III. Approval Board Meeting Minutes

a. April 29-30, 2021, Board Meeting

California State Board of Pharmacy
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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: April 29-30, 2021

Location: Teleconference Public Board Meeting
Note: Pursuant to the provisions of Governor Gavin Newsom's Executive Order N-25-20, dated March 17, 2020, neither a public location nor teleconference locations are provided.

Board Members Present:
Gregory Lippe, Public Member, President
Debbie Veale, Licensee Member, Vice President
Maria Serpa, Licensee Member, Treasurer
Lavanza Butler, Licensee Member
Shirley Kim, Public Member
Seung Oh, Licensee Member
Jignesh Patel, Licensee Member
Ricardo Sanchez, Public Member
Jason Weisz, Public Member
Albert Wong, Licensee Member

Staff Present:
Anne Sodergren, Executive Officer
Lyle Matthews, Assistant Executive Officer
Eileen Smiley, DCA Staff Counsel
Sheila Tatayan, DCA Staff Counsel
Debbie Damoth, Administration Manager
Bob Dávila, Public Information Officer

April 29, 2021

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

President Lippe called the Board Meeting to order at 3:00 p.m.

President Lippe 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 Lippe advised all individuals observing or participating in the meeting that the meeting was being conducted consistent with the provisions of Governor Gavin Newsom's Executive Order N-29-20. Mr. Lippe 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.

President Lippe advised those participating in the teleconference the Board would convene in closed session after deliberating on the open session items, except adjournment.

Roll call was taken. Board Members present: Jignesh Patel, Ricardo Sanchez, Albert Wong, Debbie Veale, Shirley Kim, Lavanza Butler, Maria Serpa, Seung Oh, Jason Weisz, and Greg Lippe. 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.

Andre Pieterse, registered pharmacists, commented in July 2019 when ADDS went into effect, it seemed straight forward to place ADDS in retail pharmacies and long-term care settings facilities. He was surprised there was an interpretation by the Board that many Pyxis machines in emergency rooms (ER) of mostly rural hospitals must be licensed. He noted in talking to colleagues most seemed to think that because the ER is licensed by the CDPH in a hospital it is exempt from the licensing requirement. He noted the ADDS self-assessment does not include general acute care hospitals. He requested the Board be aware of the widespread misunderstanding as well as investigate and review if this interpretation is valid and in line with the law. He added the licensing requirement disproportionately singles out rural hospitals and effects communities with limited resources. He requested if found to be valid, he asked the Board to educate pharmacists and give those with the legacy practice the opportunity to get the devices licensed.

Sandra Martinez commented about concerns on restrictions placed on pharmacists providing hydroxychloroquine and ivermectin as successful therapies for COVID. She stated she sent information to the Board about the drugs' safe and effective use.

Members were provided the opportunity to include any item on a future agenda.

Motion: Refer the ADDS licensing requirements for rural hospitals to be added to a future agenda at the discretion of the Board president and executive officer.

M/S: Veale/Oh

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

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

Board Member	Vote
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Support
Wong	Support

III. Approval Board Meeting Minutes

a. January 27-28, 2021, Board Meeting

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

Motion: Approve the January 27-28, 2021, minutes as presented in the meeting materials.

M/S: Patel/Sanchez

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

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

Board Member	Vote
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Support
Wong	Support

b. March 18, 2021, Board Meeting

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

Motion: Approve the March 18, 2021, minutes as presented in the meeting materials.

M/S: Sanchez/Butler

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

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

Board Member	Vote
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Support
Wong	Support

d. October 27-28, 2020, Board Meeting, Correction to Previously Approved Minutes

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

Motion: Approve the October 27-28, 2020, Board Meeting, correction to previously approved minutes, minutes as presented in the meeting materials.

M/S: Lippe/Patel

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

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

Board Member	Vote
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Support
Wong	Support

IV. Update from the Department of Consumer Affairs

President Lippe welcomed Deputy Director of Board and Bureau Relations Carrie Holmes. Ms. Holmes addressed the Board with an update from the Department of Consumer Affairs (DCA).

Ms. Holmes shared updates to the DCA Executive Team. She noted Governor Newsom appointed Monica Vargas as Deputy Director of Communications in January 2021. Ms. Vargas was an Information Officer in the Governor's Office of Emergency Services since 2015 and Information Officer at DCA. Ms. Holmes shared in February 2021 Governor Newsom appointed Sarah Murillo as Deputy Director of Administrative Services. Ms. Murillo previously held positions over 20 years in state departments including California Complete Count Census 2020.

Ms. Holmes added one of the top priorities is Board appointments with the goal of a fully seated diverse and effective Board. She noted three vacancies on the Board of Pharmacy including two public members and one license member. Ms. Holmes added Members Lippe and Wong are currently in their grace period. Having served two terms, Members Lippe and Wong are not eligible for another appointment. She encouraged interested parties to apply by finding the link at www.dca.ca.gov entitled "Board Member Resources" or reach out to DCA's Board and Bureau Relations.

Ms. Holmes thanked Board Members and staff for their dedication during the pandemic. She noted DCA office remains open with preventative measures in place to safeguard the health and safety of DCA employees and visitors. She added DCA is looking ahead to how changes can be made permanent for employee well-being and efficiency such as telework and eliminating paper processes. She encouraged visiting DCA's COVID-19 page for updates and resources on the state's reopening plans, public health guidance, vaccinator resources, and vaccine distribution.

Ms. Holmes advised when Boards and Bureaus will meet in person is unknown. She noted the Board's ability to meet remotely is tied to the Governor's executive orders and the state of emergency. Ms. Holmes clarified when the orders are lifted, the Board will be required to follow all aspects of the open meetings act including publicly noticed and accessible locations. She reported when this will happen or if changes in the law will occur before that date is unknow but DCA will do everything possible to allow for safe transition and time to plan for in-person meetings. Ms. Holmes added DCA has created a DCA background for remote meetings and can add the Board's logo if desired.

Members were provided the opportunity to comment or ask Ms. Holmes a question. Ms. Veale inquired if once orders were lifted if the opportunity for the public to participate remotely would still be available. Ms. Holmes noted it has been an option in the past but unsure of what other options may be available.

Members of the public were provided the opportunity to comment or ask questions. Richard Duenas, Mercury Pharmacy, inquired how best to submit questions about Board appointments. Ms. Holmes provided her email address of Carrie.Holmes@dca.ca.gov and referenced the Board Member Resources page at www.dca.ca.gov.

V. Board Officer Elections

President Lippe stated he was honored and proud to have served as the Board's President for two years and Board Member for 12 years. Mr. Lippe noted although he is not a pharmacist, he has tremendous respect and admiration for the profession. Mr. Lippe thanked Board Members, stakeholders, Executive Officer Sodergren and Board staff. He noted his last meeting will be May 27, 2021. Members Wong, Butler and Veale commented in appreciation for President Lippe's service and leadership.

President Lippe noted the Board's procedure manual advises terms shall be for a one-year term beginning June 1st and may be re-elected for consecutive terms. Mr. Lippe accepted nominations for the office of Board President.

President Lippe nominated Member Veale. Member Wong nominated Member Oh. Members of the public were provided the opportunity to provide comments; however, no comments were made.

Members were surveyed to see if they would like to hear statements from the nominated Members. Members agreed if nominated Members wished they could make a statement. Members Veale and Oh made statements in support of their respective nominations.

Board Member	Vote
Butler	Oh
Kim	Oh
Lippe	Veale
Oh	Oh
Patel	Veale
Sanchez	Oh
Serpa	Veale
Veale	Veale
Weisz	Oh
Wong	Oh

Member Seung Oh was elected president.

President Lippe accepted nominations for vice president. Mr. Lippe nominated Member Serpa. Member Oh nominated Member Veale. Ms. Veale respectfully declined.

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

Board Member	Vote
Butler	Yes
Kim	Yes
Lippe	Yes
Oh	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes
Veale	Yes
Weisz	Yes
Wong	Yes

Member Serpa was elected vice president.

President Lippe accepted nominations for Treasurer. Mr. Lippe nominated Member Patel. Member Oh nominated Member Sanchez who respectfully declined the nomination.

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

Board Member	Vote
Butler	Yes
Kim	Yes
Lippe	Yes
Oh	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes
Veale	Yes
Weisz	Yes
Wong	Yes

Member Patel was elected treasurer.

VI. Organizational Development Committee Report

a. Budget Update

President Lippe referenced the meeting materials and noted the Board's spending authorization for the year is $29.3 million, a 2 percent increase from the prior year. According to preliminary budget reports, the Board received $25.2 million in revenue, the majority of which comes from application and renewal fees. He advised the Board expended about $18.2 million in the first eight months of the fiscal year, including about $11.1 million in personnel, about $3 million in prorata, and almost $3.1 million in enforcement related costs.

President Lippe noted a review of the fund condition prepared by the Department indicates that at the end of the fiscal year, it is projected the Board will have 3.9 months in reserve.

b. Board Member Attendance

President Lippe referred to meeting materials summarizing Board Member Attendance.

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

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

c. Update to Board Member Procedure Manual

President Lippe noted the Board Member Procedure Manual details the operations and functions of the Board. He added as the Board has delegated functions to the President, the delegation was memorialized in the policy statement, but not reflected in the authorized duties. He referenced the meeting materials that reflect recommended changes offered by staff and summarized the proposed changes.

Motion: Accept proposed changes to the Board Member Procedural Manual.

M/S: Veale/Patel

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

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

Board Member	Vote
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Support
Wong	Support

d. Personnel Update

President Lippe noted as detailed in the meeting materials, the Board has a number of vacancies.

e. Meeting Calendar for 2021

President Lippe advised the meeting calendar for the remainder of 2021 is included in in the meeting materials. He added subsequent to the release of the meeting materials, the Board has added a Board meeting on May 27, 2021, to consider petitions.

f. Meeting Calendar for 2022

President Lippe reported included in the meeting materials is a proposed meeting calendar for 2022.

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

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

VII. Closed Session Matters

The Board moved into closed session at approximately 3:51 p.m.

VIII. Reconvene Open Session, to Adjourn for the day

The Board adjourned after closed session at approximately 5:08 p.m.

April 30, 2021

President Lippe called the Board Meeting to order at 9:05 a.m.

President Lippe 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 Lippe advised all individuals observing or participating in the meeting that the meeting was being conducted consistent with the provisions of Governor Gavin Newsom's Executive Order N-29-20. Mr. Lippe 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.

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

President Lippe advised those participating in the teleconference the Board would convene in closed session after deliberating on the open session items, except adjournment.

Roll call was taken. Board Members present included Maria Serpa, Seung Oh, Debbie Veale, Lavanza Butler, Ricardo Sanchez, Albert Wong, Shirley Kim, Jignesh Patel, Jason Weisz, and Greg Lippe. A quorum was established.

IX. Communication and Public Education Committee Report

Chairperson Sanchez reported the Communication and Public Education Committee met April 29, 2021. He provided an update from the meeting.

a. Discussion and Consideration of Possible Changes to the Notice to Consumers Poster/Display

Chairperson Sanchez recalled the Board asked the committee to consider updating the Notice to Consumers poster with any wording changes requiring rulemaking to amend CCR section 1707.6 and possibly also Business and Professions Code sections 4122 and 733. He referenced the Notice to Consumers and the relevant laws and regulation included in the meeting materials.

Chairperson Sanchez noted at the January 2021 meeting, the committee considered wording to prevent medication errors. Members agreed the poster should not overwhelm consumers with information. Staff was directed to return with possible wording focused on medication errors.

Chairperson Sanchez reported at the committee meeting, staff presented two possible options to help the committee identify important information and refine the wording for the Notice to Consumers. Copies of both options were included in the meeting materials.

Chairperson Sanchez advised Option 1 focused on preventing medication errors while Option 2 includes the wording from Option 1, plus information specified in BPC sections 4122 and 733. He noted Option 1 was more concise, but Option 2 would not require statutory changes to BPC sections 4122 and 733.

Chairperson Sanchez reported during public comment at the committee meeting, it was noted neither option informs consumers of their right to have the medication purpose printed on the label if requested by the prescriber. Staff explained the intent was to avoid overwhelming consumers with too much information in the Notice to Consumers. Staff noted additional information about consumer rights could be communicated through brochures, flyers, or other types of materials.

Chairperson Sanchez reported committee members expressed support for Option 1. The committee directed staff to work with counsel and report back on possible rulemaking language to modify CCR section 1707.6 to incorporate the wording in Option 1. Additionally, the committee directed staff to work with counsel and report back on possible statutory language to remove or modify the notice requirements in BPC sections 4122 and 733 – for example, requiring pharmacies to provide the required information on a receipt rather than in the Notice to Consumers.

Members of the Board were provided with an opportunity to provide comments. Member Butler inquired if the Board was going with Option 1 or 2. Mr. Sanchez advised staff and counsel are still working on the language. Member Veale thought the current NTC was out of date and glad to hear the committee was working on it. Member Wong commented Option 1 seemed simpler than Option 2. Mr. Sanchez confirmed the committee is working to finalize the details.

