Attachment A

October 25-26, 2022,
Board Meeting

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

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

Date: October 25-26, 2022

Location: Public participation provided via WebEx

Board Members Present:
Seung Oh, Licensee Member, President
Maria Serpa, Licensee Member, Vice President
Jignesh Patel, Licensee Member, Treasurer
Renee Barker, Licensee Member
Trevor Chandler, Public Member
Jessi Crowley, Licensee Member
Jose De La Paz, Public Member
Kartikeya "KK" Jha, Licensee Member
Kula Koenig, Public Member
Ricardo Sanchez, Public Member
Nicole Thibeau, Licensee Member

Board Members Not Present:
Indira Cameron-Banks, Public Member
Jason Weisz, Public Member

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

October 25, 2022

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

President Oh called the Board Meeting to order at 1:30 p.m. Dr. Oh reminded all individuals present that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. Where protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. Dr. Oh advised all individuals the meeting was being conducted

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

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

Roll call was taken. Board Members present included: Maria Serpa, Licensee Member; Jignesh Patel, Licensee Member; Renee Barker, Licensee Member; Trevor Chandler, Public Member; Jessi Crowley, Licensee Member; Jose De La Paz, Public Member; Kartikeya "KK" Jha, Licensee Member; Ricardo Sanchez, Public Member; Nicole Thibeau, Licensee Member; and Seung Oh, Licensee Member. A quorum was established.

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

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

The Board heard comments from representatives of CVS Health, Kaiser and the public requesting the Board add the topic of remote work to the December 2022 meeting, review elements of remote final check, extend the waiver to the end of the state of emergency, and reconsider interpretation of where a pharmacist can work.

Members agreed to add the discussion to the next Licensing Committee.

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

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

President Oh noted prior to transitioning to remote meetings, the Board routinely provided an opportunity for pharmacists licensed for 40 years to attend a Board meeting and be recognized by the Board. Dr. Oh continued although the Board has returned to remote meetings, the Board would like to provide an opportunity for the Board to recognize pharmacists that have been licensed in California for 40 years. There were no pharmacists identifying themselves to be recognized for 40 years of service as a pharmacist. President Oh thanked and congratulated pharmacists who had been licensed as a pharmacist for over 40-years. Dr. Oh thanked all pharmacy staff who worked in pharmacy serving the consumers of California.

IV. Approval of Board Meeting Minutes

a. President Oh referenced the draft minutes from the July 27-28, 2022, meeting.

Members were provided with an opportunity to provide comments.

Motion: Approve the July 27-28, 2022, minutes as presented in the meeting materials.

M/S: Patel/De La Paz

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

Support: 8 Oppose: 0 Abstain: 1 Not Present: 3 No Vote: 1

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

b. President Oh referenced the draft minutes from the August 25, 2022, meeting.

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

Motion: Approve the August 25, 2022, minutes as presented in the meeting materials.

M/S: Crowley/De La Paz

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

Support: 9 Oppose: 0 Abstain: 1 Not Present: 3

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

c. President Oh referenced the draft minutes from the September 14, 2022, meeting.

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

Motion: Approve the September 14, 2022, minutes as presented in the meeting materials.

M/S: Thibeau/Patel

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

Support: 9 Oppose: 0 Abstain: 1 Not Present: 3

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

d. President Oh referenced the draft minutes from the September 21, 2022, meeting.

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

Motion: Approve the September 21, 2022, minutes as presented in the meeting materials.

M/S: Barker/Crowley

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

Support: 9 Oppose: 0 Abstain: 1 Not Present: 3

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

V. Update from the Department of Consumer Affairs

President Oh introduced Melissa Gear as Department of Consumer Affairs' (DCA) Deputy Director, Board and Bureau Relations. Ms. Gear welcome new Members Chandler and Jha. Ms. Gear provided an overview of her experience at the Department of Insurance, California State Teachers' Retirement System, California Attorney General's Office, Legislative Analyst's Office, and California Department of Education.

Ms. Gear advised Director Kimberly Kirchmeyer established a Diversity Equity and Inclusion (DEI) Steering Committee to guide DCA in its equity strategy initiative and action plans. The Steering Committee's kick off meeting was scheduled for November 9, 2022.

Ms. Gear provided an update on the DCA Strategic Plan. Pursuant to Governor Newsom's executive order, strategic plans in effect July 2023 and beyond must be developed or updated to more effectively advance equity and drive outcomes that increase opportunity for all. DCA is revising its strategic plan to incorporate more inclusive public engagement, data analysis, and embedding diversity, equity, and inclusion into the strategic planning process. By March 2023, DCA will have updated processes and will work with the Boards and Bureaus to update strategic plans.

Ms. Gear provided an update on the 65th Our Promise Campaign that provides state employees an opportunity to give back to the communities they live. Ms. Gear advised Lourdes M. Castro Ramírez, Secretary of the Business, Consumer Services and Housing Agency was this year's Vice Chair. Ms. Gear added Chief Deputy Director

Christine Lally and Deputy Director, Board and Bureau Relations Melissa Gear were DCA's Co-Chairs. The campaign began October 1, 2022, and will end December 31, 2022, allowing Californians to donate to a nonprofit of their choice. Ms. Gear encouraged participation.

Ms. Gear advised legislation passed to allow remote meetings through June 30, 2023. Ms. Gear reminded Boards and Bureaus choosing to hold in-person meetings of best practices and recommendations for holding public meetings. Ms. Gear reminded all Board and Bureau members and staff are expected to follow the state and local public health guidelines where the meetings are held and recommended checking for updated CDPH mask guidelines before meetings to determine appropriate masking approach for meetings. Ms. Gear added if masks are recommended, please post face-covering guidance signage at meeting check in or entrance.

Ms. Gear reminded state travel must be made through the CalTravel Store/CONCUR using the most economical fair when traveling by air without considering personal convenience. If associated charges are incurred because of convenience, the traveler will be responsible for associated charges. Ms. Gear advised AB 1887 prohibits travel to the states on the travel ban for state travel. There were 23 prohibited states listed on the Attorney General's website.

Ms. Gear reported on the partnership with State Controller's Office to share information with consumers and licensees about unclaimed property program.

Members were provided the opportunity to comment. Member Barker welcomed Ms. Gear.

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

Member Koenig arrived at 2:09 p.m.

VI. Presentation on Research Underway on Senate Bill 159 (Chapter 532, Statutes of 2019) Related to HIV Preexposure and Postexposure Prophylaxis

President Oh recalled Senate Bill 159 established authority for a pharmacist who completes specified training to independently initiate and furnish HIV PrEP and PEP. Dr. Oh welcomed and introduced Ayako Miyashita Ochoa, Co-Director, UCLA Hub of Health Intervention, Policy and Practice and Co-Director, Southern California HIV/AIDS Policy Research Center and Dr. Laura Packel, Research Director from UC Berkeley to discuss the California Pharmacist Study.

Ms. Miyashita Ochoa provided an overview the California Pharmacists Study: Pharmacists-Furnished HIV Prevention and Reproductive Health Service in California including the mixed methods study including qualitative and quantitative as well as AIMS and timelines.

Dr. Packel reviewed the recruitment strategy for the qualitative strands and quantitative strands working with associations. Dr. Packel provided an overview of the main sources of outreach and the main methods of outreach including recruitment/media packet contents and expected recruitment activities. Dr. Packel requested assistance with recruitment. Dr. Packel provided most responses to survey to date were from urban centers (Los Angeles, San Francisco) and a majority of racial and ethnic (Asian and white) demographics as well. Dr. Packard requested assistance in reaching rural pharmacists and more pharmacists of color including Black and Latino.

President Oh thanked the presenters for information about the study. Dr. Oh inquired if agreeable, the Board would welcome them back after the study was completed to learn about the results.

Dr. Rafie commented getting policy and laws passed was a great first step but what they are seeing is gaps in implementation including delays or not providing the services. Dr. Rafie stated it was relevant for the Board of Pharmacy while they were creating the scope of practice but also to assist in helping to implement. Dr. Rafie would like to discuss with the Board of Pharmacy and stakeholders how to take actions on all of the research findings to help with implementation.

Members were provided an opportunity to comment.

Member Chandler thanked the presenters for their presentation and work. Mr. Chandler inquired if as part of the demographics they were asking for sexual orientation and gender identity and what make up of the LGBTQ community have participated to date. Dr. Packel advised it was part of the demographic questions but it was too early in the survey to know the results yet. Dr. Packel stated it was a good point and they will look where they are at with that representation and make efforts to reach out communities if underrepresented. Ms. Miyashita Ochoa added the participants are pharmacists which is the focus of the study and haven't reached out to community members yet. Mr. Chandler noted PrEP and PEP are so heavily focused on the LGBTQ community that pharmacists who identify as LGBTQ will have a greater education level and more suggestions than someone who is not LGBTQ.

Member Chandler inquired if reimbursement for SB 159 was impacting how pharmacists are engaging on this. Dr. Packel advised there were several questions

about reimbursement. Ms. Miyashita Ochoa provided theoretically there are mechanisms in place for reimbursement but are looking to see if the mechanisms are practical and being used. Dr. Rafie provided questions were being asked about reimbursements for drug costs and pharmacist services.

Member Chandler noted California was groundbreaking with SB 195 and other states are moving forward creating a more permanent version without limitation than California law. Mr. Chandler inquired if questions were being asked about how it might improve if limitations were removed. Ms. Miyashita Ochoa noted the qualitative interviews will give space to discuss time limits and linkages for continued health care services. President Oh noted the 60-day time limit was something that could be changed.

Member Crowley inquired about the demographics of the pharmacists in California. Ms. Miyashita Ochoa provided they discussed adding this. Dr. Crowley inquired if the demographic questions were asking if the pharmacist was fluent in another language and could help non-English speakers. Dr. Packel stated the questions were included.

Member Thibeau who works for the Los Angeles LGBTQ Center that was one of the sponsors of the bill expressed excitement about the work being done. Dr. Thibeau wasn't surprised to hear not as much information was coming from the rural areas but was hoping to hear the finding of the study as one of the big pushes on this was the hope of expanding access to rural areas. Dr. Thibeau provided there was a change in reimbursement on the patient assistance plan on the manufacturer of the PrEP drugs that is having a significantly negative impact on a lot of Ryan White HIV providers and on their ability to provide PrEP and PEP. Dr. Thibeau wondered if the survey will be able to capture how broad of an issue is it.

