California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

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

Date: July 29-30, 2020

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 (7/29/20 only)
Lavanza Butler, Licensee Member
Seung Oh, Licensee Member
Shirley Kim, Public Member (7/30/20 only)
Jignesh Patel, License Member
Ricardo Sanchez, Public Member
Albert Wong, Licensee Member

Staff Present:
Anne Sodergren, Executive Officer
Norine Marks, DCA Staff Counsel
MaryJo Tobola, Senior Enforcement Manager
Debbie Damoth, Administration Manager

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

President Lippe called the meeting to order at 10:05 am. 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 instruction 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 all the open session items, except adjournment.

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

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

Danny Martinez, CPhA, requested an item be placed on the agenda of the Enforcement and Compounding Committee related to CFR 530.13. Mr. Martinez advised the Board that CPhA members have noted the Board has started ordering notices of correction dealing with the compounding of veterinary drug products. Mr. Martinez stated in the spirit of education, this item should be agendized to review current law to eliminate confusion.

Members did not act on the request but directed staff to review the federal law to determine if there have been any changes for consideration to place the item on a future agenda for discussion.

III. Approval Board Meeting Minutes

Motion: Approve the June 18, 2020, Board Meeting minutes.

M/S: Brooks/Veale

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

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

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

IV. Update from the Department of Consumer Affairs

The Board received an update from Carrie Holmes, Deputy Director of Board and Bureau Relations. Ms. Holmes reported on new members of the new DCA leadership and reminded the Board of the DCA Director Kirchmeyer's priority to improve the regulation process. DCA developed a new regulations unit and online tracking system to assist Boards and Bureaus with regulations.

Ms. Holmes reported DCA's response to COVID-19 includes implementing teleworking and physical distancing for those who can't telework. DCA offices were temporarily closed in March to prevent the spread of COVID-19 and reopened June 15, 2020, with preventative measures in place for the safety of employees and consumers. Ms. Holmes thanked the Board for reassigning five staff members dedicated to contact tracing. Ms. Holmes added Board inspectors are assisting with compliance inspections to assess compliance with statewide mandates and guidance provisions in place to address COVID-19.

Ms. Holmes advised members that DCA has been issuing waivers needed to maintain a licensed workforce during COVID-19. To date, 38 waivers were issued ranging from topics such as telehealth, continuing education and licensure reinstatement. Ms. Holmes encouraged the Board to look at existing waivers to see what would be helpful to keep long term.

Ms. Holmes announced that DCA's Board Member Orientation Training (BMOT) has transitioned to an online WebEx training platform. Members were reminded of required training that must be completed within one year of appointment and one year of reappointment. The next BMOT is scheduled for October 2020.

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

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

V. Discussion and Consideration of Adoption of Board Approved Regulations, Comments Pending Review by the Board

a. Proposed Regulations to Amend Title 16 CCR Sections 1780-1783 et seq., Related to Dangerous Drug Distributors and Third-Party Logistics Providers

President Lippe referred to meeting materials for the proposed regulations to amend Title 16, CCR Sections 1780-1783, related to dangerous drugs distributors and third-party logistics providers noting that no comments were received during the 45-day public comment period. Mr. Lippe advised members that the Board could adopt the regulations as noticed or amend the regulation to address any concerns and notice the regulation for an additional 15-day

comment period. Mr. Lippe noted as no comments were received, he recommended the Board adopt the language as noticed.

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

Motion: Adopt the regulatory language as noticed on May 29, 2020, and delegate to the executive officer the authority to make technical or non-substantive changes as may be required by Control agencies to complete the rulemaking file.

M/S: Oh/Butler

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

The Board heard comments from Steven Gray supporting the regulation as published. Dr. Gray noted that given there are substantial differences in standards from the USP reference in the current regulation and one that will be in the latest edition, he encouraged the Board to consider education and a phased in period as wholesalers and 3PLs will need time to phase in the new requirement.

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

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

VI. Licensing Committee Report

a. Discussion and Consideration of Legislative Proposal to Expand Existing Authority for Pharmacists to Order and Administer Immunizations Approved by the FDA for the Prevention of Vaccine-Preventable Diseases

Chairperson Veale provided that Business and Professions Code (BPC) section 4052.8 establishes when a pharmacist may independently initiate and administer vaccines based on the ACIP schedule.

Chairperson Veale noted as the nation and California continues to respond to the current pandemic, it is appropriate to determine if policy changes are necessary to ensure California is positioned to readily deploy vaccines once approved by the FDA in response to the current health crisis, but future crises.

Chairperson Veale advised the FDA's Center for Biologics Evaluation and Research (CBER) is responsible for regulating vaccines in the United States. Vaccine clinical development follows a similar general pathway as for drugs and other biologics. A sponsor who wishes to begin clinical trials with a vaccine must submit an Investigational New Drug (IND) application to the FDA. The IND describes the vaccine, its method of manufacture, and quality control tests for release. Also included is information about the vaccine's safety and ability to elicit a protective immune response (immunogenicity) in animal testing, as well as the proposed clinical protocol for studies in humans.

Chairperson Veale provided vaccine approval also requires the provision of adequate product labeling to allow health care providers to understand the vaccine's proper use, including its potential benefits and risks, to communicate with patients and parents, and to safely deliver the vaccine to the public.

Chairperson Veale reported during the Licensing Committee meeting members spoke in support of a policy to expand authority for pharmacists to initiate and administer FDA approved vaccines. Further, the committee was advised of recently amended legislation, AB 1710 (Wood) seeking to facilitate such authority. Members and public discussed both the proposal provided for the committee's consideration and the broader approach being offered in the legislation. The committee directed staff to broaden the committee proposal to reflect the AB 1710 approach.

Chairperson Veale stated as part of the meeting, public comment suggested that the policy proposal should allow pharmacists to order and administer immunization when a vaccine is authorized for use by the FDA versus when the FDA approves a vaccine.

Chairperson Veale reported the committee recommendation to move forward with broadening the statutory proposal to be consistent with the language in AB 1710 to administer vaccines that are approved by the FDA and to move forward with recommending to the full Board in July. Further, staff and the committee chair to work with legal counsel to modify the language based on the policy direction discussed.

Chairperson Veale advised staff amended the proposed amendments to BPC 4052.4 to incorporate the policy changes requested by the committee. Board staff recommended that the proposal establish authority for FDA approved vaccines.

Chairperson Veale referenced the proposed language to include vaccines approved by the federal Food and Drug Administration.

Proposal to Amend BPC 4052.8.
(a) In addition to the authority provided in paragraph (11) of subdivision (a) of Section 4052, a pharmacist may independently initiate and administer vaccines approved by the federal Food and Drug Administration ~~listed on the routine immunization schedules recommended by the federal Advisory Committee on Immunization Practices (ACIP), in compliance with individual ACIP vaccine recommendations, and published by the federal Centers for Disease Control and Prevention (CDC)~~ for persons three years of age and older.

(b)In order to initiate and administer an immunization described in subdivision (a), a pharmacist shall do all of the following:
(1) Complete an immunization training program endorsed by the CDC or the Accreditation Council for Pharmacy Education that, at a minimum, includes handson injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines, and shall maintain that training.
(2) Be certified in basic life support.
(3) Comply with all state and federal recordkeeping and reporting requirements, including providing documentation to the patient's primary care provider and entering information in the appropriate immunization registry designated by the immunization branch of the State Department of Public Health.
(c) A pharmacist administering immunizations pursuant to this section, or paragraph (11) of subdivision (a) of Section 4052, may also initiate and administer epinephrine or diphenhydramine by injection for the treatment of a severe allergic reaction.

Motion: Direct staff to implement policy through existing or new vehicle in accordance with the proposed change to BPC 4052.8 as provided.

M/S: Wong/Butler

Board Members were provided with an opportunity to provide comments.

Dr. Serpa noted AB 1710 has the FDA added but did not include removing reference to the ACIPs schedule as included in the Board staff recommended language. Dr. Serpa and Dr. Oh inquired about this approach. Ms. Veale noted that a vaccine would not be included in the ACIP list unless it was FDA approved. Members discussed removing the stricken language to match the

language of AB 1710. DCA Counsel Marks indicated that FDA approved vaccines would include all vaccines includes ACIP.

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

Danny Martinez, CPhA, sponsor of AB 1710, commented it would be easier to support AB 1710 rather than having competing measures.

Steven Gray agreed with the Committee's language and noted challenges with the language in AB 1710.

Lindsay Gullahorn, CRA & NACDS, spoke in support of AB 1710 and support for the Board's proposal but wanted to allow for FDA "authorized" versus FDA "approved" to include vaccines under investigation and approved by the FDA.

Robert Stein commented on the urgency of getting the changes made. As written AB 1710 does not contain an urgency clause and will not go into effect until January 1, 2021.

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

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

b. Discussion and Consideration of Pharmacists' Authority to Perform CLIA Waived Tests for COVID-19

Chairperson Veale advised members that on May 12, 2020, DCA Director Kirchmeyer issued a waiver to allow for a pharmacist to order and administer COVID-19 tests in California for 60 days. On July 7, 2020, Director Kirchmeyer issued a 2nd waiver and extended the provision to September 9, 2020. Along with the waiver, a guidance document was issued that provided additional details regarding the temporary authorities. Ms. Veale noted that the waiver does not allow for the processing of the sample at a pharmacy, unless the pharmacy is licensed as a clinical laboratory and meets the requirements of BPC 1265.