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

Steven Gray provided he commented previously for the poster to have the patient's right to have the purpose of the medication on the prescriber label but asking the prescriber to include on the prescription label. He stated this is important for patient survey and required to be as one of four items within 50 percent of the prescription label. He encouraged Board if not included on the poster, there should be an educational campaign to education the public and save lives.

Member Wong supported having the indication on the label but the problem is that sometimes off labeled use. Member Butler spoke in support of Steve Gray's comments.

b. Discussion and Consideration of Self-Assessment Process

Chairperson Sanchez provided CCR section 1715 requires a pharmacist-in-charge to complete a self-assessment of the pharmacy's compliance with pharmacy laws.

Chairperson Sanchez reported at the January 2021 Enforcement Committee meeting, members noted self-assessment forms are important for educating licensees about pharmacy laws. Unfortunately, many licensees fail to perform the self-assessment. Other licensees fill out the forms to indicate compliance with pharmacy laws, but then are found to be noncompliant during inspections. The Enforcement Committee suggested devising a more interactive, online process for self-assessment that would engage licensees and enable the Board to verify the self-assessment was performed. The matter was referred to the Communication and Public Education Committee for discussion and consideration.

Chairperson Sanchez reported at the committee meeting, staff suggested ideas for a more interactive self-assessment process, based on discussions with DCA's SOLID unit that included:

- An electronic self-assessment form on the Board's website. Licensees would create login and password credentials to access

the forms. The Board would receive a record of completion by each licensee.

- An online form hosted by Survey Monkey. This system also would provide a record of self-assessment completion. However, there is a possibility that data could be lost if there were any changes to the account.

Chairperson Sanchez advised staff reached out to NABP for suggestions. Many details – including technical requirements, staffing, and cost – would require more research. However, staff believes these ideas provide a starting point for the Board to envision an interactive self-assessment process.

Chairperson Sanchez reported during the committee discussion, members expressed support for changing the self-assessment process. It was also recommended that any electronic process include a function allowing a pharmacist-in-charge (PIC) to complete the form in sections and save the information each time, rather than being required to complete the entire form at one time. The committee heard public comment suggesting the process also include a means for a pharmacy owner to review and sign the form in addition to the PIC.

At the committee's direction, staff will continue working with SOLID on refining possible options and report back to the committee on additional details to implement an interactive self-assessment process.

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

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

c. Update on Communication and Public Education Activities by Staff

1. The Script

Chairperson Sanchez reported the latest issue of The Script was published in March 2021. The newsletter includes articles on new pharmacy laws and CURES reporting requirements for 2021, as well as links to all disciplinary cases closed by the Board in 2020.

2. Staff Outreach

Chairperson Sanchez reported staff provided presentations on the pharmacist licensure process to students at UCSF, Touro University and

California Northstate University. He reported staff will provide CE training for pharmacists on prescription drug abuse and diversion on May 19, 2021.

3. News Media

Chairperson Sanchez provided staff responded to news media inquiries listed in the meeting materials.

Members were provided with an opportunity to provide comments. Member Butler inquired if the CE training would be provided online and if space was available. Executive Officer Sodergren advised the training will be provided through WebEx and registration has been closed although the Board hopes to provide more training later in the year.

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

d. Future Meeting Dates

Chairperson Sanchez advised the dates for remaining committee meetings in 2021 are July 14 and October 27.

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

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

X. Licensing Committee Report

Chairperson Veale reported the Licensing Committee met April 21, 2021. She provided an update from the meeting.

a. Summary of Presentation by the Accreditation Council for Pharmacy Education on Academic Dishonesty Including Accreditation Standards

Chairperson Veale reported the committee heard a presentation from Accreditation Council for Pharmacy Education (ACPE) representatives Dr. Jan Engle, Executive Director, ACPE, and Dr. Gregory Boyer, Associate Director of ACPE and Director of Professional Degree Program Accreditation. Dr. Engle and Dr. Boyer advised the committee ACPE's accreditation standard deals with academic dishonesty and it is something reviewed during site visits. They also discussed how the standards are assessed.

Chairperson Veale explained ACPE has three standards they think are involved and points to dishonesty: Standard 9.1 – Leadership and Professionalism; Standard 10.17 – Academic Integrity; and 15.3 – Standard Academic Environment including student misconduct. She advised questions are asked the students what types of program recruitment materials received when enrolled in the school, specifically the academic dishonesty policies. Ms. Veale noted ACPE talks with administrator on how academic dishonesty is handled. She noted the site visits seemed thorough and appropriate.

Chairperson Veale noted the committee appreciated the presentation by ACPE regarding academic dishonesty. Committee members were provided the opportunity to provide comment. Member Butler stated she was impressed with the ACPE site visit process.

Members were provided the opportunity to provide comment. Member Serpa encouraged members to attend site visits as an attendee and representative of the Board. Ms. Veale noted it would be a valuable experience for public and licensee Board Members.

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

b. Summary of Presentation, Discussion and Consideration of California Schools of Pharmacy Policies Related to Academic Dishonesty and Code of Conduct

Chairperson Veale reported Dr. Guglielmo, Dean, UCSF, School of Pharmacy, previously offered to assist the Committee with review of the academic misconduct policies and procedures used by the California pharmacy schools.

Chairperson Veale provided a summary of Dr. Guglielmo's presentation included in the meeting materials. Ms. Veale noted he reached out to colleagues and found additional information on the schools' websites. He found a great variability in how academic dishonesty was handled based on policies, definitions, and oaths/professionalism statements.

Chairperson Veale reported the committee considered if schools be required to have students sign statements, regular review of statements and/or develop a student professionalism policy.

Committee Recommendation (Motion): The Board develop a policy statement and delegate to the Executive Officer and the Committee Chair to work with the California Pharmacy Council (CPC), should the CPC be agreeable.

Committee and Board Members were provided with the opportunity to comment. President Lippe stated he was happy with the recommendation.

Members of the public were provided the opportunity to comment. Daniel Robinson, Dean, Western University of Health Sciences, commented this started based on a CAP student project. He noted the action of the Board has dampened the interest of doing survey related work by students.

Chairperson Veale noted the Board wasn't reacting to the survey alone as academic dishonesty has become a sensitive topic to the Board.

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

Board Member	Vote
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Support
Wong	Support

c. Summary of Presentation, Discussion, and Consideration of Report by the Office of Professional Examination Services Documenting Results of Audits of the NAPLEX and CPJE Examinations

Chairperson Veale reported the committee heard a presentation from Dr. Tracy Montez, Chief of Programs and Policy Review, DCA, of the report by the Office of Professional Examination Services documenting results of audits of the NAPLEX and CPJE Examinations. She advised Dr. Montez provided a thorough presentation of the findings.

Chairperson Veale summarized the report findings. She noted the audit found both exams valid. She noted for purposes of the report she would be reviewing the findings for the CPJE.

Chairperson Veale noted for the CPJE, OPES encouraged continuing to use a large and diverse groups of practicing pharmacists as subject matter experts (SMEs)during all stages of the examination validation. Ms. Veale reported the audit reviewed how the examination was created, methodologies, and processes. She noted as psychometricians they are focused on scoring and making sure it is fair and protected from candidate dishonesty. She added a recommendation of the audit was to rotate the SMEs and include new SMEs in

the overall process of examination development and standard setting. The audit encouraged the Board to work with the SMEs to develop a knowledge statement for CPJE's content to further delineate California knowledge required to make sure the CPJE stays relevant. A final recommendation was to monitor the different pass rates of the same candidates on CPJE and NAPLEX over time to evaluate changes made in response to OPES' review and mitigating factors.

Chairperson Veale reported the audit's findings found the examinations appropriately evaluate potential licensees and provide California practitioners who can safely provide services to Californians.

Committee Members were provided with the opportunity to comment. Member Butler stated she was impressed with OPES' presentation and appreciated the fact they will continue to work with the Board.

Members were provided the opportunity to provide comments. Member Lippe noted they determined it was necessary to continue with the CPJE. Ms. Veale agreed the audit concluded both exams were necessary.

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

d. Summary of Presentation by the National Association of Boards of Pharmacy on the Multistate Pharmacy Jurisprudent Examination (MPJE)

Chairperson Veale reported the committee heard a presentation from NABP on their MPJE as the committee has been encouraged to explore the option of adopting the MPJE and replacing the CPJE by the Sunset Review Committee and stakeholders. She reported the presentation was thorough on how the MPJE is developed, written, and compared to CPJE.

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

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

e. Discussion and Consideration of Pharmacist Licensure Examinations as required by Business and Professions Code Section 4200

Chairperson Veale reported members had an opportunity to discuss and heard from stakeholders' thoughts on examination requirements with pharmacy law and if changes in law should be made. She noted a robust discussion resulting in a committee recommendation.

Committee Recommendation (Motion): Recommend to the Board, an audit, and if appropriate, transition to the MPJE.

Board and Committee members were provided the opportunity to provide comment. Member Wong commented he would like the Board to review the MPJE to determine if it is feasible and good for the Board to change to the MPJE. Ms. Veale explained the motion would start with an audit and based on the findings a possible future recommendation to transition to the MPJE.

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

Danny Martinez, CPhA, commented in support the audit of the MPJE and possible transition. He inquired if there was a brief description of the audit and the timing of the audit. Ms. Veale provided it would be a similar audit of the MPJE exam process and would take a few months. Ms. Sodergren provided OPES thought the audit should be able to be completed by the end of December 2021 to meet the timeframe of sponsoring legislation if required.

Daniel Robinson, Dean, Western University of Health Sciences, inquired how an audit could be done on the MPJE for California when California uses the CPJE. Ms. Veale noted the audit would be for the process of how the MPJE is developed. Ms. Sodergren confirmed the audit would ensure the MPJE meets psychometric, state, and federal requirements. He commented OPES didn't address the passing rate for CPJE of 70 percent and NAPLEX of 90-95 percent. Ms. Veale noted the OPES audit recommended to watch and compare the passing rate for CPJE and NAPLEX.

Steven Gray commented the NAPLEX is an entry level exam but does not capture the full scope of practice as California has a significantly different, broader, and richer scope of practice than most other states. He noted if AB 1533 is enacted the entry level scope of practice will change. He noted the CPJE is by definition the California practice standards and jurisprudence exam to reflect the intent of the CPJE. He added it is important to recognize the different of licenses from other states.

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

Board Member	Vote
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Support
Wong	Support

f. Discussion and Consideration of Statutory Proposal to Expand the Authority for Pharmacists to Order and Perform Tests

Chairperson Veale recalled on August 25, 2020, the DCA Director issued an order that waives specified professional licensing requirements and amends the scopes of practice of pharmacists and pharmacy technicians to allow them to perform waived, point-of-care tests used to detect SARS-CoV-2. Along with the waiver, guidance was released to inform and educate pharmacies, pharmacists and pharmacy technicians of clinical laboratory requirements that apply under the DCA Order. At the October 2020 Licensing Committee Meeting and subsequent Board Meeting, the Board approved the following policy statement:

> The CDC has acknowledged that the flu and COVID-19 are both respiratory illnesses that are caused by different viruses that may be difficult to differentiate based on symptoms alone without testing to confirm a diagnosis. The Board also recognizes that community pharmacies provide unique access for patients to obtain tests in a safe and convenient location. In recognition of these facts and the existing authority pharmacists already may provide certain CLIA waived tests, the Board hereby declares its support for all efforts to secure temporary authority for pharmacists to perform CLIA-waived tests for influenza and COVID during the declared disaster, as well as a more permanent solution through statutory changes that facilitate authority for pharmacists to perform CLIA-waived COVID and influenza testing in a safe manner.

Chairperson Veale noted during prior discussions, the committee heard public comment suggesting that the Board's proposal should be expanded to include other types of testing and consideration should be given to allowing pharmacists permanent authority to engage in specimen collection of other types of tests. She added at the time since the discussion was not agendized,

consideration by the Committee could not occur. At the April 2021 meeting, members and stakeholders reviewed policy questions.

1. As COVID-19 is a respiratory illness, should pharmacist authority expand to include all CLIA waived tests for all respiratory illness?
2. As a sore throat is a common symptom of COVID-19 and strep throat, should pharmacist authority expand to include CLIA waived tests for strep throat?
3. Not related to the pandemic, but in 2019, under the provisions of SB 159 (Weiner, Chapter 532, Statutes of 2019), pharmacists were granted the authority to perform CLIA waived HIV testing. Should pharmacist authority be expanded to include other CLIA waived tests for sexually transmitted diseases.
4. Are there other CLIA waived tests that should be included as part of pandemic preparedness?
5. Are there other CLIA waived tests that should be included to reduce the spread of disease?
6. Should such testing authority be limited to certain types of specimen collection, e.g., including nasal swabs, blood, while not including other specimens such a urine collection?

Committee Recommendation (Motion): Recommend to the Board, expansion of its current policy and statutory proposal to include authority for all CLIA waived tests and make permanent the provisions related to specimen collection. Delegate to the Executive Officer and Committee Chair authority to work with the current author of the Board's proposal for possible opportunities to engage and expand the current proposal.

