California State Board of Pharmacy
1625 N. Market Blvd, N219
Sacramento, CA 95834
Phone: (916) 574-7900 Fax: (916) 574-8618
www.pharmacy.ca.gov

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

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

Date: May 7, 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
Lavanza Butler, Licensee Member
Shirley Kim, Public Member
Seung Oh, Licensee Member
Jignesh Patel, Licensee Member
Ricardo Sanchez, Public Member
Albert Wong, Licensee Member

Staff Present:
Anne Sodergren, Executive Officer
Christine Acosta, Supervising Inspector
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 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.

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 that the Board would convene in closed session after deliberating on all the open session items, except

adjournment.

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

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

Susan Bonilla, Executive Officer of the California Pharmacists Association's (CPhA), introduced herself to the Board and thanked the Board for their service.

III. Approval Board Meeting Minutes

a. January 29-30, 2020, Minutes

Motion: Approve the January 29-30, 2020, Board meeting minutes with typing errors corrected.

M/S: Sanchez/Brooks

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

Support: 10 Oppose: 0 Abstain: 0

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

b. March 27, 2020, Minutes

Motion: Approve the March 27, 2020, Board meeting minutes.

M/S: Sanchez/Butler

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

Support: 10 Oppose: 0 Abstain: 0

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

IV. Board Officer Elections

President Lippe advised that as included in the Board member procedure manual, officers shall serve one-year term, effective June 1, and may be reelected for consecutive terms.

President Lippe accepted nominations for president. Vice President Veale nominated Greg Lippe for president. Member Sanchez nominated Maria Serpa for president.

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

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

Greg Lippe was re-elected president.

President Lippe accepted nominations for vice president. President Lippe nominated Debbie Veale for vice president. Member Sanchez nominated Maria Serpa. Member Oh nominated Lavanza Butler. Dr. Butler respectfully declined the nomination.

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

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

Debbie Veale was re-elected vice-president.

President Lippe accepted nominations for treasurer. President Lippe nominated Maria Serpa for treasurer.

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

Maria Serpa was re-elected Treasurer.

V. Update from the Department of Consumer Affairs (DCA)

President Lippe referenced the supplemental meeting materials which include an update from the DCA in in lieu of an in-person update.

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

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

President Lippe advised the Board that, as agendized, it had the opportunity to consider whether a further amendment to the Board's policy granting president discretion to waive provisions of Pharmacy Law pursuant to Business and Professions Code section 4062 was appropriate. President Lippe noted that 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.

President Lippe stated the ongoing health crisis coupled with statements from experts indicating that a resurgence of the COVID-19 virus could occur later this year, it appeared appropriate to consider whether additional conditions for delegated authority or extension of existing authority should be granted to the Board president.

President Lippe reviewed questions in the meeting materials to help facilitate the discussion.

1. Should the Board consider extending authority for the president to initially approve waivers beyond 30 days? If so, what is an appropriate period of time, e.g. 150 days or until the next scheduled Board meeting, whichever is later unless extended by Board action?
2. Should the Board consider delegating authority to the president to extend waivers previously approved by the Board? If so, what is an appropriate time period, e.g., an additional 180 days or through the duration of the declared disaster as deemed appropriate by the president?

Prior to Board discussion, President Lippe provided an overview of the current approval process for waiver approvals, noting that Board staff receive waiver requests from individuals and also have identified recommended waivers that will assist during this pandemic. Some requests are initially vague and require additional follow up with the requestor. Depending on the nature of the request, various staff review the proposal which is then forwarded for consideration. Broad waiver requests are also reviewed by counsel prior to the president's review. When forwarded to the president, he receives a copy of the request and recommendation from staff on whether to approve the request.

Members discussed the policy questions including the provisions for delegation of authority to the Board president, including what an appropriate timeframe would be. Some members expressed concern that delegated authority to extend waivers for an additional 180 days was too long.

Motion: Delegate authority to the president to grant new waivers of for up to 90 days and to extend existing waivers for up to 90 additional days.

M/S: Brooks/Wong

Members of the public were provided with an opportunity to provide comments. The Board received public comment requesting clarification on the expiration date of waivers and why not all expirations aligned. Executive Officer Sodergren clarified that expiration dates vary based on actions taken by the Board as part of its March 2020 meeting.

Support: 10 Oppose: 0 Abstain: 0

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

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

President Lippe advised the Board will consider site specific waivers that, unless extended, will expire before the Board's June 18, 2020, meeting.

a. Stanford Health, Waiver of Title 16, California Code of Regulation (CCR) Sections 1735.6(e) & 1751(d)(2)

President Lippe noted that on March 9, 2020, a limited waiver was approved to allow Stanford Health to perform medium risk compounding of an investigational drug in a noncompliant hazardous compounding environment. Stanford is enrolled in a study conducted by the National Institutes for Health to evaluate the potential treatment of COVID-19.. Information received from Stanford Health confirms that the waiver has

been used in a very limited capacity, specifically for compounding two doses. Facility representatives indicate that equipment is on order and anticipate the equipment will be ready for inspection by the Board in July, which would eliminate the need for the waiver long term.

Dr. Serpa requested additional information be provided about waivers in future meeting materials and asked why Stanford Health needed a waiver for a noncompliant hazardous compounding environment. Supervising Inspector Christine Acosta answered the drug itself is not hazardous but because it is investigational, the drug is being treated as a hazardous drug. Dr. Acosta noted garbing was being done appropriately but Stanford Health didn't have the appropriate compounding environment for hazardous drugs. Dr. Acosta noted Stanford is obtaining a mobile compounding unit that is anticipated in July 2020, which will provide a long-term solution.

Ms. Veale requested more robust information to be provided including the expiration date of the waiver as well as staff recommendation.

Motion: Approve the extension of the waiver to allow compounding of a medium risk investigational drug in a noncompliant compounding environment for up to 120 days.

M/S: Veale/Butler

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

Support: 10 Oppose: 0 Abstain: 0

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

b. PETNet, Waiver of Business and Professions Code section 4126.8 & Title 16, CCR Section 1751.5

President Lippe advised the waiver for PETNet was withdrawn.

c. <u>CAP Rx, Inc, Waiver of Business and Professions Code section 4126.8 & Title 16, CCR Section 1735.1(x)</u>

President Lippe advised members, that on March 12, 2020, a limited waiver was approved for CAP Rx, to allow for an alternative use of personal protective equipment (PPE) by staff performing hazardous nonsterile compounding under the specified conditions detailed in the meeting materials. He added the approval of the waiver was granted in light of the limited supply of PPE.

Dr. Serpa expressed concern with the approval of the waiver for chemotherapy hazardous nonsterile compounding where non-chemotherapy hazardous nonsterile compounding would be appropriate. Dr. Acosta confirmed they are not doing chemotherapy preparations. Dr. Serpa stated the waiver should specify that the provisions for use is limited to non-chemotherapy hazardous nonsterile compounding. Dr. Acosta was asked if she supported the waiver and she stated her support of this waiver given the current environment and uncertainties in the supply chain of PPE.

Motion: To extend the waiver at the discretion of the President and include an additional condition for use to prohibit this practice on chemotherapy agents.