Members of the public were provided the opportunity to comment.

A representative of CVS Health requested the Board add to a future agenda the circular statute that requires pharmacists to follow CDC guidelines which requires the ordering of tests with no authority to order tests in California.

VII. Discussion and Consideration of Adoption of Board Approved Regulation, Title 16, California Code of Regulations Section 1735.2, Compounding Self-Assessment (17M-39), Including Comments Received

Chairperson Oh advised the 45-day public comment period for the proposed amendments to Section 1735.2 concluded on August 15, 2022. Dr. Oh provided one comment was received during the comment period and was included in the meeting materials with a recommended response. Dr. Oh agreed with staff's proposed

response that the comment submitted referred to a different self-assessment form that was not currently undergoing a public comment period. Dr. Oh agreed that no change to the proposed regulation was appropriate based on this comment.

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

Motion: Accept the Board staff recommended comment response and adopt the regulation text and self-assessment form as noticed for public comment on July 1, 2022. Additionally, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

Amend Section 1735.2 to Title 16 of the California Code of Regulations, to read as follows:

§ 1735.2. Compounding Limitations and Requirements; Self-Assessment.

[....]
(k) Prior to allowing any drug product preparation to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. ~~02/12~~ 1/22.) as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations. That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start date of a new pharmacist-in-charge or change of location, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

[...]

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4029, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

[Note a copy of the "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 1/22 is attached to the notes.]

M/S: Serpa/Barker

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

Support: 11 Oppose: 0 Abstain: 0 Not Present: 2

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

VIII. Discussion and Consideration of Changes to Previously Proposed Text and Reauthorization of a Regular Rulemaking to Adopt a Proposed Regulation Related to Temporary Licenses of Military Spouses and Partners, California Code of Regulations Section 1706.6

President Oh recalled July Board Meeting, the Board voted to initiate a rulemaking to establish the requirements for temporary licenses for military spouses and partners. Dr. Oh referenced meeting materials that the Board's approval, the DCA identified and was recommending additional changes to the language to provide clarification on the requirements related to the California Practice Standards and Jurisprudence

Examination (CPJE). Dr. Oh noted the meeting materials included the proposed revisions displayed as underlined text.

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

Motion: The Board hereby rescinds prior proposed text and approves the proposed regulatory text for section 1706.6 as proposed to be amended in the materials. Additionally, authorize the executive officer to further refine the language consistent with the policy discussions and as may be required by control agencies (DCA or Agency) and to make any non-substantive changes prior to initiation of the rulemaking. Further, if no adverse comments are received during the 45-day comment period and no hearing is requested, authorize the executive officer to adopt the proposed regulation at section 1706.6 as noticed for public comment and take all steps necessary to complete the rulemaking process.

Title 16. Board of Pharmacy
Proposed Text

Add section 1706.6 to Article 1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:
§ 1706.6. Temporary Licenses for Military Spouses/Domestic Partners

(a) Definitions: For the purposes of this section, the following definitions shall apply:
  (1) "Disciplined" means that the applicant's license was placed on probation, revoked, suspended, reproved, censured, reprimanded, restricted, limited, or conditioned.
  (2) "Jurisdiction" shall mean a California or another state's licensing board or agency, any agency of the federal government, or another country.
  (3) "Disciplinary proceeding" shall mean any proceeding or investigation under the authority of the licensing jurisdiction pursuant to which a licensee may be disciplined.
  (4) "Good standing" shall mean that the applicant has not been disciplined, is not the subject of an unresolved complaint or review procedure and is not the subject of any unresolved disciplinary proceeding.
  (5) "Original licensing jurisdiction" shall mean the entity that issued a license to the applicant authorizing the applicant to practice within the same scope for which the applicant seeks a temporary license from the Board.

(b) An applicant for a temporary pharmacist, advanced practice pharmacist, pharmacy technician, designated representative, designated representative-reverse distributor, designated representative-3PL or a designated paramedic license pursuant to section 115.6 of the Business and Professions Code ("Code") shall submit a completed application to the Board and meet all of the requirements of this section and section 115.6 of the Code to be eligible for a temporary license. A completed application shall provide the following information:

(1) The applicant's identifying and contact information:

(A) Applicant's full legal name ((Last Name) (First Name) (Middle Name) and/or (Suffix)),

(B) Other name(s) applicant has used or has been known by,

(C) Applicant's address of record (The address of record may be a post office box number or other alternate address.),

(D) Applicant's physical address, if different than the applicant's address of record,

(E) Applicant's email address,

(F) Applicant's telephone number,

(G) Applicant's Social Security Number or Individual Taxpayer Identification Number, and,

(H) Applicant's birthdate (month, day, and year).

(2) The applicant shall indicate that the applicant is married to, or in a domestic partnership or other legal union with, an active-duty member of the Armed Forces of the United States who is assigned to a duty station in California under official active-duty military orders and shall provide the following documentation with the application:

(A) Certificate of marriage or certified declaration/registration of domestic partnership filed with the California Secretary of State or other documentary evidence of legal union with an active-duty member of the Armed Forces, and,

(B) A copy of the military orders establishing their spouse or partner's duty station in California.

(3) The applicant shall disclose whether the applicant holds a current, active, and unrestricted license of the same type of license that the applicant is applying for, or comparable authority to practice in another state, district, or territory of the United States and provide written verification from the applicant's original licensing jurisdiction that the applicant's license or other comparable authority ("license") is in good standing in that jurisdiction. The verification shall include all of the following:

(A) the full legal name of the applicant and any other name(s) the applicant has used or has been known by,
(B) the license type and number issued to the applicant by the original licensing jurisdiction, and relevant law(s) and regulation(s) under which the license was issued,
(C) the name and location of the licensing agency,
(D) the issuance and expiration date of the license, and,
(E) information showing that the applicant's license is currently in good standing.

(4) The applicant shall disclose whether the applicant has committed an act in any jurisdiction that would have constituted grounds for denial, suspension, or revocation of the license pursuant to Sections 141, 480, or 490 of the Code, or Sections 4300, 4301, 4311 of the Code, or section 1762 of this Division. For applicants for a temporary pharmacist license, those applicants shall also disclose whether the applicant has committed an act in any jurisdiction that would have constituted grounds for denial, suspension, or revocation of the license pursuant to Sections 4305 or 4306.5 of the Code.

(5) The applicant shall disclose whether the applicant has been disciplined by a licensing entity in another jurisdiction or is the subject of an unresolved complaint, review procedure, or disciplinary proceeding conducted by a licensing entity in another jurisdiction.

(6) The applicant shall submit fingerprints for use by and accessible to the board in conducting criminal history information record checks through the California Department of Justice.

(7) For applicants for a temporary pharmacist license, the applicant has successfully completed the California Practice Standards and Jurisprudence Examination (CPJE).

(8) The applicant shall sign a statement attesting to the fact that the applicant meets all the requirements for the temporary license, and that the information submitted in the application is accurate, to the best of the applicant's knowledge.

(c) In addition to the above requirements, and prior to submission of the application specified in subsection (b), applicants for a temporary pharmacist license must successfully complete the Board's law and ethics examination designated as the California Practice Standards and Jurisprudence Examination (CPJE) for Pharmacists set forth in Section 4200 of the Code, which tests the applicant's knowledge and proficiency in state and federal laws and provisions of safe patient care, and the items set forth in Section 4200.2 and 4200.3 (d) of the Code.

(d) Upon issuance of a temporary license in accordance with Section 115.6(a) of the Code, the Board shall provide written notice to the applicant of the following:
(1) That the temporary license is nonrenewable;
(2) That the license expires 12 months after issuance, upon issuance or denial of a standard license, or upon issuance or denial of an expedited license pursuant to Section 115.5 of the Code, whichever occurs first; and,
(3) Any holder of a temporary license desiring to continue their licensure or to practice in California after expiration of their temporary license shall apply for and obtain a standard pharmacist, advanced practice pharmacist, pharmacy technician, designated representative, designated representative-reverse distributor, designated representative-3PL or a designated paramedic license, as applicable, in accordance with Sections 4200, 4202, 4210, 4053, 4053.1, 4053.2, and 4202.5 of the Code.

Authority: Sections 115.6 and 4005, Business and Professions Code. Reference: Section 30, 31, 115.6, 141, 480, 490, 4200, 4300, 4301, 4301.5, 4305, 4306.5, and 4311, Business and Professions Code.

M/S: Chandler/Patel

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

Support: 11 Oppose: 0 Abstain: 0 Not Present: 2

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

The Board took a break from 2:43 p.m. to 2:55 p.m. Roll call was taken. Board Members present included: Maria Serpa, Licensee Member; Jignesh Patel, Licensee Member; Renee Barker, Licensee Member; Trevor Chandler, Public Member; Jessi Crowley, Licensee Member; Jose De La Paz, Public Member; Kartikeya "KK" Jha, Licensee Member; Kula Koenig, Public Member; Ricardo Sanchez, Public Member; Nicole Thibeau, Licensee Member; and Seung Oh, Licensee Member. A quorum was established.

IX. Medication Error Reduction and Workforce Ad Hoc Committee Report

Chairperson Thibeau provided the Board with a summary of the Committee's efforts at its last meeting and thanked fellow members, Vice-Chair Seung Oh, Jessica Crowley, Kula Koenig, and Jignesh Patel.

Chairperson Thibeau advised during the first two meetings, the Committee focused on education of the issues medication error and workforce challenges. The Committee received presentations from the Institute for Safe Medication Practices, the National Association of State Boards of Pharmacy on Its Workforce Task Force Report, the American Pharmacist Association on the Well-being Index and Fundamental Responsibilities and Rights, as well as a presentation by the Nova Scotia College of Pharmacists on the Nova Scotia Workplace Conditions Strategic Work.

Chairperson Thibeau reported during the meeting in September, the Committee started evaluating policy issues to identify actions the Board can take to improve patient care by reducing medication errors, starting with a review of the Board's requirements for Quality Assurance (QA) Programs.

a. Discussion and Consideration of Possible Future Changes to Title 16, California Code of Regulations Section 1711 Related to Quality Assurance Programs.

Chairperson Thibeau advised California Code of Regulations (CCR) section 1711 establishes the requirements for a pharmacy to establish or participate in an established quality assurance program. Dr. Thibeau reported the program was to document and assess medication errors to determine the cause and an appropriate repose to improve the quality of pharmacy service and prevent errors. Dr. Thibeau noted the requirements for a quality assurance program have been in place for 20 years, have remained largely unchanged, and were quite broad.

