is comprised of the Board President, Vice-President, and Executive Officer. Dr. Oh noted as the Committee does not meet in public, it was not offering any recommendations. Dr. Oh referenced meeting materials that detail out the various strategic objectives and status updates are provided. Dr. Oh noted objective 5.2 related to a formal onboarding program for new members. Dr. Oh requested if Members have recommendations on ways to improve upon the initial orientation and/or process that would assist future members, please email contact the Executive Officer. Dr. Oh noted the Board is very complex and want to ensure new members are provided with helpful onboarding information and follow-up.

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

Members of the public were provided the opportunity to comment on strategic objectives for all Board Committees; however, no comments were made.

VI. Organizational Development Committee Report

a. Budget Update and Report

President Oh reported Fiscal Year (FY) 22/23 began July 1, 2022. The Board's spending authorization for the new fiscal year increased to about \$31.3 Million which was an 11 percent increase from the prior year.

President Oh reported the final budget figures for FY 2021/22 would not be available until later in the year. Dr. Oh referenced meeting materials included preliminary figures through May 2022. Dr. Oh noted the Board received about \$34.8 million in revenue with the largest source of revenue coming from licensing fees. The Board expended about \$26.7 million with the largest expenditure being personnel, followed by pro rata and enforcement.

President Oh noted a review of the fund condition prepared by the Department indicates that at the end of the FY 2021/22, it is projected the Board will have 4.8 months in reserve. As indicated in the meeting materials, under provisions of Pharmacy Law, the Board shall seek to maintain a reserve equal to approximately one year's operating expenditures. Dr. Oh advised the fund condition projects a continued depletion of the Board's fund and noted the fee analysis is currently under way. Dr. Oh reported anticipating results at the October 2022 meeting.

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

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

b. Board Member Attendance and Mail Vote Information

President Oh referenced meeting materials containing Board Member attendance and mail vote information.

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

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

c. Personnel Update

President Oh advised as detailed in the meeting materials, the Board had several vacancies including a key leadership position. The vacancy count was higher as the Board received new positions July 1. Dr. Oh advised it was his understanding several of the inspector and licensing position have active recruitments underway. Dr. Oh stated he looked forward to monitoring the progress of these recruitments as filling vacancies will help to reduce processing times and was working closely with Executive Officer on recruitment challenges.

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

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

d. Discussion and Consideration of Board Policy Related to Legislative Positions

President Oh advised the Board Member Procedure Manual, includes, among other items, delegation of various activities to identified roles within the Board. Dr. Oh noted related to the discussion is the Board's policy related to taking legislative positions on emergent bills between board meetings.

President Oh stated he believed the delegated authority established in the policy is essential as legislation can move at a quick pace and may not align with Board Meetings. Dr. Oh spoke in support of continuing the delegation process and commented as serving as the President and Chair of the Legislation and Regulation Committee, many times he had routine contact with the Executive Officer monitoring changes to legislation and authorizing actions consistent with the Board's policy. Dr. Oh continued to ensure compliance with provisions of the Open Meetings Act, it is necessary for the Board to update its policy to delegate this function to a single member. Dr. Oh recalled for a number of years the Board President and Chair of the Legislation and Regulation Committee has been the same person.

Motion: Delegate the power to the Board's president to take board positions on emergent bills between board meetings. Further, delegation also includes working with the Executive Officer to negotiate amendments consistent with the Board's direction

and update Board positions in response to changes in pending legislation that require urgent action.

M/S: Serpa/Patel

Members were provided the opportunity to comment.

Members discussed whether the point of contact with the Executive Officer should be the President or Chairperson of the Legislation and Regulation Committee. Members inquired about a possible hybrid approach but were informed two Board Member could be viewed as a Committee of the Board which would require adherence to the Bagley-Keene Open Meeting Act.

Some Members felt the Chairperson would be the appropriate contact to spread power dynamic. Other Members felt the President was a better choice as the President would have a global perspective across the Board while the Chairperson could affirm the positions.

Members of the public were provided with an opportunity to provide comments; however, no comments were provided.

Support: 6 Oppose: 3 Abstain: 0 Not Present: 2

Board Member	Vote
Barker	Not Present
Cameron-Banks	Yes
Crowley	No
De La Paz	No
Koenig	Not Present
Oh	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes
Thibeau	No
Weisz	Yes

President Oh stated he would work with counsel for more ways to include the Chair whenever possible within the statutory requirements.

e. Future Meeting Dates

President Oh referred to the meeting materials that contained the meeting calendar for the remainder 2022 as well as dates for 2023.

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

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

VII. Standard of Care Ad Hoc Committee Report

President Oh provided a summary on the informational items from the Standard of Care Ad Hoc Committee Report. Dr. Oh thanked the Standard of Care Ad hoc Committee including Maria Serpa who was serving as Vice-Chairperson, Indira Cameron-Banks, Jessica Crowley, and Nicole Thibeau.

Chairperson Oh recalled as part of the provisions of Assembly Bill 1533, the Board was required to convene a workgroup of interested stakeholders to discuss whether moving to a standard of care enforcement model would be feasible and appropriate for the regulation of pharmacy and make a recommendation to the legislature about the outcome of these discussions through a report submitted to the Legislature. The report will be due on or before July 1, 2023.

a. Summary of Presentation Provided by Kerrie Webb

Chairperson Oh reported as part of the meeting on June 22, 2022, and continuing education on the issue, the Committee received a presentation by Kerrie Webb, Counsel for the Medical Board of California. The presentation was very informative and highlighted the positives and negatives for a standard of care model and challenges with such a model. The meeting materials summarize the presentation, member comments and public comment. Dr. Oh reported the June 22 meeting was webcast and is available on the Board's website.

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

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

A pharmacist commented Ms. Webb provided excellent presentation and hoped to ask questions to Ms. Webb about her presentation. The pharmacist indicated there was a question about standard of care based on location. The

pharmacist stated standard of care is the highest quality of care the pharmacist can provide and is qualified to provide. The pharmacist stated pharmacist care in rural areas is a broader scope than urban areas.

b. Summary of Discussion and Actions Taken by Other state Boards of Pharmacy Related to Standard of Care

Chairperson Oh reported the Committee reviewed the actions undertaken by the Idaho and Washington State Boards of Pharmacy. As included in the meeting materials, provisions of the law in the respective jurisdictions were provided as well as educational materials. Dr. Oh noted that materials highlight where there are similarities and differences with California law and the other jurisdictions related to pharmacist authority to provide patient care services. This information was provided as additional education for the Committee members and interested stakeholders. Dr. Oh highlighted that the Executive Director from the Idaho Board of Pharmacy was present during the meeting and offered to answer questions from members.

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

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

b. Discussion and Consideration of Policy Questions Related to Standard of Care in the Practice of Pharmacy

Chairperson Oh provided following the presentation and consideration of the efforts undertaken by Idaho and Washington, the Committee began consideration of various policy questions intended to assist members and interested stakeholders in assessment of the large policy question before the Board, should the Board Transition to a Standard of Care Enforcement Model.

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

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

c. Summary of Discussion of Policy Questions Related to Standard of Care in the Practice of Pharmacy

Chairperson Oh reported the Committee reviewed policy questions to aid in its discussion of the very complex issue. Dr. Oh noted as detailed in the meeting materials, the Committee had not reached a conclusion. While the issue on its face may seem to be a simple one, the more discussion and consideration of the issue seems to raise more questions about the possibility and possible impact of a transition to a standard of care enforcement model, rather than leading to a conclusion.

Chairperson Oh stated the meeting materials summarize the Committee's discussion on the various questions and public comments received. Dr. Oh highlighted a few key takeaways.

Chairperson Oh reported members are seeking additional data including data that supports that a standard of care enforcement model results in improved patient care, information on the Board's enforcement timeframes and data on ownership of pharmacies in California. Dr. Oh noted although it is appropriate to learn about how other agencies may use a standard of care enforcement model, it is important to note there are differences in the scope of regulation, demographics, and other factors unique to the Board that must be contemplated and ultimately what is the impact to California consumers.

Chairperson Oh noted although the question of whether a transition to a standard of care enforcement model remains outstanding, there does appear to be general agreement from many stakeholders that it may not be appropriate for such a model to be used for all areas of practice.

Chairperson Oh reported the Committee was unclear if a standard of care enforcement model is possible and the concept of an expanded scope of practice versus of standard of care enforcement model needs to be more thoroughly contemplated. Further, the Committee must remain mindful to ensure whatever the outcome it does not result in healthcare inequities.

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

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

Member Cameron-Banks left the meeting at 10:00 a.m.

The Board took a break at 10:02 a.m. and returned at 10:17 a.m. Roll call was taken. Board Members present included: Maria Serpa, Licensee Member; Jignesh Patel, Licensee

Member; Jessi Crowley, Licensee Member; Jose De La Paz, Public Member; Ricardo Sanchez, Public Member; Nicole Thibeau, Licensee Member; Jason Weisz, Public Member; and Seung Oh, Licensee Member. A quorum was established.

VIII. Medication Error Reduction and Workforce Committee

Chairperson Thibeau advised the Medication Error Reduction and Workforce Ad Hoc Committee met June 22, 2022. Dr. Thibeau thanked fellow members including Vice Chair Seung Oh, Jessi Crowley, Kula Koenig and Jig Patel.

- a. Summary of Presentation by the National Association of Boards of Pharmacy on its Workforce Task Force Report and National Perspective on Workforce Related Issues including Discussion and Consideration

Chairperson Thibeau reported at the last meeting, the Committee continued its education on efforts undertaken by other agencies related to workforce issues and medication errors including three presentations.

Chairperson Thibeau reported the Committee received a presentation from Bill Cover, Associate Executive Director, State Pharmacy Affairs, with the National Association of Boards of Pharmacy. Mr. Cover provided information on the NABP's Task Force Report and the recommendations coming from the task force. The recommendations are detailed in the meeting materials.

Chairperson Thibeau advised the Committee noted that many of the recommendations are outcome focused. Based on information received during prior meetings, Dr. Thibeau agreed training on continuous quality improvement was important. During the Committee's January meeting, Dr. Thibeau was surprised to learn that pharmacy education may not address learning continuous improvement process which may result in some new practitioners not having training on how to implement such a process.

Chairperson Thibeau reported the Committee was advised that some corporations do not allow for the staffing of the pharmacy to be listed on medication error reports. Dr. Thibeau suggested this may be an issue to consider. Dr. Thibeau noted as the Committee was evaluating medication error reduction and workforce, such information appears to be an intersection of the two issues and that such data appears both relevant and necessary.

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

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

- b. Summary of Presentation by the American Pharmacists Association on the Well-Being Index, Pharmacist's Fundamental Responsibilities and Rights and Survey Results

Chairperson Thibeau reported during the meeting, members received a presentation from April Shaughnessy, APhA Well-being Initiative Project Manager and were provided an overview of the Well-being Index tool and that information suggests a pharmacist at risk of high distress is, among other things, at a two-fold higher risk of medication errors.

Chairperson Thibeau reported Ms. Shaughnessy discussed the Pharmacist's Fundamental Responsibilities and Rights document developed by APhA and the National Alliance of State Pharmacy Associations. Dr. Thibeau advised the document outlines fundamental responsibilities for pharmacists building upon the principles of the Oath of a Pharmacist and Pharmacist Code of Ethics and certain workplace expectations that are needed to fulfill these responsibilities. Dr. Thibeau recalled one of the recommendations from the NABP task force was to endorse this fundamentals document.

Chairperson Thibeau advised the presentation also included a review of the APhA Workplace Reports and Data that suggested pharmacy personnel report harassment and bullying from patients without support of their employers. Dr. Thibeau noted this dynamic is a real concern for pharmacists and could also be a cause of medication errors.

Chairperson Thibeau advised the Committee suggested development of a campaign highlighting the value of pharmacists. Dr. Thibeau noted many of the responsibilities and rights included in the fundamentals document are directly related to the work of the Committee.

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

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

- c. Summary of Presentation by the Nova Scotia College of Pharmacists on the Nova Scotia Workplace Conditions Strategic Work

Chairperson Thibeau advised the Committee heard a presentation from Beverly Zwicker, the CEO and Registrar of the Nova Scotia College of Pharmacists, on their workplace conditions strategic work. Dr. Thibeau noted the Nova Scotia College of Pharmacists was concerned with the rise of medication errors which results in suboptimal care for patients. Ms. Zwicker detailed the process used by her agency to evaluate the issue including review of literature, interviews with pharmacy practitioners, surveys, interviews with other stakeholders and surveys of pharmacy managers. The literature was clear about the link between workforce issues and the quality of care provided and risk of medication errors. Dr. Thibeau noted these conclusions appear consistent with the information in California reviewed including the public comments and survey responses received.

Chairperson Thibeau advised the next steps under consideration by the Nova Scotia College of Pharmacists was potential interventions based on identified barriers and research including development of a staffing formula. Dr. Thibeau noted in their jurisdiction there is a requirement for pharmacy managers to ensure that a staffing plan is commensurate with the needs of the patients receiving care in the pharmacy.

Chairperson Thibeau reported members expressed interest exploring the option of conducting similar research in the staffing formula research in California. Chairperson Thibeau advised the Committee continues to monitor the efforts of the Nova Scotia College of Pharmacists including any research that is conducted related to development of a staffing formula.

Members were provided the opportunity to provide comment. Member Serpa noted she listened to the meeting as a member of the public and encouraged members listen to the recording of the meeting as it was excellent and eye opening.

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

IX. Communication and Public Education Committee

Chairperson Sanchez provided a summary of the July 19, 2022, Communication and Public Education Committee.

- a. Discussion and Consideration of Providing Education to Licensees about the Institute for Safe Medication Practices

Chairperson Sanchez provided the Medication Error Reduction and Workforce Committee received a presentation in January 2022 about the Institute for Safe Medication Practices (ISMP). Mr. Sanchez advised ISMP provides many tools and publications to help health care workers prevent medication errors. The Medication Error Reduction and Workforce Committee suggested the Communication and Public Education Committee consider opportunities to educate licensees about ISMP and its resources for preventing medication errors. Mr. Sanchez reported at the Communication and Public Education Committee Meeting July 19 staff recommended posting a link to ISMP on the Board's website and publishing an article in The Script about ISMP and its resources for preventing medication errors. Committee members supported the recommendation.

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

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

b. Discussion and Consideration of Providing Naloxone Educational Materials for Pharmacists

Chairperson Sanchez reported at the July 2021 meeting of the Enforcement Committee, members and speakers discussed challenges in getting pharmacists to furnish naloxone. Some said pharmacists are too busy to furnish naloxone while others said the naloxone protocol requires pharmacist to engage with patients, but many pharmacists are uncomfortable or do not want to engage with patients. The Enforcement Committee recommended the Communication and Public Education Committee develop educational materials to assist pharmacists in understanding the value of naloxone and how to operationalize naloxone distribution.

Chairperson Sanchez reported at the Communication and Public Education Committee Meeting July 19, staff noted the Board's website provides many resources for pharmacists furnishing naloxone, including a [training webinar](#), [FAQs](#), [sample naloxone labels](#), [fact sheets](#) and [screening questions](#) in multiple languages. Staff recommended publishing an article in The Script about the Board's online

resources to assist pharmacists in furnishing naloxone. Committee members supported the recommendation and said the article should include examples of how to operationalize furnishing naloxone in retail pharmacies.

Members were provided the opportunity to provide comment. Member Crowley commented in appreciation for the committee taking on the issue. Dr. Crowley noted the pharmacist may not know how to initiate the conversation to recommend naloxone. Dr. Crowley noted pharmacists do not want to offend patients and suggested education on conversation starters and practice starting those conversations. Dr. Crowley noted naloxone is expensive and can be a financial barrier.