M/S: Serpa/Veale

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

Support: 10 Oppose: 0 Abstain: 0

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

The Board took a break at 10:30 am and resumed at 10:45 am. Roll call was taken after the break. Board Members present: Albert Wong, Jig Patel, Seung Oh, Shirley Kim, Lavanza Butler, Ryan Brooks, Maria Serpa, Debbie Veale, Greg Lippe and Ricardo Sanchez.

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

a. Proposed Regulation to Add Title 16, California Code of regulations (CCR) Section 1714.3, Community Pharmacy Staffing

President Lippe reminded members that at the July 2019 Board meeting, the Board approved proposed text to add section 1714.3 of Title 16, CCR, related to community pharmacy staffing to 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 Business and Professions Code (BPC) section 4113.5. President Lippe confirmed Board Members reviewed the meeting materials, including the comments received during the public comment period, as well as staff's response to each comment. President Lippe surveyed each Board Member for comments regarding the proposed regulation before the Board.

Vice President Veale noted her agreement with many of the comments submitted during the public comment period. Ms. Veale indicated the requirement to include the name of the designated person on the schedule to assist the pharmacist is too prescriptive. She noted the goal of the regulation is to protect the pharmacist in the pharmacy but doesn't agree with being over prescriptive. Ms. Veale recommended using a job classification instead of a name. Further, she noted that a timeframe for response is needed but expressed concern with the current 5-minute timeframe indicating it does not allow for the person to complete their current task and go to the pharmacy safely. Ms. Veale recommended that an average of 10 minutes was reasonable. Ms. Veale acknowledged the importance of this change and noted it to be a workable solution while protecting the pharmacist.

Treasurer Serpa agreed with Ms. Veale's two areas of concern. Dr. Serpa indicated her concern with specific names on the schedule and suggested using a staffed position to allow for coverage if someone calls in sick and to ensure the position does not go uncovered. Dr. Serpa agreed with the response time being longer and using the average time to accommodate for unexpected schedule changes.

Member Butler indicated she agreed with staff's recommendation to require the name the person to call and not a general staff title. She stated it was important to have a list of two or three people who are appropriately trained to assist the pharmacist. Dr. Butler expressed concern that pharmacists are not getting the help as intended. She added there needs to be a designated time for the person to report back to the pharmacy. Dr. Butler indicated she agreed with staff's recommendation but acknowledged between 5-10 minutes would be acceptable. Dr. Butler indicated she would prefer a pharmacy technician assist the pharmacist to ensure a safe environment for the patients of California but agreed with staff recommendations.

Member Kim commented that in light of the pandemic, pharmacists are playing a greater role in providing health care services in pharmacies and communities. She stated there is an urgency to promulgate the proposed regulation to ensure that pharmacists have adequate support. Ms. Kim agreed with Dr. Butler's comments. Ms. Kim found staff's recommendation compelling as individuals supporting the pharmacists should have minimum competencies and background checks. Ms. Kim noted she thought the 5-minute response time is consistent with the legislative intent of SB 1442 as indicated by the author's comments. Ms. Kim stated she supported the regulation as currently drafted.

Member Oh stated designating a person is necessary, not just a classification, to ensure the person providing the coverage is trained and able to help the pharmacist. He expressed concern about using an average for response time because of how important the assistance is to the pharmacist and the potential for causing confusion and additional burden of record keeping for the pharmacist. Dr. Oh stated the intent of the legislation is to assist when the need arises which is usually immediate. He noted safety concerns could be mitigated in other ways. Dr. Oh agreed with staff recommendations and hoped to vote to adopt the regulation.

Member Patel agreed using an average response time seemed to be reasonable. Dr. Patel added having people trained to fill the position should be sufficient so that a name is not required. Dr. Patel stated the bill was passed to ensure consumers receive timely assistance and pharmacist can safely practice. He inquired about the number of consumer complaints received from consumers who didn't receive their medications timely due to the pandemic.

Having provided time for each member to comment, President Lippe encouraged further discussion.

Ms. Veale noted that anyone who came back to the pharmacy would need to meet the background requirements but indicated the need to provide flexibility to determine how to ensure compliance.

Dr. Butler noted the statute was passed in January 2019. Executive Officer Sodergren added the Board approved the regulation for notice in July 2019.

Dr. Serpa noted the regulations should be specific and easy for licensees to implement as well as for inspectors to monitor.

Motion: Adopt the regulatory language as noticed on February 28, 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.

> Add section 1714.3 to Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1714.3. Community Pharmacy Staffing

This section applies to a community pharmacy that is required to comply with Business and Professions Code section 4113.5.
(a) When a pharmacy is open to the public and a pharmacist is working without another pharmacy employee currently working, the pharmacy shall make another person who is an employee of the establishment within which the pharmacy is located available to assist the pharmacist. The pharmacy shall:
(1) Designate the name(s) of one or more persons who will be available to assist the pharmacist;
(2) Ensure that each designated person is able, at a minimum, to perform the duties of nonlicensed pharmacy personnel as specified in section 1793.3;
(3) Ensure that each designated person qualifies to have access to controlled substances by conducting a background check on each person that is consistent with federal requirements for pharmacy employees with such access;
(4) Ensure that a designated person responds and is able to assist the pharmacist within five minutes after the pharmacist's request.
(b) A pharmacy shall have and maintain policies and procedures that address the following:
(1) How a pharmacist on duty will be able to identify the person(s) designated as available to assist them, and the required criteria and training for those designated person(s), which shall be consistent with subdivison (a).
(2) The process for the pharmacist to request assistance and to document the response time between the request and arrival of the designated person at the pharmacy.
(c) All impacted pharmacy employees and designated persons must read and sign a copy of the policies and procedures required by this section. For purposes of this section, "impacted pharmacy employees" means any employee of the pharmacy, whether the person works within or for the pharmacy owner, who has any duties to prepare for or to execute how or when a pharmacist may seek or obtain assistance pursuant to Business and Professions Code section 4113.5, including any pharmacist, any person who creates or approves pharmacy employees' work schedules, or who designates persons who may assist the pharmacist pursuant to this section.
(d) The pharmacy must maintain the policies and procedures in the pharmacy premises in a readily retrievable format.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4110and 4113.5, Business and Professions Code.

M/S: Butler/Oh

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

Jassy Grewal, Legislative Advocate for UFCW Western States Council, thanked the Board for their effort and work on these regulations. Ms. Grewal agreed with staff recommendations and spoke in support of the motion with no changes. She stated pharmacists should have a person to call when assistance is needed to ensure patient care is not delayed and the pharmacist shouldn't have to identify a person as part of the process. Ms. Grewal supported the staff recommendation of 5 minutes and expressed concern about how an average time period would be defined and monitored.

Jennifer Snyder spoke on behalf of California Retailers Association (CRA) and National Association of Chain Drug Stores (NACDS) expressing concern with the motion before the Board. She stated the 5-minute requirement was very restrictive and didn't account for emergencies, breaks or unexpected staffing issues. Ms. Snyder suggested using an average of 10 minutes. She stated requiring a designated name or person was overly restrictive and doesn't account for changes in staff. Ms. Snyder commented designating a position that is adequately trained is a better approach.