Chairperson Veale reported during the June 18, 2020, Board Meeting, members received public comment requesting a future agenda item to discuss the issue of pharmacists performing CLIA waived COVID-19 antigen testing. The commenter indicated that the current situation is rather murky in terms of whether a pharmacist is able to actually perform such a test as they have CLIA waived equipment and reagents. As part of the comments, members were advised that CDPH has determined that COVID-19 testing shall be performed only in an appropriately licensed lab under direction of a lab director.

Chairperson Veale noted during the committee meeting members considered relevant law establishing the authority for pharmacists to order and administer tests which reside in both provisions of pharmacy law as well as other provisions of the BPC related to the operations of clinical laboratories and authorized staff under the regulation of the California Department of Public Health, Laboratory Field Services. The committee discussion noted that under the provisions of existing law, pharmacists' ability to perform CLIA waived tests are limited to specified tests, including provisions of BPC 4052.4 which provides authority for "pharmacists routine patient assessments procedures"; however, the provisions are limited to blood glucose, hemoglobin A1c, or cholesterol tests. These tests can also be processed at the pharmacy, if the pharmacy is appropriately licensed by the California Department of Public Health, Laboratory Field Services.

Chairperson Veale advised aside from the DCA approved waiver, there is no provision of law that allows for pharmacists to order, collect specimens, or process specimens for COVID-19 tests. Further, unless licensed as a clinical laboratory under Laboratory Field Services, pharmacies cannot process specimens.

Chairperson Veale reported the committee received presentations on the current legal provisions, provisions for testing under the DCA Director issued waiver, and opportunities for expanded testing if additional authority could be granted to pharmacists. The committee was advised that 42 states allow pharmacists to perform end-to-end testing. Presenters requested the Committee and Board enhance advocacy efforts within the administration to facilitate broader authorities. The committee spoke in support of such expansion and noted that cross jurisdictional issues would need to be resolved. The committee suggested engagement with DCA and CDPH is necessary to expand access to testing and to facilitate more robust use of point of care testing, that allows for more timely access to test results.

Chairperson Veale noted subsequent to the meeting, updated testing guidance was released by the California Department of Public Health (CDPH). As indicated in the guidance, CDPH recommends first prioritizing testing of hospitalized individuals with signs or symptoms of COVID-19 infection followed by testing of other symptomatic individuals and higher risk asymptomatic

individuals and then other asymptomatic individuals when certain conditions exist. This guidance should be used for prioritization of patient populations as well as for the purposes of guiding laboratories in managing specimen processing.

Executive Officer Sodergren acknowledged challenges outside the Board's span of control. She stated, the Board's role needs to be one of advocacy as CLIA waived tests and administering the tests is within the knowledge, skills and abilities of a pharmacist. Ms. Sodergren noted, as this issue crosses jurisdictions, the committee is aware of the importance of advocating or expanding authority through a legislative change or executive order. Advocacy and education can be used to partner with others.

Chairperson Veale noted the committee feels strongly that they'd like to get to a point where pharmacist can do end to end testing beyond the three allowed tests and acknowledged we can advocate. Ms. Veale requested member comments. Dr. Patel supported advocating for tests like the flu and other point of care tests as appropriate noting it would benefit the public. Ms. Veale agreed the committee and executive officer can advocate for the Board.

Motion: Direct staff to advocate Board Policy to expand provisions of CLIA waived testing to allow for pharmacists to participate in end-to-end testing for COVID-19.

M/S: Oh/Butler

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

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

Danny Martinez, CPhA, agreed with Chairperson Veale and offered to answer questions about CPhA's presentation.

A member of the public thanked the Board for being supportive and requested the Board review federal law that may preempt state law allowing pharmacists to perform the tests as timing is of the essence and supported reaching out to the Governor.

Chairperson Veale inquired about federal law preempting state law. Ms. Marks provided an analysis would be required. Ms. Veale requested to keep it on the agenda to get clarification.

Lindsay Gullahorn, CRA & NACDS, commented in support of the Board's efforts to expand the ability of pharmacists to perform end to end tests and can be a resource, if needed.

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

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

c. Update on Implementation of SB 159 (Weiner, Chapter 532, Statutes of 2019) Related to HIV Preexposure and Postexposure Prophylaxis

Chairperson Veale reported during the committee meeting members were provided an update on the status of the Board provided training program. The training program is being developed in collaboration with subject matter experts, including experts from the Office of AIDS. Consistent with the emergency regulations, a training program must either be approved by the Board or be provided by a provider accredited by an approved accreditation agency, including the Accreditation Council for Pharmacy Education or the California Pharmacists Association.

Chairperson Veale noted the committee was advised that the California Society of Health Systems Pharmacists (CSHP) has completed development of a training program that will be offered on July 24, 2020. Members were advised that the training program is free and will be posted online following a few live training programs. The Pharmacist Letter has also developed a training but the cost is unknown. The Board's training program is due in the fall of 2020. To date, the Board has not received any requests for Board approval of training programs.

Chairperson Veale reported the committee received a comment from the public if the language allows schools of pharmacy curriculum to cover the training. The proposed language was updated by the Chairperson and Executive Officer to clarify the intent was the curriculum in a school of pharmacy in California could be used in place of the training for Preexposure and Postexposure Prophylaxis (PEP and PrEP).

Proposal to Add Section 1746.6 to Title 16 of the California Code of Regulations, to read as follows:

§ ~~1747~~ 1746.6. Independent HIV Preexposure and Postexposure Prophylaxis Furnishing.

(a) Prior to independently initiating and furnishing HIV preexposure and/or postexposure prophylaxis to a patient pursuant to Business and Professions Code sections 4052.02 and 4052.03, a pharmacist shall successfully complete a training program approved by the board, or provided by a provider accredited by an approved accreditation agency, or as part of the curriculum of a qualifying degree program completed after 2021 from an accredited California school of pharmacy. The training program shall satisfy the following criteria:
(1) Each training program shall be specific to the use of HIV preexposure and postexposure prophylaxis, and include at least 1.5 hours of instruction covering, at a minimum, the following areas:
(A) HIV preexposure and postexposure prophylaxis pharmacology.
(B) Requirements for independently initiating and furnishing HIV preexposure and postexposure prophylaxis contained in Business and Professions Code sections 4052.02 and 4052.03.
(C) Patient counseling information and appropriate counseling techniques, including at least, counseling on sexually transmitted diseases and sexual health.
(D) Patient referral resources and supplemental resources for pharmacists.
(E) Financial assistance programs for preexposure and postexposure prophylaxis, including the Office of AIDS' PrEP Assistance Program (PrEP-AP).
(F) Clinical eligibility recommendations provided in the federal Centers for Disease Control and Prevention (CDC) guidelines defined in Business and Professions Code sections 4052.02(c) and 4052.03(c).
(2) The training program shall require the passing of an assessment based on the criteria of (a)(1) with a score of 70% or higher to receive documentation of successful completion of the training program.
(b) A pharmacist who independently initiates or furnishes HIV preexposure and/or postexposure prophylaxis pursuant to Business and Professions Code sections 4052.02 and 4052.03 shall maintain documentation of their successful completion of the training program for a period of four (4) years. Documentation maintained pursuant to this subdivision must be made available upon request of the board.

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

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

Counsel Marks expressed concern with limiting it to the curriculum to just include California. Ms. Sodergren suggested keeping the language with the removal of the word California and clarify in the statement of reason that the Board intends to verify requirements with the dean or registrar of the school of pharmacy. Ms. Marks stated she believed the language should contain the requirement.

President Lippe requested Counsel Marks provide language to address her concern.

The Board took a break from 11:34 am and returned from break at 11:47 am. Roll call was taken after the break. Board Members present: Debbie Veale, Seung Oh, Ricardo Sanchez, Jignesh Patel, Lavanza Butler, Albert Wong, Ryan Brooks, Maria Serpa, and Greg Lippe. A quorum was established.

Ms. Marks presented her updated language to address her concern.

Proposal to Add Section 1746.6 to Title 16 of the California Code of Regulations, to read as follows:

§ ~~1747~~ 1746.6. Independent HIV Preexposure and Postexposure Prophylaxis Furnishing.

(a) Prior to independently initiating and furnishing HIV preexposure and/or postexposure prophylaxis to a patient pursuant to Business and Professions Code sections 4052.02 and 4052.03, a pharmacist shall successfully complete a training program approved by the board, or provided by a provider accredited by an approved accreditation agency, or as part of the curriculum of a qualifying degree program completed after 2021 from a recognized school of pharmacy. The training program shall satisfy the following criteria:

(1) Each training program shall be specific to the use of HIV preexposure and postexposure prophylaxis, and include at least 1.5 hours of instruction covering, at a minimum, the following areas:

(A) HIV preexposure and postexposure prophylaxis pharmacology.

(B) Requirements for independently initiating and furnishing HIV preexposure and postexposure prophylaxis contained in Business and Professions Code sections 4052.02 and 4052.03.

(C) Patient counseling information and appropriate counseling techniques, including at least, counseling on sexually transmitted diseases and sexual health.
(D) Patient referral resources and supplemental resources for pharmacists.
(E) Financial assistance programs for preexposure and postexposure prophylaxis, including the Office of AIDS' PrEP Assistance Program (PrEP-AP).
(F) Clinical eligibility recommendations provided in the federal Centers for Disease Control and Prevention (CDC) guidelines defined in Business and Professions Code sections 4052.02(c) and 4052.03(c).
(2) The training program shall require the passing of an assessment based on the criteria of (a)(1) with a score of 70% or higher to receive documentation of successful completion of the training program.
(3) Training obtained as part of a qualifying graduate degree program can be documented by a written certification from the registrar or training director of the educational institution or program from which the licensee graduated stating that the training is included within the institution's curriculum required for graduation at the time the applicant graduated, or within the coursework that was completed by the applicant.
(b) A pharmacist who independently initiates or furnishes HIV preexposure and/or postexposure prophylaxis pursuant to Business and Professions Code sections 4052.02 and 4052.03 shall maintain documentation of their successful completion of the training program for a period of four (4) years. Documentation maintained pursuant to this subdivision must be made available upon request of the board.
Note: Authority cited: Sections 4005, 4052.02, and 4052.03, Business and Professions Code. Reference: Sections 4052, 4052.02, and 4052.03, Business and Professions Code; Section 120972, Health and Safety Code.

