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
Public Board Meeting Minutes

Date: January 27-28, 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
Ryan Brooks, Public Member (only 1/28/21)
Lavanza Butler, Licensee Member
Shirley Kim, Public Member
Seung Oh, Licensee Member
Jignesh Patel, Licensee Member (only 1/28/21)
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

January 27, 2021

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

President Lippe called the Board Meeting to order at 4:05 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: Lavanza Butler, Shirley Kim, Seung Oh, Ricardo Sanchez, Maria Serpa, Debbie Veale, Jason Weisz, and Greg Lippe. A quorum was established. Member Albert Wong confirmed he was present at the meeting at approximately 4:19 p.m.

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

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

Steven Gray requested the proposed new DEA rule of the partial filling of Schedule II prescriptions be considered for a future agenda item for a policy discussion and potentially submitting comments to the DEA. Dr. Gray stated the DEA has proposed a rule that is considerably different from the past and what California recognizes.

Nathan Painter requested the Board consider for a future agenda a more in-depth discussion about cannabis labeling and warnings. Dr. Painter stated warnings to evaluate drug interactions should be coming from the pharmacists and not from the cannabis dispensaries.

Joe Grasela requested the Board change how public comment is made during teleconferenced/WebEx meetings.

Samuel Fakiri, pharmacist-in-charge at Ralphs in Los Angeles for the previous five years, stated concerns how pharmacy staff are being asked to do COVID-19 vaccinations and stated it is in violations SB 1442 and patient safety. He noted vaccination appointments are set up every 10 minutes with one pharmacist on staff. He stated he has seen a significant increase in prescription errors. He requested this be investigated as patient safety is paramount.

President Lippe took a roll call to ask members if they would like to include any item on a future agenda.

Member Butler requested adding Samuel's concern about pharmacists being overwhelmed and Steven's request on the DEA policy on the partial filling of Schedule IIs.

President Lippe stated there were two items to be added to future agendas including the partial fillings of Schedule IIs related to DEA's proposed policy and the issue over the COVID vaccine.

III. 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 updated the Board that in response to public health guidance as well as state and regional stay-at-home orders, DCA offices were closed to the public beginning December 7, 2020. As of Monday, January 25, 2020, California Department of Public Health lifted regional state-at-home orders and counties have returned to following the blueprint for a safer economy. With the lifting of these orders, all DCA offices will reopen no later than February 1, 2021. The Administration continues to set a goal for at least 75 percent of employees to telework and programs should continue the approach to the extent possible. Ms. Holmes continued noting that maximizing telework will help reduce COVID-19 transmission risk for all employees. Public health measures such as social distancing, face coverings and frequent hand washing are required for employees who can't telework. Ms. Holmes thanked the Board's Executive Officer Anne Sodergren and staff who have been working hard to maintain excellent customer service and protect the public.

Ms. Holmes reported on February 2, 2021, DCA will launch the new Board President training for Presidents and Vice Presidents. The two-hour session will explore the roles and duties of the positions as well as hear from past presidents on experiences and lessons learned. The training is designed to give new presidents the tools needed to run an effective meeting, work with board members and partner with the executive officer as well as assist incumbents in the positions to refine their leadership. Ms. Holmes thanked President Lippe for assisting to develop the training.

Ms. Holmes reported a new Board Member Orientation Training (BMOT) has been developed. The first BMOT will be held via WebEx March 11, 2021. Ms. Holmes reminded members that BMOT is required for appointed and reappointed members

within a year of their appointment date. She noted additional information can be found at the DCA website under Board Member Resources.

Ms. Holmes provided additional training reminders to members. She reminded members that 2021 is a mandatory sexual harassment prevention (SHP) training year. All employees and members are required to complete the training this year. Additionally, she reminded members that Form 700 are due April 1, 2021. Board Members are designated appointees and required to complete a Form 700 even if there are no reportable interests. Questions can be addressed to DCA's Conflict of Interest Filing Officer Jill Johnson in the DCA Office of Human Resources.

Ms. Holmes updated members on two new initiatives of Director Kirchmeyer for 2021 to enhance DCA's services to all boards and bureaus. First, the Executive Officer and Bureau Chief Cabinet consists of Board and Bureau Executives and will maintain regular communication, provide feedback and information to DCA, and assist with special projects impacting all boards and bureaus. Second, the Enlightened Licensing Project is a workgroup being formed to utilize licensing subject matter experts from within the entire DCA. The workgroup will help boards and bureaus streamline and make licensing processes more effective and efficient by utilizing best practices, information technology and cost-saving measures.

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

IV. Approval Board Meeting Minutes

a. October 27-28, 2020, Board Meeting

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

Motion: Approve the October 27-28, 2020, minutes as presented in the meeting materials.

M/S: Veale/Oh

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

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

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

b. November 19, 2020, Board Meeting

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

Motion: Approve the November 19, 2020, minutes as presented in the meeting materials.

M/S: Veale/Butler

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

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

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

c. December 3, 2020, Board Meeting

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

Motion: Approve the December 3, 2020, minutes as presented in the meeting materials.

M/S: Weisz/Veale

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

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

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

d. December 10, 2020, Board Meeting

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

Motion: Approve the December 10, 2020, minutes as presented in the meeting materials.

M/S: Oh/Butler

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

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

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

V. Discussion and Consideration of Requests to Waive Pharmacy Law Provisions Consistent with the Authority of Business and Professions Code section 4062

a. Consideration of Site-Specific Waiver

President Lippe advised the next item for action was the consideration of staff recommendations to extend temporary licenses issued for COVID-19 related purposes. He noted the meeting materials indicated that two of these temporary licenses were issued specifically to respond to surges in COVID-19 patients and the third was issued specifically for purposes of COVID-19 vaccine distribution.

1. CDPH Alternative Care Facility – Sacramento (Sleep Train Arena), HPE *57779*

President Lippe advised the temporary license was issued to the California Department of Public Health Alternative Care Site – Sacramento. He noted meeting materials provided the history of the license. He added the license was reactivated on November 19, 2020, and will expire February 17, 2021, unless extended. Board staff recommended an extension of the hospital license until August 31, 2021, or until the surge location is no longer operating, whichever occurs first. He stated he believed the recommendation was appropriate.

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

Motion: Extend the hospital license until August 31, 2021, or until the surge location is no longer operating, whichever occurs first.

M/S: Veale/Oh

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

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

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

2. LACC No 1 Pharmacy, PHY 57875

President Lippe advised the temporary license was issued to LACC No 1. Pharmacy. He noted licensure history was provided in the meeting materials and staff recommended an extension of the pharmacy license until August 31, 2021, or until the surge location is no longer operating, whichever occurs first.

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

Motion: Extend the pharmacy license until August 31, 2021, or until the surge location is no longer operating, whichever occurs first.

M/S: Veale/Lippe

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

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

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

3. McKesson Medical Surgical, Inc. NPL 1258

President Lippe advised the last extension of a temporary license for consideration was the nonresident third-party logistics provider license issued to McKesson Specialty. He noted the license history was provided in the meeting materials. The temporary license for this location was issued to facilitate distribution of COVID-19 vaccine. The meeting materials detail the current challenges with issuing a permanent license to this location. He reminded the Members that the Board is recommending changes to its licensure requirements to address the current barrier to permanent licensure for this location. The recommendation from staff was to extend the nonresident third-party logistics provider license until December 31, 2021, or until such time a McKesson Medical-Surgical obtains appropriate licensure in the resident state or until changes in California law are secured, whichever occurs first. He agreed with the staff recommendation.

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

Motion: Extend the nonresident third-party logistics provider license until December 31, 2021, or until such time a McKesson Medical-Surgical obtains appropriate licensure in the resident state or until changes in California law are secured, whichever occurs first.

M/S: Veale/Serpa

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

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

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

VI. Update on Pharmacist Licensure Examination Audit Performed by the Office of Professional Examination Services

President Lippe introduced Dr. Tracy Montez, Chief, Divisions of Programs and Policy Review, Department of Consumer Affairs, who provided the Board with an update on the status of the review of the North American Pharmacist Licensure Examination (NAPLEX) and the California Practice Standards and Jurisprudence Examination (CPJE).

Dr. Montez provided the Board that the DCA's Office of Professional Examination Services (OPES) completed a comprehensive review of the NAPLEX and CPJE. Dr. Montez advised the NAPLEX is administered by the National Association of Boards of Pharmacy (NABP) and the CPJE is developed by the Board in collaboration with its testing consultant PSI.

Dr. Montez noted the purpose of the review was to evaluate the suitability of using the NAPLEX and CPJE for licensure as a pharmacist in California. According to Business and Professions Code (BPC) section 139 that licensing boards and bureaus within DCA are required to ensure that examinations used in the California licensure process comply with psychometric and legal standards. Dr. Montez provided in January 2021, OPES received the final information from the Board and NABP and putting the final information into the report. Dr. Montez advised the report will be submitted to the Board before February 28, 2021.

Dr. Montez advised the Board that the report will demonstrate the NAPLEX and CPJE do comply with psychometric standards. She further noted there is evidence that the Board should continue to utilize the CPJE as a supplemental process to address those unique health and safety laws required by a pharmacist to practice in California. Dr.

Montez advised the report will go into much greater detail about the various findings and how those standards are met. She noted it will also include recommendations to strengthen the examination process as well as suggested recommendations for NAPLEX to be consistent with California's expectations.

President Lippe thanked Dr. Montez for her presentation. 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;

Danny Martinez, CPhA, inquired if the contract was available to the public. Dr. Montez provided it was public information. He further inquired if there was a comparison to using the MPJE versus the CPJE. Dr. Montez advised this was not included in the report.

VII. Closed Session Matters

The Board moved into closed session at approximately 4:54 p.m.

VIII. Reconvene Open Session, to Adjourn for the day

The Board adjourned after closed session at approximately 5:53 p.m.

January 28, 2021

President Lippe called the Board Meeting to order at 9:00 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: Ryan Brooks, Lavanza Butler, Seung Oh, Jignesh Patel, Ricardo Sanchez, Maria Serpa, Debbie Veale, Jason Weisz, Albert Wong and Greg Lippe. A quorum was established. Shirley Kim later joined the meeting at approximately 9:26 a.m.