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

c. Discussion and Consideration of Public Awareness Campaign "Treating Your Pharmacy Staff with Courtesy"

Chairperson Sanchez reported the Medication Error Reduction and Workforce Committee received a presentation in June 2022 from the American Pharmacist Association about the Well-Being Index for Pharmacy Personnel. The index is an online tool that health care professionals can use to self-assess their well-being. The index tracks levels of well-being and distress among pharmacists, student pharmacists, and pharmacy technicians nationally and by state. The Medication Error Committee expressed concern that a general lack of respect for pharmacists among the public – compared to other professionals – may contribute to distress on the job. Licensee members described being bullied and harassed by customers and being belittled as "just putting pills in a bottle."

Chairperson Sanchez reported at the Public Education Committee Meeting July 19, members supported developing a campaign to increase public awareness and appreciation for the role of pharmacy professionals in providing and protecting patient health. Members also directed staff to seek out partnerships with other agencies in developing the campaign and to educate the public about what pharmacists do to ensure consumer safety.

Members were provided the opportunity to provide comment. President Oh noted it was a great idea and encouraged improved awareness of what pharmacists do for consumers.

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

Member Cameron-Banks returned to the meeting at approximately 10:38 a.m.

Member Koenig joined the meeting at approximately 10:39 a.m.

d. Senate Resolution Designating September 2022 as Opioid, Heroin, Fentanyl, and Prescription Drug Abuse Awareness Month

Chairperson Sanchez reported State Senator Patricia Bates has introduced [Senate Concurrent Resolution 115](#) to designate September 2022 as Opioid, Heroin, Fentanyl, and Prescription Drug Abuse Awareness Month. Mr. Sanchez advised the measure is intended to increase public awareness of the dangers of abuse of opioids, heroin, fentanyl, and prescription drugs. The resolution contains important legislative findings, including:

- In 2020, more than 14,800,000 opioid prescriptions were written in California.
- From 1999 to 2020, inclusive, more than 500,000 people died from overdoses related to opioids in the United States.
- Fentanyl is 50 times more potent than heroin and 100 times more powerful than morphine. The number of deaths from fentanyl overdoses increased by more than 2,100% in California in five years.

Chairperson Sanchez reported at the Public Education Committee Meeting July 19 Staff recommended posting the resolution on the Board's website under [Prescription Drug Abuse Prevention](#) and developing a social media campaign highlighting consumer information on the website. Members discussed the problem of opioid abuse and strongly supported the recommendation.

Members were provided the opportunity to provide comment. Member Crowley commented it was a great idea and recommended highlighting prescription drug

awareness for non-opioid medications as well as non-opioid medications can be dangerous.

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

e. Update on Communication and Public Education Activities by Staff

Executive Officer Sodergren provided an update on the public education activities by the staff.

1. The Script

Ms. Sodergren reported the next issue of the newsletter is set for publication this summer. Article topics include new regulations, the new Strategic Plan, information about COVID-19 waivers, and notification requirements for PICs and pharmacies when a PIC stops acting as the PIC.

2. Staff Outreach

Ms. Sodergren reported presentations on the pharmacist exam application have been provided at Loma Linda University, UCSF, USC, Northstate University, and American University of Health Sciences. Ms. Sodergren has also provided presentations on the intern pharmacist application at USC and UCSF. Staff also noted the Board hosted a dozen listening sessions in March and April 2022 for pharmacy technicians and pharmacists in preparation for the Pharmacy Technician Summit.

3. News Media

Ms. Sodergren reported news media inquiries received during the second quarter of 2022 are listed in meeting materials.

4. Educational Resources

Ms. Sodergren reported information for licensees who want to file a complaint alleging pharmacy quotas in violation of [SB 362](#) has been disseminated via subscriber alerts. The information also will be published in The Script and a brochure. Ms. Sodergren also reported the Board's [pharmacy inspections brochure](#) is being updated with additional items inspectors will review during an inspection. The revisions are undergoing legal review.

Members were provided the opportunity to provide comment. Committee members thanked staff members for their work on all these items. Member Crowley requested staff to put together a virtual resource for out of state applicants.

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

X. Licensing Committee Report

Chairperson Oh provided the report from the Licensing Committee held on July 18, 2022, and acknowledged the work of the members of the Committee including Jig Patel, who serves as the Vice-Chair, Indira Cameron-Banks, Jessica Crowley and Jason Weisz.

a. Discussion and Consideration of Business and Professions Code section 4111 Related to Ownership Prohibitions of Pharmacy Licensure

Chairperson Oh reported during the Committee meeting the committee discussed several items, including Business and Professions Code (BPC) Section 4111 which specifies that the Board shall not issue or renew a license to conduct a pharmacy to an individual authorized to prescribe as well as to a person who shares a community or other financial interest with a prescriber. Dr. Oh referenced meeting materials provided background information on the issue including some history. Dr. Oh advised California is a community property state which generally means that property acquired by either spouse during a marriage is presumed to be equally owned by both spouses with exceptions such as prenuptial agreements, where property acquired may not be community property depending on the agreement of the parties.

Chairperson Oh advised the meeting materials provide some historical information related to the application process and assessment of prescriber ownership prohibition. Dr. Oh reported as the Board became more adept at evaluating information it discovered that representations made by applications were not substantiated by requested information. Dr. Oh noted during the meeting the Committee considered determining if the current provisions were appropriate, or if there was a means by which the legislative intent could be preserved while creating flexibility for an otherwise authorized individual to own or operate a pharmacy and possible statutory language that could balance the intent of the provisions of BPC 4111 while establishing some flexibility

for ownership for individuals seeking to own pharmacies with familial relationships to a prescriber.

Chairperson Oh advised there appeared to be consensus among Committee members that the language provided would be appropriate. Dr. Oh noted after public comment was received, the Committee tabled its motion recommending approval of the proposed language. Specifically public comment suggested that expansion of ownership authority should be included in BPC 4111(e) to allow pharmacists working under a collaborative practice agreement to own and operate a pharmacy. Dr. Oh advised as this was not contemplated in the development of the proposal the Committee was not offering a recommendation at this time.

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

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

- b. Discussion, Consideration, and Possible Recommendation to the board to Approve Draft Regulations to Implement Provisions of Assembly Bill 107 Related to Requirements to Issue a Temporary License.

Chairperson Oh advised recently enacted legislation requires the Board to issue temporary licenses to practice professions under specified conditions including a background check and passing a California Law and ethics exam. Dr. Oh provided to implement the legislation, the Board needs to promulgate regulation to define the application requirements. Dr. Oh referenced draft regulation language considered by the Committee provided in the meeting materials. Dr. Oh advised the meeting materials highlight some areas where the draft regulation language would vary from other areas of pharmacy law, including the requirement to provide the Board with an email address.

Chairperson Oh thanked counsels for their respective efforts to provide comments back on the draft language that allowed for consideration by both the Committee and the Board. This should ensure the regulation process will be completed by July 1, 2023. Dr. Oh noted the slide displays the Committee Recommendation, which is also included in the meeting materials.

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

Committee Recommendation (Motion): Recommend to the Board to approve the proposed addition to Title 16, CCR section 1706.6, Temporary Licenses for Military Spouses/Domestic Partners as revised on July 15, 2022. Initiate the regular rulemaking process. Delegate to the Executive Officer the authority to make any non-substantive changes and clarifying changes consistent with the Board's policy direction upon recommendation of the control agencies.

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

Add section 1706.6 to Article 1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1706.6. Temporary Licenses for Military Spouses/Domestic Partners

- (a) Definitions: For the purposes of this section, the following definitions shall apply:
- (1) "Disciplined" means that the applicant's license was placed on probation, revoked, suspended, reprobated, censured, reprimanded, restricted, limited, or conditioned.
 - (2) "Jurisdiction" shall mean a California or another state's licensing board or agency, any agency of the federal government, or another country.
 - (3) "Disciplinary proceeding" shall mean any proceeding or investigation under the authority of the licensing jurisdiction pursuant to which a licensee may be disciplined.
 - (4) "Good standing" shall mean that the applicant has not been disciplined, is not the subject of an unresolved complaint or review procedure and is not the subject of any unresolved disciplinary proceeding.
 - (5) "Original licensing jurisdiction" shall mean the entity that issued a license to the applicant authorizing the applicant to practice within the same scope for which the applicant seeks a temporary license from the Board.
- (b) An applicant for a temporary pharmacist, advanced practice pharmacist, pharmacy technician, designated representative, designated representative-reverse distributor, designated representative-3PL or a designated paramedic license pursuant to section 115.6 of the Business and Professions Code ("Code") shall submit a completed application and meet all of the requirements of this section and section 115.6 of the Code to be eligible for a temporary license. A completed application shall provide the following information:

- (1) The applicant's identifying and contact information:
 - (A) Applicant's full legal name ((Last Name) (First Name) (Middle Name) and/or (Suffix)),
 - (B) Other name(s) applicant has used or has been known by,
 - (C) Applicant's address of record (The address of record may be a post office box number or other alternate address.),
 - (D) Applicant's physical address, if different than the applicant's address of record,
 - (E) Applicant's email address,
 - (F) Applicant's telephone number,
 - (G) Applicant's Social Security Number or Individual Taxpayer Identification Number, and,
 - (H) Applicant's birthdate (month, day, and year).
- (2) The applicant shall indicate that the applicant is married to, or in a domestic partnership or other legal union with, an active-duty member of the Armed Forces of the United States who is assigned to a duty station in California under official active-duty military orders and shall provide the following documentation with the application:
 - (A) Certificate of marriage or certified declaration/registration of domestic partnership filed with the California Secretary of State or other documentary evidence of legal union with an active-duty member of the Armed Forces, and,
 - (B) A copy of the military orders establishing their spouse or partner's duty station in California.
- (3) The applicant shall disclose whether the applicant holds a current, active, and unrestricted license of the same type of license that the applicant is applying for, or comparable authority to practice in another state, district, or territory of the United States and provide written verification from the applicant's original licensing jurisdiction that the applicant's license or other comparable authority ("license") is in good standing in that jurisdiction. The verification shall include all of the following:
 - (A) the full legal name of the applicant and any other name(s) the applicant has used or has been known by,
 - (B) the license type and number issued to the applicant by the original licensing jurisdiction, and relevant law(s) and regulation(s) under which the license was issued,
 - (C) the name and location of the licensing agency,
 - (D) the issuance and expiration date of the license, and,
 - (E) information showing that the applicant's license is currently in good standing.

- (4) The applicant shall disclose whether the applicant has committed an act in any jurisdiction that would have constituted grounds for denial, suspension, or revocation of the license pursuant to Sections 141, 480, or 490 of the Code, or Sections 4300, 4301, 4311 of the Code, or section 1762 of this Division. For applicants for a temporary pharmacist license, those applicants shall also disclose whether the applicant has committed an act in any jurisdiction that would have constituted grounds for denial, suspension, or revocation of the license pursuant to Sections 4305 or 4306.5 of the Code.
 - (5) The applicant shall disclose whether the applicant has been disciplined by a licensing entity in another jurisdiction or is the subject of an unresolved complaint, review procedure, or disciplinary proceeding conducted by a licensing entity in another jurisdiction.
 - (6) The applicant shall submit fingerprints for use by and accessible to the board in conducting criminal history information record checks through the California Department of Justice.
 - (7) The applicant shall sign a statement attesting to the fact that the applicant meets all the requirements for the temporary license, and that the information submitted in the application is accurate, to the best of the applicant's knowledge.
- (c) In addition to the above requirements, applicants for a temporary pharmacist license must successfully complete the Board's law and ethics examination designated as the California Practice Standards and Jurisprudence Examination (CPJE) for Pharmacists set forth in Section 4200 of the Code, which tests the applicant's knowledge and proficiency in state and federal laws and provisions of safe patient care, the items set forth in Section 4200.2 and 4200.3 (d) of the Code.
- (d) Upon issuance of a temporary license in accordance with Section 115.6(a) of the Code, the Board shall provide written notice to the applicant of the following:
- (1) That the temporary license is nonrenewable;
 - (2) That the license expires 12 months after issuance, upon issuance or denial of a standard license, or upon issuance or denial of an expedited license pursuant to Section 115.5 of the Code, whichever occurs first; and,
 - (3) Any holder of a temporary license desiring to continue their licensure or to practice in California after expiration of their temporary license shall apply for and obtain a standard pharmacist, advanced practice pharmacist, pharmacy technician, designated representative, designated representative-reverse distributor, designated representative-3PL or a designated

paramedic license, as applicable, in accordance with Sections 4200, 4202, 4210, 4053, 4053.1, 4053.2, and 4202.5 of the Code.
 Authority: Sections 115.6 and 4005, Business and Professions Code.
 Reference: Section 30, 31, 115.6, 141, 480, 490, 4200, 4300, 4301, 4301.5, 4305, 4306.5, and 4311, Business and Professions Code.

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

Support: 10 Oppose: 0 Abstain: 0 Not Present: 1

Board Member	Vote
Barker	Not Present
Cameron-Banks	Yes
Crowley	Yes
De La Paz	Yes
Koenig	Yes
Oh	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes
Thibeau	Yes
Weisz	Yes

- c. Discussion and Consideration of Current Pharmacy Technician Authorized Duties, Current Pharmacist and Pharmacy Technician Ratio and Possible Changes.

Chairperson Oh reported the Committee continued its discussion on pharmacy technician including authorized duties, technician ratios and possible changes. Dr. Oh provided in April 2022, the Committee convened a Pharmacy Technician Summit where the Committee discussed the results of the listening sessions and surveys, information at the national level, and research on various related topics. Dr. Oh noted as detailed in the meeting materials, during the Committee's discussion in April, members reached consensus on some areas, including some possible new duties for pharmacy technicians including authority to administer vaccinations, authority to receive verbal prescriptions and transfers prescriptions, and authority to perform some aspects of CLIA waived testing.

Chairperson Oh reported the Committee used the prior discussion as the springboard the discussion at the previous Committee meeting, where the

Committee considered several policy questions. Dr. Oh provided the policy questions and general summary information were included in the meeting materials. Dr. Oh shared the general concepts where Dr. Oh believed the Committee had reached consensus providing staff with information to develop the general parameters for a proposal for the Committee to consider at its next meeting.

Chairperson Oh provided the general parameters included a recommendation that pharmacy technicians be provided authority to accept verbal prescriptions and transfers and accept clarifications on prescriptions that do not require professional judgement. Dr. Oh continued the proposal would include provisions for a pharmacy technician to administer vaccines and epinephrine under specified conditions, including completion of necessary training followed by authorization by the PIC for the technician to perform vaccine administration, provisions for additional pharmacy technician staffing including an increase in the pharmacist to pharmacy technician ratio where one of the pharmacy technicians is administering vaccines. Dr. Oh provided the proposal would include provisions for a pharmacy technician to perform specified tasks related to CLIA waived tests under specified conditions including training requirements and authorization by the PIC for the pharmacy technician to perform such tasks.

Chairperson Oh advised the Committee requested staff begin working on a draft proposal. Dr. Oh reported at the next meeting the Committee will consider the general parameters of the proposal and consider some outstanding policy questions including consideration of continuing education requirements and consideration of inclusion of a national certification requirement for pharmacy technicians performing expanded duties.

Chairperson Oh noted the Committee did not reach consensus on changes to the ratio beyond for purposes of vaccine administration and for purposes of moving forward the proposal, the issue of ratio beyond for vaccine administration will not be considered at this time but may be considered as part of future discussion. Dr. Oh stated the approach was appropriate as it will allow the Committee to continue moving forward in areas where there was consensus.

Chairperson Oh reported the Committee received public comment that expressed concern for the current workload of pharmacists and the need to ensure appropriate staffing. It was suggested that the proposal include strong anti-retaliation provisions for PICs. Some comments expressed support of national certification and CE requirements while others expressed

disappointment that the Committee would not be considering an increase in the ratio beyond duties related to vaccine administration at this time.

Members were provided an opportunity to provide comment.