Chairperson Veale noted once the testing is completed, there also needs to be treatment. She added it is not part of the committee recommendation but will be on a future agenda.

Board and Committee 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 comments of support from CRA/NACDS and CSHP.

Danny Martinez, CPhA, commented CPhA has a support if amended position on SB 409 but with this inclusion of expanding CLIA-waived tests to all CLIA-waived tests, CPhA will re-evaluate the position possibly to a full support.

Jassy Grewal, UFCW Western States Council, commented with additional expansion is professionalizing the industry and would like to discuss minimum staffing levels to perform the additional duties for pharmacists.

Michael Hawkins, Invitae, a genetic testing lab, commented in support of the motion. He noted SB 409 is problematic because it doesn't allow the pharmacist to send a positive sample to a lab for testing and appreciated trying to take care of that issue through the motion. He added the additional part of treatment is important. He encouraged SB 409 and AB 1328 be married to be one vehicle moving forward.

Paige Talley, CCAP, commented with the motion she believed her Board would be in support and agreed with Mr. Hawkins.

Steven Gray commented in strong support as not all pharmacists practice in retail pharmacy settings. He noted the bill would allow more pharmacist to use CLIA-waived tests for their patients. He encouraged approval of the motion or combine legislation to make it clear.

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

Board Member	Vote
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Support
Wong	Support

The Board took a break from 10:31 p.m. to 10:41 p.m. Roll call was taken. Members present included: Shirley Kim, Lavanza Butler, Jason Weisz, Jignesh Patel, Albert Wong, Ricardo Sanchez, Debbie Veale, Seung Oh, Maria Serpa, and Greg Lippe. A quorum was established.

g. Discussion and Consideration of Draft Pharmacist Workforce Survey

Chairperson Veale reported as indicated in the Board's responses to Sunset Issues, the issue of medication errors must be addressed to improve patient health. The issue warrants study in California, where conditions within a pharmacy may be different than on a national level. She noted during its January 2021 meeting, the Committee discussed a draft of the workforce survey. After the Committee and Board discussion, staff worked with the

Committee Chair on changes to the draft survey. She also noted the draft survey was also reviewed by DCA staff, including a PhD with expertise in survey design. Ms. Veale summarized the draft survey and noted the survey was intended for community pharmacy settings. Survey questions addressed the practice setting type and types of medication errors/possible contributing factors.

Committee Recommendation (Motion): Recommend to the Board approval of the workforce survey with the following changes:

- Add clarification on what is a medication error in the opening statement consistent with CCR section 1711;
- Question 6 to change the wording in the comment box from "If yes, please specify" to allow for any comments;
- Question 24 to add a box for "other" to be filled in; and
- Question 29 to add a box to allow for recommendations for reducing medication errors.

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

Members of the public were provided the opportunity to comment.

Jassy Grewal, UFCW Western States Council, thanked the Board and staff for assessing the workplace practice settings and encouraged the Board to work with associations to ensure the survey is sent to the appropriate audience.

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

Board Member	Vote
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Support
Wong	Support

Member Oh inquired about next steps for the survey. Ms. Sodergren provided it would be finalized and then sent out through the Board's listserv which all pharmacists are required to be sign up with a follow up sent a week later.

Member Wong requested the survey be clarified that it is anonymous. Ms. Sodergren indicated it can be reinforced through the listserv message.

h. Discussion and Consideration for Approval, Changes to Proposed Board Provided Training Program. Pursuant to Business and Professions Code Sections 4052.02(b), 4052.03(b)(3) Related to Furnishing HIV Preexposure (PrEP) and Postexposure (PEP) Prophylaxis

Chairperson Veale reported as part of the Board's efforts to implement the provisions of Senate Bill 159, Board staff in collaboration with experts have been developing a training program to satisfy the requirements of CCR section 1747. As part of the September 2020 Board meeting, the Board approved the training program presentation. Regrettably after the Board's approval, staff was advised that the subject matter expert identified to complete the recording of the training was no longer available.

Chairperson Veale advised a new expert, Dr. Betty Dong, has volunteered to assist the Board with finalizing the training. Dr. Dong, PharmD, FASHP, FAPHA, FCCP, AAHIVP, is a professor of clinical pharmacy and family and community medicine, University of California School of Pharmacy and Medicine. Dr. Dong has updated the presentation to include updated data and resources to reflect the most current information. Further, some of the training elements have been reorganized. The learning objectives and content areas remain the same.

Committee Recommendation (Motion): Recommend to the Board approval of the updated training program.

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

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

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

Board Member	Vote
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Support
Wong	Support

Member Jignesh Patel left the meeting at 11:57 a.m.

i. Review and Discussion of Licensing Statistics

Chairperson Veale reported the quarterly licensing statistics for fiscal year 2020/2021, were provided in the meeting materials. She reviewed the general application and deficiency mail processing times by license type are provided below reflecting data current as of April 3, 2021. The data reflects the time from when an application or deficiency response is received by the Board through to the time it is reviewed by licensing staff. The standard performance processing time is within 30 days for initial applications and is within 10 days for deficiency mail. The term "Current" means there are no items to review or staff is currently reviewing the items within 1-5 days for that specific license type. She added staff continue to work diligently and have adjusted to review applications and mail electronically during this pandemic. Processing times exceed the standard processing times resulting from a combination of factors, including impacts resulting from the pandemic. Ms. Veale noted staff has made great strides to make goals and shift as needed.

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

Members of the public were provided the opportunity to comment.

Steven Gray inquired if the COVID restrictions, shelter in place, and travel restrictions have had significant effect on the inspections of out of state pharmacies, and FDA registered facilities. He added the FDA's program has deteriorated during the last year and virtually no inspections outside the US is occurring. Ms. Sodergren noted this was discussed and is addressed in the Executive Officer's report.

j. Future Committee Meeting Dates

Chairperson Veale noted the future meeting dates are July 14, 2021, and October 27, 2021.

XI. Enforcement and Compounding Committee Report

a. Summary and Discussion on the Informational Meeting on "White Bagging"

Chairperson Serpa provided a summary the informational meeting the Enforcement Committee heard on the practice of "white bagging." The Committee publicized this informational meeting and reached out to identified stakeholders to participate, with the goal of receiving various perspectives on this practice to ensure the education on the matter is comprehensive. The Committee received a number of presentations. Dr. Serpa thanked the presenters and stakeholders who participated in the meeting or provided written comments. She noted the webcast of the meeting is posted on the Board's website.

Chairperson Serpa advised the National Association of Boards of Pharmacy (NABP) published a report on the topic and included that "white bagging" refers to the distribution of patient-specific medication from a pharmacy, typically a specialty pharmacy, to physician's office, hospital or clinic for administration. She noted it is often used in oncology practices to obtain costly injectable and infusible medications that are distributed by specialty pharmacies and may not be available in all non-specialty pharmacies. She added while the committee meeting did not cover it, it was important to note another practice called "brown bagging" which refers to the dispensing of a medication for a pharmacy directly to a patient, who then transports the medication to the physician's office. Dr. Serpa noted the practice of "white bagging" appears to have become more frequent as payors more robustly require the practice to reduce medication costs.

Chairperson Serpa advised the NABP report details some benefits to the practice of white bagging, including the potential for a greater opportunity for pharmacists to use their expertise to improve patient outcomes as well as the opportunity for physicians to reduce costs associated with purchasing and stocking expensive medications. From the payer perspective, benefits include cost savings through negotiated dispensing rates and increased transparency.

Chairperson Serpa advised safety concerns have also been identified, including the special handling that is required for many of these medications, which can pose safety, operational and unexpected financial burdens. Additional challenges may arise as specialty pharmacies may not have access to patient medical records as well as unpaid expenses resulting from coordination, storage, and handling of patients' medications until the drug is administered.

Chairperson Serpa noted the practice could present some challenges in instances where a change in dosage or strength of transition to a different class of medication is common. She noted the potential for delays in patient care resulting from difficulty acquiring or receiving the appropriate medication can and does occur.

Chairperson Serpa referenced the NABP's report that advised it may be incumbent on the Board to determine who is accountable for verifying the authenticity and integrity of the drugs before administration as well as who would be responsible when a delay in therapy occurs.

Chairperson Serpa reported many organizations provided presentations which are also posted on the Board's website along with the minutes for the meeting. She encouraged members and members of the public to review the Webcast posted on the Board's website.

Chairperson Serpa provided a summary of the presentations.

- Sarah Ream presented on behalf of California Department of Managed Health Care.
- Charles Bacchi presented on behalf of the California Association of Health Plans.
- Yvonne Choong presented behalf of the California Medical Association.
- Dr. Thomas Semrad, Medical Director of Clinical Research for the Gene Upshaw Memorial Tahoe Forest Cancer Center, provided a summary on how white bagging has impacted his practice and care for his patients.
- BJ Bartleson, California Hospital Association, advised the committee of concerns with the practice including patient safety and treatment delays.
- Representatives from the California Children's Hospital Association provided information on the risks and failure points white bagging introduces specifically for pediatric patients.
- Dr. Rita Shane presented on behalf of Cedars-Sinai Medical Center. Dr. Shane was also the originator of the request to the Board to discuss White Bagging.
- Dr. Steven Thompson presented on behalf of the California Society of Health-Systems Pharmacists and shared many of the same concerns identified by other presenters.
- Dr. Azizian presented on behalf of Keck Medical Center of USC.
- Dr. Diane McCowan presented on behalf of PIH Health.

Chairperson Serpa shared updates since the last Enforcement Committee meeting. She noted ongoing discussion by national stakeholders including a recent letter sent to the FDA by the American Society of Health-System Pharmacists and the American Hospital Association.

Chairperson Serpa reported Louisiana has pending legislation intended to ensure patient access to physician-administered drugs and related services and to ensure insurers do not interfere with patient's freedom of choice with respect to providers furnishing such drugs. Texas has pending legislation that will require a health benefit plan or pharmacy benefit manager to allow an enrollee to obtain a specialty drug from a physician's office or hospital outpatient infusion center that provides and administers a specialty drug.

Members were provided the opportunity to provide comment. Ms. Veale noted Dr. Serpa did a good job summarizing the meeting.

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

Rita Shane, Cedars Sinai, thanked the Enforcement and Compounding Committee and the Board for addressing the issue. Dr. Shane noted as chronic disease and cancer drug costs continue to escalate, policies such as white bagging are put into place to reduce cost but at the risk of impacting patient safety. She added delays in care resulted in cancer progression, exacerbation of illness and hospitalization. She stated it is a very important patient safety issue and appreciate it being evaluated.

Daniel Kudrishoff, Medication Safety Officer, Keck Medical Center of USC, commented this issue is affecting patients. He noted this is a safety and regulatory concern for his hospital and pharmacy department. He noted patients are faced with delays in receiving care and medication which are lifesaving. It also prevents providers from treating the patient because the medication hasn't arrived or the patient's clinical presentation requires a change in the medication. In this case the drug is not available and the payer does not allow institution procured medication. He requested the Board reevaluate the issue and work with the stakeholders on a solution to protect patients.

BJ Bartleson, CHA, thanked the Committee and Board for discussing the controversial topic. She noted it continues to be an escalating issue across the country as many states are looking at the issues and trying to figure out the best route moving forward. CHA and members are extremely concerned with patient safety. Ms. Bartleson noted several states are reviewing data to find the while payers may be saving money, the costs are being placed on the patients. It is a safety issue and cost enhancement to patients. Ms. Bartleson stated she hoped to be able to look at opportunities other than legislation relative to

handling this topic. She stated stakeholders are looking to the Board to understand if this practice is in concert with present regulations or not; if not, what steps need to be taken next.

LoriAnn DeMartini, CSHP, thanked the Board for convening stakeholders around white bagging as it is problematic to hospitals and patient safety. She noted other states have taken proactive action in the area addressing patient safety issue. She encouraged the Board to continue discussions to mitigate potential and actual harm to patients.

Chairperson Serpa discussed possible actions moving forward as continuing education on the topic and requesting staff to evaluate actions taken in other jurisdictions. She noted SB 524 may address some of the patient safety concerns raised during the informational meeting. Members were comfortable with Dr. Serpa's suggestions for moving forward.

b. Summary of Presentation on the National Association of Board of Pharmacy, Compounding Data Sharing

Chairperson Serpa advised the Committee received a presentation by the NABP on the development of the Compounding Data Sharing Project. The presentation covered the basic provisions of the FDA Memorandum of Understanding (MOU) and many of the obligations set forth in the MOU, including reporting and investigation activities. The presentation focused primarily, however, on the NABP system developed to assist with some of the reporting requirements established in the MOU. Dr. Serpa noted the presentation slides are included in the meeting materials.

Members were provided an opportunity to comment.

Dr. Oh inquired as to the reasons why other states are not adopting this and felt it will work only if all states participate. Dr. Serpa noted this should be addressed in the next agenda item but can discuss if not addressed.

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

c. Discussion and Consideration of FDA's Final MOU on Interstate Distribution of Compounded Drug Products.