IX. Licensing Committee Report

Ms. Veale reported the Licensing Committee met January 27, 2021. She provided an update from the meeting.

a. Summary of Presentation by University of California Schools of Pharmacy Related to Academic Dishonesty

Ms. Veale reported the committee had previously heard a presentation from a group of pharmacy students regarding academic dishonesty. The committee decided to continue the discussion. UCSD and UCSF provided a presentation about their academic definition and policy. She referenced the policy in the meeting materials.

Ms. Veale reported Dr. Guglielmo, Dean, UCSF School of Pharmacy, who offered to help benchmark the common definition of academic dishonesty and benchmark the process for what happens in each school should dishonesty occur in the schools of pharmacy in California.

Ms. Veale noted UCSF and UCSD had different but similar definitions and procedures for academic dishonesty. She added that according to the policies for UCSF and UCSD, it was the responsibility of both the student and professor to report such behavior. She added the definition included copying work and sharing test questions with other students.

Ms. Veale stated if a student is disciplined with the school, the Board is not notified. The Board is only notified if the student is disenrolled in the school as the intern license requires school enrollment. Ms. Veale indicated academic dishonesty is not included on the transcript received by the Board when a candidate is applying for licensure as a pharmacist.

Members of the Board 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.

b. Discussion and Consideration of Statutory Proposal to Expand the Authority for Pharmacists to Order and Administer CLIA Waived Tests for Influenza and COVID

Ms. Veale reported the committee and public requested to have the issue expanded to include all CLIA-waived tests as well as having pharmacy technicians assist with the effort. She noted these issues will be added to future agenda items.

Ms. Veale referenced the relevant law in the meeting materials. She noted 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 technician of clinical laboratory requirements that apply under the DCA Order.

Ms. Veale noted as part of the October 2020 Licensing Committee Meeting and subsequent Board Meeting, the Board approved a policy statement that provided the committee with direction 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.

Ms. Veale explained the committee reviewed the draft statutory proposal in three sections.

Ms. Veale reviewed the proposed draft language for BPC section 4052.4 (b) that was modified slightly with the intent to allow a pharmacist to perform any FDA approved or authorized point-of-care tests for COVID-19 and influenza in an appropriately licensed laboratory. She added the phrase "in a pharmacy" was removed.

Committee Recommendation (Motion): Accept the draft statutory proposal for BPC section 4052.4 with the one change in section BPC section 4052.4 (b) (1) to removing "in a pharmacy." Give the Executive Officer ability to make non-substantive changes.

> ***Proposal to Amend Business and Professions Code section 4052.4.***
> *(a)Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under Section 1206.5 or 1206.6. For purposes of this*

section, "routine patient assessment procedures" means: (a) procedures that a patient could, with or without a prescription, perform for himself or herself, or (b) clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration, as authorized by paragraph (11) of subdivision (a) of Section 1206.5 or Section 1206.6. A pharmacist performing these functions shall report the results obtained from a test to the patient and any physician designated by the patient. Any pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.

(b) A pharmacist may perform any aspect of any FDA approved or authorized point-of-care test for the presence of SARS-CoV-2 or influenza that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments as described in (a) under the following conditions:

1.The pharmacist completes the testing in a laboratory pursuant to BPC 1265.

2. The pharmacist has completed necessary training as specified in the pharmacy's policies and procedures.

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.

Lindsay Gullahorn, CRA and NACDS, commented in support for the proposal as drafted. She noted they supported adding pharmacy technicians to this proposal consistent with the DCA waiver.

Daniel Robinson, Dean of College of Pharmacy, Western University of Health Sciences, commented existing language was implemented before the legislature declared pharmacists as health care providers with the authority to provide health care services. He recommended rethinking the entirety of Chapter 9 and claim the place as health care providers. He noted as health care providers practice will change as knowledge and science change and services need to be based on the prevailing standard of care. He recommended a statement as authority extending to vaccines approved by the FDA under emergency use authorization would eliminate the need to make disease specific changes.

Ms. Veale clarified this motion is around testing and not vaccines. She added vaccines were addressed in the last meeting and it will be expanded.

Keith Yoshizuka, President, CSHP, spoke in support of the proposed statutory change and applauded the Board for having the vision.

Mark Johnston, CVS Health, spoke in support of the draft proposal and noted only three states limit the CLIA-waived tests that a pharmacist may perform. He commented all but three to four states allow pharmacy technician to perform CLIA-waived tests.

Paige Tally, CCAP, commented in support of the motion.

Danny Martinez, CPhA, expressed support for the amended legislative proposal and looked forward to advocating its passage in the legislature.

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

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

Ms. Veale continued with BPC section 4119.10 for a pharmacy to provide COVID-19 and flu testing. Ms. Veale provided Ms. Sodergren advised during the committee meeting the term "pharmacist-in-charge" does not need to be changed as this section refers to activity in a pharmacy.

Committee Recommendation (Motion): Accept the addition of BPC section 4119.10 to recommend to the Board. Give the Executive Officer ability to make non-substantive changes.

Add BPC section 4119.10
A pharmacy located in this state, may employ pharmacists to perform FDA approved or authorized point-of-care tests for the presence of SARS-CoV-2 or influenza that are classified as waived pursuant the Federal Clinical Laboratory Improvement Amendments of 1988 under the following conditions:

1. The pharmacy is appropriately licensed as a laboratory under BPC section 1265.
2. The pharmacy maintains policies and procedures that at minimum describe the following:
a. Establish the initial training requirements, including specimen collection techniques relevant to the test(s) being performed at the pharmacy and ongoing training.
b. Establish the necessary safety precautions to protect pharmacy staff and consumers to reduce the risk of transmission consistent with CalOSHA and CDC requirements. Such policies should, at a minimum, include provisions for use for personal protective equipment, cleaning and sanitizing procedures, appropriate biohazard waste requirements and space requirements to protect the safety of staff and consumers.
c. Ensure dedicated physical or other segregated space that allows for privacy during the testing process, provides for private consultation with the pharmacist and to limit the potential contamination of other consumers in the pharmacy.
d. Detail requirements for providing test results to the patient in a nonverbal manner, complying with mandatory reporting requirements to local and state reporting systems, and notification to primary care providers if consent is provided.
e. Ensure documentation of testing equipment maintenance and calibration.
f. Ensure appropriate storage and handling of specimens, testing reagents, etc.
3. The pharmacist-in-charge must review the policies and procedures on an annual basis. As part of this annual review the pharmacist-in-charge must also assess the pharmacy's compliance with its policies and where noncompliance is noted, document corrective actions to be taken. Documentation of the review must be maintained in a readily retrievable format for a period of three years from the date of completion.
4. The pharmacy must maintain documentation related to performing these tests that demonstrate compliance with all conditions in this subsection, including, the name of the pharmacist performing the test, the results and communication of results to a patient's primary medical provider. These documents must be maintained for period of three years from the date of making and must be maintained in a readily retrievable format.

Members of the Committee and the Board 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.

Danny Martinez, CPhA, clarified his concern with pharmacist-in-charge term related to the previous motion.

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

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

Ms. Veale continued with BPC sections 1206.5 and 1209. She clarified the pharmacist-in-charge term is appropriate for this section.

Committee Recommendation (Motion): Accept the addition of BPC sections 1206.5 and 1209 to recommend to the Board. Give the Executive Officer ability to make non-substantive changes.

Amend BPC section 1206.5.
(a) Notwithstanding subdivision (b) of Section 1206 and except as otherwise provided in Sections 1206.6 and 1241, no person shall perform a clinical laboratory test or examination classified as waived under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:
(1) A licensed physician and surgeon holding a M.D. or D.O. degree.
(2) A licensed podiatrist, a licensed dentist, or a licensed naturopathic doctor, if the results of the tests can be lawfully utilized within his or her practice.
(3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory.

(4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.
(5) A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or 3535.
(6) A person licensed under Chapter 6 (commencing with Section 2700).
(7) A person licensed under Chapter 6.5 (commencing with Section 2840).
(8) A perfusionist if authorized by and performed in compliance with Section 2590.
(9) A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).
(10) A medical assistant, as defined in Section 2069, if the waived test is performed pursuant to a specific authorization meeting the requirements of Section 2069.
(11) A pharmacist, as defined in Section 4036, if ordering drug therapy-related laboratory tests in compliance with paragraph (2) of subdivision (a) of Section 4052.1 or paragraph (2) of subdivision (a) of Section 4052.2, or if performing skin puncture in the course of performing routine patient assessment procedures in compliance with Section 4052.1 or performing testing as authorized in section 4052.4.
(12) A naturopathic assistant, as defined in Sections 3613 and 3640.2, if the waived test is performed pursuant to a specific authorization meeting the requirements of Sections 3613 and 3640.2.
(13) A licensed optometrist as authorized under Chapter 7 (commencing with Section 3000).
(14) Other health care personnel providing direct patient care.
(15) Any other person performing nondiagnostic testing pursuant to Section 1244.
(b) Notwithstanding subdivision (b) of Section 1206, no person shall perform clinical laboratory tests or examinations classified as of moderate complexity under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:
(1) A licensed physician and surgeon holding a M.D. or D.O. degree.
(2) A licensed podiatrist or a licensed dentist if the results of the tests can be lawfully utilized within his or her practice.
(3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory.
(4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.