Member De La Paz inquired how the Board arrived at the current ratio in pharmacy law. Ms. Sodergren provided a historical overview on the discussion of pharmacist-to-pharmacy technician ratio indicating changes in ratios have been discussed by the Board in the past. Ms. Sodergren noted the Medication Error Reduction and Workforce Ad Hoc Committee was working on the issue now and reviewing different studies including the Nova Scotia studies. Ms. Sodergren added there is currently a DCA waiver in place now allowing for an increase of the ratio for pharmacy technicians. She noted when comparing California's ratio to other state ratios, it is important to consider all variables in play including duties of pharmacy technicians as well as duties and ratio for unlicensed staff such as clerks. President Oh provided history on the ratios and added the Board may consider a floor or minimum staffing level rather than a ceiling. Mr. De La Paz stated the focus needs to be on consumer and patient safety rather than corporate profits and losses.

Member Crowley agreed with Member De La Paz and spoke in support of minimum staffing levels rather than adding more duties to one individual. Dr. Crowley spoke in support of national certification as continuing education is typically a requirement to maintain national certification and strong anti-retaliation language. Dr. Crowley stated the pharmacists-in-charge (PIC) and pharmacy technicians should be able to decide and not feel pressured about being required to do expanded duties.

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

The Board heard public comment from a representative of NACDS/CRA in support of discussing the issue and recognizing the importance of pharmacy technicians. The representative spoke in support of expanded duties and ratios not limited to vaccinations and noted related to the Nova Scotia report the Canadian health care system was different than the health care system in the United States.

A representative from CVS Health commented about half of the states in the nation do not have a ratio and other states have ongoing measures to increase ratios and noted it wasn't practical to only allow increase in ratios when immunizations were being administered.

A representative from CCAP agreed with the previous commentors regarding ratios and appreciated the need to continue the DCA waivers and spoke in support of including the increase in other practice settings.

A representative of United Nurses Association of California/Union of Health Care Professionals (UNAC/UHCP) commented in appreciation the discussion noting UNAC/UHCP's concern about increasing ratios as well as the survey results referenced in the meeting materials had a small sample size compared to the total number of pharmacists.

d. Licensing Statistics

Chairperson Oh referenced the year-end and three-year comparison licensing data. Dr. Oh noted that the data indicates a four percent overall growth in the receipt of applications for initial licenses with the most significant increase in the number of pharmacy technician applications. There has also been a slight increase in overall exam applications (exam and retake combined). Dr. Oh noted it was interesting that there was a large drop in the number of intern applications received over the three-year period.

Chairperson Oh reported there has been an overall decline in the number of site applications received. Dr. Oh reported appeared to be an overall growth in pharmacy applications received when combining chain and nonchain applications received; however, looking at the data separately, there is about a 13 percent decrease in nonchain pharmacy applications received. Dr. Oh added there were also increases in several of the Board's nonresident business licenses including nonresident pharmacy applications, nonresident sterile compounding applications and nonresident third-party logistics providers. Dr. Oh provided there was a significant increase in the number of temporary applications received for the three-year period, including a 16 percent increase in the number of temporary pharmacy applications received. He noted staff have previously identified this growth as one of the contributing factors for site licensing processing times. Dr. Oh advised included in the recent budget was additional staff resources to assist with the workload associated with this growth.

Chairperson Oh reported there appears to be a significant drop in the denial of applications for individual licenses. Dr. Oh presumed that is in part attributed to changes in the law that preclude the Board from considering some past arrest and conviction information. Dr. Oh noted there has been a 20 percent increase in the number of chain pharmacies discontinuing business while there has been a 33 percent decrease in other pharmacies discontinuing business.

Chairperson Oh reported the Board's overall licensee population remains about the same. Public comment suggested that the decrease in pharmacy intern applications could reflect the difficulty pharmacy schools are having in recruiting students. It was suggested that the Board monitor this issue for potential future workforce shortages.

Chairperson advised processing times exceed performance standards established by the Board and noted the Board had 7.5 vacant positions within its licensing unit. Dr. Oh expected as positions are filled and staff onboarded, there will be improvement in processing times.

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

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

The Board took a break at 11:20 a.m. and returned at 11:25 a.m. Roll call was taken. Board Members present included: Maria Serpa, Licensee Member; Jignesh Patel, Licensee Member; Indira Cameron-Banks, Public Member; Jessi Crowley, Licensee Member; Ricardo Sanchez, Public Member; Nicole Thibeau, Licensee Member; Jason Weisz, Public Member; Jose De La Paz, Public Member; and Seung Oh, Licensee Member. A quorum was established.

Member Koenig returned at 11:29 a.m.

XI. Enforcement and Compounding Committee Report

Chairperson Serpa provided the report on the July 19, 2022, meeting and thanked fellow members, Vice-Chair Jig Patel, Renee Barker, Indira Cameron-Banks, Seung Oh and Ricardo Sanchez.

- a. Discussion, Consideration, and Possible Recommendation to the Board to Approve Draft Changes to CCR Section 1715.1 related to Self-Assessment of an Automated Drug Delivery System by the Pharmacist-in-Charge of Unlicensed AUDS

Chairperson Serpa referenced the relevant sections of Pharmacy Law detailed in the meeting materials that established requirements for the use of automated unit-dose delivery systems, referred to as AUDS, under specified conditions. Dr. Serpa advised the Committee discussed AUDSs that are exempt from licensure

by the Board but must otherwise comply with all other requirements for an automated drug delivery system.

Chairperson Serpa reported one requirement was the completion of a self-assessment form for AUDS. Dr. Serpa noted although the relevant regulation currently provides that a self-assessment must be completed annually, subsequently enacted statutory changes modified the frequency for completion of a self-assessment to every odd year, which was consistent with the required frequency to complete self-assessment form for other licensees. Dr. Serpa recalled the Board has previously considered and voted to update regulation section to be consistent with statute. This regulation change was still pending.

Chairperson Serpa advised at the previous meeting, the Committee considered the policy goal of the self-assessment requirement specifically related to **unlicensed AUDSs used in hospitals** to determine if the Board should provide clarification of the requirement when a hospital is using the same device, with the same policies and procedures on the same computer platform, and if completion of a single self-assessment would be more appropriate. Dr. Serpa advised such devices operated in the same manner and under the conditions outlined, would yield the same results related to compliance with provisions of pharmacy law, whether one self-assessment was completed or several of the forms which would be the same.

Chairperson Serpa reported having a background in hospital pharmacy, Dr. Serpa knew a large hospital can use over 100 AUDSs in a single building. Dr. Serpa advised because the manufacturer is the same, the policies and procedures are the same, as is the staff, coupled with the fact that programming managing how the device will operate occurs on a single platform, Dr. Serpa believed completion of a single self-assessment is appropriate. Dr. Serpa noted there is no need for the PIC to complete over 100 forms containing the same information.

Chairperson Serpa referred to the Committee's recommendation included in the meeting materials that the Committee is recommending additional proposed changes to CCR Section 1715.1 to clarify the Board's policy for the PIC to be required to complete a single self-assessment under specified conditions.

Chairperson Serpa referenced meeting materials that included the language approved by the Committee. Dr. Serpa noted when the language presented to the Board included the additional changes recommended and reflected in

double underline and double strike-through. Dr. Serpa reviewed the specific changes related to the Committee's discussion.

- 1715.1(b)(2) appeared to be a suggested change to simplify the language.
- 1715.1(c)(5) & (c)(6) updated language to be gender neutral.
- 1715.1(f) was the new language that would clarify the Board's expectation related to completing the self-assessment form for the unlicensed AUDSs used in a hospital. Dr. Serpa noted the specified conditions included to qualify for this modified self-assessment requirement, the mechanical devices used to store, dispense or distribute dangerous drugs must be from the same manufacturer and controlled by the same software on a single system and must operate under the same policies and procedures.

Members were provided with the opportunity to comment. Member Crowley thanked Dr. Serpa for the clarification noting the language was concise and made sense.

Committee Recommendation (Motion): Recommend incorporation of the additional proposed changes to CCR Section 1715.1 as proposed into the Board's current regulation proposal and include the change from "vendor" to "manufacturer" in section 1715.1(f). Delegate to the executive the authority to make nonsubstantive changes.

Proposed Amendment to § 1715.1. Self-Assessment of an Automated Drug Delivery System by the Pharmacist-in-Charge. Changes in ~~double strike through~~ and double underline are possible changes for the Committee's consideration.

(a) The pharmacist-in-charge of each automated drug delivery system as defined under section 4119.11, 4187.5 or section 4427.3 of the Business and Professions Code (BPC) shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed ~~annually~~ before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:

- (1) A new automated drug delivery system license has been issued.

- (2) There is a change in the pharmacist-in-charge, ~~and he or she becomes the new pharmacist in charge of an automated drug delivery system.~~
 - (3) There is a change in the licensed location of an automated drug delivery system to a new address.
- (c) A pharmacist-in-charge of an automated drug delivery system shall assess the system's compliance with current laws and regulations by using the components of Form 17M-112 (Rev 12/18 22) entitled "Automated Drug Delivery System Self-Assessment". Form 17M-112 shall be used for all automated drug delivery systems and is hereby incorporated by reference.
- (1) The pharmacist-in-charge shall provide identifying information about the underlying operating pharmacy including:
 - (A) Name and any license number(s) of the underlying pharmacy and their expiration date(s);
 - (B) Address, phone number, and website address, if applicable, of the underlying pharmacy;
 - (C) DEA registration number, expiration date, and date of most recent DEA inventory;
 - (D) Hours of operation of the pharmacy; and
 - (E) ADDS license number, address, and hours of operation.
 - (2) The pharmacist-in-charge shall respond "yes", "no", or "not applicable" (N/A) about whether the automated drug delivery system is, at the time of the self-assessment, in compliance with laws and regulations that apply to that pharmacy setting.
 - (3) For each "no" response, the pharmacist-in-charge shall provide a written corrective action or action plan to come into compliance with the law.
 - (4) The pharmacist-in-charge shall initial each page of the self-assessment with original handwritten initials in ink or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form.
 - (5) The pharmacist-in-charge shall certify on the last page of the self-assessment that they have ~~he or she has~~ completed the self-assessment of the automated drug delivery system of which they are ~~he or she is~~ the pharmacist-in-charge. The pharmacist-in-charge shall also certify a timeframe within which any deficiency identified within the self-assessment will be corrected and acknowledge that all responses are subject to verification by the Board of Pharmacy. The certification shall be made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct with an original handwritten signature in ink or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form.
 - (6) The automated drug delivery system owner shall certify on the final page of the self-assessment that they have ~~he or she has~~ read and reviewed

the completed self-assessment and acknowledges that failure to correct any deficiency identified in the self-assessment could result in the revocation of the automated dispensing system's license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California with an original handwritten signature in ink or digitally signed in compliance Civil Code Section 1633.2(h) on the self-assessment form.

- (d) Each self-assessment shall be completed in its entirety and kept on file in the underlying pharmacy for three years after it is performed. The completed, initialed, and signed original must be readily available for review during any inspection by the board.
- (e) Any identified areas of noncompliance shall be corrected as specified in the assessment.
- (f) The pharmacist-in-charge of a hospital using more than one unlicensed automated drug delivery system as authorized in BPC section 4427.2(i) may complete a single self-assessment of the hospital's compliance with federal and state pharmacy law for all automated drug delivery systems under the following conditions:
 - (1) The mechanical devices used as part of the ADDS to store, dispense or distribute dangerous drugs are of the same manufacturer and controlled by the same software system on a single server; and
 - (2) The same policies and procedures required by Section 4427.2 of BPC are used.

Note: Authority cited: Sections 4119.11 and 4427.7, Business and Professions Code. Reference: Sections 4001.1, 4008, 4017.3, 4021, 4022, 4036, 4037, 4038, 4040, 4050, 4051, 4052, 4059, 4070, 4076, 4081, 4101, 4105, 4107, 4113, 4119.11, 4125, 4126, 4180, 4186, 4305, 4330, 4332, 4333, 4400, 4427, 4427.1, 4427.2, 4427.3, 4427.4 and 4427.5, Business and Professions Code; and Section 16.5, Government Code.

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

Support: 10 Oppose: 0 Abstain: 0 Not Present: 1

Board Member	Vote
Barker	Not Present
Cameron-Banks	Yes
Crowley	Yes
De La Paz	Yes
Koenig	Yes
Oh	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes
Thibeau	Yes
Weisz	Yes

b. Discussion and Consideration of the Proposed Revisions to Frequently Asked Questions Related to Automated Drug Delivery System (ADDs)

Chairperson Serpa advised related to ADDS was the consideration of updated FAQs. Dr. Serpa recalled as part of the July 2021 Board meeting, the Board approved draft FAQs related to ADDS and to ensure that Board FAQs remain relevant, updates are necessary when changes in the law occur.

Chairperson Serpa referenced meeting materials that contained a copy of the proposed updated FAQs. Dr. Serpa thanked Executive Officer Sodergren, Supervising Inspector Janice Dang and Ms. Smiley for their work updating these FAQs. Dr. Serpa believed Board licensees benefit greatly from the Board's educational efforts such as these FAQs. Dr. Serpa referred to the meeting materials noting the Committee recommends approval of the proposed revisions to the FAQs related to ADDS.

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

Committee Recommendation (Motion):

Approval of the proposed revisions to the FAQs related to ADDS.

ADDs FREQUENTLY ASKED QUESTIONS – Updated 7/2022

Question #1: My pharmacy provides pharmacy services to a psychiatric health facility (PHF) and utilizes an AUDS at the nursing units.

Are we exempt from licensure if the AUDA is used for administration only?

Answer: No. Effective January 1, 2022, the Legislature amended BPC section 4427.3 and added BPC section 4427.65 that expanded the permissible locations at which AUDA can be located to include a facility licensed by the State of California to provide pharmaceutical services. The exemptions from licensure of an AUDA are contained in BPC section 4427.2. Section 4427.2(i) exempts from licensure an AUDA operated by a licensed hospital pharmacy, as defined in BPC section 4029, and used solely to provide doses administered to patients in a licensed general acute care hospital or a licensed acute psychiatric hospital facility if the licensed hospital pharmacy owns the dangerous drugs and devices in the AUDA. A psychiatric health facility does not meet the requirements for licensure exemption unless it is a licensed acute psychiatric hospital facility as detailed in Section 4427.2(i). If a psychiatric health facility does not meet the licensure exemption criteria in BPC section 4427.2(i), it may use an AUDA, but that AUDA must be licensed with the Board and it must follow all the other requirements for an AUDA.

Note: A psychiatric health facility, as defined in Health and Safety Code § 1250.2, is required to provide pharmaceutical services pursuant to Welfare and Institution Code § 4080(e)(1)(J).

References: Business and Professions Code (BPC) section [4427.65](#), Welfare and Institution Code section [4080\(e\)\(1\)\(J\)](#), Health and Safety Code section [1250\(a\)](#), [1250\(b\)](#), [1250.2](#).

Question #2: My pharmacy provides pharmacy services to a county youth detention facility and utilize an AUDA to administer medications to the youth inmates. Are we required to obtain licensure for the AUDA?

Answer: Yes. Effective January 1, 2022, the Legislature amended BPC section 4427.3 and added BPC section 4427.65(a)(2) that expanded the permissible locations at which AUDA can be located to include a jail or youth detention facility where drugs are administered within the facility under the authority of the

medical director. However, the exemptions from the licensure requirements for an ADDS are contained in BPC section 4427.2(i) and AUDS in youth facilities are not exempt from licensure.

References: BPC section [4427.2\(i\)](#), [4427.3](#), [4427.65\(a\)\(2\)](#).

Question #3: My pharmacy has multiple licensed ADDS, do I have to complete a self-assessment for each licensed ADDS?