Motion: Approve this proposed rulemaking to include approval of the proposed addition of Section 1746.6, Independent HIV Preexposure and Postexposure Prophylaxis Furnishing and initiate the formal rulemaking process. Further, delegate to the executive officer and chairperson of the Licensing Committee the authority to make any non-substantive changes and clarifying changes consistent with the board's policy direction upon recommendations of the control agencies.

M/S: Wong/Veale

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

Danny Martinez, CPhA, requested the item be sent back to committee for further analysis. Mr. Martinez stated he was not clear what a training director would be considered at a school of pharmacy.

Executive Officer Sodergren expressed concern with such an approach noting that the emergency regulation will be expiring. Ms. Sodergren stated this is draft and will be released for the 45-day comment period for the public to provide comment to the Board for consideration.

Steven Gray commented the concept of having it as a part of the school's training program was already approved by the Committee and was inadvertently omitted when the emergency regulation was noticed. Dr. Gray agreed with Executive Officer Sodergren's comment that moving forward there will be an opportunity to fine tune the language and urged the Board to move forward to begin the 45-day comment period. Dr. Gray reminded this was part of an urgency statute and part of an urgency public health matter and as such shouldn't be delayed.

Chairperson Veale thanked Dr. Gray for confirming the Committee's direction in past Committee discussions.

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

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

d. Discussion and Consideration of Proposal to Develop a Temporary Closure Status and Mandatory Notification Requirement for Board Licensed Sites

Chairperson Veale reported in response to construction issues, declared disasters, and civil unrest, Board licensed businesses at times must temporarily close. Although not required, some facilities notify the Board when temporary

closures occur. Notification allows the Board to maintain a better operational history in an informal fashion and provides transparency to consumer, licensees and other healthcare practitioners through the Board's website license lookup.

Chairperson Veale noted current law does not establish a requirement for notification of a temporary closure status. Requiring notifications would ensure consistent reporting requirements for businesses licensed by the Board.

Chairperson Veale reported during the committee meeting, members discussed the draft policy proposal, noting the importance for the Board to have an accurate operational history as well as the importance of accurate operational status for consumers. Members spoke in support of the policy proposal but expressed concern that, as drafted, could be viewed as punitive. The punitive portion was removed in response to stakeholders. Subsequent to the meeting, staff updated the policy proposal to incorporate changes recommended by members.

> ***Proposal to Add Title 16, California Code of Regulations Section 1708.1 as follows:***
>
> ***§ 1708.1. Notification of Temporary Closure.***
> *A permit holder shall notify the board of any temporary closure of a facility as soon as any closure exceeds three consecutive calendar days. Closure dates will be public information.*
>
> *Reference: BPC 4312*

Committee Recommendation (Motion): Move forward with recommending the Board initiate the rulemaking based on the proposed language for CCR 1708.1. The Members instructed the Executive Officer and Committee Chair to work with Legal on making minimal edits to clarify when the pharmacy needs to notify the Board on the three days as discussed during the meeting.

Board Members were provided with an opportunity to provide comments. Members discussed the required number of days a pharmacy was closed before notifying the Board. Executive Officer Sodergren added from a consumer's perspective when waiting for your prescription to be filled and you do not know the pharmacy is closed, seven days is a long time. Three consecutive calendar days was selected as the threshold to contact the Board to assist the consumers in knowing if the pharmacy was closed when waiting for a prescription to be filled. A suggestion was made to have a sign if the pharmacy was closed for more than 24 hours. The members discussed temporary closure would apply to any reason the pharmacy is closed for three consecutive calendar days.

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

Danny Martinez, CPhA, opposed the motion, stating it is not necessary. Mr. Martinez inquired as to what the Board would do with the information.

Members clarified the information would be used to update the Board's website with the closure status so that patients know where to go to have their prescriptions filled.

Steve Gray commented in support that from a public perspective, a lot has changed such as 30-day supply limit and opioid prescription limits. Dr. Gray noted there were many other reasons for the Board to consider this including: pharmacy security, status of licensee and implications for patients especially for community pharmacies that do not share databases with another pharmacy who could assist the patient with their needs.

Paige Talley, as a consumer, commented in favor of putting a notice on the door if a pharmacy is closed. As a representative of CCAP, she supported the proposal stating there would not be a problem putting a sign on the door.

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

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

e. Discussion and Consideration of Proposed Amendments to Title 16, California Code of Regulations Section 1704, Change of Address

Chairperson Veale reviewed relevant law CCR Section 1704 that establishes the requirement to a licensee to provide a current residence address with the Board and to report any change in a residence address within 30 days of such change.

Chairperson Veale advised the Board has previously indicated its preference to streamline communication with applicants and licensees. Communication

through email is an efficient way to communicate with applicants and licensees; however, there is no requirement for applicants and licensees to provide the Board with an email address, nor maintain such an address when changes occur.

Chairperson Veale advised during the meeting, members considered a regulation change that would require an applicant or licensee to advise the Board of a change in email address, if they have one. Committee members agreed with the advantages of applicants and licensees providing the Board with email addresses but expressed concern that email addresses could then be released to the public. Counsel advised that personal information such as email addresses and telephone numbers are not releasable. The committee also expressed concern with language in the proposal that referenced the potential for enforcement action for noncompliance with the requirement.

Committee recommendation (Motion): Move forward with recommending to the Board imitating the rulemaking process with the proposed language and to remove subsection (c) unless the Executive Officer has determined this requirement is not included in another section of pharmacy law.

Chairperson Veale reported subsequent to the meeting, staff updated the proposal consistent with the direction of the committee.

> ***Proposal to Amend Title, 16, CCR 1704 as follows:***
> ***§ 1704. ~~Change of~~ Providing Addresses.***
> *(a) Each person holding a certificate, license, permit, registration or exemption to practice or engage in any activity in the State of California under any and all laws administered by the Board shall file a proper and current residence address with the Board at its office in Sacramento and shall within 30 days notify the Board at its said office of any and all changes of residence address, giving both the old and new address.*
> *(b) Each applicant and person holding a certificate, license, permit, or registration who has an electronic mail address shall provide to the Board that electronic mail address and shall maintain a current electronic mail address, if any, with the Board.*

Motion: Initiate a rulemaking to amend Section 1704 and to delegate to the Executive Officer the authority to make changes consistent with the Board's policy direction at the request of the control agencies or otherwise necessary.

M/S: Wong/Butler

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

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

Robert Stein commented BPC 4013 addresses email notification to the Board's notification list and requested clarification if this is a different email expectation list. Counsel Marks confirmed it was a different email expectation as discussed at the committee level.

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

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

f. Licensing Statistics

Chairperson Veale reported the quarterly licensing statistics for fiscal year 2019/2020, were provided in the meeting materials. Ms. Veale noted a review of three-year data provided in the meeting materials indicates a slight reduction in the number of individual applications received as well as licenses issued. Further, there is a modest increase in site applications received. The number of site licenses issued shows a large growth, but this is primarily a reflection of the increase in ADDS licenses and government owned clinics seeking licensure. The Board's overall licensee population remains relatively flat.

Chairperson Veale noted the general application and deficiency mail processing times by license type were provided in the meeting materials reflecting data current as of June 26, 2020. The data reflects the time from when an application or deficiency response is received by the Board through to the time it is processed by licensing staff. The standard performance processing time is within 30 days for initial applications and is within 10 days for deficiency mail.

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

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

The Board took a break for lunch from 12:32 pm and returned from break at 1:12 pm. Roll call was taken after the break. Board Members present: Ricardo Sanchez, Seung Oh, Jignesh Patel, Lavanza Butler, Maria Serpa, Albert Wong, Ryan Brooks, Debbie Veale and Greg Lippe.

VII. Enforcement and Compounding Committee Report

Chairperson Serpa provided the report which was a review of the Enforcement and Compounding Committee Meeting held on July 9, 2020. She noted draft meeting minutes were included in the meeting materials. Dr. Serpa noted there were several presentations at the meeting.

a. Summary of Presentation and Discussion on the Administrative Case Process

Chairperson Serpa provided during the committee meeting members received a joint presentation by Deputy Attorney General Kristina Jarvis and Michelle Angus, Assistant Chief Counsel, Department of Consumer Affairs on the administrative case process established in the Government Code. The committee recommended that all Board members and interested members of the public review the presentation. Dr. Serpa advised the webcast of the meeting was posted on the Board's website, which includes the presentation provided. Dr. Serpa added a general flowchart of the disciplinary process was included in the meeting materials.

Board Members were provided with an opportunity to provide comments.

Vice President Veale requested staff work with the Office of Attorney General to research if the presentation could be made into a continuing education course for the Board's consideration.

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

b. Discussion and Consideration of Board's Citation and Fine Program.

Chairperson Serpa advised BPC section 4314 establishes the authority for the Board to issue citations which may include fines and/or orders of abatement.

Chairperson Serpa reported as part of the May 2018 Board Meeting, members suggested that staff consider using the abatement provisions, especially in cases where the violations involved a medication error. Since that time, Board staff have been integrating abatements. Further, as part of the Board's October 2018 Board Meeting, the Board updated its Strategic Plan to include additional strategic goals. Related to this agenda item, Goal 2.10, Evaluation of the

Board's Citation and Fine Program, was added. Since that time, the Committee has received annual reports on the program.