Lori Walmsley of Walgreens expressed concern for the 5-minute time requirement, especially in 24-hour stores where limited staff are available and appreciated the flexibility provided with an average to account for unexpected situations.

Rob Geddes of Albertsons expressed concern with a time limit and agreed an average timeframe would make this more operational and strongly opposed the current motion.

Dr. Butler and Dr. Oh stated they did not want to amend the motion. The Board voted and the motion passed.

Support: 7 Oppose: 3 Abstain: 0

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

b. <u>Proposed Regulation to Amend Title 16, CCR, Sections 1769 and 1770, Substantial Relationship and Rehabilitation Criteria</u>

President Lippe reminded members that at the May 2019 Board meeting, the Board approved proposed text to amend sections 1769 and 1770 of Title 16, CCR, related to the Substantial Relationship and Rehabilitation Criteria. President Lippe noted the proposal will increase transparency and clarity to applicants with respect to rehabilitation criteria the Board considers when evaluating an individual's eligibility for licensure. Further, it was noted that the regulations are necessary to implement the provisions of AB 2138, Chapter 995, Statutes of 2018.

President Lippe said subsequent to the release of the meeting materials, DCA counsel provided suggested language to incorporate changes offered by the Office of Administrative Law (OAL) for other DCA programs pursuing regulations in this area. Mr. Lippe noted that the specifics changes were detailed in the revised memo and indicated that all changes recommended are non-substantial. He confirmed members had the opportunity to review the meeting materials, including the comments received, recommendations of counsel, and staff's recommendation.

Motion: Adopt the regulatory language as noticed on March 13, 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 and accept the non-substantive changes that were viewed on the computer and detailed in the memorandum offered by the control agency.

Amend section 1769 of Article 8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1769. Criteria for Rehabilitation.

(a) Examination of applicant by medical professionals to assess competency.

In addition to any other requirements for licensure, when considering the approval of an application, the board or its designee may require an applicant to be examined by one or more physicians and surgeons or psychologists designated by the board if it appears that the applicant may be unable to safely practice due to mental illness or physical illness affecting competency. An applicant's failure to comply with the examination requirement shall render his or her application incomplete. The board shall pay the full cost of such examination. The board shall seek that the evaluation be conducted within 60 days of the date the applicant is advised that an examination is required. The board shall receive the examiner's evaluation within 60 days of the date the examination is completed. The report of the examiner shall be made available to the applicant.

If after receiving the report of the evaluation, the board determines that the applicant is unable to safely practice, the board may deny the application.

(b) Denial of a license.

(1) When considering the denial of a facility or personal license under Section 480 of the Business and Professions Code on the grounds that the applicant ~~was~~ has been convicted of a crime, the board will consider whether the applicant made a showing of rehabilitation and is presently fit for a license, if the applicant completed the criminal sentence at issue without a violation of parole or probation. In making this determination, the board will consider the following criteria: ~~, the board, in evaluating the rehabilitation of the applicant and his present eligibility for licensing or registration, will consider the following criteria:~~

(~~1~~A) The nature and gravity of the crime(s).

(~~2~~B) The length(s) of the applicable parole or probation period(s).

(~~3~~C) The extent to which the applicable parole or probation period was shortened or lengthened, and the reason(s) the period was modified.

(~~4~~D) The terms or conditions of parole or probation and the extent to which they bear on the applicant's rehabilitation.

(~~5~~E) The extent to which the terms or conditions of parole or probation were modified, and the reason(s) for modification.

(~~6~~2) If the applicant has not completed the criminal sentence at issue without a violation of parole or probation, or the board determines that the applicant did not make the showing of rehabilitation based on the criteria in paragraph (1) or the denial is based on professional misconduct, ~~If subdivision (b) is inapplicable, or the board determines that the applicant did not make the showing of rehabilitation based on the criteria in subdivision (b),~~ the board will apply the following criteria in evaluating an applicant's rehabilitation:

(~~1~~A) The nature and ~~severity~~gravity of the act(s), professional misconduct, or ~~offense(s)~~crime(s) under consideration as grounds for denial.

(~~2~~B) Evidence of any act(s), professional misconduct, or crime(s) committed subsequent to the act(s), professional misconduct, or crime(s) under consideration as grounds for denial under Section 480 of the Business and Professions Code.

(~~3~~C) The time that has elapsed since commission of the act(s), professional misconduct, or crime(s) referred to in ~~subdivision~~paragraph (1) or (2) subparagraph (A) or (B).

(~~4~~D) Whether the applicant has complied with any terms of parole, probation, restitution or any other sanctions lawfully imposed against the applicant.

(~~5~~E) The criteria in ~~subdivisions (b)(1)-(5),~~ paragraphs (1)(A) through (E), as applicable.

~~(5)~~(~~6~~F) Evidence, if any, of rehabilitation submitted by the applicant, including as provided in the board's Disciplinary Guidelines, identified in section 1760.

~~(c)~~~~(d)~~(c) Suspension or revocation of a license.

When considering the suspension or revocation of a facility or a personal license on the ground that the licensee ~~or the registrant~~ has been convicted of a crime, the board~~, in evaluating the~~ will consider whether the licensee made a showing of rehabilitation ~~of such person~~ and ~~his present eligibility~~ is presently fit for a license, if the licensee completed the criminal sentence at issue without a violation of parole or probation. In making this determination, the board will consider the criteria in ~~subdivisions (b)(1)-(5).~~ subdivisions (b)(1)(A) through (E). If the licensee has not completed the criminal sentence at issue without a violation of parole or probation or the board determines that the licensee did not make the showing of rehabilitation based on the criteria in subdivisions (b)(1)(A) through (E), the board will apply the following criteria in evaluating the licensee's rehabilitation: ~~If the board determines that the licensee did not make a showing of rehabilitation based on the criteria in subdivisions (b)(1)-(5), or if a licensee has not completed the criminal sentence at issue without a violation of parole or probation, the board will consider the following criteria:~~

(1) Nature and ~~severity~~gravity of the act(s) or offenses.

(2) Total criminal record.

(3) The time that has elapsed since commission of the act(s) or offenses.

(4) Whether the licensee has complied with all terms of parole, probation, restitution or any other sanctions lawfully imposed against the licensee.

(5) The criteria in ~~subdivisions (b)(1)-(5),~~ subdivisions (b)(1)(A) through (E), as applicable.

~~(5)~~(6) Evidence, if any, of rehabilitation submitted by the licensee, including as provided in the board's Disciplinary Guidelines, identified in section 1760.

Note: Authority cited: Sections ~~482 and~~ 4005, Business and Professions Code. Reference: Sections 480, 481, 482, 488, 493, 4030, 4200 and 4400, Business and Professions Code.

Amend section 1770 of Article 8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1770. Substantial Relationship Criteria.

(a) For the purpose of denial, suspension, or revocation of a personal or facility license pursuant to Section 141 or Division 1.5 (commencing with Section 475) of the Business and Professions Code, a crime, professional misconduct, or act shall be considered substantially related to the qualifications, functions or duties of ~~a licensee or registrant~~ the practice, profession, or occupation that may be performed under the license type sought or held if to a substantial degree it evidences present or potential unfitness of ~~a~~ an applicant or licensee ~~or registrant~~ to perform the functions authorized by ~~his~~the license ~~or registration~~ in a manner consistent with the public health, safety, or welfare.