Chairperson Serpa reported following the presentation by the NABP, the Committee considered the MOU itself, to determine what if any action the Committee should offer to the Board and went through a very deliberate process to discuss the issue.

Chairperson Serpa noted the committee first focused on the larger policy questions to determine if a recommendation to enter into the MOU was appropriate. She noted the committee has received significant public comment that the Board sign the MOU and more recently, the committee received what appears to be a national petition that is signed by thousands of people – primarily members of the public, practitioners and patients throughout many states. Dr. Serpa stated after consideration and discussion of these questions the committee determined that it appears appropriate to sign the MOU.

Chairperson Serpa reported after making that determination, the committee considered several questions to assist with addressing implementation issues as detailed in the chair report. She provided the committee concluded the Board should require, as a condition of renewal, that a pharmacy advise the Board that it distributes compounded preparations for distribution outside of California. Dr. Serpa continued the committee determined it is appropriate for the Board to establish a requirement for such pharmacies to report sales information to the NABP system. She added the committee concluded it is appropriate to require pharmacies to report adverse drug experience and drug quality issues and that pharmacies that engage in interstate compounding should be required to affirm their understanding of the conditions and obligations of the MOU. Dr. Serpa noted the committee also conferred with counsel and determined it necessary to include confidentiality provisions and that the Board should develop education materials.

Dr. Serpa provided committee members the opportunity to comment prior to reviewing the committee recommendation; however, no comments were made.

Chairperson Serpa reviewed the committee's proposal that includes amendment to section 4110 as well as the addition of section 4126.9.

> Draft Statutory Proposal Related to the Interstate Distribution of Compounded Medications
>
> Amend Section 4110 of the Business and Professions Code as follows:
>
> 4110.(a) License Required; Temporary Permit Upon Transfer of Ownership; Mobile Pharmacy Requirements
> (a) No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually <u>and shall include the matters identified by the board in the renewal application, including but not limited to, notification to the</u>

board regarding compounding practices, including compounded prescriptions distributed outside of the State. The board may, by regulation, determine the circumstances under which a license may be transferred.
(b) …

Add Section 4126.9 to the Business and Professions Code as follows:
4216.9 Distribution of Compounded Drugs in Interstate Commerce by Pharmacies Located in California

a) A pharmacy located in California may only distribute compounded preparations for interstate distribution under the following conditions.

1. Between January 1 and March 31 of each year, report all required data into the Information Sharing Network established by the National Association of Boards of Pharmacy in conjunction with the federal Food and Drug Administration (FDA) to implement the Memorandum of Understanding established by the FDA Addressing Certain Distributions of Compounded Drugs.
2. On an annual basis, as a condition of renewal, the pharmacist-in-charge certifies that the reporting requirements established in section 1 have been satisfied.
3. Adverse drug experiences and product quality issues for all compounded products shall be reported to the board within 12 hours.

b) Confidential Treatment of Information Reported to the FDA Directly or Through the Information Sharing Network. All information reported by the board to the FDA directly or through the Information Sharing Network established in conjunction with the FDA is deemed to be confidential information as specified in California Government Code § 6254(f) if it relates to information regarding a complaint received or the investigation of any such complaint.

Committee Recommendation (Motion): Recommend to the Board to move forward with the draft statutory proposal including amending Business and Professions Code section 4110(a) and adding BPC 4126.9, with a modification in the notification requirement and enter into the MOU provided sufficient resources and statutory changes are secured. Delegate to the Executive Officer and Committee Chair, working with counsel, to make nonsubstantive or clarifying changes.

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

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

Danny Martinez, CPhA, commented about CPhA's request for change. CPhA noted that BPC section 4126.9 subsection (a), would apply to all pharmacies in California that distribute compounded products can only do so under the conditions listed forward. He noted the MOU does not apply to veterinary compounds and only applies to human compounds and requested the word "human" to be added. CPhA also requested adding "human" in BPC section 4110 as well so as not to impact veterinary compounds. He requested this be included in the statutory proposal. Dr. Serpa advised this is on the list of nonsubstantive changes to address with the Executive Officer. Member Oh commented in agreement with CPhA.

Support: 7 Oppose: 0 Abstain: 1 Not Present: 2

Board Member	Vote
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Not Present
Sanchez	Not Present
Serpa	Support
Veale	Support
Weisz	Abstain
Wong	Support

d. Discussion and Consideration of Compounding with Components or other Material that Could Result in Insanitary Conditions as Established in the FDA Insanitary Conditions at Compounding Facilities Guidance for Industry

Chairperson Serpa advised members that topic had been discussed several times over the course of the past few years and again more recently in detail at several meetings. She noted there is a significant amount of background information detailed in the meeting materials. Members were advised that staff discussed the issue with the FDA, who has confirmed that compounding from inappropriately graded products could result in violations of the guidance document regarding insanitary conditions. Dr. Serpa added this would be consistent not only with the FDA alerts highlighting concerns with using dietary grade ingredients but also with the FDA 483 that was included in prior meeting materials. Recently, NABP also confirmed that they share issues regarding inappropriately graded products with the state boards.

Chairperson Serpa noted as part of its ongoing education on the issue, inspectors are discussing this practice with licensees when encountering it in during inspections or other audits. Dr. Serpa added educational efforts typically focus on provisions of the law, the importance of understanding the quality of ingredients prior to use, and the importance of working with a supplier to improve the quality of bulk ingredients. She also added the meeting materials include several resources that may be provided to licensees as well.

Chairperson Serpa advised public comment received during the Committee meeting included a request that the committee consider if additional testing would assist a pharmacist in determining if an ingredient was appropriate as well as requested that the Board define "pharmaceutical grade." The committee also heard public comment on the importance of quality being built into the entire compounding process and suggestions that the Board needs to protect access. Dr. Serpa advised the committee concluded that no additional action is required. She noted staff will continue to educate and use enforcement discretion.

Members were provided the opportunity to provide comments.

Member Oh inquired if the certificate of analysis can be done to check for impurities and can be required to allow for compounding of methylcobalamin. He stated he felt CPhA's letter for solution seemed to address it and was curious the status on that issue. He stated he heard and read many patients were not able to get the medication they need.

Dr. Serpa advised this has been discussed in depth at committee level and the Board has not stopped any pharmacy from using methylcobalamin specifically. The Board has asked for specific background materials and guidance to have it be proven to be safe. If that is provided there is no issue. She noted it is not a general statement and has to be looked at the specific environment, API used, and if the certificate of analysis is valid which is also done by the FDA. She advised the FDA has cited locations with dietary grade components not just methylcobalamin but other compounded products. Dr. Serpa added in California the focus is entirely on education.

Supervising Inspector Acosta advised Board staff is doing a lot of education to licensees. She noted there is a wide variety of products being used as raw materials which is why there isn't one way that is acceptable to test to verify analysis of materials. Dr. Acosta noted there is no one test or manufacturer that can provide what is needed. She noted they had a meeting with a laboratory who said they could do testing to a consumer that would make it injectable grade which ended up not being true.

Ms. Sodergren added that this is an issue the Board is following what the FDA has directed as the FDA has established what is considered unsanitary conditions. When the FDA increased its oversight of compounding in the 503A facilities and issued these guidance documents, the Board must be mindful of the FDA's regulation in this area and expectation of the state partners. Changes made by the Board could conflict with federal requirements.

Counsel Smiley added the bulk substance evaluation and analysis resides with the FDA and not with the Board. She added currently methylcobalamin and some of the other bulk substances that are on the list only indicate the FDA has information sufficient to analyze but they haven't done the analysis yet.

Chairperson Serpa advised this has been discussed at many committee meetings where the committee is able to educate stakeholders and licensees in how to continue to supply the medication in the appropriate patient population with the appropriate products. If documented, it is not an issue. When the documentation is not seen, Board staff continue to provide education and use enforcement discretion as well as point to FDA guidance documents. She continued the Board is putting patient access as a top priority and that is why the Board has been able to focus policy on education.

Member Oh inquired if there were orders of corrections issued and further asked if the Board was not saying to not compound methylcobalamin.

Dr. Acosta stated there is nothing wrong with compounding methylcobalamin. She noted the FDA has it on their list. The issue is not with methylcobalamin; the issue is with the raw materials used to make injections. The substance is not of the appropriate impurity to make an injection.

Member Wong asked if the FDA has a list of manufacturers with ingredient pure enough for them to use. Dr. Serpa advised it is not the FDA's purview to maintain a list. She added it is the pharmacist's responsibility to obtain the API product and have it documented that the product and lot number meets the needs for the compounding. Dr. Acosta noted the FDA has a list of drug establishments which can repackage or make it but only lists who is able to make them but it doesn't note what they make. She noted there is a dietary USP monograph on methylcobalamin but for federal law a dietary substance cannot be used for anything but ingestion. She noted if a product labeled methylcobalamin USP grade it has been qualified as a dietary supplement.

Chairperson Serpa noted because of the complexity and intricacies, it is important to know the Board's approach is education with enforcement discretion to ensure access is maintained.

Member Oh appreciated hearing that the Board is not prohibiting compounding these products.

Member Wong stated it is good for the Board to work with the licensees to solve problems.

Counsel Smiley noted it is important to note the Board's policy is to continue education and exercise enforcement discretion in the appropriate cases. She noted if significant contamination was found it may warrant enforcement action.

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

Danny Martinez, CPhA, commended the Chairperson for discussion. He stated CPhA compounders are concerned about the ability to compound. He noted CPhA's concerned about the definition of pharmaceutical grade and licensees are told methylcobalamin can be compounded if appropriate grade but there is no answer for what is the appropriate grade. He noted federal law defines dietary grade but there is no definition for pharmaceutical grade. He encouraged the Board for defining pharmaceutical grade.

Chairperson Serpa noted his comments were made at the committee meeting where they discussed the difficulty that every situation is unique and so the pharmacist-in-charge (PIC) and the inspector would determine the documentation present for the individual circumstance and product. She referred to the meeting materials for the guidance provided by the FDA.

Steven Gray commended the Chairperson and staff for discussing the issue. He encouraged the forum of the schools of pharmacy in California to share the documents as sterile compounding is part of entry level practice. He referred to the committee discussion that some compounders did not have documentation that the product was necessary as an alternative therapy for all patients to which it was distributed. He inquired what is required for pharmacies compounding to have in the way of an indication on per patient basis.

Joe Grasela inquired what lab tests are needed to ensure it is a good product. He said case by case assessments are not a good idea.

Chairperson Serpa reiterated Dr. Acosta's comment that the patient specific and API specific information is required and there is no test or definition that fits all based on the FDA and science.

e. Discussion and Consideration of Opportunities to Improve Naloxone Accessibility through Auxiliary Labels for Opioid Prescriptions.

Chairperson Serpa stated during the Committee meeting members also discussed, if from a policy perspective, the Board should consider changes or if other action is appropriate to leverage the prescription dispensing encounter to provide education to patients about naloxone. She noted the committee concluded that currently labeling requirements are appropriate, and that pharmacists providing appropriate consultation should include this information when speaking to the patient.

Chairperson Serpa stated after consideration and discussion of public comment, the committee decided to discuss further at a future meeting, the Board's current naloxone protocol established in regulation to determine if changes are appropriate. As the labeling was agendized, the policy could not be discussed so the issue of the policy will go back to the committee.

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

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

f. Discussion and Consideration of Assembly Bill 2789 (Wood, Chapter 438, Statutes of 2018) Health Care Practitioners: Prescriptions: Electronic Data Transmissions

Chairperson Serpa reported that in 2018 legislation was passed to facilitate e-prescribing, noting that the legislation included a delayed effective date to allow for a period of implementation and transition. As the provisions take effect January 1, 2022, the matter was agendized to allow the committee the opportunity to consider if development of FAQs would be appropriate. Dr. Serpa referred to the meeting materials that detail the provisions of the legislation. She noted a number of exceptions to the requirement. Dr. Serpa highlighted a pharmacist who receives a written, oral, or faxed prescription is not required to verify that the prescription falls within one of the exceptions.

Chairperson Serpa stated after discussion the committee determined development of FAQs and educational materials would be appropriate and that the matter should be referred to the Communication and Public Education Committee. Topics that could be covered in the materials include the use of a single electronic health record platform for both the prescribing and dispensing and if such a system would be included in the definition of "electronic transmission" as well as the provisions for transferring a prescription.

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

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

Steven Gray reminded the Board that California was doing electronic transmission of prescriptions before DEA came out with its requirements for the electronic transmission of controlled substance prescription. He noted some practitioners who do not prescribe controlled substances are still using the former approved methods that are allowed in California. He stated the FAQs need to make that distinction as to what is allowed under California law between the DEA's requirement for controlled substances and non-controlled substances.

g. Discussion and Consideration of Federal Food and Drug Administration Final Rule Related to Importation of Certain Canadian Prescription Drugs

Chairperson Serpa reported during the meeting, the committee received a brief presentation on the FDA finalized rule. She noted presentation provided a brief overview of the Importation Program requirements including the eligible drugs, participants in this specific supply chain, provisions for testing and recall requirements. Dr. Serpa noted the presentation slides were included in the meeting materials.