(5) A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or 3535.
(6) A person licensed under Chapter 6 (commencing with Section 2700).
(7) A perfusionist if authorized by and performed in compliance with Section 2590.
(8) A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).
(9) A person performing nuclear medicine technology if authorized by and performed in compliance with Article 6 (commencing with Section 107150) of Chapter 4 of Part 1 of Division 104 of the Health and Safety Code.
(10) Any person if performing blood gas analysis in compliance with Section 1245.
(11) (A) A person certified or licensed as an "Emergency Medical Technician II" or paramedic pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code while providing prehospital medical care, a person licensed as a psychiatric technician under Chapter 10 (commencing with Section 4500) of Division 2, as a vocational nurse pursuant to Chapter 6.5 (commencing with Section 2840), or as a midwife licensed pursuant to Article 24 (commencing with Section 2505) of Chapter 5, or certified by the department pursuant to Division 5 (commencing with Section 70001) of Title 22 of the California Code of Regulations as a nurse assistant or a home health aide, who provides direct patient care, if the person is performing the test as an adjunct to the provision of direct patient care by the person, is utilizing a point-of-care laboratory testing device at a site for which a laboratory license or registration has been issued, meets the minimum clinical laboratory education, training, and experience requirements set forth in regulations adopted by the department, and has demonstrated to the satisfaction of the laboratory director that he or she is competent in the operation of the point-of-care laboratory testing device for each analyte to be reported.
(B) Prior to being authorized by the laboratory director to perform laboratory tests or examinations, testing personnel identified in subparagraph (A) shall participate in a preceptor program until they are able to perform the clinical laboratory tests or examinations authorized in this section with results that are deemed accurate and skills that are deemed competent by the preceptor. For the purposes of this section, a "preceptor program" means an organized system that meets regulatory requirements in which a preceptor provides and documents personal observation and critical evaluation, including review of accuracy, reliability, and validity, of laboratory testing performed.
(12) Any other person within a physician office laboratory if the test is performed under the supervision of the patient's physician and surgeon or podiatrist who shall be accessible to the laboratory to provide onsite, telephone, or electronic consultation as needed, and shall: (A) ensure

that the person is performing test methods as required for accurate and reliable tests; and (B) have personal knowledge of the results of the clinical laboratory testing or examination performed by that person before the test results are reported from the laboratory.
(13) A pharmacist, if ordering drug therapy-related laboratory tests in compliance with paragraph (2) of subdivision (a) of Section 4052.1 or paragraph (2) of subdivision (a) of Section 4052.2.
(c) Notwithstanding subdivision (b) of Section 1206, no person shall perform clinical laboratory tests or examinations classified as of high complexity under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:
(1) A licensed physician and surgeon holding a M.D. or D.O. degree.
(2) A licensed podiatrist or a licensed dentist if the results of the tests can be lawfully utilized within his or her practice.
(3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory if the test or examination is within a specialty or subspecialty authorized by the person's licensure.
(4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code if the test or examination is within a specialty or subspecialty authorized by the person's certification.
(5) A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or 3535.
(6) A perfusionist if authorized by and performed in compliance with Section 2590.
(7) A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).
(8) A person performing nuclear medicine technology if authorized by and performed in compliance with Article 6 (commencing with Section 107150) of Chapter 4 of Part 1 of Division 104 of the Health and Safety Code.
(9) Any person if performing blood gas analysis in compliance with Section 1245.
(10) Any other person within a physician office laboratory if the test is performed under the onsite supervision of the patient's physician and surgeon or podiatrist who shall: (A) ensure that the person is performing test methods as required for accurate and reliable tests; and (B) have personal knowledge of the results of clinical laboratory testing or examination performed by that person before the test results are reported from the laboratory.

(d) Clinical laboratory examinations classified as provider-performed microscopy under CLIA may be personally performed using a brightfield or phase/contrast microscope by one of the following practitioners:
(1) A licensed physician and surgeon using the microscope during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member or employee.
(2) A nurse midwife holding a certificate as specified by Section 2746.5, a licensed nurse practitioner as specified in Section 2835.5, or a licensed physician assistant acting under the supervision of a physician pursuant to Section 3502 using the microscope during the patient's visit on a specimen obtained from his or her own patient or from the patient of a clinic, group medical practice, or other health care provider of which the certified nurse midwife, licensed nurse practitioner, or licensed physician assistant is an employee.
(3) A licensed dentist using the microscope during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group dental practice of which the dentist is a member or an employee.

Amend BPC section 1209.
(a) As used in this chapter, "laboratory director" means any person who is any of the following:
(1) A duly licensed physician and surgeon.
(2) Only for purposes of a clinical laboratory test or examination classified as waived, is any of the following:
(A) A duly licensed clinical laboratory scientist.
(B) A duly licensed limited clinical laboratory scientist.
(C) A duly licensed naturopathic doctor.
(D) A duly licensed optometrist serving as the director of a laboratory that only performs clinical laboratory tests authorized in paragraph (10) of subdivision (d) of Section 3041.
(E) A pharmacist-in-charge of a pharmacy serving as the director of a laboratory that only performs CLIA waived tests as authorized in Pharmacy Law.
(3) Licensed to direct a clinical laboratory under this chapter.
(b) (1) A person defined in paragraph (1) or (3) of subdivision (a) who is identified as the CLIA laboratory director of a laboratory that performs clinical laboratory tests classified as moderate or high complexity shall also meet the laboratory director qualifications under CLIA for the type and complexity of tests being offered by the laboratory.
(2) As used in this subdivision, "CLIA laboratory director" means the person identified as the laboratory director on the CLIA certificate issued to the laboratory by the federal Centers for Medicare and Medicaid Services (CMS).

(c) The laboratory director, if qualified under CLIA, may perform the duties of the technical consultant, technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to persons qualified under CLIA. If the laboratory director reapportions performance of those responsibilities or duties, he or she shall remain responsible for ensuring that all those duties and responsibilities are properly performed.
(d) (1) The laboratory director is responsible for the overall operation and administration of the clinical laboratory, including administering the technical and scientific operation of a clinical laboratory, the selection and supervision of procedures, the reporting of results, and active participation in its operations to the extent necessary to ensure compliance with this act and CLIA. He or she shall be responsible for the proper performance of all laboratory work of all subordinates and shall employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests, and report test results in accordance with the personnel qualifications, duties, and responsibilities described in CLIA and this chapter.
(2) Where a point-of-care laboratory testing device is utilized and provides results for more than one analyte, the testing personnel may perform and report the results of all tests ordered for each analyte for which he or she has been found by the laboratory director to be competent to perform and report.
(e) As part of the overall operation and administration, the laboratory director of a registered laboratory shall document the adequacy of the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory test procedures and examinations. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the minimum qualifications for personnel, in addition to any CLIA requirements relative to the education or training of personnel.
(f) As part of the overall operation and administration, the laboratory director of a licensed laboratory shall do all of the following:
(1) Ensure that all personnel, prior to testing biological specimens, have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the minimum qualifications for, and the type of procedures that may be performed by, personnel in addition to any CLIA requirements relative to the education or training of personnel. Any regulations adopted pursuant to this section that specify

the type of procedure that may be performed by testing personnel shall be based on the skills, knowledge, and tasks required to perform the type of procedure in question.
(2) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to ensure that they are competent and maintain their competency to process biological specimens, perform test procedures, and report test results promptly and proficiently, and, whenever necessary, identify needs for remedial training or continuing education to improve skills.
(3) Specify in writing the responsibilities and duties of each individual engaged in the performance of the preanalytic, analytic, and postanalytic phases of clinical laboratory tests or examinations, including which clinical laboratory tests or examinations the individual is authorized to perform, whether supervision is required for the individual to perform specimen processing, test performance, or results reporting, and whether consultant, supervisor, or director review is required prior to the individual reporting patient test results.
(g) The competency and performance of staff of a licensed laboratory shall be evaluated and documented by the laboratory director, or by a person who qualifies as a technical consultant or a technical supervisor under CLIA depending on the type and complexity of tests being offered by the laboratory.
(1) The procedures for evaluating the competency of the staff shall include, but are not limited to, all of the following:
(A) Direct observations of routine patient test performance, including patient preparation, if applicable, and specimen handling, processing, and testing.
(B) Monitoring the recording and reporting of test results.
(C) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.
(D) Direct observation of performance of instrument maintenance and function checks.
(E) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.
(F) Assessment of problem solving skills.
(2) Evaluation and documentation of staff competency and performance shall occur at least semiannually during the first year an individual tests biological specimens. Thereafter, evaluations shall be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance shall be reevaluated to include the use of the new test methodology or instrumentation.

(h) The laboratory director of each clinical laboratory of an acute care hospital shall be a physician and surgeon who is a qualified pathologist, except as follows:
(1) If a qualified pathologist is not available, a physician and surgeon or a clinical laboratory bioanalyst qualified as a laboratory director under subdivision (a) may direct the laboratory. However, a qualified pathologist shall be available for consultation at suitable intervals to ensure high-quality service.
(2) If there are two or more clinical laboratories of an acute care hospital, those additional clinical laboratories that are limited to the performance of blood gas analysis, blood electrolyte analysis, or both, may be directed by a physician and surgeon qualified as a laboratory director under subdivision (a), irrespective of whether a pathologist is available.
As used in this subdivision, a qualified pathologist is a physician and surgeon certified or eligible for certification in clinical or anatomical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology.
(i) Subdivision (h) does not apply to any director of a clinical laboratory of an acute care hospital acting in that capacity on or before January 1, 1988.
(j) A laboratory director may serve as the director of up to the maximum number of laboratories stipulated by CLIA, as defined under Section 1202.5.

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.

Danny Martinez, CPhA, commented about removing the term "pharmacist-in-charge" with "pharmacist." As the language is written, only a pharmacist-in-charge could serve as the laboratory director.

Ms. Sodergren advised the Board that staff believe the appropriate person to serve as the laboratory director is the pharmacist-in-charge. notingthere is not a requirement for the laboratory director to be onsite.

Steven Gray commented there is an issue with BPC section 1209 (a) (2) (E) where it refers to a pharmacist-in-charge which may be interpreted as only a pharmacist-in-charge can serve as a laboratory director. He suggested changing BPC section 1209 (a) (2) (E) changing to a pharmacist and changing BPC section 1209 (a) (2) (F) to specify pharmacist-in-charge if done in a pharmacy.

Ms. Sodergren stated the intent of the language is to clarify where a pharmacy is seeking registration as a laboratory that a pharmacist-in-charge is authorized to serve as the laboratory director.

Robert Stein, individual, inquired why there is a limitation for drug therapy and if it could be opened to all laboratory tests as part of the pharmacist's scope of practice.

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

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

c. Discussion and Consideration of Statutory Proposal to Expand the Authority for Pharmacy Technicians to Administer COVID-19 and Influenza Vaccines.

Ms. Veale referenced legal provisions provided in the meeting materials and noted that existing law provides authority for pharmacists to independently initiate and administer vaccines lists on the routine schedules recommended by the federal Advisory Committee on Immunization Practices (ACIP) under specific conditions (BPC 4052.8). She added effective January 1, 2021, this authority was expanded to include COVID-19 vaccines that are FDA authorized or FDA approved. Ms. Veale noted previously the Board approved the policy statement related to pharmacy technician administered vaccinations included in the meeting materials. The Licensing Committee's charge was to explore a more permanent solution through statutory or regulatory changes.