(b) In making the substantial relationship determination required under subdivision (a) for a crime, the board will consider the following criteria:

(1) The nature and gravity of the offense;

(2) The number of years elapsed since the date of the offense; and

(3) The nature and duties of the ~~profession~~ practice, profession, or occupation ~~the person may perform with~~ that may be performed under the license type sought or held.

(c) For purposes of subdivision (a), substantially related crimes, professional misconduct, or acts shall include, but are not limited to, those which:

(1) Violate or attempt to violate, directly or indirectly, or to aid, abet or conspire to violate, any provision of law of this state, or any other jurisdiction, governing the practice of pharmacy.

(2) Violate or attempt to violate, directly or indirectly, or to aid, abet or conspire to violate, any provision of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or any law of this state, or any other jurisdiction, relating to controlled substances or dangerous drugs.

(3) Violate or attempt to violate, directly or indirectly, or to aid, abet or conspire to violate, any provision of law of this state, or any other jurisdiction, relating to government provided or government supported healthcare.

(4) Involve dishonesty, fraud, deceit, or corruption related to money, items, documents, or personal information.

(5) Involve a conviction for driving under the influence of drugs or alcohol.

Note: Authority cited: Sections ~~481, 493, and~~ 4005, Business and Professions Code. Reference: Sections 141, 480, 481, 490, 493, 4300, 4301, 4301.5, and 4309, Business and Professions Code.

M/S: Veale/Butler

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

Support: 10 Oppose: 0 Abstain: 0

Board	
Brooks	Support
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Wong	Support

c. Proposed Regulation to Amend Title 16, CCR, Sections 1702, 1702.1, 1702.2, 1702.5, Renewal Requirements

Members were advised that at the May 2018 Board meeting, the Board approved proposed text to amend sections 1702, 1702.1, 1702.2, and 1702.5 of Title 16, CCR, related to renewal requirements. President Lippe added the proposal updates the renewal requirement language to include all licensing programs and amended the language in a manner that will ensure that the regulatory text applies to new licensing programs as they are established, streamlining the implementation process. President Lippe said no comments were received during the comment period.

Motion: Adopt the regulatory language as noticed on February 7, 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.

Amend section 1702 in Article 1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702. Pharmacist Renewal Requirements.

(a) A pharmacist applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date.

(1) A pharmacist ~~s~~ shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the board.

(2) A pharmacist applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license, or for restoration of a retired license, an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal. Traffic infractions not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty being placed on the license, such as revocation, suspension, probation or public reprimand or reproval.

(d) <u>As a condition of renewal, a pharmacist applicant shall disclose whether he or she has complied with all continuing education requirements to renew his or her pharmacist or advanced pharmacist license as required by section 1732.5.</u>

<u>(e)</u> Failure to provide <u>under penalty of perjury</u> all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license and shall issue the applicant an inactive pharmacist license. An inactive pharmacist license issued pursuant to this section may only be reactivated after compliance is confirmed for all licensure renewal requirements.

Note: Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 141, 490, 4036, 4200.5, 4207, 4231, 4300, 4301, 4301.5, 4311 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Amend section 1702.1 in Article 1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702.1. ~~Pharmacy Technician~~ Renewal Requirements for Individual Licensees Other Than Pharmacists.

This section applies to the renewal of any license held by an individual licensee, other than an individual licensed as a pharmacist or an advanced practice pharmacist.

(a) A licensee ~~pharmacy technician~~ applying ~~icant~~ for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after January 1, 2018.

(1) The licensee ~~A pharmacy technician~~ shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the board.

(2) The licensee ~~A pharmacy technician~~ applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, ~~a pharmacy technician applicant~~ the licensee shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal. Traffic infractions not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, ~~a pharmacy technician applicant~~ the licensee shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, “disciplinary action” means an adverse licensure or certification action that resulted in a restriction or penalty against the license or

certification such as revocation, suspension, probation or public reprimand or reproval.

(d) Failure to provide under penalty of perjury all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.

Note: Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 141, 490, 4022.5, 4022.6, 4022.7, 4032, 4038, 4053, 4115, 4202, 4202.5, 4207, 4300, 4301 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Repeal section 1702.2 in Article 1 of Division 17 of Title 16 of the California Code of Regulations.

~~**1702.2. Designated Representative Renewal Requirements.**~~

~~(a) A designated representative applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after January 1, 2018.~~

~~(1) A designated representative shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the board.~~

~~(2) A designated representative applicant for renewal shall pay the actual cost of compliance with subdivision (a).~~

~~(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).~~

~~(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).~~

~~(b) As a condition of renewal, a designated representative applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal. Traffic infractions not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.~~

~~(c) As a condition of renewal, a designated representative applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section,~~

~~"disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproval.~~

~~(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.~~

~~Note: Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 141, 490, 4022.5, 4022.7, 4053, 4207, 4300, 4301 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.~~

Amend section 1702.5 in Article 1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702.5. Renewal Requirements for Premises or Facilities ~~Disclosure of Discipline, Renewal, Nonresident Wholesaler or Nonresident Pharmacy~~.

This section applies to the renewal of any license held by a premises or facility.

(a) As a condition of renewal, an applicant seeking renewal of a premises or facility license ~~as a nonresident wholesaler or as a nonresident pharmacy~~ shall report to the board any disciplinary action taken by any government agency since the issuance or last renewal of the license. ~~An applicant seeking the first renewal of a license as a nonresident wholesaler or a nonresident pharmacy shall report to the board any disciplinary action taken by any government agency since issuance of the license.~~ Failure to provide information required by this section shall render an application for renewal incomplete, and the board shall not renew the license until such time as the information is provided.

(b) For purposes of this section, "disciplinary action" means any adverse licensure or certification action that resulted in a restriction or penalty against the license or certification. Such actions include revocation, suspension, probation, or public reprimand or reproval.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 141, 4112, 4161, 4300, 4301, 4302, 4303, 4303.1 and 4316, Business and Professions Code.

M/S: Veale/Lippe

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

Support: 10 Oppose: 0 Abstain: 0

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

d. Proposed Regulation to Amend Title 16, CCR, Section 1707, Off-Site Storage

President Lippe reminded the Board that the approved proposed text to amend section 1707 of Title 16, CCR, related to off-site storage of records occurred during the January 2017 Board meeting. The proposal amends the Board's regulations to allow Board discretion to grant those cited for a records violation a waiver to store records off-site.

President Lippe stated the Board received one comment during the comment period which was included in the meeting materials. The comment appeared to be a question regarding clarification of the regulation. As noted in the meeting materials, Board staff recommended the comment be rejected. Board staff noted that the off-site storage requirements apply to nonresident pharmacies pursuant to Precedential Decision No. 2019-01 [In the matter of the Citation Against: ESI Mail Pharmacy, Inc. dba Express Scripts, (Case No. CI 2009 44657; OAH Case No. 2011060384)].

Motion: Approve the staff modified language dated April 27, 2020, reject the comment offered by staff recommendation, and initiate a 15-day public comment period. Additionally, should no negative comments be received, delegate to the executive officer the authority to adopt the modified text and make technical or non-substantive changes as may be required by the control agencies to complete the rulemaking file.