Answer: Yes, per BPC section 4427.2(c), defines when a separate application and license is required for each ADDS. Also, per BPC section 4427.7(a), a pharmacy holding an ADDS license shall complete a self-assessment performed pursuant to section 1715 of Title 16 of the California Code of Regulations (CCR), before July 1 of every odd-numbered year. Prior to January 1, 2022, BPC section 4427.7(a) required an annual self-assessment whereas 16 CCR section 1715 requires a self-assessment to be performed before July 1 of every odd-numbered year. (Effective January 1, 2022, a self-assessment must only be performed before July 1 of every odd-numbered year.) The pharmacy must maintain those records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records.

References: BPC sections [4427.2\(i\)](#), [4427.7\(a\)](#), [4427.7\(a\)](#), [4427.2\(c\)](#), 16 CCR section [1715](#)

Question #4: Do I have to complete a new self-assessment for each ADDS if my pharmacy received a new permit, had a change in pharmacist-in-charge, or the pharmacy had a change in address?

Answer: Yes, per 16 CCR section 1715(b), the pharmacist-in-charge of the pharmacy shall complete a self-assessment within 30 days whenever a new pharmacy permit has been issued, or change in PIC, or change in the licensed location of the pharmacy to a new address.

References: BPC section [4427.7](#); 16 CCR section [1715\(b\)](#)

Question #5: My pharmacy uses an ADDS located in the pharmacy dispensing area to help with the dispensing of prescription drugs. The ADDS counts the number of tablets or capsules to be dispensed and labels the

prescription container. A pharmacist is required to do the final product verification prior to the prescription medication being bagged and placed in the will call area for the patient to pick up their prescription medication at the pharmacy. As the pharmacist-in-charge, will I need to complete an ADDS Self-Assessment?

Answer: No. An ADDS or other technology installed within a licensed pharmacy that is used to select, count, package and label dangerous drugs but then requires the pharmacist to do the product verification and dispensing to a patient is not required to be licensed as an ADDS. BPC 4427.2(j). Such an ADDS or other technology also does not require the pharmacy to comply with all other requirements for an ADDS in Article 25, including the specific self-assessment for an ADDS, but is required to comply with all other pharmacy laws. In these cases, pursuant to 16 CCR section 1714(b), pharmacies are required to maintain its equipment so that drugs are safely and properly prepared, maintained, secured and distributed. Any misfilling of a prescription resulting from the use of such an ADDS or other technology should be evaluated to assure the ADDS or other technology is operating appropriately. Pursuant to 16 CCR section 1714(c), the pharmacy is also required to maintain all equipment in a clean and orderly condition. This would include such ADDS or other technology used in the dispensing process.

Reference: BPC sections [4427.2\(j\)](#), [4017.3](#), 16 CCR section [1714\(b\)](#), [1714\(c\)](#)

Question #6: A medication error was made, and a quality assurance review was completed related to the licensed ADDS, do I have to report to the Board?

Answer: Yes, per 16 CCR section 1711(f), any quality assurance record related to the use of a licensed automated drug delivery system must also be submitted to the board within 30 days of completion of the quality assurance review. A “medication error” means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716.

NOTE: Examples of medication errors related to the use of an ADDS, include, but are not limited to, the following:

- A drug removed from the ADDS that is the wrong drug,

- strength, quantity or contains incorrect directions for use.
- The nurse removes the wrong drug from the ADDS.
 - An ADDS that packages the drug in plastic pouches containing 2 tablets and should only contain one tablet as prescribed.
 - An ADDS with an open matrix configuration and the nurse selects the wrong drug.
 - An APDS dispenses a prescription container labeled and intended for another patient.

References: 16 CCR section [1711\(f\)](#), [1716](#); BPC section [4427.8](#)

Question #7: My pharmacy is located in an acute care hospital and exempt from the licensing requirements for ADDS, do I have to report ALL quality assurance records related to the use of the ADDS to the Board at the time of renewal, including quality assurance records related to near-misses, or errors caught by nursing staff?

Answer: Yes, per 16 CCR section 1711(f), any facility with an unlicensed automated drug delivery system must report the quality assurance review to the Board annually at the time of annual renewal of the facility license.

16 CCR section 1711(b) defines “medication error” as any variation from a prescription or drug order not authorized by the prescriber, as described in 16 CCR section 1716. Section 1711(b), however, expressly excludes from the definition of a medication error any variation that is corrected prior to furnishing the drug to the patient or patient’s agent or any variation allowed by law.

NOTE: Only, quality assurance records related to the use of the ADDS that caused the medication error, as defined by the section, are required to be reported to the Board at the time of renewal.

NOTE: Drugs dispensed from the ADDS are considered to have been dispensed by the pharmacy. Therefore, if a medication error occurred that resulted from an incorrect dispensing by the ADDS, the medication error is required to be reported to the Board.

References: 16 CCR sections [1711\(b\)](#), [1716](#); BPC sections [4427.8](#), [4427.4\(d\)](#).

Question #8: What information is required to be reported as part of the Quality Assurance Review?

Answer: 16 CCR section 1711(e) states, the record shall contain at least the following:

1. The date, location of the ADDS, ADDS license number, pharmacy license number and participants in the quality assurance review;
2. The pertinent data and other information related to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);
3. The findings and determinations generated by the quality assurance review; and
4. Recommended changes to pharmacy policy, procedure, systems, or processes, if any.

References: 16 CCR sections [1711\(e\)](#), [1716](#); BPC section [4427.8](#)

Question #9: Where do I submit my quality assurance reports to the Board?

Answer: Pharmacies with a licensed ADDS may submit their quality assurance reports within 30 days of completion of the quality assurance review either: 1) by mail to the address of the California State Board of Pharmacy at 2720 Gateway Oaks Drive Suite 100, Sacramento, CA 95833; or 2) by email to ADDS@dca.ca.gov.

Pharmacies operating an unlicensed ADDS must report the quality assurance review to the Board at the time of annual renewal of the facility license. Such reports may be submitted via email to ADDS@dca.ca.gov or included with the renewal application.

References: 16 CCR section [1711\(f\)](#).

Question #10: What personnel are authorized to restock the ADDS (e.g., nurses and other personnel)?

Answer: This depends on the location of the ADDS. The stocking and restocking of an ADDS shall be performed by a pharmacist, or by a pharmacy technician or intern pharmacist under the supervision of a pharmacist, except for an ADDS located in a health facility licensed pursuant to Section 1250 of the Health and Safety Code,

where the stocking and restocking of the ADDS may be performed in compliance with Section 1261.6 of the Health and Safety Code.

Pursuant to Health and Safety Code section 1261.6 (g) if the ADDS utilizes removable pockets, cards, drawers, or similar technology, or unit of use, or single dose containers, and the facility, in conjunction with the pharmacy, has developed policies and procedures to ensure the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS, then the facility and contracted personnel authorized by law to administer drugs may also restock the ADDS.

References: [June 2017 Script Newsletter](#), , BPC sections [4427.3](#), [4427.4](#), [4186](#), [4187.5](#), [4119.11](#), Health and Safety Code section [1261.6\(g\)](#)

Question #11: Are drugs required to be restocked immediately into the ADDS?

Answer: Per BPC section 4427.4(f), if drugs are not immediately transferred into an ADDS upon arrival at the ADDS location, the drugs may be stored for no longer than 48 hours in a secured room within the ADDS location. Upon retrieval of these drugs from secured storage, an inventory must be taken to detect any losses or overages.

References: BPC section [4427.4](#)

Question #12: The pharmacy uses an ADDS device with an open-matrix design allowing the user to access multiple drugs, what are the requirements for the facility?

Answer: Facilities using automated drug delivery system with an open-matrix design shall contact the California Department of Public Health for a clear understanding of the requirements for such use.

References: Health and Safety Code section [1261.6](#)

Question #13: Does my pharmacy have to review the ADDS on a monthly basis?

Answer: Yes, if the pharmacy is operating an ADDS located in: 1) a health facility pursuant to Health and Safety Code 1250 that complies with Health and Safety Code 1261.6; 2) a clinic pursuant to BPC section 4119.11; 3) a correctional clinic pursuant to BPC section 4187.5(e); 4) a facility licensed by the State of California with the statutory authority to provide pharmaceutical services; or 5) a jail, youth detention facility, or other correctional facility where drugs are administered within the facility under the authority of the medical director. A review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system

NOTE: A clinic that operates an ADDS, pursuant to BPC section 4186, is responsible for reviewing the drugs contained in the ADDS, the operations and the maintenance of the ADDS. The review must be conducted on a monthly basis by a pharmacist which includes a physical inspection of the drugs in the ADDS, an inspection of the ADDS for cleanliness, and a review of all transaction records in order to verify the security and accountability of the drugs in the ADDS.

References: Health and Safety Code (HSC) [1261.6\(h\)](#); BPC sections [4186\(d\)](#), [4187.5\(e\)](#), [4119.11\(h\)](#), [4427.3\(b\)\(2\)\(3\)\(4\)](#), [4427.65\(c\)\(7\)](#)

Question #14: Is the pharmacy required to obtain a separate Drug Enforcement Administration (DEA) registration for each licensed ADDS if the device contains controlled substances?

Answer: Pharmacies should consult the federal regulations to ensure compliance with DEA requirements and contact the DEA for any necessary clarifications regarding federal rules regarding controlled substances. Cited below are some authorities from the DEA regarding ADDS.

Reference: Code of Federal Regulations (CFR) section [1301.27](#), [ADDs FAQ](#), [Dispensing of Controlled Substances to Residents at Long Term Care Facilities](#)

Question #15: Our pharmacy offers an APDS to dispense to patients, what is required for patient consultation?

Answer: The APDS shall only be used for patients who have signed a written consent form demonstrating their informed consent to receive drugs from an APDS and the APDS has a means to identify each patient and only release the drugs to the patient or the patient's agent.

All prescribed drugs and devices dispensed from the APDS **for the first time** must be accompanied by a consultation conducted by a pharmacist licensed by the board via a telecommunications link that has two-way audio and video.

References: BPC sections [4119.11\(d\)\(6\)](#), [4427.6\(f\)](#)

Question #16: Can the pharmacist provide consultation via telephone for new prescriptions prior to placing the medication in the APDS?

Answer: No, all prescribed drugs and devices dispensed from the APDS **for the first time** shall be accompanied by a consultation conducted by a pharmacist licensed by the board via a telecommunications link that has two-way audio and video.

References: BPC section [4427.6\(f\)](#)

Question #17: Who can provide the consultation for patients using the APDS?

Answer: A pharmacist licensed by the board shall perform all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation.

References: BPC section [4427.6\(d\)](#)

Question #18: What drugs can be placed in the APDS?

Answer: The pharmacy should have policies and procedures to determine which drugs and devices are appropriate for placement in the automated patient dispensing system.

References: BPC sections [4119.11\(d\)\(1\)\(B\)](#), [4427.6\(a\)\(2\)](#)

Question #19: What shall a pharmacy do if a patient cannot use the APDS due to the drug not being in stock or the APDS is not in service?

Answer: The pharmacy must develop policies and procedures orienting participating patients on the use of the APDS, notifying patients when expected prescription medications are not available in the APDS, and ensuring that patient use of the APDS does not interfere with delivery of drugs and devices. The pharmacy shall ensure the delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.

References: BPC section [4427.6\(a\)](#)

Question #20: We are a hospital with less than 100-beds and have a licensed drug room. When patients are discharged from the hospital, the physician sometimes writes an order for the patient to be discharged with a 72-hour supply which is taken from the ADDS. The physician will remove the drugs from the ADDS and dispense the drugs to the patient that is properly labeled and meets the patient centered labeling requirements. Is the drug room exempt from licensing the ADDS located at the nursing station if the ADDS is primarily used to administer doses to patients in the hospital, but occasionally used for dispensing no more than a 72-hour supply of discharge medications to the patient?

Answer: No, the drug room is not exempt from licensing the ADDS if the location is dispensing medications to discharge patients. The drug room will be required to license the ADDS location. The drug room is only exempt if the drugs in the ADDS are solely used for administration to patients while in the acute care hospital. When drugs from the ADDS is used for dispensing, not solely for administration, the exemption no longer applies.

Should your hospital provide discharge medication from the

drug stock contained within an ADDS, your facility must secure ADDS licensure to be compliant with these requirements.

References: BPC sections [4427.2\(j\)](#), [4056](#)

Question #21: Can the facility start using the ADDS device as soon as the ADDS application is submitted or do I need to wait until the Board issues the ADDS permit?

Answer: The ADDS device cannot be used until the Board issues the ADDS permit. Reference: BPC sections [4427.1](#), [4427.2\(a\)](#), [4119.11\(a\)\(1\)](#), [4119.01\(a\)](#)

Question #22: We are a hospital with a 24-hour pharmacy. Can we utilize an ADDS to dispense a 72-hour supply of medication from our ER, if we request a license from the board for the ADDS.

Answer: No. A prescriber may only dispense a prescription medication to an emergency room patient, if the pharmacy is closed and there is no pharmacist available.

Reference: BPC section [4068\(a\)\(1\)](#)

Question #23. In the emergency room, when the pharmacy is not open, the physician will remove from the ADDS and dispense no more than a 72-hour supply of drugs to a patient to ensure a drug regimen is immediately commenced and continued pursuant to Business and Professions Code section 4068. Is the hospital pharmacy required to license the ADDS in the emergency room if the ADDS is primarily used for the administration of doses to patients in the emergency room but occasionally used to dispense a 72-hour supply of drugs to a patient discharged from the emergency room for doses removed from the ADDS by the physician?

Answer: Yes, the ADDS will be required to be licensed. The hospital pharmacy is only exempt from licensing the ADDS when the acute care hospital pharmacy solely uses the ADDS to administer drugs. When an ADDS is used to dispense drugs to a patient, the exemption no longer applies. While the ADDS must be licensed, as long as the physician removes the dangerous drug or device from the ADDS to dispense to the patient, the ADDS is not considered

to be an APDS and need not follow the APDS requirements found in BPC section 4427.6.

Should your hospital provide discharge medication from the drug stock contained within an ADDS, your facility must secure ADDS licensure to be compliant with these requirements.

NOTE: As a reminder, under provisions of BPC section 4068, medications can only be dispensed from the emergency room if the hospital pharmacy is closed and there is no pharmacist available in the hospital.

Reference: BPC sections [4017.3](#), [4068](#), [4427.2\(i\)](#), [4427.6](#).

Question #24. I submitted my application for an ADDS and have completed the pre-licensure inspection. How will I know my application has been approved before I receive the physical license to be posted?

Answer: Once the application is approved, an email will be sent to the pharmacist-in-charge (PIC). The email will notify the pharmacy the application was approved and will include the ADDS license number, type of ADDS, the primary pharmacy license, the status, the name and address of the ADDS location, and expiration date. The board requests that you print and attach a copy of the email to the location of the ADDS and replace when the original is received. Allow 4 to 6 weeks to receive the physical license in the mail at the pharmacy.

Note: To inquire about the status of your ADDS application, please email ADDS@dca.ca.gov.

Note: All references to BPC refer to the Business and Professions Code and all references to CCR refers to Title 16 of the California Code of Regulations unless otherwise specified.

Rev 7.10.2022

Members of the public were provided the opportunity to comment.

A pharmacist member of the public from Cedars Sinai requested that the examples provided in Question #6 be attributable to medication errors made by

pharmacy staff. The pharmacist commented regarding Question #13 requiring monthly review by the pharmacist would prevent the pharmacist from performing clinical and patient care activities and recommended the Board add language to include pharmacy technician and pharmacist intern under the supervision of a pharmacist.

Member Cameron-Banks left the meeting at approximately 11:41 a.m.