Chairperson Serpa reported during the July 9, 2020, meeting, members received a presentation on the Citation and Fine program by Executive Officer Sodergren. Dr. Serpa noted the presentation included summary information for the fiscal year 2019/20 including the most common violations that resulted in the issuance of a citation and fine and information on the use of orders of abatements. As part of the discussion, the committee noted the increased use of the order of abatement provisions, consistent with the policy direction previously provided to staff.

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

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

c. Discussion and Consideration of Board's Inspection Program

Chairperson Serpa noted pharmacy inspections are conducted by board inspectors and are triggered for a variety of reasons including receipt of consumer complaints, required annual inspections for specific license types or routine inspections to determine if a pharmacy complies with all state and federal laws and regulations. This process also involves an educational component, wherein licensees have an opportunity to meet and speak with board inspectors, ask questions and receive guidance. The Board established a policy to have all pharmacies inspected at least once every four years.

Chairperson Serpa advised during the committee meeting members received a presentation on inspection activities from Executive Officer Sodergren. Dr. Serpa noted the presentation was included in the meeting materials as well as posted on the meeting's webcast. Dr. Serpa advised in response to the pandemic, onsite inspections were suspended for several months. Following the presentation, members noted the number of pharmacies that have not been inspected within the last four years and requested that staff prioritize inspections of those pharmacies in the coming year.

Board Members were provided with an opportunity to provide comments. Vice President Veale commented on the high quality of the three presentations and encouraged Board Members, licensees and the public to watch the presentations.

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

d. Discussion and Consideration of Board's Enforcement Statistics

Chairperson Serpa noted enforcement statistics were included as part of the meeting materials. Dr. Serpa advised a three-year comparison of data indicates a 5% decline in the number of investigations initiated and a 21% decline in the average days for investigation. The data also indicated a 28% increase in the number of Letters of Admonishment issued, and a 34% decrease in the citations issued, and a 54% decrease in fines collected. There was also a significant decrease in the number of cases referred to the OAG and a resulting decrease in accusations filed. The number of licenses revoked remained relatively flat while the number of licenses placed on probation decreased by about 9%. Surrendered licenses increased about 31%.

Chairperson Serpa provided a three-year comparison of data for substance use which indicated about a 15% increase in participants of the Pharmacist Recovery Program and a decrease in the number of drug tests ordered. Data also suggested a reduction in relapse and cease practice orders.

Chairperson Serpa provided as of June 15, 2020, the Board had 1371 field investigations pending. Dr. Serpa noted a breakdown providing more detail in the various investigation processes was included in the meeting materials.

Chairperson Serpa reported as part of the committee's discussion, the committee noted improvement from the January data, including a slight reduction in investigation times, from 186 average days to currently 170 days as well as significant improvement in the average days to complete supervisor review which decreased from an average of 107 days as reported at our January meeting to a current average of 41 days. However, the committee also expressed concern that second level review time has doubled from an average of 20 days to currently an average of 42 days.

Board 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; however, no comments were provided.

VIII. Communication and Public Education Committee Report

Chairperson Sanchez provided a review of the Communication and Public Education Committee Meeting held on July 8, 2020. He noted draft meetings minutes were included in the meeting materials.

a. Discussion and Consideration of Communication Plan Regarding SB 159 (Wiener, Chapter 532, Statutes of 2019) Related to HIV Preexposure and Post Exposure Prophylaxis Background

Chairperson Sanchez provided at the January 2020 committee meeting, members discussed how the Board could educate pharmacists to initiate and furnish HIV preexposure and postexposure prophylaxis – known as HIV PrEP and PEP – as authorized by SB 159. Members noted the Board could partner with schools, professional organizations, and stakeholders to develop fact sheets and informational videos explaining operational issues. The committee also suggested using the Board's website, subscriber alerts and newsletter to educate and encourage pharmacists in furnishing PrEP and PEP medication.

Chairperson Sanchez advised at the July 8, 2020 committee meeting, staff reported meeting with Please PrEP Me, an advocacy group. Staff and Please PrEP Me discussed collaborating on messages about SB 159 to increase awareness and encourage participation by pharmacists. Staff also reported that Please PrEP Me went on hiatus June 30, 2020; however, staff will continue to reach out to other groups on developing and sharing messages about SB 159, including the California Department of Public Health (CDPH) and the Office of AIDS. Staff will report back to the committee on communication and education efforts.

Board 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; however, no comments were provided.

b. Discussion and Consideration of Providing Information about Possible Consequences of DUI Conviction on License Renewal Notices

Chairperson Sanchez provided at the January 2020 committee meeting, members discussed how to educate licensees about the possible professional consequences of DUI convictions. Members suggested publishing Script articles about how a DUI conviction could result in disciplinary action and about the top reasons for license revocation. At the January 2020 Board Meeting, members asked what percentage of disciplinary cases involve DUIs. At the May 2020 Board Meeting, members asked the Communication and Public Education Committee to discuss providing information to licensees about DUIs as part of the license renewal process.

Chairperson Sanchez advised at the July 2020 committee meeting, staff reported a search of closed cases from July 1, 2019, to June 26, 2020, found nine pharmacists were disciplined by the Board for violations of BPC sections 4301(h) and 4301(l), which are related to DUI incidents. However, a staff review of each case found only three of the nine cases involved DUI convictions. The remaining six cases involved activity covered by BPC sections 4301(h) and 4301(l)other than driving under the influence of alcohol or drugs. Staff noted that by

comparison, 21 pharmacists received citations and/or fines for violations of BPC sections 4301(h) and 4301(l) during the same period.

During the committee discussion, it was suggested that it would be more efficient to include DUI information in pocket license. In addition, information on the Board's website about online license renewal could include a link to DUI information.

Chairperson Sanchez reported staff researched trends in license renewals online versus by mail. Although the numbers have fluctuated each month, information provided by DCA shows the overall trend is an increase in online renewals since the Board began providing the option in December 2018.

Mr. Sanchez advised given this information, staff recommends including advisory information with the mailing of the renewal pocket license.

Board Members were provided with an opportunity to provide comments.

Board Member Wong inquired if information could be used for pharmacy technicians. Board staff indicated the same information could be provided to pharmacy technician licensees.

Board Member Butler commented she was glad to see the low number of investigations and agreed it seems necessary to provide to pharmacy technicians.

Board Member Wong expressed concern that licensees do not understand the consequences of receiving a DUI.

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

c. Update on Communication and Public Education Activities by Staff

Chairperson Sanchez advised staff reported the most recent issue of the newsletter was published in March. Planning for the next issue is expected in summer. Staff also reported plans to develop an online survey pharmacist can take to receive one hour of CE credit, as directed by the Board.

Chairperson Sanchez provided projects underway included development of an online registry of services, review of Notice to Consumer poster and summaries of disciplinary cases.

Chairperson Sanchez noted staff is developing a WebEx meeting format for providing the prescription drug abuse CE training previously provided at all-day events throughout the state. Participants will log in to the meeting to participate

in the training and will take a quiz at the end to receive CE credit. In the coming months, this will be available for licensees to participate. Staff also reported on progress in developing the 2020 Pharmacy Law webinar, which provides pharmacists with one hour of Board-provided CE in law and ethics. Subsequent to the committee meeting, the new webinar has been posted on the Board's website.

Chairperson Sanchez advised staff provided a list of recent news media inquiries and reported no in person outreach activities due to the shelter-in-place orders during the COVID-19 pandemic emergency.

Board 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; however, no comments were provided.

IX. Legislation and Regulation Committee Report

As the chairperson of the Legislation and Regulation Committee, President Lippe provided a summary of the committee's work during its July 8, 2020, meeting.

a. Discussion and Consideration of Petition Submitted to the Board for Interpretative Ruling or Policy Statement Regarding Mandatory Reporting Provision of Penal Code Section 11160 and Its Applicability to Community Pharmacists

Chairperson Lippe reminded members that as part of the June 18, 2020, meeting, the Board received public comment requesting that the Board provide a policy statement or other ruling regarding the provisions of California Penal Code Section 11160 and its applicability to community pharmacists.

Chairperson Lippe noted subsequent to the meeting, the Board received a formal request for consideration included in the meeting materials with a legal analysis provided by DCA counsel William Maguire. During the meeting, the committee discussed the petition and conclusions of DCA counsel.

Chairperson Lippe advised the legal analysis concluded that it does not appear that a community pharmacist would be considered a mandatory reporter under the provisions of the Penal Code, but it also details that there is no definition of "community pharmacist." The analysis cautions that an independent assessment of the facts should be made. Mr. Lippe shared during the committee meeting that he agreed with the recommendation of counsel that the Board refrain from issuing an interpretative ruling or policy statement for the previously stated reasons, but also because enforcement of the provision does not reside with the Board.

Chairperson Lippe advised members that the committee did not act on the item. Board 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; however, no comments were provided.

b. Discussion and Consideration of Pharmacy Security Requirements

Chairperson Lippe advised the Board that during the committee meeting members discussed the significant damage and destruction that occurred to beginning on or around May 29, in numerous pharmacies in California, and nationwide. The scope of damage ranged significantly and, in some cases, appeared to escalate over time. Some pharmacies were targeted on more than one occasion.

Chairperson Lippe provided on June 1, 2020, the Board released guidance to provide pharmacies with recommendations on actions to take and reminded licensees of the "ask inspector" email and phone number.