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

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

h. Summary of Presentation by the Office of the Attorney General on the Annual Report to the Legislature Pursuant to Business and Professions Code Section 312.2

Chairperson Serpa reported the committee received a presentation from Carl Sonne, Senior Assistant Attorney General, with the Licensing Section of the California Department of Justice for his presentation on the Attorney General's Annual report to the Legislature. She advised Mr. Sonne provided background on the policy that resulted in the reporting requirements, including the Consumer Protection Enforcement Initiative, with the goal of reducing investigation and disciplinary timelines. Mr. Sonne provided members with information on the data collection method used to develop the report. Mr. Sonne provided statistics from referrals for accusations, including the number of referrals, number of cases rejected by the Attorney General's Office, the cases returned for further investigation, and number of cases adjudicated. Mr. Sonne summarized Board specific information. Dr. Serpa noted a copy of the presentation was included in the meeting materials.

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

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

The Board took a lunch break from 12:09 p.m. and returned at 1:00 p.m. A roll call was taken after the break. Members present included Maria Serpa, Seung Oh, Debbie Veale, Lavanza Butler, Albert Wong, Ricardo Sanchez, Shirley Kim, Jignesh Patel, Jason Weisz, and Greg Lippe. A quorum was established.

i. Discussion and Consideration of Proposal to Develop an Alternative Enforcement Model

Chairperson Serpa reported the committee has been evaluating this issue for quite some time. She provided at the July 2020 meeting, the committee was provided a presentation on the administrative case process. As was shared during that presentation, the administrative case process has two fundamental guiding principles: due process of the respondent and public protection. As part of the presentation, members were reminded that the state has the duty and responsibility to ensure a licensee is competent and trustworthy. She added during the committee's discussion at its January 2021 Meeting, members directed staff to develop recommendations to achieve the policy goal to reduce case resolution times and reduce associated costs, that would not require statutory changes.

Chairperson Serpa commented meeting materials contained a pre-accusation conference that is used by the Board of Accountancy and a model used by the Department of Managed Health Care (DMHC). Dr. Serpa noted the DMHC model did not meet the criteria as it would require statutory changes.

Dr. Serpa reported the committee considered the pre-pleading conference and several policy questions related to the proposed solution which are detailed in the meeting materials. As part of its discussion members noted that the pre-pleading conference appeared to be a good solution and noted support of the concept. The committee discussed that such a conference may not be appropriate for all cases and should be limited to certain types of cases. The committee noted that the model did provide an appropriate balance of consumer protection and due process. Members also determined that use of such a process could reduce case resolution times and that the process could result in cost savings for the Board and for licensees.

Chairperson Serpa reported Mr. Sonne advised members that the AG's office considers the pre-pleading conference of great value because it provides an opportunity for the licensee to provide additional information. Mr. Sonne noted,

that if agreement is reached with the parties, it can front end the settlement after the accusation is filed. Mr. Sonne noted that not all cases may be appropriate for this process. The committee concluded that pursuing implementation of a pre-pleading conference was appropriate and requested that staff work with the AG's Office to further develop the pre-pleading conference as well as develop a flowchart that would incorporate this process.

Chairperson Serpa requested feedback about such an approach and agreement with the committee's direction. Committee members were provided the opportunity to provide comments. Member Veale commented the pre-conference would meet the stakeholders' concerns. President Lippe concurred.

Members were provided the opportunity to comment. Member Butler commented she liked this approach.

Members of the public were provided the opportunity to comment.

Danny Martinez, CPhA, commented on the Chair's work on this and stated he will make comments when presented at the next meeting.

Joe Grasela commented this is a good program and appreciated the work of the committee and President Lippe.

Chairperson Serpa advised the details of a Pre-Pleading Conference would be presented at the next committee meeting.

j. Review and Discussion of Enforcement Statistics

Chairperson Serpa provided meeting materials include enforcement statistics for the first nine months of the fiscal year.

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

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

k. Future Committee Meeting Dates

Chairperson Serpa reported the next committee meeting is scheduled for July 15, 2021.

XII. Legislation and Regulation Committee Report

a. Discussion and Consideration of Assembly Bill 5 (Gonzalez, Chapter 296, Statutes of 2019)

Chairperson Lippe advised Assembly Bill 5 effectively codified the Dynamex decision's ABC test used to determine an individual's employment status, while providing for clarifications and carve-outs for certain professions. Specifically, physicians and surgeons, dentists, podiatrists, psychologists, and veterinarians were among those professions that were allowed to continue operating under the previous framework for independent contractors. However, pharmacists were not included in the bill. Mr. Lippe noted as part of its response to the Sunset Committee's background question, the Board noted that it was aware that some pharmacists act as consultants for skilled nursing facilities and hospitals and such individuals may be negatively impacted by the exclusion of pharmacists from the new law.

Chairperson Lippe reported a request was received to place this issue on the agenda to allow for discussion of the issue. He noted the meeting materials include the correspondence received. The committee heard significant amount of public comment on the issue with some urging the Board to take no action, while others speaking in support of the need to change or clarify existing law. A common theme during the discussion was that currently the law does not provide for a distinction between practice settings such as a pharmacist working in a retail pharmacy versus a pharmacist serving as a consultant in a long term care facility, exempt hospital, or other environment where a pharmacist is providing direct patient care activities or the negative consequences to patient care because of this change in the law.

Chairperson Lippe advised the committee was not offering a recommendation. Members contemplated if this is an issue the Board should be handling or perhaps if it is more appropriate for stakeholders to work together to develop a legislative proposal that balances the various concerns.

Committee members were provided the opportunity to provide comments. Member Butler provided Mr. Lippe explained the agenda item and discussion well.

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

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

b. Discussion and Consideration of Pending Legislation Impacting the Practice of Pharmacy, the Board's Jurisdiction, or Board Operations

Chairperson Lippe referred to the meeting materials for measures to be considered by the Board.

1. Assembly Bill 2 (Fong) Regulations: Legislative Review: Regulatory Reform

Chairperson Lippe advised AB 2 passed recently out of policy committee and was referred to Assembly Appropriations. The measure would require agencies to review its regulations, identify any regulations that are duplicative, overlapping, inconsistent, or out of date and revise those identified regulations, and report to the Legislature and Governor.

Chairperson Lippe advised the committee noted the concerns raised by staff and the significant fiscal impact to the Board. Members also noted that legislation is not necessary for the Board to review its regulations. The committee also considered public comment that suggested the Board should establish an Oppose Unless Amended position and provide an extended date for compliance.

Committee Recommendation (Motion): Oppose position for the reasons cited in the meeting materials.

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

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

Support: 9 Oppose: 0 Abstain: 1 Not Present: 0

Board Member	Vote
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Abstain
Wong	Support

2. Assembly Bill 29 (Cooper) State Bodies: Meetings

Chairperson Lippe advised AB 29 would require that the notice of a meeting of a state board must include all writings or materials provided the state body by to also be made available to the public. The measure would also require the board, upon written request to send copies of such materials the same day they are disseminated to a board member or at 72 hours before the meeting whichever is earlier. He reported members noted agreement with the staff recommendation and several technical challenges with the measure. He noted the measure was currently on the Assembly Appropriations Suspense file.

Committee Recommendation (Motion): Oppose unless amended position for the reasons cited in the meeting materials.

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

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

Support: 9 Oppose: 0 Abstain: 1 Not Present: 0

Board Member	Vote
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Abstain
Wong	Support

Member Shirly Kim left the meeting at 1:21 p.m.

3. Assembly Bill 69 (Kiley) State of Emergency: Termination After 60 Days

Chairperson Lippe advised AB 69 would require a state of emergency to terminate 60 days after the Governor's proclamation of the state of emergency unless the Legislature extends it by a concurrent resolution. Prohibits a concurrent resolution from extending a state of emergency by more than 60 days. Committee members agreed with the concerns raised in the meeting materials. The committee also noted that given the legislative deadlines, it is possible the measure may not move forward.

Committee Recommendation (Motion): Oppose unless amended position for the reasons cited in the meeting materials.

Members were provided the opportunity to provide comments. Member Veale inquired about the purpose of the measure. Ms. Sodergren advised it was a philosophy.

Members of the public were provided the opportunity to provide comments. Paige Talley, CCAP, advised the measure was still in the policy committee.

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

Board Member	Vote
Butler	Support
Kim	Not Present
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Abstain
Wong	Support

4. Assembly Bill 107 (Salas) Licensure: Veterans and Military Spouses

Chairperson Lippe advised AB 107 would expand the requirement to issue temporary licenses to practice a profession or vocation to include licenses issued by any board with the Department of Consumer Affairs, except as provided. It would require a board to issue a temporary license within 30 days of receiving the required documentation if the results of a criminal background check do not show grounds for denial for an application married to, or in a domestic partnership or other legal union with, an active duty member of the Armed Forces who is stationed in California. Temporary licenses would expire 12 months after issuance, upon issuance of a standard license, or upon issuance of an expedited license, whichever occurs first. He noted as indicated in the meeting materials, the Board considered a similar measure last year and established an oppose unless amended position. The measure recently passed out of policy committee and was referred to Assembly Appropriations.

Committee Recommendation (Motion): Oppose unless amended position for the reasons cited in the meeting materials.

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

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

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

Board Member	Vote
Butler	Support
Kim	Not Present
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Abstain
Wong	Support

5. Assembly Bill 225 (Gray) Department of Consumer Affairs: Veterans: Spouses

Chairperson Lippe reported this measure would require the Board to issue temporary licenses to honorably discharged veterans. He noted under the provisions, such temporary licenses would expire 18 months after issuance and would expand eligibility for a temporary license to an applicant that meets specified criteria and who supplies evidence satisfactory to the board that the applicant is a veteran of the Armed Forces as specified. The Committee noted agreement with the Board's need to retain its ability to assess for minimum competency prior to issuing a temporary license. He noted public comment included a suggestion that the bill should be amended to also include active members of the military.

Committee Recommendation (Motion): Oppose unless amended position for the reasons cited in the meeting materials.

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

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

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

Board Member	Vote
Butler	Support
Kim	Not Present
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Abstain
Wong	Support

6. Assembly Bill 527 (Wood) Controlled Substances

Chairperson Lippe provided this measure includes Board-sponsored language related to the de-scheduling of some nonnarcotic combination products to align with federal law. As this measure contains Board-sponsored provisions, the committee recommends to formally support AB 527. This measure passed through the Assembly and is now in the Senate. The committee received public comment in support of the measure as well.

Committee Recommendation (Motion): Support.

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

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

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

Board Member	Vote
Butler	Support
Kim	Not Present
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Abstain
Wong	Support

7. Assembly Bill 646 (Low) Department of Consumer Affairs: Boards: Convictions

Chairperson Lippe advised AB 646 would require the Board to update or remove information about the revoked license resulting from a criminal conviction should the board receive an expungement order related to the conviction, as specified. Staff noted that this measure appears to build upon the policy goals of AB 2138 (Statutes of 2018) which restricted a licensing board from denying an application based on some criminal convictions and required licensing boards to amend substantial relationship criteria regulations and regulations defining rehabilitative efforts. According to the author, this bill is intended to reduce employment barriers for people with previously criminal records who have been rehabilitated and whose conviction has been dismissed, or expunged, through the judicial process.

Chairperson Lippe noted the committee was not offering a recommendation on this measure.

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

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

Steven Gray commented he received an inquiry about the ambiguity with which the bill may be handling convictions outside of California or under federal law. He noted pharmacists are susceptible to enforcement actions by federal law and in other states. California would have no control over the expungement process in other states under federal law.

8. Assembly Bill 657 (Cooper) State Civil Service System: Personal Services Contracts: Professionals

Chairperson Lippe advised the measure no longer applied to the Board and wasn't discussed by the committee.

9. Assembly Bill 671 (Wood) Medi-Cal: Pharmacy Benefits

Chairperson Lippe advised AB 671 would require the Department of Health Care Services (DHCS) to provide a disease management or similar payment to a pharmacy for specified costs and activities that are associated with dispensing specialty drugs in an amount necessary to ensure beneficiary access as determined based on result of a DHCS-contracted survey, as specified. He noted during the meeting the committee received several comments from stakeholders recommending that the Board support the measure.

Committee Recommendation (motion): Support.

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

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

Danny Martinez, CPhA, thanked the committee for the support recommendation and requested support for the CPhA sponsored measure.

Lindsay Gullahorn, CRA/NACDS, commented in support of the measure.

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

Board Member	Vote
Butler	Support
Kim	Not Present
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Abstain
Wong	Support

10. Assembly Bill 864 (Low) Controlled Substances: CURES Database

Chairperson Lippe commented AB 864 would state it is the intent of the Legislature to enact legislation to transfer the CURES system to the Department of Public Health. He noted it is a two-year bill and will continue to be monitored but the committee did not take a position.

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

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

11. Assembly Bill 1064 (Fong) Pharmacy Practice: Vaccines: Independent Initiation

Chairperson Lippe provided AB 1064 would authorize a pharmacist to independently initiate and administer any vaccine approved or authorized by the United States Food and Drug Administration for persons 3 years of age and older. He noted during the meeting, members received public comment in support of the legislation.