Chairperson Thibeau advised as reported both in the media, reports, and in public comments received, workforce strains are a contributing factor to

medication errors; however, the Committee received comments that some staff are prohibited from including staffing and other workforce issues as part of the QA report.

Chairperson Thibeau reported the Committee considered several policy questions related to the QA program to determine if changes to the Board's current regulation was appropriate. The questions and a summary of the discussion were included the meeting materials. The Committee determined changes to the Board's regulations were appropriate to incorporate some mandatory elements. Dr. Thibeau reported the Committee identified the additional elements that should be incorporated into the regulation to refine the quality assurance process and facilitate a meaningful review of the error, which in turn should result in changes to prevent future errors more fully. Dr. Thibeau advised the Committee directed staff to draft proposed regulation changes to add several elements to the quality assurance report including, the date or date range of when the error occurred, staffing information, the type of error that occurred, workload information, and documentation of the actions taken as well as recommended that the current records retention period be extended.

Members were provided the opportunity to comment.

Member Serpa was glad to hear it was being discussed not only for the contents of the QA reports and recommended the quantity or the actual documentation of the error in a QA log. Dr. Serpa noted as part of the Organizational Development Committee, she and President Oh review completed citations. Dr. Serpa noted a consumer often reports an error and there was nothing reported in the QA log.

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

b. Discussion and Consideration of Medication Errors and Possible Future Development of Medication Error Reporting Requirements, Including Use of Required Standardized Report

Chairperson Thibeau advised the Committee also discussed medication error reports. Dr. Thibeau provided the reporting of medications errors was voluntary and there were various sources that accept such reporting. Dr. Thibeau commented the issue of medication errors was not new. A study from 2003 referenced in the meeting materials back concluded that dispensing errors were a problem at a national level with about 4 errors per day in a pharmacy filling 250 prescriptions daily.

Chairperson Thibeau advised the New Hampshire State Board of Pharmacy reviewed medication errors it received between February 2007 and July 2012 and published its results that included 40 percent of the errors involved dispensing the incorrect medication and 68 percent of the errors occurred when only one pharmacist was on duty. Limitations on the results included that the reporting of errors was not mandatory.

Chairperson Thibeau recalled changes to the practice of pharmacy include pharmacies that may have integrated in technology in the dispensing process and expanded authorization for pharmacists. Dr. Thibeau noted more recent information published suggests that about 1.5 percent of all prescriptions in the community setting have a dispensing error. Dr. Thibeau added while that percentage sounds low, given the number of prescriptions dispensed in California, that estimated number of dispensing errors is staggeringly high.

Chairperson Thibeau reported the Committee consider whether the Board should establish a required to report medication errors through policy questions. The questions and a summary of the comments were included in the meeting materials. Dr. Thibeau advised the Committee reached consensus that the Board should establish a requirement to report medication errors. The Committee also indicated the need for some anonymity if the Board pursues such a requirement. The Committee agreed that the Board should not mandate use of a specific form; however, the Board should provide a template that could be used as a guideline for pharmacies. Questions remained if the Board or a third-party organization should receive the reports. Dr. Thibeau advised the Committee will continue its discussion during the next meeting.

Members were provided the opportunity to comment.

Member Chandler inquired about the rational for using a template rather than form. Dr. Thibeau advised the Committee had much discussion and determined a form might be too prescriptive given the different types of pharmacy settings.

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

c. Discussion and Review of Enforcement Actions Taken and Enforcement Authority Exercised by Other Jurisdictions Related to Workplace Conditions.

Chairperson Thibeau reported many of the issues and challenges California faced were not unique. Dr. Thibeau reported the Committee considered

enforcement authority exercised by other jurisdictions related to workplace conditions to learn about different approaches. The Committee had previously learned that in Nova Scotia, legal provisions require pharmacy managers ensure the staffing plan of the pharmacy was commensurate with the needs of the patients of the pharmacy. Further when staffing issues were related to errors, that Board can require the pharmacy owners and managers to show proof of how they insured that regulatory requirement had been met.

Chairperson Thibeau advise there were several other jurisdictions within the US that were evaluating working conditions including some establishing requirements to report unsafe working conditions while others have provisions to ensure sufficient personnel are scheduled to work and still others have notification requirements requiring a pharmacy to notify patients if the pharmacy was experiencing significant delays or could not dispense prescriptions in a timely manner.

Chairperson Thibeau recalled in California there were provisions establishing what can occur when a pharmacist is at lunch and requirements for a community chain pharmacy to ensure designated staff are available to assist a pharmacist when requested. Most recently there was a new requirement establishing a prohibition on workload quotas.

Chairperson Thibeau referenced meeting materials that contain specific legal requirements for some other states which were reviewed and considered by the Committee. Several states included a requirement for the pharmacy to ensure sufficient staffing. Dr. Thibeau didn't believe California had such a requirement.

Chairperson Thibeau reported Members generally spoke in support of the authorities from other jurisdictions including the provisions in Oklahoma. Members also liked provisions that limited the number of working hours for pharmacists but noted that could be a challenge to implement because of variances in practice settings. The Committee also considered the concept of establishing a staffing floor and considered who within a pharmacy should have the authority to establish appropriate staffing. Dr. Thibeau would be working with staff on a proposal for consideration at the next meeting.

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

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

d. Discussion and Consideration of Just Culture Approach to Managing Patient Medication Errors and Patient Safety

Chairperson Thibeau advised during both Committee meetings as well as during Board meetings, the Committee heard reference to Just Culture as a means of managing patient medication errors and patient safety. Dr. Thibeau advised a Just Culture is not a "non-punitive or blame-free culture", rather it is one focusing on the entire system to evaluate what occurred in an error and what future action can be taken to prevent such errors in the future.

Chairperson Thibeau reported sharing experience from her organization transitioning a just culture. Dr. Thibeau noted adopting this model within the organization led to identification of underlying contributing factors to errors, including for example computer system errors. Dr. Thibeau added just culture was about shared accountability for outcomes and the transition takes time and resources but resulted in a reduction in medication errors and improved patient outcomes. Dr. Thibeau shared the Committee hoped to have a presentation on just culture to learn more about it.

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

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

e. Discussion and Consideration of Pharmacist Well-Being Index State Report

Chairperson Thibeau reported the Committee received a presentation the Pharmacist Well-Being Index and noted as referenced in the meeting materials, a pharmacist at high risk of distress is at a 2-fold higher risk of medication error, among other negative outcomes. Dr. Thibeau advised during the meeting, the Committee reviewed the most recent state report which indicates a slight increase for California pharmacists and noted a copy of the most recent state report was included in the meeting materials.

Chairperson Thibeau highlighted the updated pharmacy workplace and well-being reporting, which includes data from January 10, 2022, to August 11, 2022, includes 14 positive experiences and 159 negative experiences. The negative submissions included categories focused on staffing/scheduling, workload/workload expectations, working conditions, and pharmacy metrics. Dr. Thibeau advised numerous pharmacists reported verbal or emotional

harassment, physical harm, including by patients, and discrimination. Relating this information to the specific well-being index, individuals reported that the factors increased stress, increased burnout, weakened family and personal relationships, and lessened happiness.

Members were provided the opportunity to comment.

Member Chandler commented California was in the top five for the change in distress and inquired if that was discussed as well as the possible reason why. Dr. Thibeau explained the Board put out a notice about the Index which resulted in an increase in responses.

Member Jha inquired if the Committee would be looking at the root cause analysis for the retail setting as being described as dire. Ms. Sodergren indicated this may be driven by negative experiences and advised the Communication and Public Education Committee was working on a consumer education campaign about pharmacists. Ms. Sodergren noted the workforce issue was large with many Board Committees working on pieces of the puzzle.

Member Crowley commented the Committee will keep an eye on this to see if and how it changes after the fall/winter flu season. Chairperson Thibeau hoped the Board would continue to send out reminders on the Well-Being Index to allow the Board to monitor.

Members of public were provided the opportunity to comment; however, comments were not made.

Chairperson Thibeau advised the Committee will continue to monitor these reports and the Communication and Public Education committee will be developing a campaign to educate the public about pharmacists and the important role they have in patient health.

X. Enforcement and Compounding Committee Report

Chairperson Serpa thanked fellow members, Vice-Chair Jignesh Patel, Renee Barker, Indira Cameron-Banks, Seung Oh, and Ricardo Sanchez for their work on the Committee. Dr. Serpa advised the Committee met twice since the July 2022 Board Meeting.

a. Discussion and Consideration of Regulation of Surgical Clinics Pursuant to Business and Professions Code section 4190

Chairperson Serpa referenced meeting materials that included relevant sections of Pharmacy Law covering the regulation of surgical clinics which are defined in Business and Professions Code (BPC) section 4190. As specified in this section, a surgical clinic licensed by the Board may purchase drugs at wholesale for administration from a co-mingled drug supply to patients registered for care at the clinic. The law further specifies in BPC section 4192, that a surgical clinic was required to retain a consultant pharmacist to jointly approve policies and procedures used by the surgical clinic. Further, a consulting pharmacist was required to visit the clinic regularly and at least quarterly to review operations and certify in writing if the clinic is operating in compliance with legal requirements. The written certification shall be kept on file in the clinic for three years and shall include recommended corrective actions, if appropriate.

Chairperson Serpa reported the Committee initiated its review of the Board's regulation of surgical clinics during the August 2022 meeting. The Committee discussed several policy questions and ultimately provided direction to staff to draft a proposal for consideration at the October 2022 meeting.

Chairperson Serpa advised during the October 2022 meeting, the Committee reviewed inspection findings of surgical clinicals including the most frequent discussion items and orders of corrections issued. The Committee noted the findings appear to support the need to further refine the Board's regulation of surgical clinics and development of a self-assessment process to facilitate compliance. The Committee reviewed a draft statutory proposal which was included in the meeting materials. As drafted the proposal would update renewal requirements to include confirmation of compliance with quarterly inspections by the consultant pharmacist. Further, as part of the renewal every odd numbered year, the renewal would also require submission of the most recent self-assessment. The proposal would also establish the self-assessment process. Dr. Serpa advised the Committee was recommending that the Board pursue statutory changes to amend BPC 4204 and 4192.

Members were provided the opportunity to comment; however, comments were not made.