Policy Statement – Expand Authority to Allow Pharmacy Technicians to Administer COVID-19 and Influenza Vaccinations

In recognition of the current COVID-19 crisis and consistent with the recommendations from health experts, including the CDC, on the importance of influenza and COVID-19 vaccinations, the Board supports all efforts to facilitate influenza and COVID-19 administration in a safe manner. Further, in recognition of the unique access patients have to

community pharmacies, such locations provide a safe and convenient option to receive such vaccinations. The Board further believes that influenza and COVID-19 vaccine administration may be safely performed by a specially trained licensed pharmacy technician under specified conditions and as such supports efforts to secure such temporary authority under waivers during the declared disaster, as well as a more permanent solution through statutory or regulatory changes.

Ms. Veale provided consistent with the approved policy statement the committee reviewed the draft statutory proposal. Ms. Veale explained there were two thought processes discussed by the committee. One thought was to wait until the waivers expired, the pandemic ended, and the workforce study completed. The other thought was to move forward with a permanent solution.

Committee Recommendation (Motion): Recommend to the Board to table pursuing statutory solution discussion until after the workforce study has been completed.

Members of the Licensing Committee were provided the opportunity to provide comment.

Dr. Patel stated putting this away for a future agenda is not a good idea. The Board must decide to enable licensees so that we are better prepared for any future pandemic. He stated point of care testing was just passed and noted testing and vaccines ends pandemics quickly.

Ms. Butler supported the committee recommendation that the statutory proposal is premature. She noted DCA has issued an unchallenged waiver to allow this during the pandemic. Ms. Butler added pharmacists are having to give vaccines every 10 minutes without additional help. She stated since the end of December 2020, at least 100 stores a day are reporting someone diagnosed with COVID-19. She added pharmacists are stressed out without additional help. She recommended following the committee's recommendation.

Dr. Patel commented in California we operate under some of the strictest labor laws and working conditions are not primary compared to fighting the pandemic and being ready for anything. He stated the Board approved and empowers every licensee to participate.

Ms. Butler stated the waiver provided for participation.

Dr. Oh stated comments have been heard that pharmacists are struggling but adding pharmacy technicians will not resolve the issue. This will require pharmacists who are spread thin to supervise this when they have duties they

are responsible for in pharmacies that are not being able to perform. He has colleagues under pressure because they can't do their job. Labor laws are not good enough because pharmacists are making medication errors because corporate partners are not providing adequate support. The primary focus should be adding pharmacists.

Mr. Brooks stated there are multiple ways to make sure the workflow is smooth and blanket statements about all pharmacies is not correct. Ms. Butler clarified appointments are being made every 10 minutes and the workload is too much for the pharmacist and a pharmacy technician. She added in chains the PIC does not have the ability to add more staff. Mr. Brooks suggested that is a management issue and not a health and safety issue. Ms. Butler stated the work flow is not being managed and this is a pandemic.

Dr. Serpa added the Board's purview is to provide for processes that are safe for patient care. The Board is not requiring anything but providing the option. If the employers are making it a requirement, that is a labor board issue. Dr. Serpa provided an example that there is not a maximum number of prescriptions filled requirement; that is between the employer and employee to determine staffing needs.

Dr. Oh stated it is relevant because medication and vaccine errors are happening and it impacts the public. Dr. Serpa inquired if there was data to support. Dr. Oh explained that is why the workforce study is needed. Ms. Butler stated the mandate is public protection and talked to many pharmacists who are stressed out.

Mr. Lippe inquired if the issue is that the volume of vaccinations increase and keep the pharmacy technician from helping the pharmacist. Ms. Butler responded the pharmacist is responsible for what the pharmacy technician does. Dr. Oh added the pharmacists are not given additional staff if the pharmacy technicians are administering vaccines.

Ms. Veale stated the opportunity is made available and adds flexibility to the pharmacist. She stated the Board should move forward as the Board has the information needed. She stated by not moving forward on the statutory proposal, it does not fix or resolve staff issues.

Dr. Wong agreed with Dr. Oh and Ms. Butler; the waiver is there to do now and the Board should get feedback from the survey to decide.

Mr. Sanchez stated the waivers were working and shouldn't be changed.

Mr. Brooks stated each pharmacy shouldn't have to obtain a waiver and by not having this, it limits access to vaccines. He agreed it is a labor issue.

Dr. Wong stated when the working condition is not right, the Board has to get involved. Ms. Butler added Cal OSHA is understaffed

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

Jassy Grewal, commented on behalf of UFCW Western States Council, speaking on behalf of pharmacist and pharmacy technicians in the drug retail setting. She stated the proposal is strongly opposed because DCA issued an unchallenged waiver for pharmacy technicians to administer vaccines; therefore, a bill is not needed to address this while in a pandemic. Additionally, the recent waivers and changes issued by the Board and DCA, according to calls and messages from frightened and angry pharmacists, has caused dangerous situations in community pharmacies administering COVID-19 vaccines. Staffing increases have not been realized to help with the increase of work from COVID-19 vaccine administration and testing. She reported a large chain store in LA county where pharmacists are working 12 hour shifts alone and expected to administer vaccines every 15 minutes without accounting for breaks, monitoring for allergic reactions or tasks pharmacists are responsible for such as filling prescriptions. With the vaccine being available to people 65 and older, the pharmacies are receiving numerous amounts of phone calls. Store managers have instructed vaccine appointments to not be cancelled leaving the pharmacist and/or pharmacy technician having to decide between giving vaccines or filling prescriptions. She stated some pharmacists defy store managers and cancel vaccine appointments. UFCW strongly opposes any statutory changes.

Lindsay Gullahorn, CRA and NACDS, urged the Board to move forward in support of the draft statutory proposal. She noted the current waiver is temporary. If the Board approved the draft proposal, it will be subject to the lengthy legislative process. Ms. Gullahorn noted allowing pharmacy technicians to administer vaccines is consistent with the Board's mission to protect the health and safety of Californians as it accelerates administration of the vaccine. She stated even the current public health emergency, COVID-19 will still be around and will need all available qualified health care resources to administer vaccines and prevent another crisis.

Paige Tally, CCAP, commented CCAP opposes the motion. She stated by law the Board is required to have a union representative and should listen to her.

Keith Yoshizuka, CSHP, encouraged the Board to move forward with the draft statutory proposal. He stated all bills have to be introduced by February 19, 2021, or will have to wait another year. He recalled the lengthy legislative process to add items from the workforce survey. CSHP completed the first beta

test of the pharmacy technician immunization. The pharmacy technicians are looking forward to assisting with the pandemic.

Rob Geddes, Albertsons, spoke in support of the draft statutory proposal noting pharmacist working in Idaho where pharmacy technicians can help with immunizations. He stated it allows the pharmacist the flexibility to assess which patient needs the pharmacist's time. He said it is a reallocation of the focus of the pharmacist. He clarified his company has not mandated any pharmacy technician or pharmacist to participate nor have there been threats to transfer or terminate employment for individuals who choose not to participate.

Mark Johnston, CVS Health, stated as the former executive director of the Idaho Board of Pharmacy, Idaho was the first state to allow pharmacy technicians to administer vaccinations. He stated there is a wealth of information outside of California on the subject. He stated he had not received a complaint of pharmacy technicians administering vaccines in his former position. He stated he didn't see a correlation between pharmacy technicians administering vaccinations and increased errors but rather he sees a decrease correlation and provides flexibility. He encouraged the Board to review published scientific literature to move this forward before the February bill deadline.

Danny Martinez, CPhA, commented CPhA passed policy and is in support of having pharmacy technicians to perform the technical task of administering the COVID-19 and flu vaccine. He noted this will add workload to supervising pharmacists who are overseeing the pharmacy technicians. Mr. Martinez stated pharmacy technicians are needed to assist with the vaccines and it does increase the workload of the supervising pharmacist. He suggested the Board revisit if pharmacy technicians need more scrutiny on their license.

Lori Walmsley, Walgreens, commented in support of moving the legislative proposal forward. She stated the Board needs to focus on what is right for patients which is getting patients vaccines. She encouraged the Board to look at the evidence that errors have occurred as a result of this. She referred to published peer-reviewed non-biased articles provided by stakeholders that show this is safe. Ms. Walmsley stated this was about giving the pharmacist the ability to leverage resources.

Robert Stein commented as professionals, pharmacists should be able to exercise professional discretion to ensure the pharmacy technicians and workflows are not causing danger to patients. He stated pharmacists need to speak up as professionals and not allow themselves to be forced into dangerous situations.

Eric Robles, United Nurses Association of California/Union of Healthcare Professionals, commented with the emergency waiver in place, pharmacists are

still trying to figure out how the emergency waiver is operating. He stated the legislation is very premature. He commented the current waiver process should not be taken advantage and turned into law until it is known how the waiver will work. He commented when emergency waivers are turned into law, it puts distrust into the system.

Ms. Veale clarified the motion is to table pursuing the statutory solution until after the workforce survey has been completed.

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

Board Member	Vote
Brooks	No
Butler	Yes
Kim	Yes
Lippe	No
Oh	Yes
Patel	No
Sanchez	Yes
Serpa	No
Veale	No
Weisz	Abstain
Wong	Yes

Ms. Smiley confirmed the motion failed.

Motion: Move forward with pursuing legislation

M/S: Brooks/Veale

Members were provided with an opportunity to provide comments.

Dr. Wong agreed pharmacists are professionals and should decide what they want to do. He stated he would support it if there were policies in place to prevent retaliation.

Mr. Brooks stated this issue affects minority communities the most when you don't have access to the vaccines. He encouraged the Board to look at who it hurts when decisions are made.

Ms. Butler commented she didn't see anything that would hurt the black community. She stated waiting to see how this rolls out and what happens as a result of the emergency waiver before making a statutory proposal is not trying to keep any community excluded.

Ms. Veale commented most corporations have harassment policies that includes no retaliation. Mr. Lippe provided there are also whistleblower policies.

Dr. Patel agreed access to minorities is an issue and this motion is to help increase access.

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

Steven Gray commented the motion just tied and it would wait until after the survey. He noted based on the Licensing Committee's previous discussion, the survey may take some time to resolve. The current motion would allow moving forward with the legislative process and survey results can be incorporated at a later date.

Paige Talley, CCAP, commented California has approximately 37 million people where Idaho has 1.5 million people.

Daniel Robinson, Dean, College of Pharmacy, Western University of Health Sciences, commented that while he doesn't represent Deans, he knows that Deans of pharmacy are very much supportive of things that advance the practice of pharmacy in California. He noted he chairs the California Task Force for Advancing Pharmacy Practice and is not speaking on their behalf as the issue has not been discussed but stated to advance pharmacy practice a level of support services is needed to allow pharmacists to take advantage of the fact that they are health care providers providing healthcare services. He noted pharmacy is part of a permanent solution and opportunities to advance the profession and extend opportunities for pharmacy technicians should be explored.