Chairperson Serpa clarified regarding Question #6 that the medications in the AUDS were still part of the pharmacy inventory and under the pharmacy's control. Dr. Serpa inquired if Question #13 would be able to mirror Title 22. Ms. Smiley and Ms. Sodergren recommended discussing with counsel prior to opining. Dr. Serpa inquired if this could be considered. Ms. Sodergren provided options of releasing the FAQs except for Question #13 and/or the Board could delegate to the Committee Chair to finalize the FAQs based on legal research.

The Board heard public comment from a Cedar Sinai representative regarding Question #6 who agreed the inventory was part of the pharmacy and that the PIC is responsible but requested looking at the quality assurance process as a means to follow up on any errors related to nurses or clinicians removing the incorrect drugs.

Chairperson Serpa advised the FAQs were regarding the current regulations. Dr. Serpa advised regulations were not being changed and current regulations require any error that reaches the patient go through the whole quality assurance process.

Members were provided another opportunity to provide comments. Ms. Sodergren referred to BPC section 4427.65 (7) where the law states a pharmacist shall conduct the review monthly.

Support: 1 Oppose: 8 Abstain: 0 Not Present: 2

Board Member	Vote
Barker	Not Present
Cameron-Banks	Not Present
Crowley	Yes
De La Paz	No
Koenig	No
Oh	No
Patel	No
Sanchez	No
Serpa	No
Thibeau	No
Weisz	No

President Oh advised the Committee Recommendation (motion) failed.

Members were provided the opportunity to comment on the new motion; however, no comments were provided.

Motion: Approval of the proposed revisions to the FAQs related to ADDS except for Question #13 and that Question #13 be returned to the Committee for future discussion.

ADDS FREQUENTLY ASKED QUESTIONS – Updated 7/2022

Question #1: My pharmacy provides pharmacy services to a psychiatric health facility (PHF) and utilizes an AUDS at the nursing units. Are we exempt from licensure if the AUDS is used for administration only?

Answer: No. Effective January 1, 2022, the Legislature amended BPC section 4427.3 and added BPC section 4427.65 that expanded the permissible locations at which AUDS can be located to include a facility licensed by the State of California to provide pharmaceutical services. The exemptions from licensure of an ADDS are contained in BPC section 4427.2. Section 4427.2(i) exempts from licensure an AUDS operated by a licensed hospital pharmacy, as defined in BPC section 4029, and used solely to provide doses administered to patients in a licensed

general acute care hospital or a licensed acute psychiatric hospital facility if the licensed hospital pharmacy owns the dangerous drugs and devices in the AUDS. A psychiatric health facility does not meet the requirements for licensure exemption unless it is a licensed acute psychiatric hospital facility as detailed in Section 4427.2(i). If a psychiatric health facility does not meet the licensure exemption criteria in BPC section 4427.2(i), it may use an AUDS, but that AUDS must be licensed with the Board and it must follow all the other requirements for an ADDS.

Note: A psychiatric health facility, as defined in Health and Safety Code § 1250.2, is required to provide pharmaceutical services pursuant to Welfare and Institution Code § 4080(e)(1)(J).

References: Business and Professions Code (BPC) section [4427.65](#), Welfare and Institution Code section [4080\(e\)\(1\)\(J\)](#), Health and Safety Code section [1250\(a\)](#), [1250\(b\)](#), [1250.2](#).

Question #2: My pharmacy provides pharmacy services to a county youth detention facility and utilize an AUDS to administer medications to the youth inmates. Are we required to obtain licensure for the AUDS?

Answer: Yes. Effective January 1, 2022, the Legislature amended BPC section 4427.3 and added BPC section 4427.65(a)(2) that expanded the permissible locations at which AUDS can be located to include a jail or youth detention facility where drugs are administered within the facility under the authority of the medical director. However, the exemptions from the licensure requirements

for an ADDS are contained in BPC section 4427.2(i) and AUDS in youth facilities are not exempt from licensure.

References: BPC section [4427.2\(i\)](#), [4427.3](#), [4427.65\(a\)\(2\)](#).

Question #3: My pharmacy has multiple licensed ADDS, do I have to complete a self-assessment for each licensed ADDS?

Answer: Yes, per BPC section 4427.2(c), defines when a separate application and license is required for each ADDS. Also, per BPC section 4427.7(a), a pharmacy holding an ADDS license shall complete a self-assessment performed pursuant to section 1715 of Title 16 of the California Code of Regulations (CCR), before July 1 of every odd-numbered year. Prior to January 1, 2022, BPC section 4427.7(a) required an annual self-assessment whereas 16 CCR section 1715 requires a self-assessment to be performed before July 1 of every odd-numbered year. (Effective January 1, 2022, a self-assessment must only be performed before July 1 of every odd-numbered year.) The pharmacy must maintain those records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records.

References: BPC sections [4427.2\(i\)](#), [4427.7\(a\)](#), [4427.7\(a\)](#), [4427.2\(c\)](#), 16 CCR section [1715](#)

Question #4: Do I have to complete a new self-assessment for each ADDS if my pharmacy received a new permit, had a change in pharmacist-in-charge, or the pharmacy had a change in address?

Answer: Yes, per 16 CCR section 1715(b), the pharmacist-in-charge of the pharmacy shall complete a self-assessment within 30 days whenever a new pharmacy permit has been issued, or change in PIC, or change in the licensed location of the pharmacy to a new address.

References: BPC section [4427.7](#); 16 CCR section [1715\(b\)](#)

Question #5: My pharmacy uses an ADDS located in the pharmacy dispensing area to help with the dispensing of prescription drugs. The ADDS counts the number of tablets or capsules to be dispensed and labels the prescription container. A pharmacist is required to do the final product verification prior to the prescription medication being bagged and placed in the will call area for the patient to pick up their prescription medication at the pharmacy. As the pharmacist-in-charge, will I need to complete an ADDS Self-Assessment?

Answer: No. An ADDS or other technology installed within a licensed pharmacy that is used to select, count, package and label dangerous drugs but then requires the pharmacist to do the product verification and dispensing to a patient is not required to be licensed as an ADDS. BPC 4427.2(j). Such an ADDS or other technology also does not require the pharmacy to comply with all other requirements for an ADDS in Article 25, including the specific self-assessment for an ADDS, but is required to comply with all other pharmacy laws. In these cases, pursuant to 16 CCR section 1714(b), pharmacies are required to maintain its equipment so that drugs are safely and properly prepared, maintained, secured and distributed. Any misfilling of a prescription resulting from the use of such an ADDS or other technology should be evaluated to assure the ADDS or other technology is operating appropriately. Pursuant to 16 CCR section 1714(c), the pharmacy is also required to maintain all equipment in a clean and orderly condition. This would include such ADDS or other technology used in the dispensing process.

Reference: BPC sections [4427.2\(j\)](#), [4017.3](#), 16 CCR section [1714\(b\)](#), [1714\(c\)](#)

Question #6: A medication error was made, and a quality assurance review was completed related to the licensed ADDS, do I have to report to the Board?

Answer: Yes, per 16 CCR section 1711(f), any quality assurance record related to the use of a licensed automated drug delivery system must also be submitted

to the board within 30 days of completion of the quality assurance review. A “medication error” means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716.

NOTE: Examples of medication errors related to the use of an ADDS, include, but are not limited to, the following:

- A drug removed from the ADDS that is the wrong drug, strength, quantity or contains incorrect directions for use.
- The nurse removes the wrong drug from the ADDS.
- An ADDS that packages the drug in plastic pouches containing 2 tablets and should only contain one tablet as prescribed.
- An ADDS with an open matrix configuration and the nurse selects the wrong drug.
- An APDS dispenses a prescription container labeled and intended for another patient.

References: 16 CCR section [1711\(f\)](#), [1716](#); BPC section [4427.8](#)

Question #7: My pharmacy is located in an acute care hospital and exempt from the licensing requirements for ADDS, do I have to report ALL quality assurance records related to the use of the ADDS to the Board at the time of renewal, including quality assurance records related to near-misses, or errors caught by nursing staff?

Answer: Yes, per 16 CCR section 1711(f), any facility with an unlicensed automated drug delivery system must report the quality assurance review to the Board annually at the time of annual renewal of the facility license.

16 CCR section 1711(b) defines “medication error” as any variation from a prescription or drug order not authorized by the prescriber, as described in 16 CCR section 1716. Section 1711(b), however, expressly excludes from the definition of a medication error any variation that is

corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.

NOTE: Only, quality assurance records related to the use of the ADDS that caused the medication error, as defined by the section, are required to be reported to the Board at the time of renewal.

NOTE: Drugs dispensed from the ADDS are considered to have been dispensed by the pharmacy. Therefore, if a medication error occurred that resulted from an incorrect dispensing by the ADDS, the medication error is required to be reported to the Board.

References: 16 CCR sections [1711\(b\)](#), [1716](#); BPC sections [4427.8](#), [4427.4\(d\)](#).

Question #8: What information is required to be reported as part of the Quality Assurance Review?

Answer: 16 CCR section 1711(e) states, the record shall contain at least the following:

1. The date, location of the ADDS, ADDS license number, pharmacy license number and participants in the quality assurance review;
2. The pertinent data and other information related to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);
3. The findings and determinations generated by the quality assurance review; and
4. Recommended changes to pharmacy policy, procedure, systems, or processes, if any.

References: 16 CCR sections [1711\(e\)](#), [1716](#); BPC section [4427.8](#)

Question #9: Where do I submit my quality assurance reports to the Board?

Answer: Pharmacies with a licensed ADDS may submit their quality assurance reports within 30 days of completion of the

quality assurance review either: 1) by mail to the address of the California State Board of Pharmacy at 2720 Gateway Oaks Drive Suite 100, Sacramento, CA 95833; or 2) by email to ADDS@dca.ca.gov.

Pharmacies operating an unlicensed ADDS must report the quality assurance review to the Board at the time of annual renewal of the facility license. Such reports may be submitted via email to ADDS@dca.ca.gov or included with the renewal application.

References: 16 CCR section [1711\(f\)](#).

Question #10: What personnel are authorized to restock the ADDS (e.g., nurses and other personnel)?

Answer: This depends on the location of the ADDS. The stocking and restocking of an ADDS shall be performed by a pharmacist, or by a pharmacy technician or intern pharmacist under the supervision of a pharmacist, except for an ADDS located in a health facility licensed pursuant to Section 1250 of the Health and Safety Code, where the stocking and restocking of the ADDS may be performed in compliance with Section 1261.6 of the Health and Safety Code.

Pursuant to Health and Safety Code section 1261.6 (g) if the ADDS utilizes removable pockets, cards, drawers, or similar technology, or unit of use, or single dose containers, and the facility, in conjunction with the pharmacy, has developed policies and procedures to ensure the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS, then the facility and contracted personnel authorized by law to administer drugs may also restock the ADDS.

References: [June 2017 Script Newsletter](#), , BPC sections [4427.3](#), [4427.4](#), [4186](#), [4187.5](#), [4119.11](#), Health and Safety Code section [1261.6\(g\)](#)

Question #11: Are drugs required to be restocked immediately into the ADDS?

Answer: Per BPC section 4427.4(f), if drugs are not immediately transferred into an ADDS upon arrival at the ADDS location, the drugs may be stored for no longer than 48 hours in a secured room within the ADDS location. Upon retrieval of these drugs from secured storage, an inventory must be taken to detect any losses or overages.

References: BPC section [4427.4](#)

Question #12: The pharmacy uses an ADDS device with an open-matrix design allowing the user to access multiple drugs, what are the requirements for the facility?

Answer: Facilities using automated drug delivery system with an open-matrix design shall contact the California Department of Public Health for a clear understanding of the requirements for such use.

References: Health and Safety Code section [1261.6](#)

~~Question #13: Does my pharmacy have to review the ADDS on a monthly basis?~~

~~Answer: Yes, if the pharmacy is operating an ADDS located in: 1) a health facility pursuant to Health and Safety Code 1250 that complies with Health and Safety Code 1261.6; 2) a clinic pursuant to BPC section 4119.11; 3) a correctional clinic pursuant to BPC section 4187.5(e); 4) a facility licensed by the State of California with the statutory authority to provide pharmaceutical services; or 5) a jail, youth detention facility, or other correctional facility where drugs are administered within the facility under the authority of the medical director. A review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the~~

security and accountability of the system

~~**NOTE:** A clinic that operates an ADDS, pursuant to BPC section 4186, is responsible for reviewing the drugs contained in the ADDS, the operations and the maintenance of the ADDS. The review must be conducted on a monthly basis by a pharmacist which includes a physical inspection of the drugs in the ADDS, an inspection of the ADDS for cleanliness, and a review of all transaction records in order to verify the security and accountability of the drugs in the ADDS.~~

References: Health and Safety Code (HSC) [1261.6\(h\)](#); BPC sections [4186\(d\)](#), [4187.5\(e\)](#), [4119.11\(h\)](#), [4427.3\(b\)\(2\)\(3\)\(4\)](#), [4427.65\(c\)\(7\)](#)

Question #14: Is the pharmacy required to obtain a separate Drug Enforcement Administration (DEA) registration for each licensed ADDS if the device contains controlled substances?

Answer: Pharmacies should consult the federal regulations to ensure compliance with DEA requirements and contact the DEA for any necessary clarifications regarding federal rules regarding controlled substances. Cited below are some authorities from the DEA regarding ADDS.

Reference: Code of Federal Regulations (CFR) section [1301.27](#), [ADDs FAQ](#), [Dispensing of Controlled Substances to Residents at Long Term Care Facilities](#)

Question #15: Our pharmacy offers an APDS to dispense to patients, what is required for patient consultation?

Answer: The APDS shall only be used for patients who have signed a written consent form demonstrating their informed consent to receive drugs from an APDS and the APDS has a means to identify each patient and only release the drugs to the patient or the patient's agent.

All prescribed drugs and devices dispensed from the APDS **for the first time** must be accompanied

by a consultation conducted by a pharmacist licensed by the board via a telecommunications link that has two-way audio and video.

References: BPC sections [4119.11\(d\)\(6\)](#), [4427.6\(f\)](#)

Question #16: Can the pharmacist provide consultation via telephone for new prescriptions prior to placing the medication in the APDS?

Answer: No, all prescribed drugs and devices dispensed from the APDS **for the first time** shall be accompanied by a consultation conducted by a pharmacist licensed by the board via a telecommunications link that has two-way audio and video.

References: BPC section [4427.6\(f\)](#)

Question #17: Who can provide the consultation for patients using the APDS?

Answer: A pharmacist licensed by the board shall perform all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation.

References: BPC section [4427.6\(d\)](#)

Question #18: What drugs can be placed in the APDS?

Answer: The pharmacy should have policies and procedures to determine which drugs and devices are appropriate for placement in the automated patient dispensing system.

References: BPC sections [4119.11\(d\)\(\(1\)\(B\)](#), [4427.6\(a\)\(2\)](#)

Question #19: What shall a pharmacy do if a patient cannot use the APDS due to the drug not being in stock or the APDS is not in service?

Answer: The pharmacy must develop policies and procedures orienting participating patients on the use of

the APDS, notifying patients when expected prescription medications are not available in the APDS, and ensuring that patient use of the APDS does not interfere with delivery of drugs and devices. The pharmacy shall ensure the delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.

References: BPC section [4427.6\(a\)](#)

Question #20: We are a hospital with less than 100-beds and have a licensed drug room. When patients are discharged from the hospital, the physician sometimes writes an order for the patient to be discharged with a 72-hour supply which is taken from the ADDS. The physician will remove the drugs from the ADDS and dispense the drugs to the patient that is properly labeled and meets the patient centered labeling requirements. Is the drug room exempt from licensing the ADDS located at the nursing station if the ADDS is primarily used to administer doses to patients in the hospital, but occasionally used for dispensing no more than a 72-hour supply of discharge medications to the patient?

Answer: No, the drug room is not exempt from licensing the ADDS if the location is dispensing medications to discharge patients. The drug room will be required to license the ADDS location. The drug room is only exempt if the drugs in the ADDS are solely used for administration to patients while in the acute care hospital. When drugs from the ADDS is used for dispensing, not solely for administration, the exemption no longer applies.