Committee Recommendation (Motion): Recommend the Board pursue statutory changes to BPC 4204 and 4192 as it relates to surgical clinics, as presented in the meeting materials.

Proposed Amendment to Business and Professions Code section 4204 as follows:

(a) Each application for a license under Section 4190 shall be made on a form furnished by the board. The form of application for a license under this article shall contain the name and address of the applicant, whether the applicant is licensed, the type of services the facility will offer, the name of its professional director, the name of its administrator, and the name of its consulting pharmacist.

(b) Each initial application shall contain a statement from a consulting pharmacist certifying that the policies and procedures of the clinic's drug distribution service, relative to inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation are consistent with the promotion and protection of health and safety of the public. Upon the filing of the application and the payment of a fee in subdivision (s) of Section 4400, the board shall make a thorough investigation to determine whether the applicant and the premises for which application for a license is made qualify for a license. The board shall also determine whether this article has been complied with, and shall investigate all matters directly related to the issuance of the license. The board shall not however, investigate any matters connected with the operation of a premises, including operating hours, parking availability, or operating noise, except those matters relating to the furnishing, sale, or dispensing of drugs or devices. The board shall deny an application for a license if either the applicant or the premises for which application for a license is made do not qualify for a license under this article.

(c) If the board determines that the applicant and the premises for which application for a license is made qualify for a license under Section 4190, the executive officer of the board shall issue a license authorizing the clinic to which it is issued to purchase drugs at wholesale pursuant to Section 4190. The license shall be renewed annually upon payment of a renewal fee prescribed in subdivision (s) of Section 4400 and shall not be transferable. <u>As part of the renewal process the consulting pharmacist shall certify compliance with the quarterly inspections as required in Section 4192. Further, as part of the renewal process of every odd numbered year, the most recent self-assessment form completed as provided in Section 4192 shall also be provided to the Board.</u>

Proposed Amendment to Business and Professions Code section 4192 as follows:

(a) Each clinic that makes an application for a license under this article shall show evidence that the professional director is responsible for the safe, orderly, and lawful provision of pharmacy services. In carrying out

the professional director's responsibilities, a consulting pharmacist shall be retained to approve the policies and procedures in conjunction with the professional director and the administrator. In addition, the consulting pharmacist shall be required to visit the clinic regularly and at least quarterly. However, nothing in this section shall prohibit the consulting pharmacist from visiting more than quarterly to review the application of policies and procedures based on the agreement of all the parties approving the policies and procedures.

(b) The consulting pharmacist shall certify in writing quarterly that the clinic is, or is not, operating in compliance with the requirements of this article. Each completed written certification shall be kept on file in the clinic for three years and shall include recommended corrective actions, if appropriate. Before July 1 of every odd-numbered year, the consulting pharmacist shall complete a Surgical Clinic Self-Assessment Form as determined by the board as a means to promote compliance through self-examination and education. The self-assessment shall assess the clinic's compliance with current laws and regulations and include information on compounding practices as specified on the most recent version of the Surgical Clinic Self-Assessment Form approved by the Board and posted on its website. The professional director of the clinic and consulting pharmacist shall certify on the final page of the Surgical Clinic Self-Assessment Form that they have read, reviewed and completed self-assessment to the best of their professional ability and acknowledge that failure to correct any deficiency identified could result in action by the Board. The completed form shall be signed under penalty of perjury and kept on file in the clinic for three years and made available to the Board or its designee upon request.

(c) For the purposes of this article, "professional director" means a physician and surgeon acting in his or her capacity as medical director or a dentist or podiatrist acting in his or her capacity as a director in a clinic where only dental or podiatric services are provided.

(d) Licensed clinics shall notify the board within 30 days of any change in professional director on a form furnished by the board.

Members of public were provided the opportunity to comment; however, comments were not made.

Support: 11 Oppose: 0 Abstain: 0 Not Present: 2

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

b. Discussion and Consideration of Potential Draft Regulations Including a Self-Assessment Form Related to Outsourcing Facilities.

Chairperson Serpa advised the Board released FAQs providing guidance to outsourcing facilities that intend to dispense patient-specific prescriptions in California in response to changes in provisions for outsourcing facilities related to authority to dispense patient-specific prescriptions under specified conditions. At the end of the FAQs a link to the Board's pharmacy self-assessment form was provided as another tool for outsourcers to use to aid in understanding the relevant provisions of pharmacy law related to dispensing of medications that are required when dispensing patient-specific compounded preparations. Dr. Serpa noted it was suggested that the Board develop regulations to define the requirements more clearly for outsourcing facilities when dispensing patient-specific compounded preparations. Dr. Serpa reported the Committee started its discussion of the issue during the August meeting including possible implementation of a self-assessment requirement

Chairperson Serpa reported following the initial discussion, staff refined the regulation language and a draft self-assessment form for consideration at the Committee's October meeting. The Committee noted it was important that outsourcing facilities have a clear understanding of the requirements to operate within or into California especially related to patient-specific requirements. Dr. Serpa referenced meeting materials that included the recommended regulation language and self-assessment form approved by the Committee.

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

Committee Recommendation (Motion): Recommend initiation of a rulemaking to add Title 16, California Code of Regulations sections 1750 and 1750.1 Related to Outsourcing Facilities. Delegate to the Executive Officer authority to make any technical or non-substantive changes that are identified through the pre-review process and release for the public comment period. If no adverse comments are received during the 45-day comment period and no hearing is requested, authorize the executive officer to take all steps necessary to complete the rulemaking, make any nonsubstantive changes to the package and adopt the regulation.

Title 16. Board of Pharmacy

Proposal To Add Article 6.5 and Sections 1750 and 1750.1 in Division 17 of Title 16 of the California Code of Regulations to read as follows:

Article 6.5 Outsourcing Facilities

1750 Outsourcing Facility Requirements

(a) Each outsourcing facility defined under section 4034 of the Business and Professions Code shall compound all sterile products and nonsterile products in compliance with federal current good manufacturing practices (cGMP) applicable to outsourcing facilities under section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 USC § 351(a)(2)(B)) and shall meet the requirements of this Article.

(b) In addition to subsections (a) and (c), an outsourcing facility licensed pursuant to Business and Professions Code sections 4129.1 or 4129.2 shall comply with all applicable federal and state laws and regulations, including all of the following:

(1) Code of Federal Regulations, Title 16, Chapter II, Subchapter E, Part 1700 (commencing with section 1700.1) – Poison Prevention Packaging,

(2) Code of Federal Regulations, Title 21, Chapter I, Subchapter C, Part 210 (commencing with section 210.1) – Current Good Manufacturing Practice in Manufacturing, Processing, Packaging, or Holding of Drugs; General,

(3) Code of Federal Regulations, Title 21, Chapter I, Subchapter C, Part 211 (commencing with section 211.1) – Current Good Manufacturing Practice for Finished Pharmaceuticals,

(4) Code of Federal Regulations, Title 21, Chapter II, Parts 1301 (commencing with section 1301.01) – Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances,

(5) Code of Federal Regulations, Title 21, Chapter II, Part 1304 (commencing with section 1304.01) – Records and Reports of Registrants with the Drug Enforcement Administration,

(6) Code of Federal Regulations, Title 21, Chapter II, Part 1305 (commencing with section 1305.01) -- Orders for Schedule I and II Controlled Substances,

(7) Code of Federal Regulations, Title 21, Chapter II, Part 1306 (commencing with section 1306.01) -- Prescriptions,

(8) Code of Federal Regulations, Title 21, Chapter II, Part 1311 (commencing with section 1311.01 -- Requirements for Electronic Orders and Prescriptions,

(9) The Uniform Controlled Substances Act (Health and Safety Code, Division 10 (commencing with section 11000),

(10) Chapters 1, 4, 6 and 8 of the Sherman Food, Drug, and Cosmetics Law (Health and Safety Code, Division 104, Part 5 (commencing with Section 109875) -,

(11) United States Code, Title 21, Chapter 9, Subchapter V, Part A (commencing with section 351) – Drugs and Devices, and,

(12) United States Code, Title 21, Chapter 13, Part C (commencing with section 821) – Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances, except for sections 821, 822a, and 826a of that Part.

(c) An outsourcing facility licensed pursuant to Business and Professions Code sections 4129.1 or 4129.2 shall dispense patient-specific compounded preparations pursuant to a prescription for an individual patient in compliance with all applicable provisions of state and federal laws and regulations relating to a pharmacy as follows:

(1) Orally transmitted prescriptions are received and reduced to writing by a pharmacist consistent with the provisions of Business and Professions

Code section 4070 and section 1717(c) of this Division and are issued by an appropriately licensed prescriber.

(2) Internet prescriptions are only dispensed pursuant to a prior good faith examination as required in Business and Professions Code section 4067(a) and are issued only by an appropriately licensed prescriber.

(3) Electronic prescriptions meeting the requirements of Business and Professions Code section 688 are issued only by an appropriately licensed prescriber.

(4) Controlled substances prescriptions meet the requirements of Health and Safety Code sections 11164(a), 11164.5, 11167.5, and 11162.1 and Business and Professions Code section 688.

(5) Each prescription contains all information required by Business and Professions Code sections 4040 and 4070.

(6) Each prescription label complies with the provisions of Business and Professions Code sections 4076, 4076.5, and 4076.6 and section 1707.5 of this Division.

(7) Drug warnings are provided orally or in writing consistent with the provisions of Business and Professions Code sections 4074 and 4076.7, section 1744 of this Division, and section 290.5 of Title 21 of the Code of Federal Regulations.

(8) Prescriptions are dispensed in containers meeting the requirements of section 1473(b) of Title 15 of the United States Code, section 1700.15 of Title 16 of the Code of Federal Regulations, and section 1717(a) of this Division.

(9) Patient consultation is provided consistent with the provisions of section 1707.2 of this Division.

(10) Prior to consultation as required in section 1707.2, a pharmacist shall review drug therapy and patient medication records consistent with the provisions of section 1707.3 of this Division.

(11) The facility shall maintain medication profiles consistent with the provisions of section 1707.1 of this Division.

(12) All Schedule II through V controlled substance dispensing data are reported to the CURES Prescription Drug Monitoring Program as required in Health and Safety Code section 11165.

(13) A pharmacist communicates with the patient or patient's agent if a medication error occurs consistent with the provisions of section 1711.