Chairperson Lippe advised for several weeks Board staff communicated with pharmacies who experienced damages and losses, primarily during the period of May 29-June 2, 2020. Based on the voluntary reporting of closures, damages and controlled substance losses, as of June 30, the Board was aware of 286 pharmacies reporting damage or destruction. The reporting indicated that 98 of the pharmacies sustaining damage were independent pharmacies and five remain closed. Further, the reporting revealed that 187 chain store pharmacies were impacted, with 100 either still closed or the Board was unclear on the status.

Chairperson Lippe noted that to fully understand the scope and severity of the damage and destruction as well as to demonstrate what appears to be planned and coordinated efforts on the part of the looters, the meeting materials provided a summary of the types of damage sustained including but not limited to:

- Front and back doors, including iron gates were smashed and pried open.
- Safes and controlled substance cabinets were stolen, pried or smashed open.
- Surveillance videos inside some pharmacies showed groups arriving in cars and trucks with hammers, drills, saws, chains, and bolt cutters. In some cases, there appeared to be coordination between several groups, with each following in close succession.
- Refrigerator doors were left open and fire extinguishers were used leaving retardant throughout pharmacies.

- Two pharmacies were set on fire.
- Pharmacies were looted while the pharmacy was open, closed, even after windows and doors were boarded up.
- Many alarm systems were activated but law enforcement did not respond.
- Drugs, prescription records, cash registers and cash, computers, as well as licenses (pharmacy, pharmacist, pharmacy technician and DEA) were also taken in some cases.
- Over the counter and other front-end products were stolen.

Chairperson Lippe reported committee members expressed concern that alarms were activated, but law enforcement could not respond. Further, the committee expressed concern with potential privacy breaches stemming from stolen records. The committee received public comment indicating that even boarded up pharmacies were subsequently compromised.

Chairperson Lippe noted as a committee, no action was taken but have requested that staff research the issue further and determine if best practices or other standards should be developed.

Board Members were provided with an opportunity to provide comments.

Board Member Wong inquired if the Board was working with the local police departments or DEA for quicker responses in the future. Executive Officer Sodergren indicated staff was facilitating education to licensees and other actions board staff can take.

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

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

Chairperson Lippe advised in response to the public health crisis, both the Senate and Assembly recessed unexpectedly in March, returning in May. Further, the return from the summer recess was also delayed as such it was unclear which measures will meet policy deadlines.

Chairperson Lippe noted the committee was offering recommendations on a few of the measures and advised members about additional measures where it was similarly appropriate to establish a formal position.

<u>AB 710 (Wood) Pharmacy Practice: Vaccines</u>

Chairperson Lippe provided AB 1710 would expand the authority for pharmacists to administer vaccines that are approved by the FDA, removing current limitations.

Chairperson Lippe advised because of the time of the amendments to AB 1710, this measure was not considered by the committee. Mr. Lippe noted the Licensing Committee discussed a similar policy and is in support of such expansion. He recommended that the Board establish a support position on this measure.

Motion: The Board establish its position on AB 1710 (Wood) as Support.

M/S: Veale/Oh

Board 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.

The Board heard comments from Lindsay Gullahorn, CRA and NACDS, in support of AB 1710.

Ms. Sodergren clarified the Board's overall policy goal and direction of expanding access to immunization through expanded authority for pharmacists.

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

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

AB 2028 (Aguiar-Curry) State Agencies: Meetings

Chairperson Lippe provided AB 2028 would require state agencies to post meeting materials within one business day of providing them to members or, or at least 48 hours in advance of the meeting, whichever is sooner. Under the provisions of the measure, additional flexibility is provided for pending legislation. Mr. Lippe noted during the committee meeting, members were advised the measure was amended and that it appeared the amendments would address at least some concerns. Given the amendments, the committee did not take a

position on the measure, to allow staff and counsel the opportunity to review and evaluate the provisions.

Chairperson Lippe noted in reading the revised analysis of the measure, staff remain concerned with several technical challenges with the measure that could negatively impact the Board's ability to fully consider all relevant information and could inadvertently impede public comment. The analysis indicated that under the provisions of the measure, it does not appear that meeting materials could be used for emergency Board Meetings nor could meeting materials be provided at Board Meetings. Further, the analysis detailed problems with convening petition hearings during Board Meetings.

Chairperson Lippe stated he agreed with the staff's recommended position, Oppose Unless Amended. As included in the analysis, amendments would include clarification that the provisions do not apply to petition hearings. Further, amendments should allow that subsequent to 48-hour time period, dissemination of information to members is permissible if the information is also immediately posted on the Board's website.

Motion: The Board establish its position on AB 2028 (Aguiar-Curry) as Oppose Unless Amended.

M/S: Serpa/Sanchez

Board 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.

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

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

AB 2077 (Ting) Hypodermic Needles and Syringes

Chairperson Lippe provided AB 2077 bill extends, until January 1, 2026, the sunset date of current law that allows the retail sale or furnishing of a hypodermic needle or syringe to a person 18 years of age or older without a prescription. As indicated in the meeting materials, the Board has historically supported such measures. The committee is recommending a support position on the measure.

Committee Recommendation (Motion): The Board establish its position on AB 2077 (Ting) as Support.

Board 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; however, no comments were provided.

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

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

AB 2113 (Low) Refugees, Asylees, and Immigrants: Licensing

Chairperson Lippe provided Assembly Bill 2113 would require Boards within the DCA to expedite the initial licensure process for an applicant who supplies satisfactory evidence to the Board that the applicant is a refugee, been granted political asylum, or possesses a special immigrant visa. Mr. Lippe noted the committee nor staff offered a recommendation on this measure.

Board 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; however, no comments were provided.

AB 2549 (Salas) Department of Consumer Affairs: Temporary Licenses

Chairperson Lippe reported AB 2549 would require the Board to issue temporary licenses to military spouses and require the Board to promulgate regulations. The temporary license would be good for up to 12 months. The bill analysis includes some consumer protection concerns with the measure in its current form. Mr. Lippe noted that staff recommended an Oppose Unless Amended position, noting that legal requirements and practice standards for pharmacists vary between jurisdictions and suggests it may be appropriate to specify that passing the CPJE must be a requirement prior to issuing a temporary pharmacist license.

Chairperson Lippe advised the committee did not offer recommendation on this measure. Mr. Lippe agreed with staff's recommendation of Oppose Unless Amended and that such a requirement would be consistent with the Board's consumer protection mandate.

Motion: The Board establish its position on AB 2549 (Salas) as Oppose Unless Amended to require the CPJE.

M/S: Veale/Oh

Board 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; however, no comments were provided.

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

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

AB 2983 (Holden) Pharmacies: Automatic Refills

Chairperson Lippe provided AB 2983 would prohibit a pharmacy from automatically contacting a prescriber to request refill authorization unless the prescriber or patient has expressly authorized such contact.

Chairperson Lippe noted as indicated in the bill analysis, the Board has a pending regulation change that supports the staff's recommendation for a support position on this measure. Staff notes that as part of its pending regulations, it would prevent a pharmacy from automatically enrolling an individual into an auto refill program and notes that some of patient safety concerns being addressed in the Board's regulation proposal would also be remedied by the proposed legislation. Mr. Lippe provided the committee was advised during the meeting that the National Association of Chain Drug stores has an oppose position on the measure.

Chairperson Lippe advised the committee is not offering a recommendation on this measure. Mr. Lippe noted he agreed with staff recommendation and requests that members consider establishing a support position on the measure.

Motion: The Board establish its position on AB 2983 (Holden) as Support.

M/S: Veale/Butler

Board 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.

Lindsay Gullahorn, CRA and NACDS, commented in opposition of AB 2983. Ms. Gullahorn noted some of the concerns have been addressed in the June revision but some concerns remain outstanding.

Vice President Veale inquired about the purpose of the bill's author. Ms. Sodergren referenced the legislative declaration and finding in the measure that outlines the reasons the legislation is necessary. The measure notes that auto refills can be helpful but the intent of the legislature is that prescribers should retain a little more discretion over the number of refills. Ms. Sodergren indicated the Board receives complaints from physicians about the automated process that continually request refills in an automated function that appears to be an issue in the medical field. Mr. Lippe added prescriptions are automatically filled when not needed.

Vice President Veale inquired how a prescriber would authorize being contacted by the automated system. Ms. Sodergren clarified a provision of the legislation is the use of an automated computer system.

Vice President Veale withdrew her motion.

Motion: The Board establish its position on AB 2983 (Holden) as Support.

M/S: Butler/Wong

Joel Hawkman, independent pharmacy owner, commented while the intent of this bill is to prevent mail order pharmacies from overfilling prescriptions, this harms independent pharmacies who have personal relationships with their patients and prescribers. This bill places an unnecessary burden on independent pharmacies.

Steven Gray commented this is a long-standing debate when a computer contacts the physician without a pharmacist involved. Dr. Gray cited California law that requires only licensed personnel may contact a prescriber for authorization unless directed by a pharmacist. In this case, the computer is contacting the prescriber without direction of a pharmacist.

Board Member Oh suggested that the Board refrain from taking a position on the bill and focus on the Board's auto refill regulation. Members determined a larger policy goal discussion would be needed in the future.

The motion was subsequently withdrawn.

AB 3045 (Gray) Department of Consumer Affairs: Boards: Veterans

Chairperson Lippe provided AB 3045 would require Boards within the DCA to issue a license to an applicant if the applicant meets specified requirements, including that the applicant was honorably discharged from the armed forces, or is married or in a domestic partnership or other legal union with an active duty member.

Chairperson Lippe advised the committee was not offering a recommended position. However, Mr. Lippe noted concerns raised by staff indicated that under the provisions of the bill the Board would lose its ability to ensure minimum competency prior to issuing a license. Given these concerns, staff recommended an Oppose Unless Amended position. Mr. Lippe noted he agreed that it would be appropriate to request amendment to allow the Board to at minimum to require passage of the CPJE for pharmacist applicants.