Should your hospital provide discharge medication from the drug stock contained within an ADDS, your facility must secure ADDS licensure to be compliant with these requirements.

References: BPC sections [4427.2\(j\)](#), [4056](#)

Question #21: Can the facility start using the ADDS device as soon as the ADDS application is submitted or do I need to wait until the Board issues the ADDS permit?

Answer: The ADDS device cannot be used until the Board issues the ADDS permit. Reference: BPC sections [4427.1](#), [4427.2\(a\)](#), [4119.11\(a\)\(1\)](#), [4119.01\(a\)](#)

Question #22: We are a hospital with a 24-hour pharmacy. Can we utilize an ADDS to dispense a 72-hour supply of medication from our ER, if we request a license from the board for the ADDS.

Answer: No. A prescriber may only dispense a prescription medication to an emergency room patient, if the pharmacy is closed and there is no pharmacist available.

Reference: BPC section [4068\(a\)\(1\)](#)

Question #23. In the emergency room, when the pharmacy is not open, the physician will remove from the ADDS and dispense no more than a 72-hour supply of drugs to a patient to ensure a drug regimen is immediately commenced and continued pursuant to Business and Professions Code section 4068. Is the hospital pharmacy required to license the ADDS in the emergency room if the ADDS is primarily used for the administration of doses to patients in the emergency room but occasionally used to dispense a 72-hour supply of drugs to a patient discharged from the emergency room for doses removed from the ADDS by the physician?

Answer: Yes, the ADDS will be required to be licensed. The hospital pharmacy is only exempt from licensing the ADDS when the acute care hospital pharmacy solely uses the ADDS to administer drugs. When an ADDS is used to dispense drugs to a patient, the exemption no longer applies. While the ADDS must be licensed, as long as the physician removes the dangerous drug or device from the ADDS to dispense to the patient, the ADDS is not considered to be an APDS and need not follow the APDS requirements found in BPC section 4427.6.

Should your hospital provide discharge medication from the drug stock contained within an ADDS, your facility must secure ADDS licensure to be compliant with these requirements.

NOTE: As a reminder, under provisions of BPC section 4068, medications can only be dispensed from the emergency room if the hospital pharmacy is closed and there is no pharmacist available in the hospital.

Reference: BPC sections [4017.3](#), [4068](#), [4427.2\(i\)](#), [4427.6](#).

Question #24. I submitted my application for an ADDS and have completed the pre-licensure inspection. How will I know my application has been approved before I receive the physical license to be posted?

Answer: Once the application is approved, an email will be sent to the pharmacist-in-charge (PIC). The email will notify the pharmacy the application was approved and will include the ADDS license number, type of ADDS, the primary pharmacy license, the status, the name and address of the ADDS location, and expiration date. The board requests that you print and attach a copy of the email to the location of the ADDS and replace when the original is received. Allow 4 to 6 weeks to receive the physical license in the mail at the pharmacy.

Note: To inquire about the status of your ADDS application, please email ADDS@dca.ca.gov.

Note: All references to BPC refer to the Business and Professions Code and all references to CCR refers to Title 16 of the California Code of Regulations unless otherwise specified.

Rev 7.10.2022

M/S: Serpa/Patel

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

Support: 9 Oppose: 0 Abstain: 0 Not Present: 2

Board Member	Vote
Barker	Not Present
Cameron-Banks	Not Present
Crowley	Yes
De La Paz	Yes
Koenig	Yes
Oh	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes
Thibeau	Yes
Weisz	Yes

c. Presentation and Discussion on Board's Inspection Program

Chairperson Serpa advised members received an update on the Board's inspection program from the Board's Chief of Enforcement, Julie Ansel. Dr. Serpa advised presentation slides were included in meeting materials. Dr. Serpa stated appreciation to the staff for their efforts towards meeting the Board's strategic objective related to routine inspections.

Chairperson Serpa reported she was pleased to see the data shows that pharmacies with no inspection or no inspection since 2013 has dropped from 2080 pharmacies 2 years ago to 463 this year. Dr. Serpa noted it appeared that this issue may be completely addressed within this fiscal year. Dr. Serpa reminded members that when this goal was established, the Board did not secure additional resources, rather, these inspections are being completed in addition to the current workload of inspections. Dr. Serpa noted concern that there continues to be issues with pharmacist consultation not being provided to patients.

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

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

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

Chairperson Serpa reported the Committee received an annual presentation on the Board's citation and fine program with presentation slides included in the meeting materials. Dr. Serpa reported the Committee was advised that the Board had issued two fines pursuant to the new fine authority established in BPC section 4317.5. Dr. Serpa advised consistent with the Board's strategic objective, Dr. Serpa assumed the common violations will be used as educational materials.

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

Members of the public were provided the opportunity to comment. The Board heard a comment from a pharmacist representing Kaiser about the concern for the frequency of citations issued to pharmacists and pharmacies for medication errors. The representative stated pursuant to CCR 1775.2 when assessing a fine, good/bad faith effort should be factored. The pharmacist noted the process was distressing and demoralizing rather than corrective while the Medication Error and Reduction Workforce was focused on workplace burnout and just culture. The commentor recommended the two Committees discuss approaches.

Chairperson Serpa advised the citation and fines were not meant to be punitive but also confidential. Dr. Serpa noted often the people who speak the loudest are the ones that receive the fine but often times a fine is not issued.

Executive Officer Sodergren advised the Board reports annually on the citation and fine program noting the citations are public information but the Board does not post them on the Board's website. Ms. Sodergren noted often there are changes due to use of the order of abatement that is used to encourage additional education or training for the pharmacist. Ms. Sodergren added citations are issued on a case-by-case basis considering all factors involved, transparent through the process as they are made public when closed and Board leadership reviews copies of closed citations.

Members were provided the opportunity to provide comments. Members discussed the administrative process and the amount of workforce available as well as workplace systems. Members discussed the Citation and Fine presentation as it was informative and recorded. Members discussed the possibility of having ISMP present on just culture as well as the culture of medication error reporting.

- e. Discussion and Consideration of Community Pharmacy Staff Requirements Including Business and Professions Code Section 4113.5 and Title 16, California Code of Regulations Section 1714.3

Chairperson Serpa reported the meeting materials detailed the relevant sections of pharmacy law specifically BPC section 4113.5 provides that a pharmacist shall not be required to engage in the practice of pharmacy unless another employee of the pharmacy or an employee of the establishment is made available to assist the pharmacist at all times. Dr. Serpa advised the Board's regulation detailed the requirements pharmacies must meet to satisfy the requirements of the statute.

Chairperson Serpa requested members, staff and public keep comments general in nature as there were investigations pending in this area and wanted to avoid any inadvertent exposure to information that would then preclude members from involvement in our role as a decision maker in an enforcement matter.

Chairperson Serpa noted the materials detail out the implementation strategy used by staff, where staff initially focused efforts on education of the requirements. Dr. Serpa advised staff efforts transitioned to issuing orders of correction to gain compliance. Dr. Serpa reported after a significant period to allow pharmacies to comply with the provisions, depending on the egregiousness of the violation, staff determined the appropriate outcomes. Dr. Serpa reported to date, the Board has issued two citations for violations of these provisions and there were several investigations currently pending.

Chairperson Serpa advised there appeared to be a misunderstanding by some about the requirements of the statute as well as frustration by some pharmacists who are not requesting assistance because such assistance would not be made available even if such a request was made. Dr. Serpa advised during the meeting members were reminded of information recently released for pharmacy personnel describing how to file a complaint with the Board and some information on whistleblower protections. Although the information was related to implementation of another measure, both the process and protections are the same.

Chairperson Serpa noted public comment during the meeting suggested that the Board should provide more education on the requirements as a possible means to address the misunderstanding of the law. Dr. Serpa stated it was suggested that the Board should develop a more interactive online complaint process that would walk an individual through the filing process. The commenter

also encouraged the Board to use its higher fine authority when violations of the provisions are substantiated.

Members were provided the opportunity to comment. Member Crowley commented about the ties to minimum staffing. Dr. Crowley commented after the outcomes of the pending issues, the Board will be better able to assess.

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

f. Review and Discussion of Enforcement Statistics

Chairperson Serpa advised meeting materials included the year-end and three-year statistics for the Board's enforcement relative activities.

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

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

The Board adjourned open session at 12:12 p.m. and convened in closed session until 1:00 p.m. Adjournment for the day followed closed session at 1:00 p.m.

July 28, 2022

President Oh called the Board Meeting to order at approximately 9:02 a.m. President Oh reminded all individuals present that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. Dr. Oh stated where protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

President Oh advised all individuals the meeting was being conducted via WebEx. Dr. Oh advised participants watching the webcast could only observe the meeting. He noted anyone interested in participating in the meeting must join the WebEx meeting using the instructions posted on the Board's website. Department of Consumer Affairs' staff provided general instructions for the WebEx Board Meeting for members of the public participating in the meeting.

Roll call was taken. Board Members present included: Maria Serpa, Licensee Member; Indira Cameron-Banks, Public Member; Jessi Crowley, Licensee Member; Ricardo Sanchez, Public Member; Nicole Thibeau, Licensee Member; Jason Weisz, Public Member; and Seung Oh, Licensee Member. Quorum was established.

Member Koenig joined the meeting at 9:07 a.m.

Member De La Paz joined the meeting at 9:15 a.m.

XIII. Presentation on the Pharmacist Recovery Program

Virginia Matthews, RN, BSN, MBA, Project Director Maximus provided a presentation on the Board's Pharmacist Recovery Program (PRP) administered by Maximus.

Ms. Matthews provided a corporate overview of Maximus and reviewed the definition of substance use disorder (SUD). Ms. Matthews reviewed driving under the influence (DUI) impacts, blood alcohol content (BAC), alcohol content of Kombucha, and impact of cannabis in California.

Ms. Matthews reported to the Board the elements of the PRP including the goals of the program, participant review committee, return to work process and SB 1441 Uniform Standards. Ms. Matthews reviewed drug frequencies, additional drug testing requirements, exceptions and lab-based vs. rapid drug testing. Ms. Matthews continued with screening and confirmation, cutoffs, concerns of testing, and importance of what is done with the result more than the result of the testing itself. Ms. Matthews discussed the limits of testing laboratories, validity testing (SVT) and result interpretation including hair testing. Ms. Matthews reviewed transition year

demonstrating successful completion criteria, transition period requirements and transition/successful completion criteria.

Members were provided the opportunity to ask questions and provide comments.

Member Crowley noted interested topics including kombucha and foods (sauerkraut and kimchi) contained alcohol that could have DUI implications; DUI complications of sleeping it off in the car; and hair testing controversies. Dr. Crowley inquired about controversial issues regarding hair testing. Ms. Matthews indicated she would provide additional information upon further research.

Member Koenig left the meeting at 10:19 a.m.

Member Weisz inquired about the intake process upon entering the PRP and check ins. Ms. Matthews advised intake includes eligibility confirmation; intake meeting including using an in-take form and meeting with a register nurse; basic assessment for participant; review any probationary/disciplinary documents; and set up for intake assessment, testing appointments, and three-day assessment for health care professionals. Ms Anita Mireles advised check ins begin weekly then monthly and discuss medications/medication adjustment, review treatment provider reports, clinical assessments, status of programs and sponsors, discuss finances, day-to-day progress, and self-care.

Members of the public were provided the opportunity to provide comments.

A member of the public inquired if the providers in the treatment were overseen by Maximus and how participants select providers (e.g., through Maximus, PCP, etc.). Ms. Matthews advised there are many factors considered such as insurance coverage, provider list, use of preferred providers and individual factors.

The Board took a break from 10:27 a.m. – 10:40 a.m. Roll call was taken. Board Members present included: Maria Serpa, Licensee Member; Indira Cameron-Banks, Public Member; Jessi Crowley, Licensee Member; Jose De La Paz; Public Member; Nicole Thibeau, Licensee Member; Jason Weisz, Public Member; and Seung Oh, Licensee Member. Quorum was established.

XIV. Discussion, Consideration and Possible Approval of Recommended Changes to Proposed Regulations to Amend Title 16, CCR Section 1793.5 Related to Pharmacy Technician Application, Section 1793.6 Related to the Pharmacy Technician Training Requirements, and Section 1793.65 Related to the Pharmacy Technician Certification Programs

President Oh reported for consideration were recommended changes to the Board's Pharmacy Technician regulation proposal to address concerns identified during postadoption review. Dr. Oh noted as indicated in the meeting materials, this regulation package initially was approved by the Board in 2016. Dr. Oh stated the history of the rulemaking package was included in the meeting materials as well as a as part of the postadoption review, a conflict was identified with recently enacted changes to the state's education code.

President Oh advised provided in the meeting materials was the recommended language that could be used to remedy this conflict. Dr. Oh noted the proposed changes to the language is reflected in double underline and double strike-through and displayed on the meeting slide. Dr. Oh added the meeting materials detail out possible options for the Board and I recommended that the Board consider moving forward with option 1, which would be to accept the staff-recommended modified language to section 1793.6(c)(2) and notice the modified text for a 15-day comment period.

Member Koenig joined the meeting at 10:43 a.m.

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

Motion: Accept the recommended modified language as presented and initiate a 15-day public comment period. Additionally, if no adverse comments are received during the 15-day comment period, authorize the Executive Officer to take all steps necessary to adopt the proposed regulations at Sections 1793.5, 1793.6, and 1793.65 and to complete the rulemaking. Further, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

Proposed text for 1793.6(c)(2):

(2) In addition to the content of coursework specified in subdivision (c)(1), the course of training must also satisfy all of the following:

(A) Prior to enrollment in any classes or admission into the course of training, an administrator or instructor shall ~~conduct a criminal background check on the applicant that is consistent with inform applicants of~~ the criminal background check required for a pharmacy technician license per Business and Professions Code section 4202(c). ~~If the criminal background check reveals the applicant has committed acts that would constitute grounds for denial of licensure, the administrator or instructor shall counsel~~

applicants about the negative impact to securing licensure. An administrator or instructor shall counsel applicants about the negative impact to securing licensure if the criminal background check reveals that the applicant has committed acts that would constitute grounds for denial of licensure.

M/S: Weisz/Thibeau

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

Support: 8 Oppose: 0 Abstain: 1 Not Present: 2

Board Member	Vote
Barker	Not Present
Cameron-Banks	Yes
Crowley	Yes
De La Paz	Yes
Koenig	Abstain
Oh	Yes
Patel	Yes
Sanchez	Not Present
Serpa	Yes
Thibeau	Yes
Weisz	Yes

XV. Legislation and Regulation Committee Report

Chairperson Crowley reported on the Committee's work at the July 18, 2022, Committee Meeting. Dr. Crowley thanked fellow committee members, Vice Chair Jose De La Paz, Seung Oh, Maria Serpa, and Nicole Thibeau for their time.

Chairperson Crowley reported during the last meeting, the Committee considered several measures. Dr. Crowley noted legislation was very dynamic and there had been changes to some measures since the Board's and Committee's discussions in April. Dr. Crowley noted other measures previously considered by the Board that were not moving this year. The measures could not be discussed but wanted to ensure that members were aware of the updates and why they are not included on the list of pending legislation impacting the Board.

- Assembly Bill 2055 which would have transitioned the CURES operations to the

Board.

- Assembly Bill 2265 which would have required opioids to be dispensed in lockable vials
- Assembly Bill 2948 which would have required the Board to advise a complainant of the outcome of an investigation within 60 days of closure.
- Senate Bill 958 which was the Medication and Patient Safety Act of 2022, related to brown bagging and white bagging
- Senate Bill 1031 which would have reduced the renewal fee for an inactive license.
- Senate Bill 1379 which was the Board's remote processing proposal.

Chairperson Crowley reported on the pending measures that would impact the Board or the practice of pharmacy if enacted.