(14) Medication errors must be documented as part of the facility's quality assurance program consistent with the provisions of Business and Professions Code section 4125 and section 1711 of this Division.
(15) Patient information and prescriptions are kept confidential consistent with the provisions of the Confidentiality of Medical Information Act (Civil Code sections 56 and following), and section 1764 of this Division.
(16) Prescription refills must comply with Business and Professions Code section 4063, Health and Safety Code section 11200, and sections 1717 and 1717.5 of this Division.
(17) All records of disposition are maintained for at least three years consistent with Business and Professions Code sections 4081 and 4105.

(d) For the purposes of this section, "appropriately licensed prescriber" shall mean any health care professional listed in Section 4040(a)(2) of the Business and Professions Code.

Proposal to Add Section 1750.1 to Article 6.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1750.1 Self-Assessment of an Outsourcing Facility (Resident and Nonresident)

(a) Each outsourcing facility as defined under section 4034 of the Business and Professions Code shall complete a self-assessment of its compliance with federal and state pharmacy law. The assessment shall be performed by the outsourcing facility's designated quality control personnel, before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education, for compliance with federal current good manufacturing practices as referenced in section 1750 (cGMP) and provisions of state law related to pharmacies, Pharmacy law and this Division related to patient specific prescriptions. For the purposes of this section, "designated quality control personnel" shall mean an individual or individuals from the quality control unit as defined in section 211.22 of Title 21 of the Code of Federal Regulations ("quality control unit") identified by the outsourcing facility as the person or persons responsible for the facility's operations as detailed in the FDA Current Good Manufacturing Practice – Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act, Guidance for Industry.

(b) Each outsourcing facility shall designate a member of the quality control unit to be responsible for compliance with this section. The name and job

title of the designated member must be maintained as part of the records of the outsourcing facility in accordance with Business and Professions Code section 4081.

(c) In addition to the self-assessment required in subdivision (a) of this section, the designated quality control personnel shall complete a self-assessment within 30 days whenever:
  (1) A new outsourcing facility license is issued.
  (2) There is a change in the designated quality control personnel.
  (3) There is a change in the licensed physical location of an outsourcing facility to a new address.

(d) Each outsourcing facility licensed pursuant to Business and Professions Code sections 4129.1 or 4129.2 shall complete the "Outsourcing Facility Self-Assessment," Form 17M-117 (New. 9/2022), which is hereby incorporated by reference and contains the following components:
  (1) The designated quality control personnel shall provide identifying information about the outsourcing facility including:
    (A) Name, license number of the premises, and the license expiration date;
    (B) Address, phone number, website address, if applicable, and type of ownership;
    (C) U.S. Food and Drug Administration (FDA) Federal Establishment Identification number, expiration date and date of most recent inspection completed by the FDA pursuant to Section 360 of Title 21 of the United States Code;
    (D) Federal Drug Enforcement Administration (DEA) registration number and expiration date and date of most recent DEA inventory pursuant to Title 21, Code of Federal Regulations section 1304.11; and,
    (E) Hours of operation of the licensee.
  (2) The designated quality control personnel shall list the name of each staff person involved in the dispensing of patient specific prescriptions at the facility at the time the self-assessment is completed, and each person's role within the facility's operations.
  (3) The designated quality control personnel shall respond "yes", "no" or "not applicable" (N/A) about whether the licensed premises is, at the

time of the self-assessment, in compliance with each of the requirements.

(4) For each "no" response, the designated quality control personnel shall provide a written corrective action or action plan describing the actions to be taken to come into compliance with the applicable law or regulation cited on the self-assessment form for which a "no" response was provided.

(5) The designated quality control personnel shall initial each page of the self-assessment form with original handwritten initials in ink or digitally signed in compliance with Civil Code section 1633.2(h) on the self-assessment form.

(6) The designated quality control personnel shall certify, under penalty of perjury of the laws of the State of California, on the final page of the self-assessment that:

(A) They have completed the self-assessment of the licensed premises for which they are responsible;

(B) Any deficiency identified within the self-assessment will be corrected and list the timeframe for correction;

(C) They acknowledge receiving the following notice: "All responses on this form are subject to verification by the Board of Pharmacy"; and,

(D) The information provided in the self-assessment form is true and correct.

(E) The certification, made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct, may be an original handwritten signature in ink or digitally signed in compliance with Civil Code section 1633.2(h) on the self-assessment form.

(7) The licensed premises owner, partner or corporate officer shall certify on the final page of the self-assessment that they have read and reviewed the completed self-assessment and have received notice that failure to correct any deficiency identified in the self-assessment could result in the revocation of the license issued by the board. The certification shall be made, under penalty of perjury of the laws of the State of California, that the information provided in the self-assessment form is true and correct with an original handwritten signature in ink or

digitally signed in compliance with Civil Code section 1633.2(h) on the self-assessment form.

(e) Each self-assessment shall be completed in its entirety and kept on file in the licensed premises for three years after it is completed. The completed, initialed, and signed original must be readily available for review during any inspection in accordance with Business and Professions Code section 4081.

(f) The outsourcing facility is responsible for compliance with this article.

(g) Any identified areas of deficiency identified in the self-assessment shall be corrected as specified in the timeframe listed in the certification as provided in subsection (d)(6).

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4034, 4129- 4129.9, Business and Professions Code.

Note: A copy of the Outsourcing Facility Self-Assessment (17M-117 New 9/2022) is attached to these minutes.

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

Support: 11 Oppose: 0 Abstain: 0 Not Present: 2

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

c. Discussion and Consideration of Proposed Chane to the Board's Citation and Fine Authority Related to Unlicensed Activity

Chairperson Serpa referred to relevant sections of pharmacy law were included in the meeting materials. Dr. Serpa noted the sections were related to the Board's citation and fine authority. Most relevant to the discussion was the Board's current authority to issue a citation of up to $5,000 when an investigation reveals unlicensed activity. Members noted that the Board's current authorized maximum fine did not appear sufficient to address unlicensed activity in some cases.

Chairperson Serpa reported the Committee discussed this at the August 2022 and October 2022 meetings. During the Committee's initial discussion in August 2022, Members determined that the Board's current maximum fine amount was not sufficient to address unlicensed activity and requested that staff draft a possible statutory proposal to increase the fine authority. Dr. Serpa continued more recently, during the October 2022 meeting, Members considered a possible statutory proposal. At the Committee meeting, Members expressed concern with the patient risks associated with unlicensed activity including the potential distribution of adulterated products.

Committee Recommendation (Motion): Recommend to the Board pursuit of a statutory proposal consistent with the policy discussion to increase fine assessment for unlicensed activity.

> **Statutory Proposal to Add Business and Professions Code Section 4316.5**
>
> Notwithstanding any other law, the Board may assess administrative fines and issue orders of abatement to any unlicensed entity who engages in any action that requires licensure under the jurisdiction of the Board, not to exceed $5,000 for each occurrence pursuant to a citation issued by the Board.

Members were provided the opportunity to comment.

Members discussed the rationale behind the amount of $5,000. Dr. Serpa advised the Committee was trying to keep the amount close to other regulatory cite and fines. Ms. Sodergren added the provision was to assess per purchase from an unlicensed source which would be per a prescription for a pharmacy. Some Members thought $5,000 per an occurrence was too low and it should be modeled after the online/internet fines of $25,000 per an occurrence and inquired about amending the motion but were advised the Committee Recommendation couldn't be amended.

Members of the public were provided the opportunity to comment.

A representative of UFCW Western States Council urged the Board to reject the motion and accept a higher fine for behavior was detrimental to the consumer.

Support: 7 Oppose: 4 Abstain: 0 Not Present: 2

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

d. Discussion and Consideration of Enrolled or Recently Signed Legislation Impacting the Practice of Pharmacy

Chairperson Serpa referenced various measures considered by the Committee were in the meeting materials.

a. Assembly Bill 852 (Wood) Health Care Practitioners: Electronic Prescribing

Assembly Bill 852 was signed by the governor on September 25, 2022. This measure made several changes to the e-prescribing requirements in California. Changes included authority for pharmacies, pharmacists, and authorized practitioners to decline to dispense or furnish based on an electronic prescription submitted via software that does not meet specified requirements. The measure creates additional exemptions from electronic prescriptions as specified and exempts the prescription transfer requirements under specified conditions. In addition, it requires a prescriber to register with the Board and state they meet one or more of the specified criteria for exemption. Such registration is required on an annual basis.

Chairperson Serpa noted Members noted agreement with staff recommendations for implementation which will include education of the changes as well as additional activities related to the online registration. Specifically, related to the online registration, staff suggested that implementation be substantially similar to the online registration process used for drug-take back locations or the Board's health services registry. Staff proposed that the online registry include the prescriber's name, license number, email address, and exemptions being claimed. Except for the email address, this information will be posted and available on the Board's website. As annual registration is required, it is recommended that the annual registration occur consistent with the calendar year. The prescriber's email address will be used to facilitate the reminder.

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

Members of the public were provided the opportunity to comment.

A representative from CRA/NACDS requested the Board provide guidance of what constitutes compliance. The representative expressed support for provisions related to the transfer and dispensing of prescriptions and appreciated the Board's work. The representative expressed concerns with section 688b which requires a pharmacy to accept prescriptions from any e-prescription vendor without having time to work with new vendors and upgrade pharmacy systems to be compatible noting some vendors were providing misleading information to physicians.

b. Assembly Bill 2194 (Ward) Pharmacists and Technicians; Continuing Education Cultural Competency

Chairperson Serpa advised this measure was approved by the governor on September 30, 2022, and requires that, effective January 1, 2024, pharmacists, and pharmacy technicians must complete at least a one-hour course in cultural competency during the two years preceding the renewal application period. Further the measure would prohibit the Board from renewing a pharmacist or pharmacy technician license unless the individual has completed the course. Members again noted agreement with the recommendations for implementation of the measure including development of a system to establish a renewal process incorporating a continuing education requirement for pharmacy technicians. As part of

the implementation the Board would need to establish a records retention period and will mirror the requirements for pharmacists, which require maintenance of records for four years. Staff suggested that implementation of the provisions included amendments to existing CCR section 1732.5 to update the renewal requirements for pharmacists.

Chairperson Serpa indicated in the meeting materials the Board previously recommended changes to CCR section 1732.5 to consolidate all CE related requirements for pharmacists into a single regulation to assist pharmacists with compliance. Dr. Serpa noted staff was advised that such an approach may not be appropriate. At that time, giving the pending legislation, it was recommended that the two issues be considered together if AB 2194 was enacted. The Committee was suggesting that implementation activities be completed under the purview of the Licensing Committee. Staff would evaluate the potential to update online, and system generated renewal notices to determine if updates can be made in advance of the effective date.