Eric Robles, United Nurses Association of California/Union of Healthcare Professionals, clarified the position that they were supportive of the previous motion but opposes the proposal to move a bill on the current issue.

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

Board Member	Vote
Brooks	Yes
Butler	No
Kim	No
Lippe	Yes
Oh	No
Patel	Yes
Sanchez	No
Serpa	Yes
Veale	Yes
Weisz	Abstain
Wong	No

Ms. Veale suggested returning the issue to the Licensing Committee to discuss further.

The Board took a break from 10:59 a.m. to 11:10 a.m. Roll call was taken after the break. Members present included Ryan Brooks, Lavanza Butler, Seung Oh, Jignesh Patel, Ricardo Sanchez, Maria Serpa, Debbie Veale, Jason Weisz, Albert Wong and Greg Lippe. Shirley Kim joined the meeting at approximately 11:21 a.m.

d. Discussion and Consideration of Board's Current Policy Related to Authority for Pharmacy Technicians to Administer Vaccines to Determine if Inclusion of Additional Vaccines is Appropriate

Ms. Veale reported the committee agreed to combine this agenda item with the previous agenda item and was advised to make a motion.

Committee Recommendation (Motion): Combine the topics discussion and consideration of a statutory proposal to expand the authority for pharmacy technicians to administer COVID-19 and influenza vaccines with discussion and consideration of the Board's current policy related to the authority for pharmacy technicians to administer vaccines to determine if inclusion of additional vaccines is appropriate.

The Board decided to send this item back to the Licensing Committee.

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

Keith Yoshizuka, President, CSHP, commented he looked forward to working with the Licensing Committee on this item.

e. Discussion and Consideration of Draft Pharmacist Workforce Survey

Ms. Veale reminded members of the Board's responses to Sunset Issues, specifically, the issue of medication errors must be addressed to improve patient health. She noted the issue warrants study in California, where conditions within a pharmacy may be different than on a national level. Further, consideration should be given to determine if the Board or some other entity should receive reports of medication errors to gain a better understanding of the scope of the issue and report on the findings. She noted it appeared appropriate to conduct a survey on working conditions to ascertain if conditions in California may be a contributing factor.

Ms. Veale reported the members and the stakeholders determined:
1.) The survey must remain anonymous.
2.) In addition to the first draft of the survey, additional items to be added will include immunization; clarification of management position; and pharmacist-in-charge.
3.) Board staff will work with DCA to revise the flow of the survey and return to the next meeting with an updated survey.

Ms. Veale noted there was no action on this agenda item.

Members were provided the opportunity to provide comment.

Dr. Serpa inquired if comments can be submitted as most of the survey was related to the outpatient/ambulatory setting. She suggested adding options for other, acute care, home infusion, long-term care, etc. Dr. Serpa recommended to specify in the beginning of the survey if it was limited to certain practice settings.

Ms. Veale asked Ms. Sodergren if the medication errors focused on outpatient or all practice settings. Ms. Sodergren stated it was crafted for community setting but can include other settings if the Board wished.

Ms. Veale reported there was interest in having an outside entity to administer the survey for the Board so that it could remain anonymous. She indicated other options will be researched.

Ms. Sodergren reported the Sunset Issues does not speak only to medication errors in the community but the background information in the paper speaks to the community setting.

Ms. Veale confirmed Dr. Serpa's recommendation of identifying specific practice settings.

Dr. Wong inquired if all settings would be sent the survey. Ms. Veale indicated it would be sent to everyone via the Board's listserv list. Dr. Wong encouraged licensees to participate in the survey.

Members of the public were provided the opportunity to make a public comment.

Paige Talley, CCAP, thanked Dr. Serpa for specifying community outpatient pharmacy.

Steven Gray commented he worked for Kaiser for over 15 years and worked with two PhDs to develop surveys at Kaiser. He recommended keeping the survey as simple as possible. He suggested being very specific on the practice setting. He stated there is no law requiring pharmacies to report errors to the Board. The law requires the errors that have left the pharmacy are tracked and all pharmacies should have the data for at least one year. He noted the Board also receives complaints and reported settlements but these two can't be used alone to obtain an error rate.

f. Discussion and Consideration of Waiver Request of Business and Professions Code Section 4131(b) Related to the Location of the Supervising Pharmacy and Remote Dispensing Site Pharmacy

Ms. Veale reported subsequent to the release of the agenda, the request for consideration was withdrawn. No action was required or taken.

g. Review and Discussion of Licensing Statistics

Ms. Veale referred to the licensing statistics in the meeting materials. She noted staff continues to work hard to adjust review applications and mail as efficiently as possible during the pandemic. She noted it does impact processing times but staff has made a great effort to try to keep them as normalized as possible.

Members were provided with an 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. Future Committee Meeting Dates

Ms. Veale reported the future meeting dates of the Licensing Committee are April 21, 2021; July 14, 2021; and October 27, 2021.

X. Enforcement and Compounding Committee Report

Dr. Serpa reported the Enforcement and Compounding Committee met January 20, 2021. She provided an update from the meeting.

a. Discussion and Consideration of Presentation on the Pharmacist Recovery Program

Dr. Serpa reported the Enforcement Committee received a presentation on the Pharmacists Recovery Program by Virginia Matthews, Project Manager, for Maximus, California Health Professionals Recovery Program (PRP). She added the PRP program is established to rehabilitate pharmacists and intern pharmacists whose competency may be impaired due to abuse of alcohol, drug use, or mental illness. The statute also provides that the intent of the program is to return pharmacists and interns to the practice of pharmacy in a manner that will not endanger the public health and safety. Consistent with the provisions of the statute, the Board contracts with a qualified vendor to administer the program. The current contractor is MAXIMUS, Inc. Dr. Serpa encouraged all Board members and members of the public to view the presentation on the Board's website adding the presentation was excellent, educational and very informative. She reported the item was informational and has no action.

Members were provided an opportunity to comments. Ms. Veale commented the presentation was excellent.

Members of the public were provided an opportunity to comment.

Steven Gray, CSHP, encouraged the Board to consider making the recovery program open to pharmacy technicians in addition to pharmacists and pharmacist interns. Dr. Serpa noted it will be on a future agenda item to determine the scope and if statutory changes would be required.

b. Discussion and Consideration of Board Policy Related to Transparency Involving the Issuance of Citations and Fines

Dr. Serpa reported the issue was a continuation of an issue originally discussed in 2018, related to the Board's disclosure policy for citations and fines. She referenced the chair report for a history of prior discussion and discussion at the last committee meeting.

Dr. Serpa advised the committee reviewed policy questions. She reported the committee discussed that routine citations and fines originating from routine inspections or investigations of complaints that do not merit discipline are not posted but are only available upon request. The committee received public

comment indicating that the Board's current policy is appropriate. The committee decided to maintain the current policy. There was no action on this agenda item.

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

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

Paige Talley, CCAP, requested clarification if this issue was included in the Sunset bill. Ms. Sodergren noted the Board has a statutory proposal that will amend the cite and fine statute to clarify it does not constitute discipline. She noted that is different than the policy goal of whether or not a citation is posted on the Board's website. The Sunset is specific to a statutory change that would specify a citation is not discipline.

c. Discussion and Consideration of Proposed Revisions to Self-Assessment Forms

Dr. Serpa referenced the meeting materials and noted the committee reviewed several proposed edits to the self-assessment forms required under Pharmacy Law. She added the self-assessment process is intended to be an education and self-monitoring tool for licensees to evaluate for compliance.

Dr. Serpa advised current self-assessment forms are in various stages of review and regulatory promulgation. She noted the Wholesaler and ADDS self-assessments were not discussed at the committee meeting and will be discussed after completion of the current review before adding additional changes.

a. Community Pharmacy/Hospital Out-Patient Self-Assessment (17M-13)

Dr. Serpa advised the changes were detailed in the meeting materials.

Committee Recommendation (Motion): Accept the updated Community Pharmacy/Hospital Outpatient Self-Assessment Form with corrections, as noted.

Members were provided with an 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: 11 Oppose: 0 Abstain: 0 Not Present: 0

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

b. Compounding Self-Assessment (17M-39)

Dr. Serpa reported the committee discussed this new form to replace the current version of the self-assessment, the 2012 version, with the proposed one included in the meeting materials. She noted when the Board updated its compounding regulations in 2017, the self-assessment form was not included in the rulemaking and no subsequent rulemaking was pursued to update the self-assessment form to reflect the regulation changes that took effect at that time. Dr. Serpa advised since the new regulations took effect both the 2012 version and the draft 2016 version have been available on line. She noted this is essentially a new form as a repeal and replace.

Committee Recommendation (Motion): Initiate the rulemaking process to update the Community Pharmacy and Hospital Outpatient Pharmacy Compounding Self-Assessment Form.

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

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

Paige Talley, CCAP, requested if the version of the self-assessment form discussed at the committee meeting was revised to ensure BPC section 1751.4 (k) was accurately reflected.

Dr. Serpa inquired if a new motion was needed. Ms. Smiley advised on having a new motion with a second as the committee recommendation changed.

Motion: Initiate the rulemaking process to update the Community Pharmacy and Hospital Outpatient Pharmacy Compounding Self-Assessment Form and to include any minor corrections as needed to match current regulation.

M/S: Serpa/Veale

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

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

Paige Talley, CCAP, thanked the Board for the adjustment.

Steven Gray commented all self-assessment changes must go through the regulation process which typically include in the motion the authority for the executive officer to make correction. He stated there will be a time for the public and stakeholders to make additional comments.

Support: 11 Oppose: 0 Abstain: 0 Not Present: 0

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

c. Hospital Pharmacy Self-Assessment (17M-14)

Dr. Serpa advised the changes were detailed in the meeting materials.

Committee Recommendation (Motion): Accept the updated Hospital Pharmacy Self-Assessment Form with corrections, as noted.

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

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

Steven Gray commented these are very valuable documents in teaching students for the law exam and practice. He noted that until the versions are adopted through the regulatory process, the required documents will be the versions current in regulation but would encourage PICs and interested parties to use the draft versions for practice and environment. He requested clarification if that was still the process.