1. Assembly Bill 852 (Wood) Health Care Practitioners: Electronic Prescriptions.

Chairperson Crowley reported AB 852 had not previously been considered by the Board as it initially related to nurse practitioners. As amended this measure would make changes to the e-prescribing requirements including some Board-sponsored provisions related to requirements to transfer controlled substances prescriptions. Dr. Crowley noted the measure would also require the Board to maintain a list of health care practitioners that are exempt from the requirements. Dr. Crowley noted it appeared staff believe this could be facilitated through an online registry which would not involve significant resources. Dr. Crowley advised the Committee was recommending establishment of a support position on the measure.

Chairperson Crowley advised as part of the public comments received during the meeting, commenters suggested that a period of transition would be necessary to make computer changes. Dr. Crowley noted some provisions include a one-year implementation timeframe to accommodate such changes.

Committee Recommendation (Motion): Support

Members were provided with an opportunity to provide comments; however, none were provided.

Members of the public were provided with an opportunity to provide comments; however, no comments were provided.

Member Sanchez returned to the meeting at approximately 10:50 a.m.

Support: 8 Oppose: 0 Abstain: 1 Not Present: 2

Board Member	Vote
Barker	Not Present
Cameron-Banks	Yes
Crowley	Yes
De La Paz	Yes
Koenig	Yes
Oh	Yes
Patel	Not Present
Sanchez	Yes
Serpa	Yes
Thibeau	Yes
Weisz	Abstain

2. Assembly Bill 1328 (Irwin) Clinical Laboratory Technology and Pharmacists

Chairperson Crowley advised this measure would amend several provisions of the BPC to expand the authority for pharmacists to perform CLIA-waived tests either approved or authorized by the FDA upon patient request or hospital authorization if there is a valid and respective CLIA certificate of waiver and laboratory license, with some exceptions. Dr. Crowley reported this measure would amend Pharmacy Law to declare that pharmacy practice is a patient and public health-oriented health service that is continually evolving to include more sophisticated and comprehensive patient care and public health activities. Dr. Crowley advised there have been no changes to the measure, and it appeared there were no updates available on its status. The Board previously established a support position.

Chairperson Crowley reported the Committee was not recommending a change in the Board's current position.

Members were provided with an opportunity to comment; however, none were provided.

Members of the public were provided with an opportunity to comment; however, none were provided.

3. Assembly Bill 1662 (Gipson) Licensing Boards: Disqualification from Licensure: Criminal Conviction

Chairperson Crowley advised AB 1662 would allow a prospective applicant to request a preapplication determination based on information provided by the

prospective applicant regarding their criminal conviction. Dr. Crowley noted it would also require the Board to determine if the prospective applicant could be disqualified from licensure based upon the information submitted with the request.

Chairperson Crowley reported the measure was amended April 27, 2022. Dr. Crowley added the amendments establish authority for the Board to assess a fee of not more than \$50 to perform the workload required. Dr. Crowley noted as part of its determination, the Board was required to provide a summary of the criteria used by the Board, the process for an applicant to request a copy of their conviction history, notification of the right to appeal the Board's decision.

Chairperson Crowley advised the Board initially sought a Support, if amended position as the policy goal of the measure appears to align with the Board's policy in this area but that Board staff have indicated that the Board will need to promulgate regulations should this measure be enacted. The measure was scheduled to be heard in Senate Appropriations on August 1, 2022. Dr. Crowley advised the Committee agreed that the Board's current position is still appropriate.

Members were provided with an opportunity to provide comments; however, none were provided.

Members of the public were provided with an opportunity to provide comments; however, no comments were provided.

4. Assembly Bill 1733 (Quirk)

Chairperson Crowley advised reported AB 1733 would expand authority for the Board to convene meetings held entirely by teleconference under specified conditions which are detailed in the report. Dr. Crowley noted regrettably the hearing on this measure was postponed by the Committee and during its prior consideration of the measure the Board established a Support, if amended position.

Chairperson Crowley reported the data provided in the meeting materials demonstrates that remote meetings expand access to participation in meetings, including by individuals who may not otherwise be available to participate because of health, costs or other barriers. Dr. Crowley provided this transition back to in person meetings demonstrates that members of the public largely prefer to continue to participate via WebEx.

Chairperson Crowley advised as indicated in the meeting materials, the Board was able to resume full teleconference meetings for an additional year

because of temporary changes to the Government Code. Dr. Crowley noted as these changes are temporary, the Committee determined that the Board's current position on the measure remain appropriate. Dr. Crowley suggested at the Committee meeting that the Board consider having a discussion at a later meeting on how to return to awarding CE credits to individuals participating remotely in Board and Committee meetings. Dr. Crowley also provided the Committee discussed how meetings convened via teleconference provide equity allowing everyone to participate in public meetings. Public comments received during the meeting indicated support for remote meetings, but that members should be required to participate from a single location.

Members were provided with an opportunity to provide comments; however, none were provided.

Members of the public were provided with an opportunity to provide comments; however, no comments were provided.

5. Assembly Bill 2194 (Ward) Pharmacists and technicians; continuing education: cultural competency

Chairperson Crowley advised AB 2194 would require that at least one of the 30 hours of required continuing education (CE) for pharmacists include participation in a cultural competency course, as defined. Dr. Crowley noted the bill would also prohibit the board from renewing a pharmacist or pharmacy technician license unless the applicant submits proof to the board of completion of at least one hour of participation in a cultural competency course. Dr. Crowley stated the intent of the bill is to help ensure that pharmacies through the pharmacists and pharmacy technicians are providing culturally competent care to members of the LGBTQ+ community and the bill was co-sponsored by the California Pharmacists Association (CPhA) and Equality California.

Chairperson Crowley reported at the April Meeting, the Board established a support if amended position, requesting a delayed implementation to allow licensees time to complete the required coursework and also to confirm that an audit-based approach for compliance would be consistent with the provisions. Dr. Crowley understood the author's office confirmed that an audit-based approach for compliance is appropriate and will be amending the measure to delay implementation.

Chairperson Crowley shared during the Committee meeting, Dr. Crowley supported this measure was an important first step in opening doors for education in this area, but wished it was a bit more inclusive of other marginalized

communities. Dr. Crowley pointed out with such a diverse population California pharmacists may differ in the cultural competency training that would best help them serve their specific patients. Dr. Crowley provided for example, a pharmacist with multiple Deaf or Hard of Hearing patients would potentially benefit from a CE on serving patients with disabilities, Health literacy, or utilization of ASL interpreters in pharmacies. Dr. Crowley noted Other marginalized communities that need better care include, but are not limited to, undocumented residents, patients who speak English as a second language, patients with poor literacy, and residents with poor Social Determinants of Health. Dr. Crowley added this measure highlights an important issue for the Committee.

Chairperson Crowley reported the Committee determined that the Board's current position is appropriate as the amendments were not yet in print. The Committee agreed that it appeared appropriate to schedule discussion on how the Board can promote education on other marginalized communities and perhaps development of a policy statement in the area.

Members were provided with an opportunity to provide comments; however, none were provided.

Members of the public were provided with an opportunity to provide comments; however, no comments were provided.

6. Senate Bill 731 (Durazo) Criminal Records: Relief

Chairperson Crowley advised this measure was recently amended to expand automatic relief to include arrests for felonies punishable by state prison. Further the measure would expand automatic conviction relief to certain felonies under specified conditions. Dr. Crowley noted that serious and violent felonies, and felonies requiring sex registration were excluded. Dr. Crowley advised the Board previously established an Oppose, unless amended, position.

Chairperson Crowley stated during the Committee meeting that Dr. Crowley appreciated that the intention of the bill may be seeking to remedy some injustices and racial disparities, specifically regarding a disproportionate number of arrests among Black and Latino Californians. Dr. Crowley struggled with the implementation approach; however, as it took away discretion for the Board to decide consistent with the Board's mandate, Dr. Crowley noted there may be some felony drug offenses for example that the Board should be able to consider as part of its licensing decision. Dr. Crowley stated there are a spectrum on drug related offenses and the Board should have the discretion to decide on the appropriate outcome for an individual with previous felonies, which may differ for

an individual with marijuana convictions versus an individual that manufactured methamphetamine that is now seeking licensure. Dr. Crowley reported the Committee determined that the Board's current position is still appropriate.

Members were provided with an opportunity to provide comments; however, none were provided.

Members of the public were provided with an opportunity to provide comments; however, no comments were provided.

7. Senate Bill 872 (Dodd) Pharmacies: Mobile Units

Chairperson Crowley advised Senate Bill 872 was amended on June 15, 2022. Dr. Crowley reported the policy goal remained the same - - providing for the use of mobile units to bring pharmacy services to Californian's that may not otherwise have access but the approach offered has not changed. Dr. Crowley stated rather than requiring licensure, the approach now is to allow for the use of the mobile unit as an extension of the pharmacy. The provisions continue to be limited to city or county to operate a mobile unit to provide prescription medications within its jurisdiction to individuals without a fixed address, individuals living in county-owned or city-and-county-owned housing facilities and individuals enrolled in Medi-Cal plans operated by the local jurisdiction or health department.

Chairperson Crowley advised the Committee concluded that the Board's previous issues surrounding the operational requirements are addressed as all relevant provisions of pharmacy law would be required. The Committee noted that there may be utility for the use of mobile units beyond those established in the measure and that should the measure be enacted, it may be helpful for the Board to issue some FAQs or other education materials detailing out how some of the provisions of pharmacy law are applicable to the use of the mobile unit. Dr. Crowley advised the Committee is recommending a change to a Support position.

Committee Recommendation (Motion): Change to a Support Position

Members were provided with an opportunity to provide comments; however, none were provided.

Members of the public were provided with an opportunity to provide comments; however, no comments were provided.

Support: 8 Oppose: 0 Abstain: 1 Not Present: 2

Board Member	Vote
Barker	Not Present
Cameron-Banks	Yes
Crowley	Yes
De La Paz	Yes
Koenig	Yes
Oh	Yes
Patel	Not Present
Sanchez	Yes
Serpa	Yes
Thibeau	Yes
Weisz	Abstain

8. Senate Bill 988 (Hueso)

Chairperson Crowley advised Senate Bill 988 was also amended since the Board's last discussion. Dr. Crowley recalled as discussed during the Committee meeting, last year Senate Bill 311 established provisions for a terminally ill patient within a hospital to access their medicinal cannabis noting late amendments to the measure created conflicts with several provisions of state and federal law. Dr. Crowley reported the amendments appear consistent with the language of the letter published in the Senate Journal, wherein the author's office conveyed the intentions of the measure. Dr. Crowley added the approach now offered in the measure was different from the prior version, the measure still remedies the conflicts created in last year's legislation. Dr. Crowley reported the Committee determined the Board's current position remains appropriate.

Members were provided with an opportunity to provide comments; however, none were provided.

Members of the public were provided with an opportunity to provide comments; however, no comments were provided.

9. Senate Bill 1237 (Newman)

Chairperson Crowley reported Senate Bill 1237 would expand the provisions for a fee waiver for a member of the military "called to active duty," and the term active duty would have the same meaning as "active duty" as defined in federal law. The measure would be considered by the Assembly Appropriations Committee on August 3, 2022. Dr. Crowley reported the Board established a support position in

April and the Committee determined the Board's current Support position was appropriate.

Members were provided with an opportunity to provide comments; however, none were provided.

Members of the public were provided with an opportunity to provide comments; however, no comments were provided.

10. Senate Bill 1259 (Laird)

Chairperson Crowley reported Senate Bill 1259 had not previously been considered by the Board as it originally related to retail installment contracts. Dr. Crowley noted as amended this measure would expand authority for pharmacists and allow pharmacists to furnish any opioid antagonist approved by the FDA under specified conditions. Dr. Crowley added if enacted the Board would need to promulgate regulations in coordination with other specified agencies including the Medical Board, California Society of Addiction Medicine and the California Pharmacists Association. Dr. Crowley noted given the Board's long history of supporting access to life saving medications including naloxone, the Committee was recommending establishment of a support position.

Chairperson Crowley noted that expanding access points for patients is extremely important. Dr. Crowley stated the Board must realize that the costs of these medications may be beyond what an individual could pay. Noting the affordability issue was a barrier beyond the Board's purview, Dr. Crowley believed it was important to acknowledge.

Committee Recommendation (Motion): Establish a Support Position

Members were provided with an opportunity to provide comments; however, none were provided.

Members of the public were provided with an opportunity to provide comments; however, no comments were provided.

Support: 8 Oppose: 0 Abstain: 1 Not Present: 2

Board Member	Vote
Barker	Not Present
Cameron-Banks	Yes
Crowley	Yes
De La Paz	Yes
Koenig	Yes
Oh	Yes
Patel	Not Present
Sanchez	Yes
Serpa	Yes
Thibeau	Yes
Weisz	Abstain

11. Senate Bill 1346 (Becker)

Chairperson Crowley advised Senate Bill 1346 would expand provisions for redistribution of unused donated medications. Dr. Crowley noted the measure had been amended since the last Board meeting when the Board established an Oppose, unless amended position. Dr. Crowley noted amendments expand the entities authorized to donate medications to redistribution programs and limit expansion of specified provisions for redistribution programs to specified counties as well as place a sunset date on the county programs. Dr. Crowley noted the Board will be required to submit a legislative report.

Chairperson Crowley stated at the Committee meeting that Dr. Crowley shared all of the patient safety concerns previously raised by the Board as well as the broad civil and criminal immunity provisions. Dr. Crowley advised the Committee determined that the Board's current Oppose Unless amended position was appropriate. Dr. Crowley noted should the measure pass, Dr. Crowley suggested that staff as part of its evaluation and assessment of these programs, pay special attention to IV and infused medication if they are allowed to be redistributed under a county program. Dr. Crowley suggested that if the measure was passed, that the Board receive annual updates on the program and any issues that arrive.

Members were provided with an opportunity to provide comments; however, none were provided.

Members of the public were provided with an opportunity to provide comments; however, no comments were provided.

- b. Discussion and Consideration of Board Adopted Regulations Undergoing Final Review by the Office of Administrative Law
 - 1. Proposed Regulation to Amend Title 16, CCR Section 1715.65 Related to Inventory Reconciliation
 - 2. Proposed Regulation to Amend Title 16, CCR Section 1708.1 Related to the Temporary Closure of Facilities
- c. Discussion and Consideration of Board Adopted Regulations Undergoing Final Review by the Department of Consumer Affairs or Business, Consumer Services and Housing Agency
 - 1. Proposed Regulations to Amend Title 16, CCR Section 1715 to Update Self-Assessment Forms 17M-13 and 17M-14
 - 2. Proposed Regulation to Amend Title 16, CCR Section 1784 to Update the Wholesale/3PL Self-Assessment Form 17M-26
 - 3. Proposed Regulations to Amend Title 16, CCR Section 1793.5 Related to Pharmacy Technician Application, Section 1793.6 Related to the Pharmacy Technician Training Requirements, and Section 1793.65 Related to the Pharmacy Technician Certification Programs
- d. Discussion and Consideration of Board Approved Regulations Undergoing Pre-Notice Review by the Department of Consumer Affairs or Business, Consumer Services and Housing Agency
 - 1. Proposed Regulation to Amend Title 16 CCR Section 1707.6 Related to the Notice to Consumers
 - 2. Proposed Regulation to Amend Title 16, CCR Section 1709.1, Related to the Designation of Pharmacist-in-Charge
 - 3. Proposed Regulation to Amend Title 16, CCR Section 1715.1 Related to the ADDS Self-Assessment Form 17M-112
 - 4. Proposed Regulation to Amend Title 16, CCR Section 1760 Related to the Disciplinary Guidelines
- e. Discussion and Consideration of Recently Approved Section 100 Regulation Change to Title 16, CCR Section 1730.1 Related to Advanced Practice Pharmacists

Chairperson Crowley advised the remaining items were for information only. Dr. Crowley noted as detailed in the meeting materials, the Board had a number of regulations in various stages of promulgation. Dr. Crowley reported that since the release of the meeting materials, the Board's inventory reconciliation regulation was approved. Dr. Crowley advised the information on the Board's website was updated to reflect this approval. Dr. Crowley noted with this approval, the Board had one regulation undergoing final review by the Office of Administrative Law, related to Temporary Closures. The Board had three undergoing final review by DCA or Business, Consumer Services and Housing Agency and four regulations undergoing pre-notice review by DCA.