Members were provided the opportunity to comment. Members were excited to see this and discussed availability of the required training. Members expressed interest in offering the training and looking into the intersectionality of LGBTQ+ individuals. Ms. Smiley advised Members it was acceptable to send this item to the Licensing Committee.

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

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

Chairperson Serpa advised Senate Bill 731 was approved by the governor on September 29, 2022, which expands automatic relief to include arrests for felonies punishable by state prison. Further, the measure will expand automatic relief to certain criminal felonies committed after January 1, 2005, under specified conditions. The Committee reviewed implementation activities which include staffing reviewing relief notifications to determine what if any action is necessary and working with the Attorney General's Office to determine any potential impact on pending matters.

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

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

d. Senate Bill 872 (Dodd, Chapter 220, Statutes of 2022) Pharmacies: Mobile Units

Chairperson Serpa advised Senate Bill 872 was chaptered on August 29, 2022. The Committee discussed the measure which allows a county, city and county, or special hospital authority to operate a mobile unit as an extension of the pharmacy license held. The measure authorized the mobile unit to dispense prescription medications under specified conditions and requires notification to the Board 30 days prior to commencing use as well as 30 days prior to discontinuing use of a mobile unit.

The Committee noted agreement with the staff recommendation to develop a standardized notification process. During prior Board discussion of the measure, the Board noted the need to develop FAQs and referred the development to the Communication and Public Education Committee. The Committee recommend that the FAQs include among other items, expectations on operational issues including provisions for pharmacist breaks and lunches, security of the mobile unit, who maintains keys to the unit and the notification process.

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

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

e. Senate Bill 988 (Chapter 988, Statutes of 2022) Compassionate Act or Ryan's Law

Chairperson Serpa advised Senate Bill 988 was approved by the governor on September 2, 2022, and repealed the requirement that a hospital manage a terminal patient's personal use of medical cannabis in the same manner as Schedule II-IV drugs. The Committee noted that implementation was straightforward and would include education on the changes in the law in the Board's newsletter, online resources, and Board-provided CE on pharmacy law.

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

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

f. Senate Bill 1346 (Beck) Surplus Medication Collection and Distribution

Chairperson Serpa advised Senate Bill 1346 was approved by the governor on September 30. This measure, which was related to surplus medication collection and distribution programs, expands the entities that are eligible to donate medications to a county operating such a program. The measure also establishes pilot programs in specified counties to allow for the expansion of county run programs. The measure requires the Board to evaluate the pilot program and prepare a report to the Legislature on January 1, 2028. Members expressed agreement with the implementation efforts detailed. The Committee will receive updates on the pilot project and anticipates the first update will be provided in 2024, allowing time for recruitment of staff and to begin the evaluation process. Dr. Serpa noted that additional Implementation will include education on the changes in the law in the Board's newsletter, online resources, and board provided CE on pharmacy law.

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

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

e. Review and Discussion of Enforcement Statistics

Chairperson Serpa referred to meeting materials that included enforcement statistics reflecting enforcement related activities between July 1 and September 26, 2022. The Board received 848 complaints during this period and closed 614 investigations. The Board secured two interim suspensions orders and one penal code 23 restriction. Also as of September 26, the Board had 1,404 field investigations pending. The average days for various stages of the investigation process were included in the meeting materials.

Members were provided the opportunity to comment. Member Chandler requested a historical view of data in the future. Ms. Sodergren provided at the

end of the fiscal year, a 3-year comparison of enforcement statistics were provided.

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

Open session concluded at approximately 4:12 p.m. The Board entered closed session at approximately 4:22 p.m. and ended closed session at 5:30 p.m. The Board Meeting concluded at approximately 5:30 p.m.

Wednesday, October 26, 2022

9:03 a.m. start time

President Oh called the Board Meeting to order at 9:03 a.m. Dr. Oh reminded all individuals present that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. Where protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. Dr. Oh advised all individuals the meeting was being conducted via WebEx. Dr. Oh advised participants watching the webcast could only observe the meeting. He noted anyone interested in participating in the meeting must join the WebEx meeting using the instructions posted on the Board's website.

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

Roll call was taken. Board Members present included: Maria Serpa, Licensee Member; Jignesh Patel, Licensee Member; Renee Barker, Licensee Member; Trevor Chandler, Public Member; Jessi Crowley, Licensee Member; Kartikeya "KK" Jha, Licensee Member; Kula Koenig, Public Member; Ricardo Sanchez, Public Member; and Seung Oh, Licensee Member. A quorum was established.

XIII. Presentation on Implementation of DSCSA Provisions Provided by the National Association of Boards of Pharmacy

President Oh introduced and welcome Josh Bolin, Associate Executive Director, Federal Affairs and Strategy to provide a presentation on the DSCSA and upcoming requirements.

Mr. Bolin provided an overview of NABP, the impact of DSCSA on State regulation, NABP's message on DSCSA and background leading up to the implementation of NABP's message on DSCSA. Mr. Bolin reviewed the DSCSA interoperability network's primary goal, network standards and network outcomes. A review of Quarter 1 2022 DSCSA Pilot outcomes was provided as well as the definition and characteristics of a Trading Partner Directory (TPD).

Mr. Bolin provided a demo on the system and provided an overview of State regulator and industry participation. Mr. Bolin reviewed what was to be expected to be included in the system. Mr. Bolin provided next steps including industry collaboration on integration, expand DSCSA engagement including solution providers in key integration work as well as objectives, timing and goals.

Members were provided an opportunity to comment.

President Oh inquired about timing requirements and what was needed to be completed by November 23rd. Mr. Bolin provided when responding to the state regulators, manufactures and wholesalers have 24 hours and pharmacies have 48 hours to respond to the request. Mr. Bolin provided baseline compliance including pharmacies being able to identify suspect product with policies and procedures to detail steps to take; dispensers have a system to receive and store transaction information in a secure electronic and interoperable manner; may use the wholesaler but using the wholesaler has limits (e.g., wholesaler can't quarantine product, have a system in place to respond to regulators, conduct investigation into suspect or illegitimate product nor can they perform product verifications/product traces) and respond to regulator trace request. Mr. Bolin advised NABP was working with many organizations (e.g., APHA, ASHP, NCPA, NASPA, etc.) to form educational webpage - www.dscsa.pharmacy.

Member Barker inquired what was the notification if the information was not good. Mr. Bolin provided the transaction history would trace the pedigree of who purchased what from whom. Dr. Barker asked what a pharmacy would need to do to initiate. Mr. Bolin advised the pharmacy would initiate a product verification and to conduct the trace. If product is suspect, it should be quarantined and investigated under obligation of the law with a follow up to manufacturer and Form 3911.

Members of the public were provided an opportunity to comment.

The Board heard a comment from a pharmacist noting the importance of security and if the security is not trusted by trading partners will have serious effects including relationships with manufacturers and purchasers will disappear resulting in an increase in medication prices. The pharmacist inquired of processes for physicians and clinics not licensed by the Board of Pharmacy.

Mr. Bolin responding there was an understanding of what was needed to do to protect proprietary information and understand the need for trading partners. Mr. Bolin advised the intention of NABP would be provide the platform noting the FDA said product shouldn't move until received transaction information and it would be needed to keep commerce moving.

XIV. Presentation on Reports of Fee Audit Report Prepared by Dan Edds, Capital Accounting Partners, LLC

President Oh welcomed Dan Edds with Capital Accounting Partners to provide a presentation on the fee audit report prepared.

Mr. Edds thanked Executive Officer Sodergren and her team for the quick response time when data was needed for the fee audit. Mr. Edds provided the scope and methodology of the fee audit; basic assumptions to the analysis; assuring quality data and results; and key findings of the fee audit.

Mr. Edds provided the recommendations and next steps of the fee audit: set feeds to recover full cost plus additional for reserves (12 months); raise statutory cap to cover regular fee increases for at least 5 years (10 years better); establish pricing guidelines; and conduct a fee audit or assessment every 3-5 years.

Members were provided an opportunity to comment.

Member Chandler inquired if probation costs were covered by those on probation. Ms. Sodergren explained probation expenses include direct probation costs such as hours of inspection but does not include probation monitoring activities nor distributive costs. Mr. Edds provided the fines and revenues are not factored in as the Board has little control over fine revenue.

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

The Board took a break from 10:21 a.m. to 10:35 a.m. A roll call was taken. Members present included: Maria Serpa, Licensee Member; Jig Patel, Licensee Member; Renee Barker, Licensee Member; Trevor Chandler, Public Member; Jessi Crowley, Licensee Member; Kartikeya "KK" Jha, Licensee Member; Kula Koenig, Public Member; Ricardo Sanchez, Public Member; and Seung Oh, Licensee Member. A quorum was established.

XV. Standard of Care Ad Hoc Committee Report

Chairperson Oh thanked Members Maria Serpa, Renee Barker, Indira Cameron-Banks, Jessica Crowley, and Nicole Thibeau. Dr. Oh reported the Committee had a great discussion and significant stakeholder engagement at the October 25, 2022, Committee Meeting.

a. Discussion and Consideration of Results of Pharmacist Survey Related to Current Practice and Possible Movement to Standard of Care Enforcement Model

   Chairperson Oh advised to facilitate engagement by licensees not available to participate in public meetings, the Committee previously developed a survey to solicit feedback for the Committee's consideration. The survey was available September 12 through October 3, 2022. The Board received 1,788 responses. Dr. Oh

reported during the Committee Meeting on October 25, 2022, the Committee received a brief presentation on the survey results. Dr. Oh noted a copy of the presentation slides was included in the meeting materials. The results of the survey helped in part to evaluate the policy questions.

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

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

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

Chairperson Oh reminded everyone present of the language provided in Business and Professions Code Section 4301.3: "On or before July 1, 2023, the board shall convene a workgroup of interested stakeholders to discuss whether moving to a standard of care enforcement model would be feasible and appropriate for the regulation of pharmacy and make recommendations to the Legislature about the outcome of these discussions through a report submitted pursuant to Section 9795 of the Government Code."

Chairperson Oh reminded attendees present, it was important to remember what the legislature was asking of the Board - - Is moving to a standard of care **enforcement model** is both feasible and appropriate for pharmacy law?