Motion: The Board establish its position on AB 3045 (Gray) as Oppose Unless Amended.

M/S: Veale/Oh

Board 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; however, no comments were provided.

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

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

The Board recessed into closed session at approximately 2:55 pm. The Board convened in closed session at approximately 3:00 pm and adjourned after closed session at approximately 5:00 pm.

July 30, 2020

President Lippe called the meeting to order at 9:05 am. 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 would only be able to observe the meeting. He noted anyone interested in participating in the meeting must join the WebEx meeting with instructions posted on the Board's website.

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

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

President Lippe resumed the Legislation and Regulation Committee report.

AB 3342 (Bauer-Kahan) Child Day Care Facilities: Epinephrine Auto Injectors

Chairperson Lippe provided as related to the Board's jurisdiction, AB 3342 would authorize a pharmacy to furnish epinephrine auto-injectors to the State Department of Health Care Services under the program created pursuant to this bill, subject to similar requirements. Mr. Lippe provided staff noted in its analysis, that the Board historically supported such measures and is recommending that

the Board establish a support position. The committee did not make a recommendation.

Board Members were provided with an opportunity to provide comments. Vice President Veale commented that the Board should support this bill.

Motion: The Board establish its position on AB 3342 (Bauer-Kahan)as Support.

M/S: Veale/Butler

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

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

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

SB 878 (Jones) Department of Consumer Affairs Licensing: Applications

Chairperson Lippe provided SB 878 would require Boards within the DCA to prominently display the current timeframe for processing initial and renewal license applications on its internet website. Mr. Lippe provided staff noted in the analysis provided, the Board publicly reports application processing times as part of the quarterly Licensing Committee and Board Meetings. Mr. Lippe noted that the committee was not recommending a position on this measure and he personally agreed a position is not necessary. He provided the Board will continue to publicly report processing times and can transition to meet the provisions of the measure.

Board Members were provided with an opportunity to provide comments. Vice President Veale commented as Chairperson of the Licensing Committee noted processing times are discussed quarterly and there is no need to legislate this reporting.

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

SB 1474 (Committee on Business, Professions and Economic Development)

Chairperson Lippe provided SB 1474 would extend the operations of several Boards for one year. In December 2019, the Board submitted its Sunset Review Report in anticipation of review by oversight committees this year. Due to the COVID-19 Pandemic and the unprecedented nature of the 2020 Legislative Session, oversight review was postponed. The extension provided in this measure will allow for the Board to be evaluated via the comprehensive Sunset Review Process next year. Mr. Lippe noted that the committee was recommending establishment of a support position on the measure.

Committee Recommendation (Motion): The Board establish its position on SB 1474 (Committee on Business, Professions and Economic Development) as Support.

Board 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; however, no comments were provided.

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

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

Chairperson Lippe provided information in the Regulations portion of the report is for information only.

d. Proposed Regulations Approved by the Office of Administrative Law

Chairperson Lippe provided The Board has two regulation packages that were recently approved by the Office of Administrative Law.

Proposed Regulation to Amend Title 16 CCR Section 1706.2 Related to Abandonment of Applications

Chairperson Lippe advised this regulation change updated the application abandonment language to ensure the provisions applied to all application types. As amended, the regulation ensures that all applicants have proper notice about requirements for application abandonment. The amended regulation becomes effective on October 1, 2020.

Proposed Regulation to Amend Title 16 CCR Section 1707.2 Related to Duty to Consult

Mr. Lippe advised this regulation amends the Board's regulations regarding the duty to provide consultation for mail-order pharmacies. These changes also take effect on October 1, 2020.

Board 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; however, no comments were provided.

e. Discussion and Consideration of Board Adopted Regulations Undergoing Final Review by the Office of Administrative Law

Chairperson Lippe advised the Board has two regulations undergoing final review by the Office of Administrative Law.

Proposed Regulation to Add Title 16, Section 1714.3, Community Pharmacy Staffing

Chairperson Lippe provided this proposal will establish the criteria a pharmacy must meet to identify and ensure a person is assigned to assist the pharmacist as needed when the pharmacist is working alone in compliance with BPC section 4113.5.

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

Mr. Lippe provided this proposal will increase transparency and clarity to applicants with respect to rehabilitation criteria the board considers when evaluating an applicant's eligibility for licensure.

Board 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.

Rob Geddes, Albertsons, inquired about the effective date of the community pharmacy staffing and was advised that it is anticipated an effective date in mid-September.

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

Chairperson Lippe advised the Board has two regulations undergoing formal review.

Proposed Regulation to Amend Title 16, Sections 1702, 1702.1, 1702.2, 1702.5, Renewal Requirements
Chairperson Lippe advised this proposal updates the renewal requirement language to include all licensing programs and reduce the administrative workload associated with the need for frequent amendments when new licensing programs are established. The proposal is undergoing formal review by DCA.

Proposed Regulation to Amend Title 16, Section 1707, Off-Site Storage
Mr. Lippe provided this proposal amends the Board's regulations regarding the waiver requirements for off-site storage of records to allow those cited for a records violation to receive a waiver to store records off-site. This proposal is also undergoing formal review by DCA.

Board 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; however, no comments were provided.

g. Discussion and Consideration of Board Approved Regulations Undergoing Public Comment

Chairperson Lippe advised the Board has two regulations in the public comment period.

Proposed Regulations to Amend Title 16 CCR Section 1711 Related to Quality Assurance Programs for ADDS, Section 1713 Related to Use of Receipt and Delivery of Prescriptions and Prescription Medications, and Add Section 1715.1 Related to ADDS Self-Assessment Form 17M-112
Chairperson Lippe advised the proposed regulations would will require submission of quality assurance records to the Board, update the Board regulations with respect to the use of an APDS, and identify the specific requirements for the annual completion of the ADDS self-assessment form. The 45-day comment period for this package ends on August 17. Mr. Lippe noted he anticipated this proposal will be considered for action during the September Board Meeting.

Proposed Regulations to Add Title 16 CCR Sections 1717.5 Related to Automatic Refill Programs

Mr. Lippe noted this proposal establishes regulatory requirements for automated refill programs. Pre-Notice review was completed on this regulation package following release of the meeting materials. The public comment period will end on August 31, 2020.

Board 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; however, no comments were provided.

h. 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

Chairperson Lippe provided at the time of releasing the materials, the Board has six regulation packages undergoing pre-notice review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency.

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

Mr. Lippe noted this proposal establishes the training requirements and certification programs and updates the application for licensure as a pharmacy technician. Mr. Lippe noted this regulation package was originally approved by the Board in October 2016 and that changes have been requested on a few occasions. The package was resubmitted in for Pre-Notice review in October 2018 and returned to the Board for amendments to implement provisions of AB 2138 in December 2019.

Proposed Regulations to Amend Title 16 CCR Section 1715 to Update Self-Assessment Forms 17M-13 and 17M-14

Mr. Lippe advised this proposal updates the Self-Assessment forms 17M-13 (rev. 10/16) and 17M-14 (rev. 10/16) as incorporated by reference in Title 16 CCR section 1715. Additionally, this regulation updates section 1715 with clarifying language as to the completion and certification requirements of the self-assessment forms. Mr. Lippe noted it has been undergoing Pre-Notice review since December 2018.

Proposed Regulations to Amend Title 16 CCR Section 1784 to Update the Wholesaler/3PL Self-Assessment Form 17M-26

Mr. Lippe provided this proposal updates the Self-Assessment form 17M-26 (rev. 10/16) as incorporated by reference in Title 16 CCR section 1784. Additionally,

this regulation updates section 1784 with clarifying language as to the completion and certification requirements of the self-assessment form. This regulation proposal has also been undergoing Pre-Notice review since December 2018.

Proposed Permanent Regulation to Add Title 16 CCR Section 1747 Related to Independent HIV Preexposure and Postexposure Prophylaxis Furnishing
Mr. Lippe advised this proposal will make permanent the emergency regulations that establish the criteria for training programs to meet in order to be offered to pharmacists so that the pharmacists may independently initiate and furnish preexposure and postexposure prophylaxis. Pre-Notice review on this package started on February 7, 2020. The current emergency regulation will expire on October 28, 2020.

Mr. Lippe commented during the committee meeting, members discussed the provisions for extending the current emergency regulation if necessary. Members were advised, the Board can seek two 90-day extensions of the emergency regulation if necessary.

Proposed Regulation to Amend Title 16 CCR Section 1715.65 Related to Inventory Reconciliation
Mr. Lippe provided this proposal amends and clarifies the requirements for the completion of the inventory reconciliation report. The package was referred to DCA for Pre-Notice review on May 11, 2020.

Proposed Regulation to Amend Title 16 CCR Section 1715.6 Related to Drug Losses
Mr. Lippe advised this proposal amends the drug loss reporting requirements to further define when drug losses must be reported to increase clarity for the regulated public. The package was referred to DCA for Pre-Notice review on June 3, 2020.

Board 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; however, no comments were provided.

i. 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

Chairperson Lippe advised the Board has one regulation package currently with staff.

Proposed Regulation to Amend Title 16 CCR Section 1709 Related to Pharmacy Ownership, Management, and Control, Including Through Trusts

Mr. Lippe noted this proposal amends the Board's regulations regarding ownership to include provisions relating to trust ownership of pharmacies. The package was returned to the Board on April 22, 2020. This package was originally approved by the Board in October 2016. As with the prior regulation, changes have been requested on several occasions.

Board 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; however, no comments were provided.