Committee Recommendation (Motion): Support.

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

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

Danny Martinez, CPhA, thanked the committee for the support recommendation and requested support for the CPhA sponsored measure.

Lindsay Gullahorn, CRA/NACDS, commented in support of the measure.

Steven Gray, CSHP, commented in appreciation for CPhA and CRA/NACDS for their support. He noted a crisis of regular vaccines not being administered and this measure can help.

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

Board Member	Vote
Butler	Support
Kim	Not Present
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Abstain
Wong	Support

12. Assembly Bill 1236 (Ting) Healing Arts: Licensees: Data Collections

Chairperson Lippe advised AB 1236 would require the Board to request at the time of electronic application for a license and license renewal, or at least biennially, specified demographic information from its licensees and, if designated by the board, its registrants and to post the information on the internet websites that they each maintain. The bill specifies that licensees and registrants are not required to provide the requested information. This information provided to the Board would then be reported to the Office of Statewide Health Planning and Development. He noted the committee acknowledged the concerns raised by staff that Board would be required to serve as a collection and repository agency for another state agency as well as cost impacts, including both staff resources and IT systems.

Committee Recommendation (Motion): Oppose unless amended position for the reasons cited in the meeting materials.

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

Members of the public were provided the opportunity to provide comments; however, none were provided.

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

Board Member	Vote
Butler	Support
Kim	Not Present
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Abstain
Wong	Support

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

Chairperson Lippe advised AB 1328 would expand authority for pharmacists to perform CLIA-waived tests either approved or authorized by the FDA upon patient request or hospital authorization provided that there is a valid and respective CLIA certificate of waiver and laboratory license, with some exceptions. Exceptions would include CLIA-waived tests that are used for surgery, diagnosis or treatment of heart failure, female fertility, or ovulation prediction. He noted the measure would require a pharmacist to notify the patient's primary care provider, or other appropriate physician and surgeon, of any abnormal test results. In the event the patient refuses consent or does not have a primary care provider, the pharmacist shall provide the patient a list of physicians, clinics, or other health care service providers to contact for ongoing patient care. It 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.

Chairperson Lippe noted the committee discussed this measure and noted the upcoming recommendation by the Licensing Committee. Committee comments included general support of the measure, assuming pharmacists have sufficient resources. Members also received public comment in support of the measure including that the measure will broaden access to care.

Chairperson Lippe noted the committee did not take action to allow for a broader understanding of the Board's position following discussion and consideration under the related item in the Licensing Committee Chair Report.

Members were provided the opportunity to provide comments. Member Serpa noted there is a discussion with the Licensing Committee on this measure.

Motion: Support

M/S: Veale/Patel

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

The Board heard comments in support from CRA/NACDS, CSHP, and CCAP.

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

Board Member	Vote
Butler	Support
Kim	Not Present
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Abstain
Wong	Support

14. Assembly Bill 1430 (Arambula) Pharmacy: Dispensing Controlled Substances

Chairperson Lippe advised AB 1430 would require a pharmacist who dispenses a Schedule II drug to do so in a lockable vial and require the pharmacist to provide a copy of an Opioid Factsheet for Patients published by the federal Centers for Disease Control and Prevention and include the appropriate passcode in any patient notes maintain in the pharmacy's system. Under the provisions, exceptions are provided and include dispensing that occurs in a hospital or the patient or patient's agent requests that the medication not be dispensed in a lockable vial.

The Act would also establish a funding mechanism for pharmacies to seek reimbursement for the cost of the lockable vials from the manufacturer of a controlled substance. The Board would be charged with assessing a civil penalty in the event a manufacturer is delinquent in reimbursing the pharmacy.

Chairperson Lippe noted as a committee we discussed many of the challenges with this measure, including patient safety concerns and the impact to Board staff resources. The committee also questioned if such legislation is necessary given current provisions of the law related to displaying these products and noted that Schedule II drugs include more that opioids questioning the requirement to provide the Fact Sheet in all instances. Members also noted that the provisions of the measure should be voluntary. The committee also received public comment in opposition to the measure noting workflow challenges, reimbursement challenges and patient safety concerns.

Committee Recommendation (Motion): Oppose

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

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

The Board heard comments in support of the motion from CRA/NACDS, CCAP, CPhA, and Steven Gray.

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

Board Member	Vote
Butler	Support
Kim	Not Present
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Abstain
Wong	Support

15. Assembly Bill 1533 (Assembly Business and Professions Committee) Pharmacy

Chairperson Lippe advised AB 1533 would extend the operations of the Board until January 1, 2026, and make several other changes detailed in the meeting materials. The measure passed out of the Assembly Business and Professions Committee earlier this week. He noted during the meeting members received public comments in support of the measure, with some comments noting support for the extension of the Board but concern about the fine provisions.

Committee Recommendation (Motion): Support.

Members were provided the opportunity to provide comments.

Member Serpa commented on the letter from CVMA that was sent to Assembly Member Low. She noted misstatements made in the letter and wanted to address for the record. Dr. Serpa noted she was surprised with CVMA's lack of understanding of how collaborative agreements work. She noted physicians and veterinarians would need to agree to the practice to provide medication, consultation, and treatments which is not done without prior authorization and there are protocols that need to be understood. She continued by discussing the elimination of this practice from veterinarians, she didn't think CVMA understood how this is being used in the veterinary practice. Dr. Serpa noted there are large veterinarian schools and large practices where veterinarians employee pharmacists to work with them together. Dr. Serpa stated she was confused why CVMA didn't understand how this was being used.

Member Veale inquired who established the dollar amounts for the fines. Mr. Lippe advised it sets upper limits in specific situations. He noted the Board did not come up with the amount of the fine.

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

Lindsay Gullahorn, CRA/NACDS, advised Assembly Business and Professions came up with the fines. She noted support for extending the Board of Pharmacy but are concerned about the language to establish fines against chain store pharmacies ranging from $100,000 for a second violation and up to $1,000,000 for a fourth violation. She wasn't aware of other states that had similar fines. She noted an appeals process should be included and fleshed out.

Paige Talley, CCAP, commented CVMA is seeking to have a compounding pharmacist Board Member on the Board of Pharmacy. She

commented in support of a compounding pharmacists on the Board of Pharmacy

Jassy Grewal, UFCW Western States Council, commented in support for AB 1533 and spoke in support of the fines noting they are only for common ownership and represent ceilings for fines not floors for fines.

Joe Grasela commented in support of having a compounding pharmacist on the Board of Pharmacy.

Member Veale noted that the Board has open positions and a compounding pharmacist could apply. Ms. Sodergren noted one of the provisions in the bill would convert one of the Board Member positions to a compounding pharmacist specialized in human drug preparation.

Member Veale inquired about the definition of chain. Ms. Sodergren indicated she didn't think it was defined in the bill.

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

Board Member	Vote
Butler	Support
Kim	Not Present
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Abstain
Wong	Support

16. Senate Bill 306 (Pan) Sexually Transmitted Disease: Testing

Chairperson Lippe reported SB 306 would allow a pharmacist to dispense a drug prescribed pursuant to EPT provisions without an individual name if the prescription includes either "expedited partner therapy" or EPT. He noted the section provides that a pharmacist would not be liable in, and not subject to a civil, criminal, or administration action if the use of EPT was done in compliance with the law, unless otherwise specified. Mr. Lippe

advised members discussed the concerns raised by staff and also received public comment to support the measure.

Mr. Lippe advised members of the Committee's recommendation to the Board is to establish a Support if Amended position to address the patient safety concerns, possible options for consultation, and liability concerns.

Committee Recommendation (Motion): Support if amended position to address the patient safety concerns, possible options for consultation, and liability concerns.

Members were provided the opportunity to provide comments. Member Veale didn't understand the liability concerns. Ms. Sodergren advised it was a concern raised by Member Butler and counsel was going to make sure she felt that the liability protections there would cover the expressed concerns.

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

Danny Martinez, CPhA, commented CPhA has a support position on the bill. He noted physicians can prescribe EPT for the patient and patient's partner. However, pharmacists cannot fill the partner's prescription due to requirements on prescriptions. This would also help with STIs/STDs. He requested Board support on this measure.

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

Board Member	Vote
Butler	Support
Kim	Not Present
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Abstain
Wong	Support

17. Senate Bill 362 (Newman) Community Pharmacies: Quotas

Chairperson Lippe advised SB 362 bill would prohibit a community pharmacy from establishing a quota, defined as a fixed number or

formula related to the duties for which a pharmacist or pharmacy technician license is required to complete, or against which the community pharmacy or its agent measures or evaluates the pharmacist or pharmacy technician's performance of those duties in the community pharmacy. The measure includes significant penalties some of which staff have identified as potentially problematic. He ensured members received the two letters of support received. He noted in the letter from the author, amendments will be forthcoming to address the concerns identified by staff. Committee members received public comment both in support of and in opposition to the measure.

Committee Recommendation (Motion): Support if amended for the reasons cited in the meeting materials.

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

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

Steven Gray commented he had personal support and concerns about the bill and it requires further discussions. The issues of staffing exist in other professions.

Danny Martinez, CPhA, commented the measure is a CPhA/UFCW joint sponsor measure. He noted the amendments are being addressed with the author.

Lindsay Gullahorn, CRA/NACDS, commented in opposition as drafted. She noted while the bill may be well intentioned, it jeopardizes patient safety; will prohibit using metrics to evaluate work of pharmacists; will prohibit using performance metrics imposed by the board such as wait time for consultation of a mail order prescription or assistance for the pharmacist. She added it forces pharmacists to choose which laws they have to break. She agreed with removal of license suspension and revocation.

Paige Talley, CCAP, commented CCAP doesn't have a position and is waiting for amendments.

Jassy Grewal, UFCW Western States Council, commented quota is defined in the bill as a fixed number or formula related to any of the following: prescriptions filled, services rendered to patients, programs offered to patients, and revenue obtained. She clarified it would not limit the ability of community pharmacies to be able to measure how long a patient waited in line, services rendered, or prescription refilled. She further

clarified pharmacists cannot be told to do something in "x" amount of time. She stated it doesn't impede on regulations or laws passed. She noted the pharmacy closure language will be removed and the fines can be from $5,000 to $1,000,000 not to exceed $1,000,000.

Support: 6 Oppose: 2 Abstain: 1 Not Present: 1

Board Member	Vote
Butler	Support
Kim	Not Present
Lippe	Support
Oh	Support
Patel	No
Sanchez	Support
Serpa	Support
Veale	No
Weisz	Abstain
Wong	Support

The Board took a break from 2:31 p.m. and returned at 2:41 p.m. Roll call was taken after break. Members present included Albert Wong, Debbie Veale, Jignesh Patel, Ricardo Sanchez, Lavanza Butler, Maria Serpa, Seung Oh, Jason Weisz, and Greg Lippe.

18. Senate Bill 409 (Caballero) Pharmacy Practice: SARS-CoV-2 and Influenza Testing

Chairperson Lippe provided SB 409 is a Board-sponsored measure that would authorize pharmacists to provide CLIA-waived COVID-19 and influenza tests. He added the meeting materials note that this measure has enjoyed support; however, some comments indicate that the measure should be expanded. He noted as it is Board-sponsored a support position is not necessary.

Members were provided the opportunity to provide comments. Member Veale inquired how it would be handled as Licensing is also working on the issue as well. Ms. Sodergren provided this report was reviewing the discussion of the committee. She noted Licensing will be assisting with the author's office.

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

Loriann DeMartini, CSHP, sponsor of AB 1328, thanked the Board for the consideration to expand for all CLIA-waived tests and looks forward to working with the Board.

Danny Martinez, CPhA, commented with the inclusion of amendments, CPhA will reevaluate position and hopeful for a full support position.

19. Senate Bill 524 (Skinner) Health Care Coverage: Patient Steering

Chairperson Lippe provided Senate Bill 524 would prohibit patient steering, which is also defined in the measure. Members noted general support for the measure, but deferred action, pending the Board's discussion on "White Bagging" that would be occurring under the Enforcement Committee Report. He noted the committee received public comment in support of the measure.

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

Motion: Support

M/S: Patel/Sanchez

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

Danny Martinez, CPhA, appreciate the motion to support the CPhA sponsored measure.

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

Board Member	Vote
Butler	Support
Kim	Not Present
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Abstain
Wong	Support

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

Chairperson Lippe advised SB 731 would expand the conditions for relief for arrest and convictions. He noted some of the staff's concerns. As this issue is complex, he requested Ms. Smiley to provide members with her assessment of the bill and its potential impacts to the Board.

Counsel Smiley advised SB 731 builds on what AB 1076 which restricted the criminal conviction information provided to Board's in specific circumstances. AB 1076 applied to misdemeanors and certain crimes but SB 731 extends the automatic relief and the Board's ability to get information for felonies after January 1, 1973, if the sentence was completed. She noted different exemptions for people applying to be a peace officer. Given that the Board's licensees are involved in preparing and dispensing as well as having access to dangerous drugs and controlled substances that this is excluding the Board from considering a large amount of criminal conduct of serious offenses in making licensing decisions.