Dr. Serpa stated that is the current policy of the Board. Ms. Sodergren stated the Board encourages the use of the draft version but cannot require it until approved. She noted the Board believes the self-assessment is more meaningful if the draft is used.

Support: 11 Oppose: 0 Abstain: 0 Not Present: 0

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

Dr. Serpa reminded the Board the last two Self-Assessment forms will be discussed after completion of the current regulatory review before adding additional changes.

d. Wholesaler Dangerous Drugs and Devices Self-Assessment (17M-26)

e. Automated Drug Delivery System Self-Assessment (17M-112)

Dr. Serpa noted members also contemplated if changes to the self-assessment process may be appropriate such as online interactive process. She stated the

committee recommended this for a future agenda item and suggested that such discussion may be more appropriate for the Communication and Public Education Committee.

President Lippe requested to have the self-assessment process be sent to the Communication and Public Education Committee for discussion.

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

Dr. Serpa reported the committee and stakeholders continue to have robust discussion on the potential of an Alternative Enforcement Model to reduce time and cost associated with resolving a disciplinary matter. She added the administrative case process has two fundamental guiding principles -- due process of the respondent and public protection.

Dr. Serpa noted policy questions for consideration by the committee were used to facilitate the discussion. Included in the meeting materials was a memo provided by DCA Counsel Smiley and the proposal from CPhA to previous language that is no longer under consideration. Dr. Serpa added the committee discussed the importance to decide based on data as opposed to responding to anecdotal information. She noted any suggestions for change will require a change in statute and legislation.

Dr. Serpa reported another lively discussion with committee members and stakeholders, the committee had no motion for the Board. She advised the committee directed staff to look at non-legislative options available to meet the policy goals to determine if other considerations are effective before working on a legislative process that will require significant Board time to sponsor and move forward. She noted the committee will continue to evaluate and study the issue.

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

Dr. Serpa opened public comment period and requested members of the public refrain from speaking on case specific information to preserve the Board's authority to act on pending matters in the future. She also cautioned members that at times the Board receives public comments that reflect an individual's opinion of events but may not be consistent with the public record on a matter.

Danny Martinez, CPhA, commented providing history of the previous discussions and requested presenting to the committee.

Dr. Serpa clarified Mr. Martinez and CPhA will provide additional information on current regulations at the next committee meeting.

Paige Talley, CCAP, commented it is an important issue to be discussed.

Steven Gray, CSHP, commented on the duration of the process and noted members may not be familiar with the background. He noted staff was asked to look at other California examples for alternative enforcement models as well as in other states as well as benefits and problems of alternative enforcement models used in other Boards of Pharmacy. He stated CSHP looked forward to a vigorous discussion of alternatives because they believe that there is significant feelings and probably good evidence that in some cases due process is not at the highest standard.

e. Discussion and Consideration of the Discrepancies Between the State and Federal Controlled Substances Schedules

Dr. Serpa provided a history of the Board's recent policy discussion on the issue, including prior legislative efforts and noted information was included in the meeting materials. She noted as discrepancies remain between the state and federal schedules, the committee decided additional efforts should be pursued to synchronize or otherwise address the discrepancies. Dr. Serpa noted the committee used policy questions to facilitate the discussion. The committee decided to focus on the following most troublesome drugs: Fioricet, Donnatal, Librax and Chlordiazepoxide. These drugs are not on the same schedules on the state and federal controlled substances.

Dr. Serpa noted during public comment it was suggested that the Board should consider using the schedules for different purposes, for example, using the state schedule for criminal matters and the federal schedule for medical purposes. She added the committee decided not to pursue policy changes but only to look at the four drugs: Fioricet, Donnatal, Librax and Chlordiazepoxide.

Committee Recommendation (Motion): Pursue a statutory change to match the federal schedule for the 4 identified drugs: Fioricet, Donnatal, Librax and Chlordiazepoxide.

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

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

Steven Gray commented this has been a long-standing issue with the submissions to CURES. This was resolved by requiring the federal schedule for submission to CURES. This action will help. He noted in the federal schedule there is a difference for buprenorphine which is Schedule V in California and Schedule III or IV in the federal schedule.

Dr. Serpa clarified the committee was focused on those four drugs that are unscheduled in the federal schedule but scheduled in California.

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

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

The Board took a lunch break from 12:13 p.m. to 1:00 p.m. Roll call was taken. Members present included Ryan Brooks, Lavanza Butler, Shirley Kim, Seung Oh, Jignesh Patel, Ricardo Sanchez, Maria Serpa, Debbie Veale, Jason Weisz, Albert Wong and Greg Lippe.

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

Dr. Serpa advised in October 2020, the FDA finalized its draft Memorandum of Understanding (MOU) that establishes an agreement between the respective state authority and the FDA regarding the distribution of inordinate amounts of compounded human drug products interstate as well as investigation requirements for such state's that enter the MOU.

Dr. Serpa noted detailed in the committee report is information on the conditions of the agreement, staff identified some significant challenges with the MOU. Counsel Smiley shared with the committee that she has concerns regarding the MOU. Additionally, the Board cannot sign the MOU now because the Board does not have a reporting mechanism in place. The committee discussed this complex issue using this policy questions to guide the conversation. The committee heard public comment expressing concern if the Board does not sign the MOU. She noted without an MOU in place, pharmacies that ship patient-specific products including total parenteral nutrition (TPN) to

patients outside the state would be impacted. Further, patients in some states already have no or limited access to these custom life-sustaining medications.

Dr. Serpa reported the committee received public comment encouraging the Board to sign the MOU but took no action on this item. Ms. Smiley will continue to investigate the issue so the Board can readdress before the FDA signing deadline. The committee also requested that NABP be contacted to provide a presentation on the information sharing project addressed in the MOU.

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

Ms. Smiley added if the Board does not sign the MOU by October 2021, the FDA will start to enforce the five percent limit on compounding pharmacies.

Ms. Sodergren provided once the Board's policy direction is known, staff can develop what it believes would be necessary to implement the provision of the MOU. Sodergren offered to contact the FDA and NABP to see if there is flexibility as a point of information.

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

Lauren Hood commented in support of signing the MOU as she has been on TPN her 26 years of life. She receives her TPN from a company in California while she resides in Florida and has been able to have her liver enzymes controlled for over 20 years. Ms. Hood added after 53 surgeries, her TPN has helped to keep her healthy.

Steven Gray commented items that need to be considered include what are the resources required from the legislature. He stated the FDA doesn't have the resources to monitor the compounding. He noted it will impact people throughout the nation and many states are looking to California for its action.

Dr. Serpa noted the committee heard about the required reporting in the MOU. Ms. Sodergren noted significant reporting obligations including transaction data, prescription volume data, and required information at the pharmacy level. There is additional reporting requirements with respect to complaint investigations and different types of notifications and recalls. She stated it is difficult to project resources needed as that depends if the Board is interested in participating in the MOU and noted a statutory change could be required to put some of the reporting obligations on the pharmacies.

Dr. Serpa noted the committee did not have enough information to make a policy recommendation but did not want to prevent people from receiving life sustaining products.

Dr. Wong requested the Board does not add more regulation and requirements on the pharmacies if the current system is not broken.

Richard Leong, pharmacist, Nutrishare, home infusion pharmacy that specializes in TPN, commented Nutrishare has patients nationwide because Nutrishare is able to provide what their patients' local providers are not able to do. He encouraged the Board to sign the MOU.

Rod Okamoto, founder of Nutrishare, commented the MOU in the current state is in an acceptable form because the consequence of exceeding the 50 percent is that this elevated reporting mechanism is instituted. He estimated the number of complaints would be small and the Board has systems in place to investigate complaints. He added Nutrishare's sterile pharmacy compounding experience over 30 years has not resulted in a single contaminated bag of TPN. He noted for states that sign the MOU, the FDA has contracted with NABP to develop the pharmacy reporting systems if there is an adverse patient product complaint. He added the Kentucky Board of Pharmacy reported it would not be a big impact for Kentucky surveyors.

Dr. Wong clarified he was not speaking of this case but in general. He clarified in this case, it is broken and he is in favor of signing the MOU.

Christy Pointdexter indicated a request to provide comment but was not available for public comment when called.

Daniel Martinez, CPhA, commented a letter was sent to the Board and mentioned if the Board requires pharmacies to report information to the FDA that would be a violation of the MOU. He indicated the Board would need to request resources from the legislature to participate in the MOU.

Gibran Maciel, Nutrishare, commented the MOU process has been going on for over 10 years and an extension should not be required. He stated the legislature is focused on COVID and urged to use the regulatory process for this issue. He stated he would need time to implement changes from a business operational standpoint or to the consumers who rely on Nutrishare for life sustaining nutrition.

Dr. Serpa advised this was informational and the committee will be working on the issue due to the urgency.

g. Discussion and Consideration of FDA Guidance Document, Insanitary Conditions at Compounding Facilities, Guidance for Industry

Dr. Serpa provided this agenda item was intended for education and referred to information in the meeting materials. She noted as indicated in the guidance

document, the FDA encourages states to take appropriate action and to contact the FDA when such an agency identifies a compounding facility that is engaged in poor practices and where insanitary conditions are identified.

Dr. Serpa advised the Board received new information on January 28, 2021, on an FDA warning letter and press release regarding the use of bulk drug substances. The FDA encourages compounders to know their bulk drug substance (API) supplier because drugs represent risk to patients.

Members were provided with an 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. Discussion and Consideration of the Compounding of Methylcobalamin

Dr. Serpa reported the committee again discussed this very complicated issue that was asked to be re-addressed during a previous Board meeting's public comment. Previously no action was taken on this item. Methylcobalamin has been discussed in detail at previous Compounding Committee meetings discussing USP Standards and impacts to Board proposed compounding regulations. This chemical continues to be a challenging discussion in light of the legal and safety issues. FDA inspection reports (called 483 reports) have noted observations where compounding facilities are using raw materials that are potentially insanitary (or containing hazardous contaminates). This sample is in the meeting materials committee report. There appears to be no pharmaceutical grade methylcobalamin available that would be acceptable for patient use. However, public comment was made indicating pharmaceutical grade chemical was available. This could not be validated and if available, would appear to make this a moot issue with the FDA and Board. The committee discussed the issue including access and options for patients to obtain products under the current provisions to balance product access with safety.

Dr. Serpa provided the committee received significant public comment for individuals with personal experience and prescribers detailing the benefits of methylcobalamin. All urged the Board to not take action on this issue. The committee thanked members of the public for their testimony.