X. Organizational Development Committee Report

President Lippe advised none of the items within this report require action.

a. CE Policy for attendance at Committee and Board Meetings

Mr. Lippe provided under existing law, a pharmacist or pharmacy technician may earn continuing education for attending a Board or Committee meeting. As indicated in the chair report, with the transition to the WebEx platform, credit for attendance at Board and Committee meetings cannot be given at this time given the requirements of the regulation.

b. Budget Update and Report

Mr. Lippe advised the Board's budget authority for the fiscal year is $29.3M, which is about a 2% increase from last year. He noted meeting materials provided preliminary budget figures for the first 11 months of last fiscal year which reflects that about 89% of the revenue received is from licensing fees, with 7% coming from cost recovery and 3% from fines assessed.

Mr. Lippe noted personnel was the Board's largest expenditure at 63% followed by 13% in pro rata, 17% in enforcement and 3% in facility operations.

Mr. Lippe provided a review of the fund condition indicates that end of FY 2019/20, the fund was down to 2.7 months in reserve. This is in large part due to a $2.4M loan to the general fund. Continued monitoring will be required to ensure the financial solvency of the Board.

c. DCA Annual Pro Rata Report

Mr. Lippe advised the meeting materials included a copy of DCA's annual report to the legislature detailing the accounting of its pro rata calculations. As

included in the report, the Board's allocated distributed costs for the fiscal year will be about $4M.

d. Board Member Attendance Report

Mr. Lippe advised the meeting materials included a summary of Board Member attendance for last fiscal year.

e. Personnel Update

Mr. Lippe advised the meeting materials indicated the Board currently has 14 vacant positions, including the Assistant Executive Officer position.

f. Meeting Calendar for Remainder of 2020

Mr. Lippe advised the meeting materials included the meeting schedule for the remainder of the year. Mr. Lippe noted his appreciation for everyone's flexibility as the Board responds to the current public health crisis. Mr. Lippe noted the date for the next Licensing Committee meeting changed.

g. Proposed Meeting Calendar for 2021

Mr. Lippe advised the proposed meeting dates for next calendar year were included in meeting materials. Until conditions approve, the Board is unable to confirm if the meetings will be in person or via WebEx. Mr. Lippe noted the Board will continue to use our website and subscriber alert system to keep people informed.

Board Members were provided with an opportunity to provide comments. Board Member Wong inquired who selects the Assistant Executive Officer. Ms. Sodergren advised she completes the hiring and confers with the Board President and Vice President.

XI. Executive Officer's Report

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

Ms. Sodergren provided the Board has been very active since March 2020 in the response to the COVID-19 public health crisis. She advised the Board included in her report is a summary of Board actions as well as those taken by other entities.

Ms. Sodergren reported the Board began issuing waivers to pharmacy law on March 11, 2020. Since that time, the Board has approved 20 broad waivers and 88 site specific waivers. While some broad waivers are developed both in response to site specific waivers that indicate larger applicability, others are developed and recommended by staff or President Lippe. Approval of

waivers with broad application are communicated through the Board's subscriber alert system and posted on the website.

Ms. Sodergren thanked Board staff for their work and flexibility through this crisis. She recognized this has impacted the Board throughout the organization. She noted short term solutions must be evaluated for long term applicability.

Ms. Sodergren noted the Board's work with the DCA and other agencies during this pandemic. She reported working together on guidance documents, coordinating licensure at surge capacity locations, waiver requests and communication plans. Agencies are taking different approaches based on authority. For example, DCA has the authority to waive provisions through the duration of the declared emergency while CDPH has suspended regulatory enforcement with stated exceptions.

Ms. Sodergren provided an update on the Board's operational changes in response to the pandemic. Some of the Board's rate limiting factors includes equipment and reliance on paper and manual processes. She noted in March, the Board's office closed to the public and staff transitioned to full time or a rotational teleworking schedule. While closed to the public, the Board's office and field staff continued operations. Prior to reopening offices to the public and resumption of some core functions, including inspections, reopening plans were developed and training provided to all staff.

Ms. Sodergren reported Board staff estimates it has incurred about $46,000 direct expenses in supplies and equipment and approximately 2,800 staff hours dedicated to the COVID-19 response. This increased in July when five Board staff were temporarily redirected to perform contact tracing activities for the administration. Additionally, as part of the inspection process, field staff will be evaluating for compliance with statewide guidance including the use of face masks and other operational changes. It is anticipated that this redirection will be necessary for several months and steps are being taken to minimize the operational impact of this redirection.

Board Members were provided with an opportunity to provide comments. Vice President Veale commented that Ms. Sodergren has done an outstanding job leading the organization through this unscripted time. President Lippe concurred.

b. Update on the CURES System and Implementation of AB 149 (Cooper, Chapter 4, Statutes of 2019)

Ms. Sodergren reported the CURES system continues to serve a vital tool for pharmacists in exercising corresponding responsibility. She noted there will be anticipated future changes with the system and is hopeful annual data will be available soon.

Ms. Sodergren reminded Members and stakeholders of upcoming changes to reporting requirements to the CURES system, including the reporting of C-V prescription and the requirement to report to the CURES system within one business day from dispensing.

Ms. Sodergren noted changes to the controlled substance security forms are provided in the meeting materials. Those changes will be noted in the Board's continuing education for law and the newsletter as well as a joint message with the Medical Board and Department of Justice.

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

c. Updates on National Issues

1. FDA Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products

Ms. Sodergren advised members that staff identified problems with the draft MOU addressing compounded human drug products but have recognized there are restrictions on businesses as well. Ultimately this will need to be discussed by the Enforcement and Compounding Committee and the Board but staff are monitoring it now.

2. Summary of the Annual Meeting of the National Association of Boards of Pharmacy

Ms. Sodergren reported the annual meeting of the NABP was conducted virtually on May 14, 2020. President Lippe served as the voting delegate. She noted the meeting materials contain a summary of resolutions addressed and findings of workgroup reports provided.

Ms. Sodergren reported NABP's new Executive Director is Al Carter. The NABP District Meeting will be held virtually October 13, 2020. The NABP Annual Meeting is scheduled for May 13-15, 2021.

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

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

Danny Martinez, CPhA, requested clarification if field inspectors will be evaluating licensees or the public for compliance with statewide guidance

including the use of face masks and other operational changes. Ms. Sodergren advised field inspectors will be looking for overall compliance with the public and facility. Field inspectors have guidance documents and ensuring there is education to achieve compliance. To date, compliance seems to be good. The Board is reporting to the administration the findings.

The Board took a break from 9:54 am and returned from break at 10:04 am. Roll call was taken after the break. Board Members present: Maria Serpa, Lavanza Butler, Debbie Veale, Shirley Kim, Jignesh Patel, Ricardo Sanchez, Albert Wong and Greg Lippe. A quorum was established.

XII. Review of Policy Granting President Discretion to Waive Provisions of Pharmacy Law Pursuant to Business and Professions Code section 4062, Including the Authority to Extend Waivers

President Lippe provided at the March 2020 meeting, the Board delegated the authority to the Board president to extend previously granted waivers not considered by the Board for up to 90 days. Following during the May 2020 meeting, the Board delegated authority to the Board president to grant a waiver for up to 90 days and to extend an existing waiver for up to 90 days.

President Lippe reported as COVID cases continue to rise, it appears that waivers of pharmacy law and its regulations may be necessary for a longer duration that originally anticipated. Several waivers are reaching the maximum period for the president to issue or extend. He added this item is on the agenda to provide an opportunity to determine if any additional changes should be made to the existing delegated authority or if it is the preference of the Board to review such waivers moving forward. He noted as discussed in the Executive Officer's report agencies are taking various approaches to waivers.

President Lippe noted if the Board wished to delegate addition authority, it will require formal action. If the Board decides the current delegated authority is appropriate, future actions to extend future waivers as part of Board Meetings can be determined. Mr. Lippe requested Members share thoughts on this issue and suggest a motion if desired. He provided there is still a need for some of the waivers.

Dr. Wong inquired if the current waiver system is working sufficiently. Ms. Sodergren provided waivers are being monitored by calls to pharmacies to see what waivers are being used as well as inquiries during desk audits and inspections. Site specific waivers are also evaluated for possible broad application.

Members discussed time frames for extending waivers. Members agreed issuing/extending waivers for 90 days and not to exceed 9 months. This would include current and new waivers. As the waivers are issued, emails are sent. Waivers will be kept on the Board agenda.

Motion: Motion to extend authority to allow the president to issue or grant extensions to issue up to 90 days with extensions, not to exceed 9 months. Include a public report of waivers granted.

M/S: Wong/Sanchez

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

Danny Martinez, CPhA, commented in support of the motion and inquired what would happen in the instance when a waiver is needed after the two 90-day extensions. President Lippe advised the full Board would be acting on the waiver.

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

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

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

President Lippe explained this agenda item was added in case the President's waiver ability was not extended. Mr. Lippe stated this was a good opportunity to review the current waivers set to expire soon with the Board and provided an overview of the waivers.

1. Signature Requirement for Receipt of Delivery of Drugs (BPC section 4059.5)
   Waives the signature requirement for the receipt of the delivery of drugs under specified conditions. This waiver will expire on September 22, 2020.

2. Prescriber Dispensing Medication to Emergency Room Patient (BPC sections 4068(a)(1), 4068(a)(5), and 4068(a)(6))
   Waives the prohibition against a prescriber dispensing medications to an emergency room patient under specified conditions. This waiver will expire on September 22, 2020.

3. Requirement for Consulting Pharmacist to Perform Visits to Clinic (BPC section 4182(a) & (b) and section 4192(a) & (b))
   Waives the requirement for a consulting pharmacist to perform quarterly visits to a clinic under specified conditions. This waiver will expire on September 22, 2020.