Committee Recommendation (motion): Oppose unless Board of Pharmacy is exempted.

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

Members of the public were provided the opportunity to provide public comment. Steven Gray commented in support of the motion.

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

Board Member	Vote
Butler	Support
Kim	Not Present
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Abstain
Wong	Support

Chairperson Lippe advised the information provided if for information only and included in the meeting materials.

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

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

Chairperson Lippe noted the next meeting of our committee is scheduled for July 15, 2021.

XIII. Executive Officer Report

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

Ms. Sodergren provided education samples using subscriber alerts. The Board also maintains a homepage with COVID-19 specific information including links and methods by which to request site specific waiver. The Board continues to issue and extend waivers.

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

Ms. Sodergren referred to a question earlier for licensing and provisions for compounding pharmacies. She noted it is included under site-specific waivers. Ms. Sodergren provided the Board transitions to a desk audit model during various phases of the pandemic and continues to use for that for its nonresident locations. She reported President Lippe reviewed those before a waiver is approved consistent with delegated authority.

b. Appointment to Advisory Committee on Examinations (ACE)

Ms. Sodergren advised she was appointed to serve on the NABP's Advisory Committee on Examinations (ACE). It is a three-year term that begins in June 2021.

Members were provided the opportunity to provide public comment. Member Serpa congratulated Ms. Sodergren on her appointment to NABP's ACE.

c. Biannual Report of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) and the North American Pharmacist Licensure Examination (NAPLEX)

Ms. Sodergren provided the CPJE statistics are posted on the Board's website and have been sent to the Deans of the schools of pharmacy in California.

Members were provided the opportunity to provide public comment. Member Veale inquired the OPES audit recommendation to compare CPJE and NAPLEX passing rates. Ms. Sodergren advised the CPJE is psychometrically sound and continue to work with OPES.

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

XIV. Adjournment

President Lippe advised the next Board Meeting will be May 27, 2021.

Member Butler noted she would not be at the next Board Meeting and thanked President Lippe and how he served as President. She commended him and thanked him for his service.

The Board adjourned at 3:00 p.m.

III. Approval Board Meeting Minutes

b. May 27, 2021, 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: May 27, 2021

Location: Teleconference Public Board Meeting
Note: Pursuant to the provisions of Governor Gavin Newsom's Executive Order N-29-20, dated March 17, 2020, neither a public location nor teleconference locations are provided.

Board Members Present:
Gregory Lippe, Public Member, President
Debbie Veale, Licensee Member, Vice President
Maria Serpa, Licensee Member, Treasurer
Seung Oh, Licensee Member
Shirley Kim, Public Member
Jignesh Patel, Licensee Member
Ricardo Sanchez, Public Member
Albert Wong, Licensee Member

Staff Present:
Anne Sodergren, Executive Officer
Lyle Matthews, Assistant Executive Officer
MaryJo Tobola, Senior Enforcement Manager
Eileen Smiley, DCA Staff Counsel
Dani Rogers, DCA Staff Counsel
Sheila Tatayon, DCA Staff Counsel
Debbie Damoth, Administration Manager

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

The meeting was called to order at 9:03 a.m. As part of the opening announcements, President Lippe reminded everyone that the meeting was being conducted consistent with the provisions of Governor Gavin Newsom's Executive Order N-29-20.

Provisions for providing public comment throughout the meeting were reviewed.

President Lippe advised those participating in the teleconference the Board would convene in closed session after deliberating on the open session items, except adjournment.

Roll call was taken. Board Members present: Seung Oh, Debbie Veale, Maria Serpa, Jignesh Patel, Albert Wong, Shirley Kim, Ricardo Sanchez, and Greg Lippe. A quorum was established.

Vice President Debbie Veale recognized and thanked President Greg Lippe and Dr. Albert Wong for their work and contributions to the protection of California consumers and the profession of pharmacy during their tenure as Board Members. Ms. Veale provided a summary of Dr. Wong and Mr. Lippe's contributions as Board Members. She noted both Dr. Wong and Mr. Lippe served their terms and grace year period which will end June 1, 2021.

Dr. Wong stated it had been a pleasure working on the Board. He thanked Board Members and Board staff. Dr. Wong thanked Mr. Lippe for his leadership.

Mr. Lippe stated it was an honor to work with and for the Board. He noted admiration to the profession and thanked Board staff.

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

During the meeting members of the public were provided the opportunity to provide public comment on items not on the agenda.

Danny Martinez, CPhA, thanked President Lippe and Member Wong for their service on the Board and appreciated their advocacy for pharmacists.

Robert Stein thanked President Lippe and Member Wong as advocates for consumers and appreciated the work they have done.

Lindsay Gullahorn, CRA and NACDS, thanked President Lippe and Member Wong for their work on the Board showing expertise and dedication to patient safety.

Members Patel, Kim and Sanchez thanked President Lippe and Member Wong.

III. Discussion and Consideration of Request to Waive Pharmacy Law Provisions Consistent with the Authority of Business and Professions Code (BPC) section 4062

President Lippe advised there were two recommendations from staff to extend temporary permits beyond the current 180-day timeframe authorized in the law. The motions for agenda items III. (a) and III. (b) were considered and voted at the same time.

a. Consideration of Site-Specific Waiver

1. McKesson Medical-Surgical, Inc, BPC 4161, Temporary License NPL 1274

Mr. Lippe reported the first waiver for consideration would allow for the extension of the Nonresident Third Party Logistics Provider license issued to McKesson Medical-Surgical, INC, license number NPL 1274. As included in the meeting materials, approval of this waiver would allow this facility to continue to distribute vaccines. Mr. Lippe provided staff recommended language to approve an extension of the nonresident 3PL license until January 1, 2022, or until such time as either McKesson Medical-Surgical, Inc., obtains appropriate licensure in the resident state or until changes in California Law are secured, whichever occurs first.

2. McKesson Corporation dba McKesson Drug Company, BPC 4161, Temporary license, NPL 1277

Mr. Lippe reported the second waiver would allow for the extension of the Nonresident Third Party Logistics Provider license issued to McKesson Corporation, license number NPL 1277. He noted like the previous waiver, approval of this waiver would allow this facility to continue to distribute vaccines. Mr. Lippe provided staff recommend language to approve an extension of the nonresident 3PL license until January 1, 2022, or until such time as either McKesson Medical-Surgical, Inc., obtains appropriate licensure in the resident state or until changes in California Law are secured, whichever occurs first.

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

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

Motion: Approve an extension of the nonresident 3PL license (NPL 1274) until January 1, 2022, or until such time as either McKesson Medical-Surgical, Inc obtains appropriate licensure in the resident state or until changes in California Law are secured, whichever occurs first.

Approve an extension of the nonresident 3PL license (NPL 1277) until December 31, 2021, or until such time as either McKesson Medical-Surgical obtains appropriate licensure in the resident state or until changes in California Law are secured, whichever occurs first.

M/S: Oh/Sanchez

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

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

Board Member	Vote
Butler	Not Present
Kim	Yes
Lippe	Yes
Oh	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes
Veale	Yes
Weisz	Not Present
Wong	Yes

IV. Discussion and Consideration of Board Approved Regulation, Title 16 California Code of Regulations Section 1717.5 Related to Automatic Refill Programs to Address Comments by the Office of Administrative Law

Mr. Lippe referred to the meeting materials that included a cover memo providing a brief history of the rulemaking and information regarding why this rulemaking was back before the Board for consideration. He noted the Office of Administrative Law (OAL), through its review, requested that the Board clarify its policy decisions more clearly in the text of the regulation itself with specific changes requested by OAL detailed in the meeting materials. Mr. Lippe also noted that the meeting materials provided excerpts from the October 2020 meeting where the Board voted, as part of its motion memorializing Board's policy. He noted OAL has requested the Board clarify three specific areas:

1. The Board further define "each prescription" in subsection (a)(2).
2. The Board memorialize its policy regarding the need for annual consent.
3. The Board ensure the proposal consistently uses the terms "prescription" and "prescription medication" throughout the text.

Mr. Lippe advised the proposed modified text was provided in the meeting materials. Changes offered were reflected in italicized double underline to reflect new text, and italicized double strikethrough to reflect text recommend being removed.

Mr. Lippe stated based on Board action today, a 15-day comment period would be initiated to provide stakeholders with the opportunity to provide comments on the proposed revisions. He added it is important to note that the scope of the comments

will be limited to just the modified text voted at the meeting. Mr. Lippe stated he believed the Board must act to address the comments provided by the OAL or the regulation will not be approved.

Members were provided an opportunity to comment.

Motion: Approve the amended regulation text and initiate a 15-day comment period. Additionally, should no negative comments be received, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Office of Administrative Law to complete the rulemaking file.

M/S: Serpa/

Member Patel commented the word "prescriber" should be removed from (a) (2). Dr. Patel stated the word was redundant and could impact consumer protection.

Member Serpa inquired if an additional 15-day comment period would be required if "prescriber" was removed. Counsel Rogers confirmed the 15-day comment period would be required.

DCA Counsel Dani Rogers explained the edits as requested by OAL was to be consistent with current regulation at Title 16 section 1717 (b) (4) related to new prescription. Ms. Rogers expressed concern about removing "prescriber" as she was not sure if OAL's opinion would change based on the removal of "prescriber." She noted if OAL has additional concern, it could come back to the Board for reconsideration.

Member Patel noted medication adherence is an issue for patients. He noted automatic refill programs help patients to be healthy. He added prescribers often change for various reasons such as insurance. If the patient must be re-enrolled, patients' adherence and patients' health could be in jeopardy. Dr. Patel noted if the word "prescriber" is not removed, the regulation could result as a hurdle with negative impact for the patients' care.

Member Serpa withdrew her motion.

Member Veale agreed with Member Patel that the prescriber could be a barrier to the automatic refill program and would be a disservice to the public.

Ms. Rogers confirmed removing "prescriber" would be part of a 15-day comment period.

Member Wong commented he heard some automatic refill programs refill without getting permission from the doctor. He wanted to ensure that when a prescription has no refills the physicians are contacted to authorize a refill.

Member Oh agreed with Member Patel. Dr. Oh requested clarification from Ms. Rogers that the change from "prescription medication" to "prescriptions" included prescription items in addition to medications. Ms. Rogers confirmed it meant the paper prescription.

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

Lindsay Gullahorn, CRA/NACDS, commented in support of the motion to strike the word "prescriber" and Board Member comments.

Robert Stein commented in support of the motion. He added the regulation is necessary with pharmacies abusing automatic refills and complaints. He looks forward to it becoming law.

Mark Johnston, CVS, commented requesting the issue be returned to committee.

Motion: Approve the amended regulation text as provided along with the removal of "prescriber" from (a) (2) and initiate a 15-day comment period. Additionally, should no negative comments be received, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Office of Administrative Law to complete the rulemaking file.

Proposal to add § 1717.5 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1717.5. Automatic Refill Programs.

(a) A pharmacy may offer a program to automatically refill prescription<u>s</u> ~~*medications*~~ provided the pharmacy complies with this section.

(1) The pharmacy shall have written policies and procedures describing the program, which shall set forth, at a minimum, how the pharmacy will comply with this section~~, as well as a list of medications that may be refilled through the program~~.

(2) <u>Before a patient enrolls, the pharmacy shall provide a written or electronic notice summarizing the program to the patient or patient's agent. Such notice shall include, at a minimum, instructions about how to withdraw a prescription medication from refill through the program or to disenroll entirely from the program.</u> The patient or patient's agent

shall enroll by written, online, or electronic informed consent to participate in the program for each *new* prescription *wherein there is a change in the prescription medication, strength, dosage form, or directions for use*.

(3) For each prescription to be refilled through the program, the pharmacy shall obtain annual renewal of each prescription from the patient or patient's agent no later than 12 months after the prescription was enrolled in the program.

(~~3~~ *4*) The pharmacy shall keep a copy of the written or electronic informed consent to enroll on file for one year from date of dispensing.

~~(4) When a patient enrolls, the pharmacy shall provide a written notice summarizing the program to the patient or patient's agent. Such notice shall include, at a minimum, instructions about how to withdraw a prescription medication from refill through the program or to disenroll entirely from the program.~~

(~~5~~ *4 5*) The pharmacy shall complete a drug regimen review for each prescription refilled through the program at the time of refill.

(~~6~~ *5 6*) Each time a prescription is refilled through the program, the pharmacy shall provide a written or electronic notification to the patient or patient's agent confirming that the prescription medication is being refilled through the program.

(~~7~~ *6 7*) The patient or patient's agent shall at any time be able to withdraw a prescription medication from automatic refill or to disenroll entirely from the program. The pharmacy shall document and maintain such withdrawal or disenrollment for one year from the date of withdrawal or disenrollment and shall provide confirmation to the patient or patient's agent.

(~~8~~ *7 8*) The pharmacy shall provide a full refund to the patient, patient's agent, or payer for any prescription medication refilled through the program if the pharmacy ~~is~~ was notified that the patient did not want the refill, regardless of the reason, ~~and~~ or the pharmacy had been notified of withdrawal or disenrollment from the program prior to dispensing the prescription *medication*.