Proposed changes to the current regulation language are shown by strikethrough for deleted language and underline for added language.

Proposed changes to the initial proposed text are shown by double underline for added language.

Proposal to Amend § 1707 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read:

§ 1707. Waiver Requirements for Off-Site Storage of Records

(a) Pursuant to subdivision (e) of Section 4105 of the Business and Professions Code and subdivision (c) of Section 4333 of the Business and Professions Code, a waiver ~~shall~~ may, on a case-by-case basis, be granted to any entity licensed by the board for ~~off-site~~ storage of the records outside the licensed area of the pharmacy described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code~~ unless the applicant has, within the preceding five years, failed to produce records pursuant to Section 4081 of the Business and Professions Code or has falsified records covered by Section 4081 of the Business and Professions Code~~. The board may consider space limitations within the pharmacy, cost, previous compliance with records requirements, ease of access to records stored outside of the licensed area, and any other factor presented by the licensee in making its determination.

(b) An entity that is granted a waiver pursuant to subdivision (a) shall:

(1) maintain the storage area so that the records are secure, including from unauthorized access; and

(2) be able to produce the records within two business days upon the request of the board or an authorized officer of the law.

(c) In the event that a licensee fails to comply with the conditions set forth in subdivision (b), the board may cancel the waiver without a hearing. Upon notification by the board of cancellation of the waiver, the licensee shall maintain all records at the licensed premises.

(d) A licensee whose waiver has been cancelled pursuant to the provisions set forth in subsection (c) may reapply to the board when compliance with the conditions set forth in subsection (b) can be confirmed by the board.

(e) Notwithstanding any waiver granted pursuant to subdivision (a), all prescription records for non controlled substances shall be maintained on the licensed premises for a period of one year from the date of dispensing.

(f) Notwithstanding any waiver granted pursuant to subdivision (a), all prescription records for controlled substances shall be maintained on the licensed premises for a period of two years from the date of dispensing.

(g) Notwithstanding the requirements of this section, any entity licensed by the board may store the records described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code in a storage area at the same address or adjoining the licensed premises without obtaining a waiver from the board if the following conditions are met:

(1) The records are readily accessible to the pharmacist-in-charge (or other pharmacist on duty, or designated representative) and upon request to the board or any authorized officer of the law.

(2) The storage area is maintained so that the records are secure and so that the confidentiality of any patient-related information is maintained.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4105 and 4333, Business and Professions Code.

M/S: Veale/Sanchez

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

Support: 10 Oppose: 0 Abstain: 0

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

IX. Discussion and Consideration of the Board's Strategic Plan

The Board approved its current strategic plan during the October 26-27, 2016, meeting. Historically, the Board has conducted an annual review of its plan as the strategic plan is intended to be a living document and updated to reflect changes in Board priorities that may result from changes in the marketplace, legislation, etc. Strategic plans typically span five years. President Lippe stated it is anticipated the Board will engage in the strategic planning process in 2021.

President Lippe noted status updates for strategic goal areas were provided in the meeting materials. Each committee chairpersons reviewed their respective committees as well as highlighted any potential changes or priorities for the coming year.

Vice President Veale as Chairperson of the Licensing Committee reviewed the Licensing Committee's updates and goals provided in the meeting materials.

Ms. Veale reported Goal 1.1 to implement online applications, license renewals, and fee payment for applicants and licensees was being addressed through business modernization activities and would ultimately lead to better applicant, licensee, and consumer engagement. Ms. Veale note that a transition to a more robust paperless process will be a significant outcome of business modernization.

Ms. Veale noted Goal 1.2 reflects the commitment to completing a comprehensive review of at least five licensure categories and to update requirements as appropriate. Ms. Veale indicated that good progress was made toward completing this goal and sought member input on the next licensing program to be evaluated. Ms. Veale noted that absent comments from members, the Licensing Committee will determine the next licensing programs to evaluate.

Ms. Veale noted Goal 1.3 speaks to improving the application process, including providing guidance to applicants. Ms. Veale added more needs to be done in this area and sought input from members and the public when setting agendas for the upcoming fiscal year. She added the committee previously discussed the high deficiency rate for pharmacy applications and noted that staff have offered to provide a presentation on the application process.

President Lippe inquired if there were issues with the Advanced Practice Pharmacist (APH) application. Ms. Sodergren noted the challenge experienced with many APH applicants was the criteria for the pathways to licensure. Ms. Sodergren added the Board will be pursuing legislation to clarify the requirements for licensure. Once this is remedied, the challenges with the APH application will be resolved. Ms. Veale indicated the pharmacy and pharmacy technician applications tend to experience deficiency issues. She asked that pharmacy technicians be added to the agenda for review.

Ms. Veale advised Goal 1.4 called on the Committee to establish requirements to form a licensing process for alternative worksites and vendors in the marketplace. She recommended in the upcoming year the Licensing Committee focus on evaluation of call centers and remote order entry provisions.

Ms. Veale stated Goal 1.5 is to identify opportunities to expand electronic interfaces with licensees to allow for online application and renewal and explained is addressed by business modernization efforts.

Ms. Veale added the Committee is current with implementing new licensing programs as measured by Goal 1.6. She noted for Goal 1.7, the Committee will perform benchmarking activities as part of its assessment of licensing programs.

Treasurer Serpa as the Chairperson of the Enforcement and Compounding Committee reviewed the Enforcement and Compounding Committee's updates and goals provided in the meeting materials.

Dr. Serpa reported Goal 2.1 is to implement processes to shorten the cycle times from investigation to resolution of cases, with special focus on prioritized critical cases, to minimize patient harm and enhance consumer protection. Dr. Serpa noted that investigation processing times are reported at meetings. She added the Committee is also considering parameters for an alternative enforcement model.

Dr. Serpa provided Goal 2.2 is to strengthen patient consultation outcomes and increase medication safety. Dr. Serpa noted this is also reported annually on what is reported through the inspection process.

Dr. Serpa added Goal 2.3 is to collect data and report to the Board about enforcement trends in a multi-year format.

Dr. Serpa reported Goal 2.4 is to evaluate industry technology trends to develop future regulatory infrastructures that promote patient safety. She noted this has been done for the use and licensure of automated drug delivery systems (ADDS).

Goal 2.5 is to evaluate the disciplinary process and initiate process improvements for enhanced efficiency and effectiveness. In coordination with the Office of the Attorney General, the Board has initiated processes to improve the efficiency of the disciplinary process.

Dr. Serpa advised Goal 2.6 is to investigate options on the interoperability with a National Prescription Drug Monitoring Program. She added legislation was passed (AB 1751, Low, Chapter 478, Statutes of 2018) and established the authority for the Department of Justice to enter into an agreement with an entity operating an interstate data sharing hub for purposes of interstate sharing of controlled substances reporting information. The Department of Justice is in the process of implementing these provisions.

Dr. Serpa provided Goal 2.7 is to develop a process to submit complaints about inspectors anonymously and report back to the Board. Last year the Board developed a brochure to be distributed to licensees at the time of inspection. Included in the brochure is information on filing a comment or complaint about the inspector.