Dr. Serpa reported the committee has no action on this item. Staff was asked to continue to educate licensees when the practice is identified and exercise appropriate discretion. Staff will work with the FDA and counsel on the issue and keep the Board updated.

Members were provided with an opportunity to provide comments.

Dr. Wong commented the participation and involvement of the stakeholders was helpful.

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

Danny Martinez, CPhA, commented this topic is important and emotional as it needs to be allowed. He stated there are many concerns that inspectors are de facto banning pharmacists from compounding appropriate grade methylcobalamin. He stated he made the comment that there are appropriate grade methylcobalamin available. He cannot disclose the source as that information is a trade secret. He noted on the FDA's website there is a national drug code directory where members of the public can search for unfinished drug product by NDC or name. He asked if this would be an appropriate way to verify for use.

Dr. Serpa referred Mr. Martinez to the FDA website with the press release that verifies the compounder must validate the source of their API. She noted it is documented some products are mislabeled and may not be appropriate for human use.

Dr. Serpa asked Ms. Sodergren to respond to the rumors on the de facto banning as that is not the case. Ms. Sodergren provided if a Board inspector identifies a problem with an ingredient, they will typically walk through what the issues are with the ingredient and provide education. Ms. Sodergren stated she was not aware of the Board issuing any cease and desist or interim suspension orders.

Mr. Martinez stated if the FDA requires the pharmacist has to verify the supplier and the supplier has to validate that its an appropriate grade, one of the requirements is that it has to be from an FDA registered facility. He continued if that is the case, wouldn't that by itself qualify the API is fine.

Dr. Serpa referred Mr. Martinez to the FDA press release.

Rachel Israel, general counsel and family owner of Lee Silsby Compounding pharmacy in Cleveland, Ohio, licensed in California and 45 other states commented they are similar to TPN providers as they have specialized expertise and patients rely on them. Specifically, about methylcobalamin, with respect to Board action, a cease and desist order or interim suspension order is the last thing any compounding pharmacy would want to face. She stated that disciplinary action is risky. She stated it is not accurate to say Board inspectors are not putting pressure on compounders. She continued Board inspectors are putting pressures on the compounders to stop compounding this product even

though there is nothing in California law or FDA regulations. She stated citations, orders of correction and pressure are put on compounders to stop. She stated it is not fair if there is not a law to prevent it.

Member Kim rejoined at 2:17 p.m.

Steven Gray commented that a PIC reported at the committee meeting who had a long history of compounding this product and was visited by a Board inspector. Based on what the Board inspector said the PIC stopped making the product and now the patients are out of the product that the patients consider life or death. Dr. Gray stated he tried researching the term "pharmaceutical grade" but couldn't find in federal or state law a legal definition. He stated there may be a problem with communication or understanding. Dr. Gray's understanding was that the law requires compounders to have reliable sources and meet the standard of practice for what they are compounding. He stated methylcobalamin is a metabolite of regular B12 cobalamin and because it is a metabolite, it can get past the blood brain barrier that other products can't. He stated it has to be compounded because it has to be preservative free and not likely produced on a massive scale because of the amount needed and that it is not patentable.

Dr. Serpa stated a licensee may choose to stop compounding but is not being required. She also noted the individual's specific information because it was site specific and the committee can't publicly discuss a site inspection.

Ms. Sodergren noted the FDA has taken a position on this and included is a sample 483 (FDA inspection reports) that speaks specifically to this issue. She noted there are multiple regulators and when we look at the unsanitary conditions that the FDA has established as well as some of the actions that they've taken, the Board may be providing those information points to the licensees. She noted the FDA is also doing the same.

i. Review and Discussion of Enforcement Statistics

Dr. Serpa reported the meeting materials contain enforcement statistics for the first six months of the year starting in July.

Members were provided with an 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.

Member Weisz noted he had to step out of the meeting at 2:25 p.m.

j. Future Committee Meeting Dates

Dr. Serpa reported future meeting dates in 2021 include: April 29, July 15 and October 20. She added an informational meeting on "white bagging" will be scheduled for February 18 or March 4. Information will be released when available. Dr. Serpa asked members of the public to contact the Executive Officer Anne Sodergren if interested in presenting at the informational meeting.

XI. Communication and Public Education Committee Report

Mr. Sanchez reported on the Communication and Public Education Committee Meeting held January 27, 2021.

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

Mr. Sanchez referenced relevant law in the meeting materials. He noted changes to the wording of the Notice to Consumer (NTC) would require a change in regulation and possible statute changes.

Mr. Sanchez provided at the committee's direction staff reported receiving input on refreshing the NTC from the California Alliance of Retired Americans (CARA), the California Pan-Ethnic Health Network (CPEHN), and Health Access California as well as Board Inspectors. Approximately 24 suggestions were received and included in the committee report. He provided staff recommended using more pictures and focusing the most important elements to convey to the consumer in the poster. He noted the committee accepted staff suggestions and directed staff to report back to the committee with suggested wording for a revamped poster, sample of design and sample draft regulation language that would be required to change the language.

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

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

Steven Gray commented the law allows for a video display to provide information to patients while in the pharmacy. He suggested the committee should examine encouraging or requiring video displayed to get to the public more effectively this information.

b. Discussion and Consideration of Requirement for Pharmacies to Provide a Telephone Number on Prescription Labels

Mr. Sanchez provided at the November 2019 Board meeting, the Board adopted language to amend CCR section 1707.2 related to mail order pharmacy consultation. He noted the regulation requires mail order pharmacies to provide a phone number for patients to receive consultation from a pharmacist; however, it was noted that out-of-state pharmacies must provide a toll-free number to facilitate communication between patients and pharmacists, and the number must be provided on the prescription label. He reported currently there is no requirement for in-state pharmacies to provide a phone number on labels. The Board directed the Communication and Public Education Committee to discuss and consider whether all pharmacies should be required to provide a phone number on prescription labels.

Mr. Sanchez referenced relevant law included in the meeting materials. He noted staff surveyed neighboring and same sized states. Arizona and Nevada do not require a phone number on prescription labels but Nevada requires mail order pharmacies must provide a toll-free number on a label affixed to each dispensed container. Mr. Sanchez added Texas and New York do require it.

Mr. Sanchez added staff noted a change in statute or regulation would be required and may require additional costs for pharmacies.

Mr. Sanchez noted public comment was received indicating while most pharmacies do include the phone number, the call may go to an answering service or call center which makes it difficult for a patient to receive consultation. The committee requested more information whether the Board should pursue a statutory or regulatory change. The committee directed staff to reach out to consumer groups and report back to the committee with feedback regarding the pharmacy phone number on prescription labels.

Members were provided with an opportunity to provide comments.

Dr. Wong commented it would not make sense to not have your phone number on the label and a live person should answer the telephone. Ms. Butler agreed with Dr. Wong.

Ms. Veale inquired how this issue came to the committee's attention. Board Public Information Officer Bob Dávila advised this was sent to committee following a Licensing Committee and Board Meeting in November 2019 so that consumers can have a way to reach pharmacist consultation. Ms. Sodergren added staff will reach out to consumer groups to see if there is a problem.

c. Discussion and Consideration of Developing Information Materials about the Board of Pharmacy for Consumers

Mr. Sanchez advised the Board provides the public with important information about patient care, consumer protection, and regulatory issues through a variety of print and electronic materials. These materials include brochures about counterfeit prescription drugs, an online directory of drug take-back locations, and webpages with links to drug abuse prevention resources.

Mr. Sanchez reported staff will be developing additional educational materials about the mission and work of the Board of Pharmacy. As an example, materials would provide basic information about the Board's membership – number of members, licensees and public members, Board committees, how to participate in meetings, etc. Other information could explain the rulemaking process, how complaints are investigated, the disciplinary process, and other ways that the Board performs its consumer protection functions. In addition, educational materials could explain why consumers should talk to their pharmacists and what consumers should ask about their medications.

Mr. Sanchez provided information would be posted on the Board's website and also available to download, print and distribute. Hard copies would be available to disseminate to the public at Board meetings, training events, and public outreach activities. He added these materials would increase general awareness of the Board and educate the public about the Board's role as a consumer protection agency. The committee directed staff to report back on the types of materials currently provided as well as new materials developed for public information.

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

Members of the public were provided the opportunity to provide comment on agenda items 11 b and 11c.

Steven Gray commented on agenda item 11 b that there are limited number of organizations that do not put the phone number of the pharmacy on the prescription bottle but rather the phone number of a call center or answering service. He noted this is difficult if someone has another person picking up the prescription. He stated this is very serious consumer protection issue. This is an issue for EMT and emergency room pharmacists who need to get in touch with a patient's pharmacy. He encouraged the Board to require a phone number on the prescription label that is to the pharmacy.

d. Update on Communication and Public Education Activities by Staff

1. The Script

Mr. Dávila reported articles planned for the next issue of The Script include new pharmacy laws for 2021; reminder about the new security prescription form requirements; new CURES reporting requirements; and tips for completing a pharmacy technician application. Publication is anticipated in February 2021.

2. Board-provided Training

Mr. Dávila advised inspectors and staff provided continuing education via WebEx on "Prescription Drug Abuse and Diversion – What a Pharmacist Needs to Know" on October 7 and December 16, 2020, consisting of about 150 pharmacists participating in these events.

3. Staff Outreach

Mr. Dávila noted the staff outreach activities were included in the meeting materials.

4. News Media

Mr. Dávila reported a list of new media inquiries responded to by staff were included in the meeting materials.

Members were provided with an opportunity to provide comments.

Dr. Wong inquired how the continuing education was provided. Mr. Dávila provided via WebEx.

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

e. Future Meeting Dates

Mr. Sanchez reported future meeting dates in 2021 include: April 29, July 14 and October 27.

Members were provided the opportunity to provide comment.

Dr. Wong inquired if the committee could help increase participation in the workforce survey. Ms. Sodergren advised Licensing Committee is currently working on the survey.

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

XII. Legislation and Regulation Committee Report

Mr. Lippe provided an update as the Chairperson of the Legislation and Regulation Committee. He reported the committee did not meet during the past quarter because the legislative deadline for bill introductions was February 19, 2021.