Chairperson Oh advised the Board already uses a standard of care enforcement model. Consistent with the legislative mandate to see if there are opportunities to use such a model more robustly in enforcement, Dr. Oh referred to meeting materials containing two examples of how the standard of care enforcement model was currently applied in investigations in enforcement.

Chairperson Oh reported at the previous Committee Meeting, the Committee discussed several policy questions, which were detailed in the chair report. Dr. Oh shared where there appeared to be consensus with the Committee members and stakeholders. Dr. Oh advised there appeared to be consensus that the Board's current enforcement model, which is a hybrid, was appropriate for facilities licensed by the Board. The Committee noted that unlike pharmacists, facilities do not have extensive education and experience, nor do they exercise professional judgement. Dr. Oh advised there appeared to be a consensus that the Board's current enforcement model was appropriate in the regulation of non-pharmacists licensed personnel such as pharmacy technicians, designated representatives and

interns. Members noted that there may be an opportunity to expand the scope of practice for pharmacy technicians; however, pharmacy technicians operate under the direct supervision and control of a pharmacist. Members noted that technicians should not have discretion.

Chairperson Oh advised the Committee transitioned its discussion to evaluation of the questions related to pharmacists and pharmacist-in-charges (PICs). It was noted that the Board may need to draw a distinction between a pharmacist and a PIC, noting that a PIC is responsible for compliance with the law. Members also noted the different types of practice settings and functions that a pharmacist may perform and the need to perform clinical judgement. There appeared to be some consensus that there was opportunity to use a more robust standard of care enforcement model for pharmacists. Public comment also appeared to agree there was opportunity for more robust use of a standard of care enforcement model for pharmacists. One large challenge identified during the discussion was how a PIC can be autonomous and control the operations of a pharmacy when corporate practices exist that undermine the PICs autonomy and authority.

Chairperson Oh reported the Committee transitioned to a larger question regarding opportunities to expand the scope of practice for pharmacist. There was again consensus that opportunities do exist and noted there were many opportunities for regulations to be less restrictive. Members also noted some challenges with such a transition including if pharmacists would be empowered to provide clinical services autonomously. Members indicated the need for some consistency and to ensure pharmacists are appropriately educated and trained to provide the service. Members also considered if current CE requirements related to specific authorities would still be necessary.

Chairperson Oh advised public comment also appeared to be in support with some commenters noting the number of specialties available for pharmacists. Comments indicated that a standard of care enables pharmacist to exercise professional judgement. Members concluded also that changes to regulation should not be limited to specific practice settings.

Chairperson Oh reported the Committee appeared to reach consensus that a transition to standard of care could result in expanded access to care and improved patient outcomes. Members noted that some conditions may be necessary and cautioned that as the Board moves forward it was necessary to make sure that the unintended consequence was not a lowering of the standard of care. Public comment agreed. Members also considered if minimum requirements on training or education was necessary or requirements to ensure baseline competencies were met. Members noted some challenges. Some

Members noted the need for some minimum training while others cautioned about being too specific.

Chairperson Oh advised the Committee will resume its discussion at its next meeting and hopes to have a draft report in time for its November 2022 meeting.

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

Members of the public were provided an opportunity to comment.

A representative of CSHP commented this could have prevented delays in care and provided the example of how during the pandemic it took a while to get pharmacists the authority to test and immunize.

XVI. Licensing Committee Report.

Chairperson Oh thanked Committee Members: Jig Patel, Indira Cameron-Banks, Jessica Crowley, and Jason Weisz.

a. Discussion and Consideration of Possible Statutory Proposal to Expand Current Pharmacy Technicians Authorized Duties, Current Pharmacist to Pharmacy Technician Ratio and Possible Changes**.**

Chairperson Oh advised the Board has dedicated significant time to assessing the role of pharmacy technicians. The Committee's meeting in October 2022 was the first time the Board considered a draft statutory proposal. The proposal was drafted after considerable opportunities for participation and discussion by both members and stakeholders. Dr. Oh publicly acknowledged and thanked Members and stakeholders for the robust engagement. Dr. Oh recognized that sometimes policy changes do not move as quickly as some would like but the deliberative and thoughtful process used in the Board's efforts was necessary to ensure actions taken by the Board and consistent with the Board's consumer protection mandate.

Chairperson Oh referred to history of various actions detailed in the meeting materials. Dr. Oh noted that following consideration of information received and in response to various policy questions, the Committee identified areas of consensus, which was used as the framework for the statutory proposal. Dr. Oh referred to meeting materials that included a draft copy of the statutory proposal reviewed and approved by Members during the previous meeting. The proposal served as a compliment to activities underway in other committees including the Medication Error Reduction and Workforce Committee.

Committee Recommendation (Motion): Pursue a statutory proposal to amend Business and Professions code section 4115 as presented and amended to further refine the language contained in 4115(g)(1).

4115.

(a) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist. The pharmacist shall be responsible for the duties performed under his or her supervision by a technician.

(b) In addition to the tasks specified in subdivision (a) a pharmacy technician may administer vaccines, administer epinephrine, perform specimen collection for CLIA waived tests, receive verbal prescriptions, receive prescription transfers, and accept clarification on prescriptions under the following conditions:

1. The pharmacist-in-charge of the pharmacy at which the tasks are being performed has deemed the pharmacy technician competent to perform such tasks and documented such determination in writing. Documentation must be maintained in the pharmacy.

2. The pharmacy has scheduled another pharmacy technician to assist the pharmacist by performing the tasks provided in subdivision (a).

3. The pharmacy technician is certified pursuant to Section 4202(a)(4) and maintains such certification.

4. The pharmacy technician has successfully completed at least six hours of practical training approved by the Accreditation Council for Pharmacy Education and includes hands-on injection technique, the recognition and treatment of emergency reactions to vaccines, and an assessment of the pharmacy technician's injection technique.

(~~b~~ c) This section does not authorize the performance of any tasks specified in subdivision (a) & (b) by a pharmacy technician without a pharmacist on duty.

(~~c~~ d) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.

(~~d~~ e) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the supervision of a pharmacist. Any pharmacy that employs a pharmacy technician shall do so in conformity with the regulations adopted by the board.

(~~e~~ f) A person shall not act as a pharmacy technician without first being licensed by the board as a pharmacy technician.

(f g) (1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). A pharmacy with only one pharmacist shall have not more than one pharmacy technician performing the tasks specified in subdivision (b). Where a pharmacy technician is performing the tasks specified in subdivision (b), a second pharmacy technician must be assisting a pharmacist with performing tasks specified in subdivision (a). The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of Corrections and Rehabilitation, and for a person receiving treatment in a facility operated by the State Department of State Hospitals, the State Department of Developmental Services, or the Department of Veterans Affairs.

(2) The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for a single pharmacist in a pharmacy and two pharmacy technicians for each additional pharmacist, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117.

(3) A pharmacist scheduled to supervise a second pharmacy technician may refuse to supervise a second pharmacy technician if the pharmacist determines, in the exercise of his or her professional judgment, that permitting the second pharmacy technician to be on duty would interfere with the effective performance of the pharmacist's responsibilities under this chapter. A pharmacist assigned to supervise a second pharmacy technician shall notify the pharmacist in charge in writing of his or her determination, specifying the circumstances of concern with respect to the pharmacy or the pharmacy technician that have led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule. An entity employing a pharmacist shall not discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this paragraph.

(g h) Notwithstanding subdivisions (a)–(c) and (b), the board shall by regulation establish conditions to permit the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy. During these

temporary absences, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. The pharmacist shall be responsible for a pharmacy technician and shall review any task performed by a pharmacy technician during the pharmacist's temporary absence. This subdivision shall not be construed to authorize a pharmacist to supervise pharmacy technicians in greater ratios than those described in subdivision (~~f~~ g).

(~~h~~ i) The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician supervised by that pharmacist.

(~~i~~ j) In a health care facility licensed under subdivision (a) of Section 1250 of the Health and Safety Code, a pharmacy technician's duties may include any of the following:

(1) Packaging emergency supplies for use in the health care facility and the hospital's emergency medical system or as authorized under Section 4119.

(2) Sealing emergency containers for use in the health care facility.

(3) Performing monthly checks of the drug supplies stored throughout the health care facility. Irregularities shall be reported within 24 hours to the pharmacist in charge and the director or chief executive officer of the health care facility in accordance with the health care facility's policies and procedures.

Members were provided the opportunity to comment.

Member Jha inquired if with regard to additional duties of pharmacy technicians if the PIC has to determine the competency of the technician in doing such duties and will there be standardized training as well as providing any guidance and how to manage. Ms. Sodergren advised the Board could provide guidance and did require certification but that it was the determination of what the PIC thought was appropriate. Ms. Sodergren advised the same would apply to pharmacy technicians testing.

Members of the public were provided the opportunity to comment.

A representative from CRA/NACDS thanked the Board and Committee for the draft and spoke in support of expansion. Regarding (b) and CLIA-waived testing, the language limits what pharmacy technicians can do to just performing specimen collection where federal law allows the lab director/PIC to determine who can perform testing. Allowing the pharmacy technician to collect but not test will interrupt workflow. Regarding the pharmacist/pharmacy technician ratio, the proposal was restrictive as it limits the types of duties performed by additional

pharmacy technician. The representative noted it was a step in the right direction but believed expansion should be broader to help improve patient care and consumer safety and reduce workforce pressure in the pharmacy.

A representative from CSHP applauded the Board and Committee for looking into this area noting inpatient hospitals use pharmacy technicians extensively and was a model to be considered where it might be expanded to outpatient. Pharmacy technicians are invaluable in efforts to get immunizations done by administering and drawing doses. The representative encouraged the recommendation.

Support: 9 Oppose: 0 Abstain: 0 Not Present: 4

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

b. Discussion and Consideration of Possible State Protocol Consistent with Provisions of Business and Professions Code Section 4052.01 as amended in Senate Bill 1259 (Chapter 245, Statutes of 2022)

Chairperson Oh advised the Board previously considered and established a support position on Senate Bill 1259 which sought to amendment BPC section 4052.01 to provide the authority for a pharmacist to furnish federal Food Drug and Administration approved opioid antagonist in accordance with standardized procedures or protocols developed under specified conditions. The governor signed this measure which will become effective January 1, 2023. Dr. Oh reported as required in the statute, the Board and the Medical Board of California must approve the regulation with consultation with the California Society of Addiction Medicine, the California Pharmacists Association, and other

appropriate entities. The statute also specifies areas that must be included in the standardized procedures.