(~~9~~ *8 9*) A pharmacy shall make available any written or electronic notification required by this section in alternate languages as required by state or federal law.

(b) A licensed health facility, as defined in Health and Safety Code section 1250, that automatically refills prescription*s* ~~*medications*~~ for its patients need not comply with the provisions of this section.

(c) Pharmacies automatically refilling prescriptions ~~*medications*~~ for inmates of an adult correctional facility or a juvenile detention facility need not comply with the provisions of this section if the facility has written policies and procedures describing how a patient may request that a medication be automatically refilled and how a patient may refuse the medication.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4001.1, 4005, 4063 and 4076.6, Business and Professions Code and Section 1250, Health and Safety Code.

M/S: Patel/Veale

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

Board Member	Vote
Butler	Not Present
Kim	Yes
Lippe	Yes
Oh	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes
Veale	Yes
Weisz	Not Present
Wong	Yes

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

Administrative Law Judge Jonathan Lew presided over the following petition hearings:

a. Dina El-Sayed, RPH 43830
b. Patrick LeRoy, RPH 58396
c. Hope Pharmacy, PHY 48589
d. Jadine Mah, RPH 45475
e. Central Drugs, PHY 49146
f. Nayan Patel, RPH 48867

Member Kim left the meeting at 11:22 a.m.

The meeting recessed from 11:44 a.m. to 12:30 p.m. Following the recess, a roll call was again taken. Members present included Ricardo Sanchez, Albert Wong, Shirley Kim, Jignesh Patel, Seung Oh, Maria Serpa, Debbie Veale, and Greg Lippe. A quorum was established.

The meeting was in recess from 1:05 p.m. to 1:10 p.m. Upon returning from recess, roll call was taken with the following members present included Debbie Veale, Maria Serpa, Seung Oh, Jignesh Patel, Albert Wong, Ricard Sanchez, and Greg Lippe. A quorum was established.

V. Closed Session Matters

The Board recessed into closed session at approximately 1:57 p.m.

VI. Reconvene Open Session

The Board adjourned after closed session at approximately 2:30 p.m.

III. Approval Board Meeting Minutes

c. June 17, 2021, Board Meeting

California State Board of Pharmacy
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Sacramento, CA 95833
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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: June 17, 2021

Location: Teleconference Public Board Meeting
Note: Pursuant to the provisions of Governor Gavin Newsom's Executive Order N-29-20, dated March 17, 2020, neither a public location nor teleconference locations are provided.

Board Members Present:
Seung Oh, Licensee Member, President
Maria Serpa, Licensee Member, Vice President
Lavanza Butler, Licensee Member
Shirley Kim, Public Member
Ricardo Sanchez, Public Member
Debbie Veale, Licensee Member
Jason Weisz, Public Member

Staff Present:
Anne Sodergren, Executive Officer
Lyle Matthews, Assistant Executive Officer
MaryJo Tobola, Senior Enforcement Manager
Eileen Smiley, DCA Staff Counsel
Dani Rogers, DCA Staff Counsel
Sheila Tatayon, DCA Staff Counsel
Debbie Damoth, Administration Manager

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

The meeting was called to order at 9:04 a.m. President Oh reminded everyone that the meeting was being conducted consistent with the provisions of Governor Gavin Newsom's Executive Order N-29-20. Provisions for providing public comment throughout the meeting were reviewed.

President Oh advised those participating in the teleconference the Board would convene in closed session after deliberating on the open session items, except adjournment.

Roll call was taken. Board Members present included Maria Serpa, Lavanza Butler, Shirley Kim, Ricardo Sanchez, Jason Weisz, Debbie Veale, and Seung Oh. A quorum was established.

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

During the meeting members of the public were provided the opportunity to provide public comment on items not on the agenda.

Elizabeth Huber, a faculty member at a university, commented some physicians and pharmacists are being prevented from dispensing therapeutics for COVID-19 including hydroxychloroquine, ivermectin, and budesonide.

The Board heard a public comment from a resident of California who has required both exogenous testosterone and compounded HCG for treatment over the past four years. The commenter stated he understood the Board has decided to disapprove the access to compounded HCG which is needed for his treatment. He wanted to bring this to the Board's attention that many residents in California need access to compounded HCG. He stated he wanted to understand why this was happening and what can be done about it.

Sandra Martinez commented on restrictions being placed on pharmacists to fill medications off-label for COVID-19 patients. She stated concern about future antibody dependent enhancement induced by the COVID vaccines. She stated ivermectin and hydroxychloroquine safely and effective treat COVID, cytokine storm, and blood disorders that accompany COVID as well as problems related to the COVID vaccines and antibody dependent enhancement. She requested the Board rescind restrictions to save lives.

Samuel Plantowksy commented in support of the use of hydroxychloroquine and ivermectin as a beneficial treatment protocol. He stated denial or interference places well beings of patients at risk. He noted the mRNA emergency youth use authorization vaccines will place many at risk through pathogenic priming from spike proteins who would also benefit in the same treatment protocols. He requested the Board let medical professionals treat patients with ivermectin and hydroxychloroquine.

Members were provided the opportunity to include items from public comment on a future agenda item.

Motion: President and executive officer to review if there are restrictions on ivermectin and hydroxychloroquine and determine appropriate

committee to be addressed or to provide additional education, as needed.

M/S: Veale/Butler

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

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

Elizabeth Huber commented she understands doctors and pharmacists can provide the medications. However, they are being coerced or living under fear of prescribing and providing hydroxychloroquine, budesonide, and ivermectin. She stated she had COVID and her doctor was afraid to provide these medications where she had to get medical attention from a different doctor.

Sandra Martinez commented pharmacists are afraid to fill these prescriptions. She stated their licenses and businesses have been covertly threatened. She stated she knew one out of every five medications are prescribed off label. She stated hydroxychloroquine and ivermectin as well as budesonide and fluvoxamine are safe in treating COVID and the various symptoms.

Support: 7 Oppose: 0 Abstain: 0 Not Present: 1

Board Member	Vote
Butler	Support
Kim	Support
Oh	Support
Patel	Not Present
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Support

III. Discussion and Consideration of Adoption of Board Approved Regulation, 16 California Code of Regulations Section 1717.5 Related to Automatic Refill Programs, and Discussion and Consideration of Public Comments Received during the 15-day comment period on the proposed new modifications to the Regulation

President Oh advised during the May 2021 meeting, in response to comments received by the Office of Administrative Law (OAL), the Board voted to further amend the regulation text proposed in section 1717.5 related to Automatic Refill Programs. The proposed modifications were released for an additional 15-day comment period beginning May 28, 2021. The comment period ended June 12, 2021.

President Oh noted as included in the meeting materials, the Board received comments from three individuals during the comment period. Staff prepared recommendations in response to each of the comments which were also provided along with the regulation text. Dr. Oh noted agreement with the recommendations of staff.

Members were provided with an opportunity to provide comments.

Member Veale requested clarification as Dr. Geddes from Albertsons requested an implementation date change from 1/1/2022 to 7/1/2022. Ms. Veale stated she understood the reasoning for the request and noted there was no implementation date in the proposed text. Ms. Veale requested clarification of the implementation date.

Ms. Sodergren provided the effective date is established through communications with the OAL. Ms. Sodergren provided the Board previously voted to delay the implementation to 1/1/2022. After the Board adoption, the regulation was reviewed by control agencies. During the review by OAL, comments were made and brought back to the Board which initiated the 15-day comment period in May 2021 to address the concerns raised by OAL.

Ms. Veale inquired if a change in implementation date to 7/1/2022 would need to be added to the motion. DCA Counsel Rogers confirmed the motion was required. If approved, the Board would need to file an amended Form 400 with OAL.

Motion: Accept the Board's staff recommended comment responses with the exception of the implementation date to have adjusted to 7/1/2022 and adopt the regulation language as noticed for the 15-day comment on May 28, 2021. Additionally, delegate to the executive officer the authority to make technical or nonsubstantive changes as may be required by the Office of Administrative Law to complete the rulemaking file.

Proposal to add § 1717.5 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1717.5. Automatic Refill Programs.

(a) A pharmacy may offer a program to automatically refill prescription<u>s</u> ~~*medications*~~ provided the pharmacy complies with this section.

(1) The pharmacy shall have written policies and procedures describing the program, which shall set forth, at a minimum, how the pharmacy will comply with this section~~, as well as a list of medications that may be refilled through the program~~.

(2) Before a patient enrolls, the pharmacy shall provide a written or electronic notice summarizing the program to the patient or patient's agent. Such notice shall include, at a minimum, instructions about how to withdraw a prescription medication from refill through the program or to disenroll entirely from the program. The patient or patient's agent shall enroll by written, online, or electronic informed consent to participate in the program for each *new* prescription *wherein there is a change in the prescription medication, strength, dosage form, or directions for use*.

(3) For each prescription to be refilled through the program, the pharmacy shall obtain annual renewal of each prescription from the patient or patient's agent no later than 12 months after the prescription was enrolled in the program.

(~~*3*~~ *4*) The pharmacy shall keep a copy of the written or electronic informed consent to enroll on file for one year from date of dispensing.

~~(4) When a patient enrolls, the pharmacy shall provide a written notice summarizing the program to the patient or patient's agent. Such notice shall include, at a minimum, instructions about how to withdraw a prescription medication from refill through the program or to disenroll entirely from the program.~~

(~~*5*~~ *5*) The pharmacy shall complete a drug regimen review for each prescription refilled through the program at the time of refill.

(~~*6*~~ *6*) Each time a prescription is refilled through the program, the pharmacy shall provide a written or electronic notification to the patient or patient's agent confirming that the prescription medication is being refilled through the program.

(~~*7*~~ *7*) The patient or patient's agent shall at any time be able to withdraw a prescription medication from automatic refill or to disenroll entirely from the program. The pharmacy shall document and maintain such withdrawal or disenrollment for one year from the date of withdrawal or disenrollment and shall provide confirmation to the patient or patient's agent.

(~~*8*~~ *8*) The pharmacy shall provide a full refund to the patient, patient's agent, or payer for any prescription medication refilled through the program if the pharmacy ~~is~~ was notified that the patient did not want the refill, regardless of the reason, ~~and~~ or the pharmacy had been notified of withdrawal or disenrollment from the program prior to dispensing the prescription *medication*.

(~~9~~8 9) A pharmacy shall make available any written or electronic notification required by this section in alternate languages as required by state or federal law.

(b) A licensed health facility, as defined in Health and Safety Code section 1250, that automatically refills prescription*s* ~~*medications*~~ for its patients need not comply with the provisions of this section.

(c) Pharmacies automatically refilling prescription*s* ~~*medications*~~ for inmates of an adult correctional facility or a juvenile detention facility need not comply with the provisions of this section if the facility has written policies and procedures describing how a patient may request that a medication be automatically refilled and how a patient may refuse the medication.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4001.1, 4005, 4063 and 4076.6, Business and Professions Code and Section 1250, Health and Safety Code.

M/S: Veale/Sanchez

Members of the public were provided with an opportunity to provide comments. The Board heard support of the motion and delay of the implementation date to allow time for implementation from Lindsay Gullahorn of CRA/NACDS and Paige Talley of CCAP.

Support: 7 Oppose: 0 Abstain: 0 Not Present: 1

Board Member	Vote
Butler	Support
Kim	Support
Oh	Support
Patel	Not Present
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Support

The Board took a break from 9:31 a.m. and returned at 10:41 a.m. Roll call was taken. Members present included Maria Serpa, Lavanza Butler, Ricardo Sanchez, Debbie Veale, Jason Weisz, Shirley Kim, and Seung Oh.

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

Administrative Law Judge Sawyer presided over the following petition hearings:

a. Olugbenga Oduyale, RPH 42719
b. Mohamadali Abolahrar, RPH 47336
c. Keith Chung, RPH 50486
d. Maher Kaldas, RPH 39184

Member Kim left the meeting at 10:19 a.m. DCA Counsel Smiley noted with Member Kim's departure, the Board is proceeding as a committee pursuant to Business and Professions Code section 4309(c).

The meeting recessed from 11:06 a.m. to 11:11 a.m. Following the recess, a roll call was again taken. Members present included Maria Serpa, Debbie Veale, Lavanza Butler, Ricardo Sanchez, Jason Weisz, and Seung Oh. DCA Counsel Smiley noted the Board is proceeding as a committee pursuant to Business and Professions Code section 4309(c).

The meeting recessed from 12:18 a.m. to 1:00 p.m. Following the recess, a roll call was again taken. Members present included Maria Serpa, Debbie Veale, Jason Weisz, Ricardo Sanchez, Lavanza Butler, and Seung Oh. President Oh noted the Board is proceeding as a committee pursuant to Business and Professions Code section 4309(c).

V. Closed Session Matters

The Board recessed into closed session at approximately 2:42 p.m.

VI. Reconvene Open Session

The Board adjourned after closed session at approximately 4:28 p.m.