Mr. Lippe introduced Sheila Tatayan as new DCA Counsel assigned to work with the Boards on its regulations.

a. Board Adopted Regulations Approved by the Office of Administrative Law

1. Proposed Regulation to Amend Title 16, Sections 1769 and 1770, Substantial Relationship and Rehabilitation Criteria

Mr. Lippe advised this regulation proposal that was approved by the Office of Administrative Law on December 28, 2020, with an immediate effective date. He referenced meeting materials provided the regulation allows for transparency and clarity to applicants regarding rehabilitation criteria the board considers when evaluating eligibility for licensure.

Members were provided with an 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 Board Adopted Regulations Undergoing Final Review by the Office of Administrative Law

Mr. Lippe advised the Board three regulations were undergoing post-adoption review, including proposed regulations related to renewal requirements, offsite storage, and regulations related to dangerous drug distributors and third-party logistics providers. He noted summary information was provided in the meeting materials.

1. Proposed Regulation to Amend Title 16, Sections 1702, 1702.1, 1702.2, 1702.5, Renewal Requirements
2. Proposed Regulation to Amend Title 16, Section 1707, Off-Site Storage
3. Proposed Regulations to Amend Title 16 CCR Sections 1780-1783 et seq., Related to Dangerous Drug Distributors and Third-Party Logistics Providers

Members were provided with an 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.

c. Discussion and Consideration of Board Adopted Regulations Undergoing Formal Review by the Department of Consumers Affairs or the Business, Consumer Services and Housing Agency

Mr. Lippe reported the Board has two regulations undergoing post-adoption review by the Department including the Board's rulemaking related to automatic refill programs and its regulations specific to quality assurance reports, use of automated drug delivery systems, including the self-assessment form requirements. Summary information was provided in the meeting materials.

1. Proposed Regulations to Add Title 16 CCR Sections 1717.5 Related to Automatic Refill Programs
2. Proposed Regulation to Amend Title 16 CCR Section 1711 Related to Quality Assurance Programs for ADDS, Section 1713 Related to Use of an APDS, and Add Section 1715.1 Related to the ADDS Self-Assessment Forms 17M-112

Members were provided with an 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.

d. Discussion and Consideration of Board Approved Regulations Undergoing Pre-Notice Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency

Mr. Lippe advised the Board has five regulations undergoing pre-notice review by DCA including and noted summaries were included in the meeting materials:

- Regulations regarding ownership, including provisions related to ownership of pharmacies by trusts
- Updates to the Community and Hospital Self-Assessment Forms
- Updates to the Wholesaler/Third Party-Logistics Provider Self-Assessment Form.
- Amendments to the Board's inventory reconciliation requirements
- Amendments to the Board's drug loss reporting requirements

He added one regulation has moved to the next step in the rulemaking process since the release of the agenda. The Board's regulation to establish the criteria for training programs that a pharmacist must completed to provide HIV preexposure and postexposure prophylaxis was recently filed with the Office of Administrative Law. As indicated in the meeting materials, it is anticipated that the 45-day comment period will begin on January 29, 2021.

1. Proposed Regulation to Amend Title 16 CCR Section 1709 Related to Pharmacy Ownership, Management, and Control, Including Through Trusts
2. Proposed Regulation to Amend Title 16 CCR Section 1715 to Update Self-Assessment Forms 17M-13 and 17M-14
3. Proposed Regulation to Amend Title 16 CCR Section 1784 to Update the Wholesaler/3PL Self-Assessment Form 17M-26
4. Proposed Permanent Regulation to Add and Amend Title 16 CCR Section 1747 Related to Independent HIV Preexposure and Postexposure Prophylaxis Furnishing
5. Proposed Regulation to Amend Title 16 CCR Section 1715.65 Related to Inventory Reconciliation
6. Proposed Regulation to Amend Title 16 CCR Section 1715.6 Related to Reporting Drug Losses

Members were provided with an 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.

e. Discussion and Consideration of Board Approved Text to Initiate Rulemaking – Staff Drafting Documents for Pre-Notice Review by the Department of Consumer Affairs and the Business, Consumer Services and Housing Agency

Mr. Lippe advised staff are drafting the necessary documents for three rulemaking packages as a precursor to submission for pre-notice review. The rulemakings include:

- The proposal to establish training requirements and certification programs and updates the application for pharmacy technician licensure, which is incorporated by reference in the regulation.
- The Board's proposal related to requirements to maintain a current electronic mail address with the Board, should a licensee have one.
- The Board's proposal related to notification requirements for the temporary closure of licensed facilities.

1. Proposed Regulations to Amend Title 16 CCR Section 1793.5 Related to the Pharmacy Technician Application, Section 1793.6 Related to the Pharmacy Technician Training Requirements, and Section 1793.65 Related to the Pharmacy Technician Certification Programs
2. Proposed Regulation to Amend Title 16 CCR Section 1704 Related to Address Change Notification
3. Proposed Regulation to Add Title 16 Section 1708.1 Related to the Temporary Closure of Facilities

Members were provided with an 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. Future Committee Meeting Dates

Mr. Lippe reported the next committee meeting is scheduled for April 29, 2021.

XIII. Organizational Development Committee Report

a. Budget Update and Report

Mr. Lippe referenced meeting materials that report- 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 has received $14.2 million in revenue, the majority of which comes from application and renewal fees.

Mr. Lippe noted the Board has expended $11.2 million in the first five months of the fiscal year, including almost $6.9 million in personnel, almost $2 million in prorata, and almost $1.8 million in enforcement related costs. 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 3.5 months in reserve.

b. Board Member Attendance Information

Mr. Lippe provided a summary of Board Member attendance was included in the meeting materials.

c. Personnel Update

Mr. Lippe provided a personnel update was included in the meeting materials.

d. Meeting Calendar for 2021

Mr. Lippe advised the meeting calendar for the remainder of 2021 was included in the meeting materials. He noted the Board's next meeting is scheduled for March 18, 2021.

Members were provided with an 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.

XIV. Discussion and Possible Board Action for the Increase in the Exempt Level and Salary of the Executive Officer Position

Mr. Lippe introduced Olivia Trejo, Section Chief, Office of Human Resources, Department of Consumer Affairs.

Ms. Trejo addressed the Board regarding the possible Board action for the increase in the exempt level and salary of the executive officer. She referenced the memo that was provided as part of the meeting materials.

Ms. Trejo explained the executive officer for the Board of Pharmacy is currently at Exempt Level G. She further explained there is a compaction issue between that classification and the salary range with that of the assistant executive officer and supervising inspectors classifications. Ms. Trejo advised when increasing the exemption level, factors to consider include program complexity, program growth, health and safety considerations and salary compaction with classifications reporting to the executive officer.

Members spoke in support of increasing the exemption level and salary of the executive office due to the reasons listed by Ms. Trejo including salary compaction.

Members inquired how it was possible the lower reporting to the executive officer made more than the executive officer. Ms. Trejo explained the positions that are civil service (e.g., assistant executive officer, supervising inspector, etc.) go through cost of living increases or recruitment and retention pay that the executive officer is not eligible because it is an exempt position.

Members discussed recommending and increase to Exempt Level E. Ms. Trejo explained the process would be to submit a justification for approval through the Department, Agency and Governor's Office and the California Department of Human Resources for approval. She informed the Board that to increase two levels is not common. She indicated the request may be approved, denied or modified.

Members discussed going one or two levels at one time or attempt an increase in one level one year and pursing the next increase the following year. Members agreed Ms. Sodergren has done an incredible job and should get as much of an increase as possible. Members expressed concern for their request being denied and not securing any increase based on previous attempts.

Ms. Trejo explained when submitting the justification the focus should be the program complexity, the various licenses, Board growth and salary compaction.

Motion: Submit a request to the Department of Consumer Affairs to increase the exempt level of the Board's executive officer position to a level E and further increase the salary of the executive officer to the maximum of the salary range for level E.

M/S: Oh/Veale

Members were provided with an opportunity to provide comments.

Members expressed concern for no increase being received if the request is denied in full. However, their sense from Ms. Trejo was that the request could be approved, denied or modified.

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

Steven Gray commented in requests like these, you never get more than you ask for and in other states the Board of Pharmacy have received a consideration of complexity over other licensing boards because Boards of Pharmacy license people and facilities in the home state as well as outside of the home state. Additionally, Boards of Pharmacy must deal on a national level with the FDA whereas the FDA doesn't regulate the practice of medicine or dentistry. He also suggested benchmarking to other licensing boards.

Paige Talley, CCAP, requested the motion be re-read. Mr. Lippe re-read the motion.

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

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

XV. Executive Officer Report

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

Ms. Sodergren provided an update to the broad waivers issued and specifically waiver issued January 27, 2021, under the president's delegated authority, specific to supervision of interns providing vaccinations as there was no allowance for interprofessional supervision. The waiver provides interprofessional supervision for pharmacist interns.

Ms. Sodergren advised both site specific waivers were still being issued commonly to allow for the renewal of licenses without an inspection. She noted mobile pharmacies were being issued consistent with BPC 4062 to allow for vaccinations to occur outside of the pharmacy where they are using pharmacy technicians.

Ms. Sodergren reported Board offices were re-opened after meeting materials were released. Inspectors are focused on case investigation report and mediations. Inspectors are not going out into the field unless it is an eminent public danger situation. The Board anticipates inspections resuming in a few weeks.

Ms. Sodergren advised CDPH is spearheading the vaccine effort and the Board is lending support where it can to help facilitating vaccine distribution.

b. Update on Implementation of Controlled Substances Security Forms as required by Assembly Bill 149 (Statutes of 2019)

Ms. Sodergren provided an update on the implementation of AB 149 which changed the security prescription form. Provisions had been in the law for over a year but there was a transition period. New requirements took effect January 1, 2021. The Board has been educating licensees since enactment of AB 149 and at the end of the 2020 began working with prescriber boards and the Department of Justice to facilitate additional education and reminders in the hopes of avoiding patients being negatively impacted by the transition.

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

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

Paige Talley requested clarification if there was a waiver in place to allow pharmacy technicians to provide vaccines outside of the pharmacy premises. Ms. Sodergren clarified there is not a waiver but the Board is issuing mobile pharmacies for that purpose. She added DCA issued a waiver that will allow

pharmacy technicians to administer vaccines, but under the law pharmacy technicians can only work inside a pharmacy. She further explained under BPC 4062 the provisions for a mobile pharmacy are being used so that pharmacy technicians can administer vaccines outside of a pharmacy as deemed appropriate by the supervising pharmacist.

XVI. Adjournment

The Board adjourned at 3:10 p.m.