Goal 2.8 is to assess the collateral consequences of discipline. She provided the Enforcement Committee will review the Board's Disciplinary Guidelines.

Dr. Serpa noted Goal 2.9 is the evaluation of the Board's citation and fine program. She noted the Committee has received several presentations on the citation and fine program and will continue to receive annual updates.

Goal 2.10 is to review the role and responsibilities of the pharmacist-in-charge (PIC). Dr Serpa noted there is an opportunity for discussion that will occur with the review of the Disciplinary Guidelines.

The Board took a break for lunch from 11:58 am and returned from break at 12:30 pm.

Roll call was taken after the break. Board Members present: Debbie Veale, Maria Serpa, Ryan Brooks, Lavanza Butler, Shirley Kim, Seung Oh, Jig Patel, Ricardo Sanchez, Albert Wong, and Greg Lippe.

President Greg Lippe as Chairperson of the Legislation and Regulation Committee reviewed the Legislation and Regulation Committee's updates and goals provided in the meeting materials.

President Lippe stated Goal 3.1 is to educate the Board on national pharmacy initiatives impacting consumers and the future of pharmacy and align with the Board's efforts where the profession was going to be in 2020. He added in the past, the former executive officer would provide updates from national meetings she attended. Since the retirement of the former executive officer, Board staff have not had the opportunity to attend the National Association of Boards of Pharmacy (NABP) meeting. He added the president and executive officer will attend the May 2020 virtual NABP annual meeting.

President Lippe noted Goal 3.2 is to support legislative and regulatory proposals from Board approval to enactment to effectuate the goals of the Board. He noted the Board submitted its Sunset Report in December 2019, which included several legislative priorities. Members were advised that due to COVID-19 pandemic, the Legislature has been in recess for a few months, delaying consideration of the Board's Sunset Report and legislative proposals. Further, Mr. Lippe noted that the Board currently has 17 regulation packages in various status of promulgation.

President Lippe provided Goal 3.3 is to advocate for or against legislation that impacts the Board's mandate for consumer protection. He added due to COVID-19 pandemic, the Legislature has been in recess for a few months. As such the Board has not considered legislation.

Goal 3.4 is to establish a systemized, ongoing review process for board regulations to improve and maintain clear and relevant regulations. President Lippe stated staff and counsel continue to collaborate to improve the quality of regulation packages including ensuring regulation language is clear, consistent, and necessary. Further, the DCA has established a regulations unit to perform pre-review of regulation packages.

Dr. Serpa commented that it is good for the Board to be present and participating at national meetings and forums. She also indicated the Board needs to be vocal at the national forums and provide information at the national level on how California is being proactive.

Dr. Butler agreed with Dr. Serpa that it is important that the president and executive officer are involved at the national level.

Member Sanchez, the Chairperson of the Communication and Public Education Committee, reviewed the Communication and Public Education Committee's updates and goals provided in the meeting materials.

Goal 4.1 is to develop and implement a communication plan for licensees and consumers to improve communication and keep stakeholders better informed. Mr. Sanchez provided a

status update that although the Board has expanded its communications to both consumers and licensees, these efforts do not follow a written communication plan.

Mr. Sanchez advised Goal 4.2 is to identify and use additional resources for public and licensee outreach services to implement the communication plan. He provided a status update that the Board has expanded into social media to communicate with the public and licensees, in addition to relying on its website, newsletter and subscriber alerts. The Board hosted live CE training events throughout the state and produced three online CE webinars for licensees. The Board moved its meeting locations throughout the state, increasing public exposure and awareness of the Board's activities.

Goal 4.3 is to establish a process to collect email addresses and mobile numbers for text messaging from all licensees to improve communication. Mr. Sanchez noted the Board implemented regulations requiring pharmacists, intern pharmacists, pharmacy technicians and designated representatives to register their email addresses to receive subscriber alerts.

Mr. Sanchez advised Goal 4.4 is to provide implementation guidance on newly enacted changes to pharmacy law by publishing summaries and explaining implementation tactics. The Board maintains a pharmacy lawbook online and publishes annual summaries of new laws online and in *The Script*. The Board also issued subscriber alerts and published FAQs and guidance information on major laws and policies, including inventory reconciliation, compounding matters and changes to security prescription forms.

Mr. Sanchez noted Goal 4.5 is to inspect pharmacies at least once every four years to provide a forum for licensee/inspector communication and education in practice settings. The Board is creating an informational brochure and provides information in *The Script* to improve communication between inspectors and licensees during inspections. Mr. Sanchez reported that inspector staff are performing routine inspections. Common discussion points are shared among inspector staff to facilitate more standardized communication.

Goal 4.6 is to communicate the availability of new or specified pharmacy services and locations so that the public is aware of pharmacies that can meet their needs. Mr. Sanchez stated the Board created an online search tool to help consumers find drug take-back locations. Staff is also developing a search tools to help consumers find pharmacies providing special health care services.

Mr. Sanchez noted Goal 4.7 is to revise consumer-facing materials (e.g., posters, point-to-your-language notices, television messages) to achieve better consumer understanding of their rights and optimal use of medications. The Board updated a consumer brochure about the risks of buying drugs online. Staff is also working to review and update additional consumer materials as needed.

Mr. Sanchez noted Goal 4.8 is to promote Board initiatives to improve patient knowledge, medication adherence, and medication safety. He noted prior to the pandemic, Board staff was working to attend more outreach events targeting consumers as well as licensees.

Recently staff worked with DCA to publish an online article with consumer tips on filling opioid prescriptions and talking to their pharmacist.

Member Wong suggested the Board include information about DUIs as part of the renewal notice. This item will be scheduled as a possible agenda item for future discussion.

President Lippe as Chairperson of the Organizational Develop Committee referred to the goals outlined meeting materials. He stated the goals included are all still appropriate.

President Lippe provided Goal 5.1 is to conduct a full annual review of the Board's strategic plan to monitor progress. He noted the Board's Strategic Plan was updated October 2016, 2018, and 2019 as well as at the May 2020 Board meeting.

President Lippe advised Goal 5.2 is to provide leadership training opportunities to managers to expand skills and improve performance. He added all management staff completed biennial Sexual Harassment Prevention training in 2019. Leadership Communication and Performance Management trainings were scheduled but subsequently cancelled due to Governor Gavin Newsom's Executive Order N-25-20, dated March 12, 2020.

President Lippe noted Goal 5.3 is to expand annual individual development plans for staff to promote growth and development. He added approximately three Individual Development Plans and 21 Performance Appraisals were provided to inspector and office staff. Because of changes to union contracts, annual individual development plans are no longer required. Rather, staff must elect to participate in the process.

Goal 5.4 is to collaborate with the Department of Consumer Affairs to explore the feasibility of procuring electronic management tools to increase efficiencies and reduce reliance on paper. President Lippe noted the Board continues to work with the DCA on Business Modernization which will replace legacy systems as well as include workflow design improvements and scanning management.

President Lippe advised Goal 5.5 is to maintain procedure manuals to capture institutional knowledge and enable consistent operations. The inspector training manual was revised in February 2020. Standardized training plans were developed and are used to onboard new staff.