Members were provided with an opportunity to provide comments; however, none were provided.

Members of the public were provided with an opportunity to provide comments; however, no comments were provided.

XVI. Executive Officer Report

a. Discussion of Board's Response to COVID-19 Pandemic and Actions Taken by Other Agencies

Executive Officer Sodergren provided an overview of the Board's response to the COVID-19 pandemic including board waivers, site specific waivers and temporary licenses as well as efforts taken by DCA including DCA Director Waivers.

b. Update on Business Modernization Activities

Ms. Sodergren provided an explanation of the Business Modernization required to update systems and provided a status for the Board.

c. Annual CURES Update

Ms. Sodergren provided an update on the CURES program including system usage, controlled prescriptions reported and AB 528 CURES reporting implementation.

d. Medical Board of California Interested Parties Meeting

Ms. Sodergren advised the Medical Board was reviewing its prescribing guidelines. Ms. Sodergren noted if there are changes, the Board will ensure Board licensees are notified and aware of the changes as it could potentially impact the practice of pharmacy.

e. Department of Health Care Access and Information – Licensure Data Collection

Ms. Sodergren referenced meeting materials that contain licensure data collection project underway by the Department of Healthcare Access and Information. Ms. Sodergren noted it was intended to receive information from licensees and

understand workforce. Ms. Sodergren noted they can be invited to future meetings if the Board desires.

f. Report of Actions Taken at the Annual National Association of Boards of Pharmacy

Ms. Sodergren advised President Oh attended and represented the Board of Pharmacy at the National Association of Boards of Pharmacy (NABP) Annual Meeting. Ms. Sodergren referenced the resolutions made at the Annual Meeting in the meeting materials.

Members were provided with an opportunity to provide comments; however, none were provided.

Members of the public were provided with an opportunity to provide comments; however, no comments were provided.

XVII. Petitions for Reinstatement of Licensure, Early Termination or other Modification of Penalty

Administrative Law Judge Erin Koch-Goodman presided over the hearings. Petitions included:

a. Chi Nguyen, RPH 46977

The Board took a lunch break from 12:07 p.m. to 1:03 p.m. Roll call was taken. Board Members present included: Maria Serpa, Licensee Member; Indira Cameron-Banks, Public Member; Jessi Crowley, Licensee Member; Kula Koenig, Public Member; Ricardo Sanchez, Public Member; Nicole Thibeau, Licensee Member; Jason Weisz, Public Member; and Seung Oh, Licensee Member. Quorum was established.

Member De La Paz returned to the meeting at approximately 1:40 p.m.

Member De La Paz left the meeting at approximately 1:58 p.m.

b. Colin Boggs, RPH 36395

XVIII. Closed Session Matters

Following completion of the open session at 2:00 p.m. the Board convened in closed session at 2:10 p.m. for the stated purposes indicated on the agenda. Due to technological limitations, adjournment for the day was not broadcast. The meeting adjourned at 2:10 p.m.

Attachment B

**August 25, 2022,
Board Meeting**



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
DRAFT Public Board Meeting Minutes**

Date: August 25, 2022

Location: Note: Pursuant to the provisions of Government Code section 11133, neither a public location nor teleconference locations are provided. Public participation also provided via WebEx

Board Members

Present: Seung Oh, Licensee Member, President
Maria Serpa, Licensee Member, Vice President
Jignesh Patel, Licensee Member, Treasurer
Renee Barker, Licensee Member
Jessica Crowley, Licensee Member
Jose De La Paz, Public Member
Ricardo Sanchez, Public Member
Nicole Thibeau, Licensee Member
Jason Weisz, Public Member

Board Members

Not Present: Indira Cameron-Banks, Public Member
Kula Koenig, Public Member

Staff Present: Anne Sodergren, Executive Officer
Laura Freeman, DCA Staff Counsel
Debbie Damoth, Executive Specialist Manger

August 25, 2022

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

President Oh called the Board Meeting to order at approximately 4:01 p.m.

President Oh reminded all individuals present that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. Where protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. Department of Consumer Affairs' staff provided

general instructions for the WebEx Board Meeting for members of the public participating in the meeting.

Roll call was taken. Board Members present included: Maria Serpa, Licensee Member; Jig Patel, Licensee Member; Renee Barker, Licensee Member; Jessi Crowley, Licensee Member; Ricardo Sanchez, Public Member; Nicole Thibeau, Licensee Member; Jason Weisz, Public Member; and Seung Oh, 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 with an opportunity to provide comments; however, no comments were made.

III. Discussion and Consideration of Waiver of Pharmacy Law Provisions Consistent with the Authority in Business and Professions Code Section 4062 In response to State of Emergency related to Monkeypox

a. Prescriber Dispensing of TPOXX Oral Antiviral Medication to Emergency Room Patient

President Oh advised Business and Professions Code (BPC) section 4062 provides authority for the Board to issue a waiver of Pharmacy Law or its regulations adopted pursuant to it, if in the Board's opinion, the waiver will aid in the protection of public health or the provisions of care. Dr. Oh stated in response to Governor Newsom's state of emergency declaration to support the state's response to MPOX, through authority delegated to the Board President, Dr. Oh approved a waiver to allow for the dispensing of TPOXX, an oral antiviral medication, to an emergency room patient under specified conditions. Dr. Oh advised consistent with the delegated authority, the waiver would remain in place until September 1, 2022, unless the Board took action to extend it. Dr. Oh advised that the TPOXX waiver included the same approach as the Board's similar waiver to allow for dispensing for COVID therapeutics.

Members were provided with an opportunity to provide comments. Members discussed if a rolldown is necessary and spoke for the need noting the long incubation period for MPOX. Member Thibeau suggested that the Board take a strong stance and suggested 90 days following the end of the declared disaster.

Member De La Paz joined the meeting at 4:10 p.m.

Motion: Approve an extension of the waiver to allow for the dispensing of TPOXX oral antiviral medication to an emergency room patient under specified conditions until 90 days following end of the declared emergency.

M/S: Thibeau/Sanchez

Members of the public were provided with an opportunity to provide comments. The Board heard a comment inquiring if the generic name of the drug should be included.

Support: 9 Oppose: 0 Abstain: 0 Not Present: 2

Board Member	Vote
Barker	Support
Cameron-Banks	Not present
Crowley	Support
De La Paz	Support
Koenig	Not present
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibeau	Support
Weisz	Support

- b. Policy Granting President Discretion to Waive Provisions of Pharmacy Law Related to the State of Emergency Declared for MPOX

President Oh advised there was an opportunity for the Board discuss the ability to delegate additional authority to the President to waive provisions related to MPOX, like the approach used to respond to COVID. Dr. Oh recalled as part of the April 2022 Board meeting, the Board voted to delegate to the President the authority to approve or extend waivers through December 31, 2022, or until 90 days following the end of the declared disaster, whichever is later.

President Oh referenced the meeting materials prepared by staff for a possible motion that could be used to expand delegated authority to the President to issue or approval waivers in response to MPOX. Dr. Oh highlighted the possible motion does not include a clause at the end to link the delegation to the end of the declared disaster.

Members were provided with an opportunity to provide comments. Member Serpa commented as this appeared to be a long-term issue it would be prudent for the Board to have similar types of delegation to the president as the COVID delegation.

Motion: Authorize the president to approve waivers related to the MPOX public health emergency for up to 90 days following the end of the disaster.

M/S: Serpa/Patel

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

Support: 9 Oppose: 0 Abstain: 0 Not Present: 2

Board Member	Vote
Barker	Support
Cameron-Banks	Not Present
Crowley	Support
De La Paz	Support
Koenig	Not Present
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibeau	Support
Weisz	Support

VII. Closed Session

President Oh adjourned at approximately 4:26 p.m.

Attachment C

**September 14, 2022,
Board Meeting**



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
 DRAFT Public Board Meeting Minutes**

Date: September 14, 2022

Location: Pursuant to the provisions of Government Code section 11133, neither a public location nor teleconference locations are provided.

Board Members

Present: Seung Oh, Licensee Member, President
 Maria Serpa, Licensee Member, Vice President
 Renee Barker, Licensee Member
 Indira Cameron-Banks, Public Member
 Jessica Crowley, Licensee Member
 Jose De La Paz, Public Member
 Kula Koenig, Public Member
 Ricardo Sanchez, Public Member
 Nicole Thibeau, Licensee Member

Board Members

Not Present: Jignesh Patel, Licensee Member, Treasurer
 Jason Weisz, Public Member

Staff Present: Anne Sodergren, Executive Officer
 Eileen Smiley, DCA Staff Counsel
 Debbie Damoth, Executive Specialist Manger

September 14, 2022

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

President Oh called the Board Meeting to order at approximately 2:01 p.m.

President Oh reminded all individuals present that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. Where protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. Department of Consumer Affairs' staff provided

general instructions for the WebEx Board Meeting for members of the public participating in the meeting.

Roll call was taken. Board Members present included: Maria Serpa, Licensee Member; Renee Barker, Licensee Member; Indira Cameron-Banks, Public Member; Jessica Crowley, Licensee Member; Jose De La Paz, Public Member; Ricardo Sanchez, Public Member; and Seung Oh, Licensee Member. A quorum was established.

Member Kula Koenig joined the meeting at 2:05 p.m.

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

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

III. Closed Session

Open session concluded at approximately 2:05 p.m. The Board entered closed session at approximately 2:15 p.m. and ended closed session at 3:32 p.m. The Board Meeting concluded at approximately 3:33 p.m.

Attachment D

**September 21, 2022,
Board Meeting**



**California State Board of Pharmacy
 Department of Consumer Affairs
 DRAFT Public Board Meeting Minutes**

Date: September 21, 2022

Location: Note: Pursuant to the provisions of Government Code section 11133, neither a public location nor teleconference locations are provided

Board Members

Present: Seung Oh, Licensee Member, President
 Renee Barker, Licensee Member
 Jessica Crowley, Licensee Member
 Jose De La Paz, Public Member
 Kula Koenig, Public Member
 Nicole Thibeau, Licensee Member

Board Members

Not Present: Jignesh Patel, Licensee Member, Treasurer
 Maria Serpa, Licensee Member, Vice President
 Indira Cameron-Banks, Public Member
 Ricardo Sanchez, Public Member
 Jason Weisz, Public Member

Staff Present: Anne Sodergren, Executive Officer
 Eileen Smiley, DCA Staff Counsel
 Debbie Damoth, Executive Specialist Manger

September 21, 2022

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

President Oh called the Board Meeting to order at approximately 9:00 a.m.

President Oh reminded all individuals present that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. Where protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

President Oh advised all individuals the meeting was being conducted in person at locations in Sacramento and San Diego as well as via WebEx. Dr. Oh advised participants watching the webcast they could only observe the meeting. He noted anyone interested in participating in the meeting must join the WebEx meeting using the instructions posted on the Board's website.

Department of Consumer Affairs' staff provided general instructions for the WebEx Board Meeting for members of the public participating in the meeting.

Roll call was taken. Board Members present included: Renee Barker, Licensee Member; Jessica Crowley, Licensee Member; Jose De La Paz, Public Member; Nicole Thibeau, Licensee Member; and Seung Oh, Licensee Member. A quorum was not established. As noticed on the agenda, if a quorum of members is not present, as part of President Oh's discretion, the Board proceeded as a committee.

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

Members of the public were provided with an opportunity to provide comment for items not on the agenda or agenda items for a future meeting; however, no comments were made.

III. Recognition and Celebration of Pharmacists Licensed in California for 40 Years and other Recognitions

President Oh reminded members several years ago, the Board changed its recognition program for pharmacists and currently recognizes pharmacists that have been licensed for 40 or more years. Dr. Oh noted the information was posted on the Board's website and pharmacists are provided with a certificate.

President Oh noted prior to transitioning to remote meetings, the Board routinely provided an opportunity for pharmacists licensed for 40 years to attend a Board meeting and be recognized by the Board. Dr. Oh continued although the Board has returned to remote meetings, the Board would like to provide an opportunity for the Board to recognize pharmacists that have been licensed in California for 40 years.

There were no pharmacists identifying themselves to be recognized for 40 years of service as a pharmacist.

President Oh thanked and congratulated pharmacists who had been licensed as a pharmacist for over 40-years. Dr. Oh thanked all pharmacy staff who worked in pharmacy serving the consumers of California.

President Oh advised consistent with the provisions of Business and Professions Code (BPC) section 4309(c) and the Board's policy, as a quorum of the Board was not present, a committee of the Board will consider the petitions today and make recommendations to the

full Board that will be subject to review by the full Board in accordance with Government Code section 11517. Members proceeded with hearing petitions.

IV. Petitions for Reinstatement of Licensure, Early Termination or Other Modification of Penalty.

Administrative Law Judge Ed Washington presided over the hearings. Pursuant to Business and Professions section 4309(c) as quorum was not obtained, the members at the President's discretion continue pursuant to discuss items from the agenda and make recommendations to the full Board at a future meeting. Petitions heard by members as a committee included:

a. Jason Chvat, RPH 53345

The Board took a break from approximately 9:50 a.m. to 9:55 a.m. Roll call was taken after break. Members present included: Renee Barker, Licensee Member; Jessica Crowley, Licensee Member; Jose De La Paz, Public Member; Nicole Thibeau, Licensee Member; and Seung Oh, Licensee Member. A quorum was not established. As noticed on the agenda, if a quorum of members is not present, as part of President Oh's discretion, the Board proceeded as a committee.

b. Laura Trovato, RPH 39463

The Board took a break from approximately 10:40 a.m. to 10:51 a.m. Roll call was taken after break. Members present included: Renee Barker, Licensee Member; Jessica Crowley, Licensee Member; Jose De La Paz, Public Member; Nicole Thibeau, Licensee Member; and Seung Oh, Licensee Member. A quorum was not established. As noticed on the agenda, if a quorum of members is not present, as part of President Oh's discretion, the Board proceeded as a committee.

c. Farnaz Mahdavi, RPH 42814

The Board took a break from approximately 11:33 a.m. to 1:00 p.m. Roll call was taken after break. Members present included: Renee Barker, Licensee Member; Jessica Crowley, Licensee Member; Jose De La Paz, Public Member; Nicole Thibeau, Licensee Member; and Seung Oh, Licensee Member. A quorum was not established. As noticed on the agenda, if a quorum of members is not present, as part of President Oh's discretion, the Board proceeded as a committee.

d. Adel Yacoub Al-Badawi, RPH 30945

Member Kula Koenig joined the meeting at 1:13 p.m.

The Board took a break from approximately 1:49 a.m. to 1:55 p.m. Roll call was taken after break. Members present included: Renee Barker, Licensee Member; Jessica Crowley, Licensee Member; Jose De La Paz, Public Member; Kula Koenig, Public Member; Nicole Thibeau, Licensee Member; and Seung Oh, Licensee Member. A quorum was not established. As noticed on the agenda, if a quorum of members is not present, as part of President Oh's discretion, the Board proceeded as a committee.

- e. Procure Pharmacy, PHY 46937
- f. Vijay Shelat, RPH 45111

V. Closed Session

Open session concluded at approximately 3:08 p.m. The Board entered closed session at approximately 3:15 p.m. and ended closed session at 4:13 p.m. The Board Meeting concluded at approximately 4:13 p.m.