4. USP <797> Requirements Related to Use of Personal Protective Equipment (BPC section 4126.8)
   Waives USP <797> requirements related to the use of PPE, to allow for a PPE mask and gown to be reused by staff performing sterile compounding under specified conditions. This waiver will expire on September 22, 2020.

5. Use of PPE in Certain Compounding Aseptic Isolators or Compounding Aseptic Containment Isolators (Title 16, California Code of Regulations, section 1751.5)
   Allows for the potential waiver of required PPE requirements for compounding performed in a CAI or CACI under specified conditions. This waiver will expire on August 30, 2020.

6. Prelicensure Inspection at Proposed Location of an Automated Drug Delivery System (ADDS) - Business and Professions Code sections 4119.11(a)(9) and BPC 4427.2(e)
   Waives the inspection requirement a condition of licensure of an ADDS under specified conditions. A significant number of ADDS are placed in skilled nursing facilities. This waiver will expire on October 9, 2020.

7. Restoration of Retired or Canceled Pharmacist License – BPC section 4200.5(d), Related to Retired Licensees; BPC section 4402(b), Related to Canceled Pharmacist Licenses; and BPC section 4403, Related to Payment of Fees for Reissuance or Renewal of License
   Waives conditions for reinstatement of a cancelled or retired pharmacist license. This waiver will expire October 1, 2020.

8. Duty to Consult (Title 16, California Code of Regulations, section 1707.2(a))
   Waives the requirement for in-person consultation under specified conditions. This waiver will expire September 29, 2020.

9. Remote Processing (BPC section 4071.1(a))
   Waives limitations on the provisions of remote order entry. This waiver will expire September 22, 2020.

Board Members were provided with an opportunity to provide comments. Dr. Oh had a question regarding the remote processing waiver to clarify what was allowed and what was added with the waiver. Ms. Sodergren explained some entities may have exceeded what was allowed in the law prior to COVID-19 pandemic.

Dr. Wong inquired why PPE was being extended as his understanding was that there was no shortage. Dr. Serpa clarified there is still a shortage.

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

John Gray, Kaiser Permanente, commented that most of the waivers on the list were important to continue at the current time and most likely during the current emergency.

The Board took a break at 10:35 am and returned at 10:53 am. Roll call was taken. Board Members present included: Lavanza Butler, Shirley Kim, Maria Serpa, Seung Oh, Debbie Veale, Jignesh Patel, Albert Wong, Ricardo Sanchez, and Greg Lippe. A quorum was established.

President Lippe advised he would be taking public comment on items not on the agenda/agenda items for a future meeting.

Dean Daniel Robinson of Western University College of Pharmacy spoke on behalf of the 13 schools of pharmacy in California requesting consideration to add to a future the Board agenda, review, justification and continued use of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE).

Motion: Motion to add to the future agenda of the Licensing Committee.

M/S: Wong/Butler

Board 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.

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

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

There was no other public comment for items not on the agenda or items for future agendas.

The Board took a break at 11:00 am and returned at 12:00 pm. Roll call was taken. Board Members present included: Maria Serpa, Seung Oh, Lavanza Butler, Shirley Kim, Jignesh Patel, Albert Wong, Debbie Veale, and Greg Lippe. A quorum was established. Ricardo Sanchez joined at 12:05 pm.

XIV. Presentation, Discussion and Consideration of Published Research, Examining Students' Attitudes toward Academic Dishonesty in California Pharmacy Schools

President Lippe noted that included in the Winter 2020 issue of the Journal of Contemporary Pharmacy Practice, was published original research, "Examining Students' Attitudes Toward Academic Dishonesty in California Pharmacy Schools." Mr. Lippe welcomed:

- Dr. Paul Gavaza, lead author on the article and associate professor of pharmaceutical and administrative sciences.
- Dr. Farnoosh Zough, associate professor of pharmacy practice, director of IPPE program, and co-adviser for CAPSLead.
- Dr. Lawrence Chui, graduate of the class of 2020 and CAPSLead team who carried out the research.
- Dr. Nancy Kawahara, assistant dean for co-curriculum and mentorship, associate professor of pharmacy practice, and co-adviser of CAPSLead.

Dr. Lawrence Chui presented the findings of "Examining Students' Attitudes Toward Academic Dishonesty in California Pharmacy Schools." The objective of the study was to explore California student-pharmacists' opinion of academic dishonesty. The methods used included convenience sampling with an electronic survey sent to 13 California pharmacy schools to evaluate student's definition of cheating, motivating factors, views, and perceived long-term consequences.

Dr. Chui provided the sample size was 249 students. He added most of the participants were female, less than 30 years old, achieved a bachelor's degree, possessed a GPA above 3.0 and were 1st or 2nd year students. He noted the definition of cheating was up to interpretation to the participants. Some of the key findings of great concern include:

- 78.3% indicated they would cheat if that meant passing a class and 74.4% would cheat if everyone else was cheating.
- 45.4% agreed they felt more tempted to cheat in a difficult class than an easier one.
- 63.6% disagreed that it is not easy for them or others to cheat in pharmacy school.
- 86.0% disagreed that faculty and staff at their school take appropriate measures to prevent cheating.

Dr. Chui indicated the findings were consistent to other similar findings such as Rabi SM, Patton LR, Fjortoft N, et al (2006) and Ip EJ, Nguyen K, Shaw BM, et all (2016) related to cheating awareness and participation. He added the recent occurrences with the CPJE demonstrates the academic behavior of cheating translates into future cheating.

Dr. Chui identified the limitations of the study as suboptimal response rate with no response from one school; controversial and sensitive topic minimized due to anonymity; cross-sectional study and as a result no causality of variables may be inferred; and unable to validate actual behavior with response.

Dr. Chui concluded there is variability in definitions and behaviors amongst pharmacy students. He added academic dishonesty is prevalent and a major issue. Team efforts amongst students, school administrators and faculty are needed to curb academic dishonesty.

Board members were provided with the opportunity to ask questions about the study.

When inquired about the methodology, Dr. Chui provided the link to the survey was provided to the CAPSLead contact to assist in dissemination and added the link to the Loma Linda University Facebook page. Dr. Chui provided the team took receiving responses from schools as indication that it was sent to the students by the CAPSLead contacts.

Members and presenters discussed possible options of what could be done to prevent this including pass/no pass grading; and intervention at the institution on the definition of academic dishonesty with students. They also discussed how alarming it is that students are aware this is happening and yet this isn't shared with faculty and administration. There is a social stigma associated with those who report students who cheat to administration. They discussed how actions in the classroom can translate into their professional practice.

Members of the public were provided the opportunity to comment and ask questions.

Bob Stein, KGI, expressed gratitude to the Loma Linda University team that did the survey. Dr. Stein commented as a professor of law and ethics the findings were disturbing and he will be using this study as a required reading. Dr. Stein stated this behavior is common but unacceptable in the profession.

Lori Hensic as a former faculty member and current preceptor inquired if the research team proactively approached ACPE with this information so that ACPE can assist in translating to action. She found it interesting that 48.8% agree cheating in pharmacy school will yield unethical pharmacists. A similar question that says a student who cheats in school is likely to cut corners as a pharmacist and yet only 12% agree. She inquired if the team had a comment on the opposing responses. Dr. Kawahara provided the survey results have not been forwarded to ACPE yet the topic of

academic dishonesty is a high focus of ACPE. Dr. Kawahara suspected cutting corners was too vague and the students who responded didn't think it was the same as being unethical. Dr. Zough provided moving forward she recommended using this study as required reading, having open dialogues with students to ensure understanding and assessing testing procedures.

Steve Gray as a professor of law and ethics commented the stigma of reporting cheating is worldwide. If a law is passed to require reporting dishonesty of others, it takes away a lot of the stigma associated with reporting of students cheating. Schools and the Board could adopt rules requiring the reporting of cheating. Dr. Gray added the cheating continues into continuing education. He noted all students are all licensed professionals yet the schools feel they are prohibited from reporting cheating and recommended the Board having a discussion on expectations. Dr. Kawahara provided students caught egregiously cheating are removed from school and the Board is notified.

Members discussed prevention over punishment and prevalence of cheating in other medical professions. Dr. Chui provided the team did a literature search which included medical, nursing and dental professions. Members discussed that cheating scandals in other states have been published in literature and should be taken into consideration.

Dr. Tracy Montez, Ph.D., Chief, Division of Programs and Policy Review for DCA, commented there is an increase in cheating across licensure examinations at DCA. There seems to be consensus among candidates that it is acceptable to share questions after taking a licensing examination, which is not correct. Dr. Montez indicated the best diversion is when a cheater is caught and made an example.

Dr. Stein commented he didn't see an exception to the Family Educational Rights and Privacy Act (FERPA) that would permit an educational institution to report academic dishonesty to a state licensing agency.

Members and presenters discussed how to have the students share with the Board. They discussed starting in the schools but also understanding the honesty of being a professional. They also discussed reporting anonymously. Members discussed the security of the CPJE and the documents signed by candidates who take the CPJE are not allowed to share information on the CPJE.

As an action item, the Board sent this item to the Licensing Committee.

XV. <u>Discussion and Consideration for Board Approval of Proposed Board Provided Training Programs as Required by SB 159 (Wiener, Chapter 532, Statutes of 2019) Related to HIV Preexposure and Postexposure Prophylaxis</u>

President Lippe provided subsequent to the release of the agenda, the Board received notice that the proposed training program is not ready for our review as it is

undergoing review by experts. Mr. Lippe stated he is hopeful that the training program will be complete and ready for our review at the September Board Meeting.

The Board adjourned at approximately 1:06 pm.