Goal 5.6 is to establish customer service metrics to track Board efforts to meet customer expectations. President Lippe noted approximately 40 post-inspection surveys were conducted by Chiefs of Enforcement prior to Governor Gavin Newsom's Executive Order N-25-20, dated March 12, 2020.

President Lippe noted Goal 5.7 is to evaluate options for improvement of licensing renewal processes to allow for online renewal. He added in 2019, the Board implemented online license renewal payments for individual licenses and is working with the DCA to secure online renewal payment for facilities.

President Lippe provided Goal 5.8 provides, that in collaboration with the executive officer, ensure appropriate resources for Board issues relating to staff activities and development. President Lippe said during the past 18 months, field staff have completed USP training. In addition, several field staff completed cGMP training and limited staff participated in training provided by the FDA. In addition, field staff participated in Board-provided trainings covering new laws, inspections, and requirements for new licensing programs. Office staff completed customer service training, and management staff received training on the Budget Change Proposal process.

President Lippe added that as inspections resume, he would like to see an increase in the number of post-inspection surveys completed. He also noted he would like to receive more formal semi-annual updates on the Board's Business Modernization efforts.

There were no motions to change any goals to the strategic plan.

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

X. Licensing Committee

a. Update on Implementation of Recently Enacted Legislation -- SB 159 (Weiner, Chapter 532, Statutes of 2019) Related to HIV Preexposure and Postexposure Prophylaxis

Chairperson Veale announced that on April 30, 2020, the Office of Administrative Law (OAL) approved the Board's emergency regulation establishing the training course parameters for pharmacists to provide PrEP and PEP under the authorities of SB 159.

Ms. Veale noted that, as previously discussed, Board staff, in collaboration with the Department of Health Care Services, Office of AIDS, and an expert in the area, are developing a training program that would comply with the provisions. Unfortunately, in response to the public health crisis, there has been a delay in completing the training program. Ms. Veale indicated she hopes that the detailed framework for the training will be ready for Committee and Board consideration at either the June 2020 or July 2020 Board meeting. She noted trainings sponsored by other entities could be available.

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

b. Review of Licensing Statistics

Ms. Veale reported licensing statistics for the first three quarters of the fiscal year. Additional licensing statistics received indicate in April, the Board issued 784 licenses, including 486 pharmacy technician licenses, 88 intern licenses, 70 advanced practice

pharmacist licenses and 5 pharmacist licenses. Ms. Veale noted that only one individual took the examination during the April 21st administration.

Ms. Veale provided processing times as of April 24, 2020, as well as the processing times from January, for comparison. She noted a reduction in the processing times for some application types, indicating that with the exception of nonresident pharmacy and clinics applications, all initial application processing times are at or below 30 days. Ms. Veale indicated that overall this reflects improvement from prior reporting. There was also improvement noted in the processing time for deficiency mail, including significant reduction in such processing times for pharmacies, nonresident pharmacies and sterile compounding applications.

Ms. Veale thanked staff for their effort to decrease the processing times.

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

XI. Enforcement and Compounding Committee

a. Discussion and Consideration of Policy Statement Regarding Applicability of Board Compounding Regulations and USP Compounding Chapters While Pending Appeals Before USP

Chairperson Serpa stated on September 23, 2019, USP announced a delay in the official date of the revised Chapters <795> and <797> and the new Chapter <825> until further notice. The delay resulted from appeals received on certain provisions of the respective chapters. Subsequent to that action, as part of its November 2019 meeting, the Board voted and released a policy statement to ensure stakeholders have a clear understanding of the legal requirements for pharmacies compounding drug preparations.

Dr. Serpa further advised that on March 12, 2020, USP issued final decisions on appeals to the revisions to Chapters <795> and <797> and new Chapter <825>. Specifically, the appeals panel granted the appeals to General Chapters <795> and <797> and is remanding the Chapters to the Compounding Expert Committee with the recommendation for further engagement on the issues raised concerning the beyond-use-date provisions. The appeals panel denied the General Chapter <825> and encouraged the appellant to submit the narrower request presented at the hearing to the Chemical Medicines Monograph 4 Expert Committee as a request for revision.

The draft policy statement text was included in the meeting materials. (Note: a copy of the text is provided below.)

Draft Policy Statement Text:

Compounding Requirements Following USP Appeal Decisions,
May 7, 2020

In light of USP's March 12, 2020, final decision on appeals of the proposed revised Chapters <795> and <797> and the new Chapter <825>, the California State Board of Pharmacy (Board) provides its stakeholders with this current status of the legal requirements for pharmacies compounding drug preparations.

As the Board reads the decisions, some of the appeals to Chapters <795> and <797> were granted, sending the chapters back to the committee for further discussion. Accordingly, the current chapters of <795> (last revised in 2014) and <797> (last revised in 2008) remain official. In addition, all licensees must adhere to all relevant sections of Pharmacy Law and regulations, including but not limited to the Board's current regulations – title 16, California Code of Regulations, section 1735 et. seq. (Article 4.5, Compounding); section 1751 et. seq. (Article 7, Sterile Compounding); and section 1708.3 to section 1708.5 (related to radioactive drugs) – and Business and Professions Code section 4126.8 and other relevant sections.

Although USP has indicated that Chapter <800> is informational and not compendially applicable unless and until Chapters <795> and <797> are revised and reference Chapter <800>, the Board's current regulations on compounding hazardous drug preparations remain in effect. Like USP, the Board encourages utilization of Chapter <800> in the interest of advancing public health.

The Board's Compounding Committee has been reintegrated into the Board's Enforcement Committee. At this time, the Board does not intend to pursue changes to the current regulations governing compounded preparations. The Board will continue to communicate with stakeholders as information becomes available.

This is a link to the Appeals Panel decisions on USP Chapters <795>, <797>, and <825>: https://www.usp.org/sites/default/files/usp/document/our-work/compounding/decisionsappeals-fs.pdf.

The Board reminds licensees that in response to the COVID-19 pandemic, waivers to provisions of Pharmacy Law have been granted. Information regarding the waivers is provided on the Board's website, ww.pharmacy.ca.gov.

Motion: Approve the revised draft policy statement as provided in the meeting materials

M/S: Serpa/Lippe

Members of the public were provided with an opportunity to provide comments. The Board heard a comment from a member of the public requesting the status of the

Board's pending regulation. The member of the public was advised the Board does not currently have pending regulations regarding compounding.

Support: 10 Oppose: 0 Abstain: 0

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

b. Review of Enforcement Statistics

Enforcement Statistics were included in the meeting materials.

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

XII. Communication and Public Education Committee

a. Update on Communications to Licensees and Stakeholders Regarding COVID-19

Mr. Sanchez advised members that on March 4, 2020, Governor Gavin Newsom declared a state of emergency in California in response to the COVID-19 pandemic. Mr. Sanchez reported the Board acted quickly and continuously to communicate important information to licensees and stakeholders. Staff also has worked closely with DCA to review and coordinate all public messages related to COVID-19.

Mr. Sanchez noted on March 5, 2020, staff issued a subscriber alert advising licensees about how they could request waivers to Pharmacy Law provisions in order to aid in the protection of public health or provide patient care. He added on March 17, 2020, staff began issuing subscriber alerts advising licensees each time new Pharmacy Law waivers were approved. All waivers issued to date also have been posted on the Board's website.

Mr. Sanchez indicated that staff posted frequently asked questions related to COVID-19 on the website, along with a statement regarding improper prescribing of treatments

issued jointly by the Board of Pharmacy, the Medical Board of California, and DCA. The website also contains additional resources for licensees and the public, including guidance documents issued by state and federal agencies, and links to COVID-19 websites established by the Governor's Office, CDPH, CDC and FDA.

Dr. Butler thanked the staff for the Frequently Asked Questions on COVID-19.

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

b. Discussion and Consideration of Committee's Strategic Goals

This item was discussed under Agenda Item IX.

XIII. Legislation and Regulation Committee

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

1. Proposed Regulation to Amend Title 16 CCR Section 1746.3 Related to Naloxone Fact Sheet

President Lippe provided the proposed regulation to amend Title 16, CCR, section 1746.3 related to the naloxone fact sheet was included in the meeting materials. This regulation was approved by the Office of Administrative Law on January 27, 2020, and took effect on April 1, 2020.

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

President Lippe provided summaries of regulations undergoing final review by the Office of the Administrative Law.

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

President Lippe advised the proposed regulation to amend Title 16, CCR, section 1707.2 amends the board's regulations regarding a pharmacist's duty to provide consultation for mail-order pharmacies.

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

President Lippe advised the proposed regulation is to amend Title 16, CCR, section 1706.2 will update the application abandonment language to include all licensing

programs to ensure that all applicants have appropriate notice about the requirements for abandoning an application. As included in the meeting materials, the proposal will also reduce the administrative workload associated with the need for frequent amendments when new licensing programs are established.

3. **Emergency Regulation to Add Title 16, CCR, Section 1747 Related to Independent HIV Preexposure and Postexposure Prophylaxis Furnishing**

   President Lippe advised members that the proposed emergency regulation to add Title 16, CCR, section 1747 related to independent HIV Preexposure and Postexposure Prophylaxis furnishing was approved on by the Office of Administrative Law on April 30, 2020.

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

c. 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

President Lippe indicated the Board has seven regulations that are in various stages of pre-notice review.

1. **Proposed Regulation to Add Title 16, CCR, Section 1717.5 Related to Automatic Refill Programs**

   President Lippe advised this regulation is proposed to add Title 16, CCR, section 1717.5 which will establish regulatory requirements for automated refill programs. He noted as indicated in the meeting materials, this rulemaking package was returned to Board staff to make additional modifications. Staff anticipates completing necessary revisions and resubmitting the package this month.

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

   President Lippe indicated this regulation is proposed to amend Title 16, CCR, section 1709 to include provisions relating to trust ownership of pharmacies. This package is currently undergoing pre-notice review by DCA.

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

   President Lippe advised the proposed regulations to amend Title 16, CCR, sections 1780-1783 et seq., would establish the regulatory framework for third-party logistics providers. This package is undergoing review by Agency.

4. **Proposed Regulation to Amend Title 16, CCR, Section 1715 to Update Self-Assessment Forms 17M13 and 17M-14**

   President Lippe advised the proposed regulation related would update the requirements of self-assessment and the related forms, by amending title 16, section 1715. He reported this package is undergoing pre-notice review by DCA.

5. **Proposed Regulation to Amend Title 16, CCR, Section 1784 to Update the Wholesaler/3PL Self-Assessment Form 17M-26**

   President Lippe noted that the regulation is related to updating self-assessment requirements and forms for wholesalers, specifically amending title 16, section 1784. He reported this package is undergoing pre-notice review by DCA.

6. **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**

   President Lippe advised the proposed regulations to amend Title 16, CCR, sections 1711 and 1713 and add section 1715.1 was approved by DCA and is now undergoing review by Agency. This rulemaking proposal 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.

7. **Proposed Permanent Regulation to Add Title 16, CCR, Section 1747 Related to Independent HIV Preexposure and Postexposure Prophylaxis Furnishing**

   President Lippe indicated that the regulation is the proposed permanent regulation to add Title 16 CCR section 1747 Related to Independent HIV Preexposure and Postexposure Prophylaxis Furnishing. The permanent rulemaking is undergoing pre-notice review.

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

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

President Lippe reported the remaining three rulemakings are all pending with staff to draft the necessary rulemaking documents for submission to the DCA to begin the pre-notice review.

1. **Proposed Regulations to Amend Title 16, CCR, Section 1793.5 Related to the Pharmacy Technician Application, Section 1793.6 Related to the Pharmacy Technician Training Requirements, and Section 1793.65 Related to the Pharmacy Technician Certification Programs**

   President Lippe advised this proposed regulation to amend Title 16, CCR, sections 1793.5, 1793.6 and 1793.65 would modify the training requirements and certification programs and update the application for licensure for pharmacy technicians. As indicated in the meeting materials, this rulemaking was returned to Board staff to integrate in changes necessary to implement AB 2138 requirements. Staff believe this rulemaking package will be ready for resubmittal this month.

2. **Proposed Regulation to Amend Title 16, CCR, Section 1715.6 Related to Drug Losses**

   President Lippe indicated the proposed regulation amends the drug loss reporting requirements to further define when drug losses must be reported to the Board and will provide greater clarity for the regulated public by amending Title 16, CCR, section 1715.6. Members were advised that Board staff anticipate this rulemaking package will be submitted to DCA for pre-notice review in early June.

3. **Proposed Regulation to Amend Title 16, CCR, Section 1715.65 Related to Inventory Reconciliation**

   President Lippe advised this proposed regulation amends and clarifies the requirements for the completion on inventory reconciliation activities and reporting as proposed to be amended, Title 16, CCR, Section 1715.65 Related to Inventory Reconciliation. He indicated that Board staff anticipate this rulemaking will be submitted to DCA for pre-notice review later this month.

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

XIV. Organizational Development Committee

a. Budget Update/Report

President Lippe reported a budget update was provided in the meeting materials. Final budget figures are now available for FY 2017/18. Mr. Lippe reviewed budget information noting that during that fiscal year the Board received over $19.9 million in revenue and expended over $23 million. Budget year figures for FY 2018/19 are not yet final.

President Lippe advised members that the Board's authorized expenditures for the current fiscal year are about $26 million. Preliminary budget figures for the first eight

months indicate the Board has received about $19.9 million in revenue and expended over $17.5 million. It is estimated that the Board's fund will have about 3.7 months in reserve at the end of the fiscal year and will remain relatively flat for the next few years.

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

b. Board Member Attendance Information

President Lippe thanked the Board Members for their continued commitment to the Board and California consumers.

c. Personnel Update

President Lippe noted the Board has 15 vacancies in various stages of recruitment.

d. Board and Committee Calendar for Remainder of 2020

President Lippe noted as this crisis continues and conditions continued to evolve, he anticipated changes could occur with the schedule and appreciated flexibility and understanding.

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

XV. Closed Session Matters

The Board recessed into closed session at approximately 1:27 pm.

XVI. Reconvene Open Session

Board staff left closed session at 1:59 pm. The meeting adjourned after closed session at approximately 2:20 pm.