Chairperson Oh reported during the meeting last week, the Committee discussed some history on the initial legislation and noted changes that have occurred and additional access points for patients to access naloxone hydrochloride, including authority for pharmacies to furnish naloxone hydrochloride to law enforcement agencies and to school districts, county office of education, or charter schools under specified conditions. This expansion has occurred to ensure ready access to this life saving medication and does not appear to create some of the same requirements as the Board's current protocol. The required protocol for pharmacists was included in CCR section 1746.3 and established the requirements of the standardized procedures for a pharmacist to furnish naloxone hydrochloride pursuant to section BPC section 4052.01.

Chairperson Oh noted the Committee agreed with the implementation detailed in the meeting materials. The Committee will continue moving forward to in its development of regulation changes to facilitate implementation of the legislation while streamlining the process.

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

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

c. Discussion and Consideration of Proposal to Establish Requirements for a Pharmacist-in-Charge

Chairperson Oh referred to meeting materials detailing out the relevant provisions of pharmacy law including the definition of a "pharmacist-in-charge" (PIC) as a pharmacist proposed by a pharmacy and approved by the Board as the supervisor or manager responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. As required by law every pharmacy must designate a PIC. Dr. Oh noted the Board also designated a precedential decision, that confirmed that a PIC of a pharmacy could be disciplined for a pharmacy's violation of BPC section 4081 resulting from a pharmacy technician's theft of controlled substances without the pharmacist having actual knowledge of, or authorizing, the violations.

Chairperson Oh recalled one of the strategic objectives established in the Board's new strategic plan was to determine if the application requirements for a PIC are appropriate to ensure sufficient knowledge, skills and abilities for individuals seeking to serve as a PIC. Dr. Oh provided the Committee previously discussed that it was not uncommon for investigations to substantiate violations where a pharmacist may be designated as a PIC in name only or the designated PIC fails to exercise appropriate oversight of the operations. Although the egregiousness of the violations varies there were many instances where such an individual pharmacist ultimately is disciplined including losing their pharmacist license through the administrative process.

Chairperson Oh reported as part of the January 2022 Board Meeting, the Board previously approved a draft attestation that would be required to be completed by the proposed PIC as part of the approval process. The language of the attestation was included in the meeting materials. Members also voted to required completion of a board-provided training program for a proposed PIC, also as part of the approval process. These changes were sought through proposed amendments to Section 1709.1. Following the Board's action, the rulemaking materials were submitted to the Department. As part of its review, the Department has suggested additional changes to the language to provide clarification on the attestation statement and process and to include the name of the training program in the regulation text.

Chairperson Oh reported the Committee was offering two recommendations related to this item, one specifically related to the regulation language and a second related to a delayed effective date.

Committee Recommendation (Motion): The Board hereby rescinds prior posted text and approves the proposed regulatory text and changes to CCR section 1709.1 as proposed to be amended in the meeting materials, authorize the executive officer to further refine the language consistent with the policy discussions and direct staff to submit all approved text to the Director of the Department of Consumer Affairs and Business, Consumer Services and Housing Agency for review. if no adverse comments, authorize the Executive Officer to take all steps necessary to initiate the rulemaking process, make any non-substantive changes to the package, and set the matter for hearing if requested. If no adverse comments are received during the 45-day comment period and no hearing is requested, authorize the executive officer to take all steps necessary to complete the rulemaking and adopt the proposed regulation at section 1709.1 as noticed for public comment.

Title 16. Board of Pharmacy

Proposed Text

Proposed changes to current regulation text are indicated with ~~single strikethrough~~ for deletions and single underline for additions. Recommended proposed additions are indicated in double underline and recommended proposed deletion with ~~double strikethrough~~.

Amend Section 1709.1 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read:

§ 1709.1. Designation of Pharmacist-In-Charge

(a) The pharmacist-in-charge (PIC) of a pharmacy shall be employed at that location and shall have responsibility for the daily operation of the pharmacy. Prior to approval of the board~~, a proposed pharmacist-in-charge shall complete an attestation confirming their understanding of the roles and responsibilities of a pharmacist-in-charge and the legal prohibitions of the pharmacy owner to subvert the efforts of a pharmacist-in-charge.~~ and as part of the application and notice process set forth in Section 1709 of this Division ("application"), a pharmacy shall submit its proposed PIC. The PIC shall have completed the board-provided Pharmacist-in-Charge Overview and Responsibility training course within two years prior to the date of application. The PIC shall complete an attestation statement in compliance with this section. For purposes of this section, a completed attestation statement shall include all of the following: name of the proposed pharmacist-in-charge, the individual's license number, a statement that they have read Sections 4036.5, 4081, 4113, and 4330 of the Business and Professions Code and this section, and a statement identifying the date that the proposed PIC took the board's training course, and a declaration signed under penalty of perjury of the laws of the State of California that the information provided by the individual is true and correct.~~ The proposed pharmacist-in-charge shall also provide proof demonstrating completion of a Board approved training course on the role of a pharmacist-in-charge within the past two years.~~
(b) The pharmacy owner shall vest the pharmacist-in-charge with adequate authority to assure compliance with the laws governing the operation of a pharmacy.
(c) No pharmacist shall be the pharmacist-in-charge of more than two pharmacies. If a pharmacist serves as pharmacist-in-charge at two pharmacies, those pharmacies shall not be separated by a driving distance of more than 50 miles.

(d) No pharmacist shall be the pharmacist-in-charge of a pharmacy while concurrently serving as the designated representative-in-charge for a wholesaler or a veterinary food-animal drug retailer.
(e) Notwithstanding subdivision (a), a pharmacy may designate any pharmacist who is an employee, officer or administrator of the pharmacy or the entity which owns the pharmacy and who is actively involved in the management of the pharmacy on a daily basis as the pharmacist-in-charge for a period not to exceed 120 days. The pharmacy, or the entity which owns the pharmacy, shall be prepared during normal business hours to provide a representative of the board with documentation of the involvement of a pharmacist-in-charge designated pursuant to this subdivision with the pharmacy and efforts to obtain and designate a permanent pharmacist-in-charge.
(f) A pharmacist may refuse to act as a pharmacist-in-charge at a second pharmacy if the pharmacist determines, in the exercise of his or her professional judgment, that assuming responsibility for a second pharmacy would interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law. A pharmacist who refuses to become pharmacist-in-charge at a second pharmacy shall notify the pharmacy owner in writing of his or her determination, specifying the circumstances of concern that have led to that determination.
(g) A person employing a pharmacist may not discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this section.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4036.5, 4081, 4113, 4305 and 4330, Business and Professions Code.

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

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

Support: 9 Oppose: 0 Abstain: 0 Not Present: 4

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

Committee Recommendation (Motion): Include within the rulemaking package for CCR Section 1709.1 A request to the Office of Administrative law for a later effective date that is six months following the date of approval of the amendments to CCR section 1709.1.

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

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

Support: 9 Oppose: 0 Abstain: 0 Not Present: 4

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

d. Discussion and Consideration of Discontinuance of Business by a Pharmacy and Potential Changes to Pharmacy Law to Ensure Continuity of Patient Care

Chairperson Oh advised the Committee initiated discussion on the Board's requirements for discontinuance of business (DOB). The Board's current DOB process requires notification to the Board. Current provisions in the law do not establish conditions for continuity of patient care which the Committee determined to be very problematic and contrary to the Board's mandate. Dr. Oh referenced meeting materials included two general areas of complaints received related to this issue including scenarios where a pharmacy has closed, and a patient cannot receive a refill because they are unable to contact the pharmacy to request a prescription transfer or where a pharmacy has closed and transferred patient prescription refills to another pharmacy not of the patient's choosing. Members considered several policy questions with a summary provided in the meting materials. Dr. Oh reported staff will work on development of a proposal for future consideration by the Committee.

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

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

e. Discussion and Consideration of Legal Requirements for Nonresident Pharmacies include Possible Change to Require Licensure by the Pharmacist-in-Charge

Chairperson Oh advised California law requires that any pharmacy located outside this state that provides services into California shall be considered a nonresident pharmacy. The section requires licensure as a nonresident pharmacy. There are no current requirements for pharmacists working in these pharmacies to be licensed in California even when providing care to California patients nor is there a requirement for the PIC of the nonresident pharmacy to be licensed in California. California law currently establishes a prohibition for a pharmacist to provide services to California patients if the pharmacist's license was revoked in California.

Chairperson Oh reported the National Association of Boards of Pharmacy established model rules for Boards to consider as part of its regulation of the practice of pharmacy. Regarding the regulation of nonresident pharmacies, the model rules included a requirement for a pharmacist to be licensed in the state in which it is providing services to patients. Dr. Oh noted meeting materials reflect states have a range of requirements for licensure of staff working out of state but providing care to their residents. The materials also provide a few examples of actions taken against nonresident pharmacies. Dr. Oh added as the Board was considering changes to strengthen the requirements for a pharmacist-in-charge, it was appropriate to also ensure pharmacists appointed as a PIC in nonresident pharmacy also have a full understanding of the law to ensure that Californians who receive prescription drugs from nonresident pharmacies have protections that are like those received by resident pharmacies in California.

Chairperson Oh reported Members reviewed how some other states regulate this area. Members considered if a PIC working in a nonresident pharmacy should be required to be licensed in California. Members generally spoke in support of a requirement for a California licensed pharmacist to be the PIC of a nonresident pharmacy providing services into California while noting potential gaps in care. Members noted the need for a transition period of compliance to mitigate potential gaps in care. Public comment suggested that the Board should consider a registration requirement like the Iowa model versus a licensure requirement. Dr. Oh will be working with staff on the development of a proposal for consideration at a future meeting.

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

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

f. Licensing Statistics

Chairperson Oh referred to meeting materials including licensing data for the first quarter of the fiscal year. Dr. Oh noted during the quarter, the Board issued over 3,000 individual licenses and 129 site licenses. The Board also issued 91 temporary licenses, 55 of which are for community pharmacies. The Board received over 4,500 applications during this quarter including 90 applications for community chain pharmacies, the vast majority of which are for nonchain pharmacies. In addition, the Board received 124 temporary applications during the quarter including 65 for community pharmacies.

Chairperson Oh highlighted specifically the pharmacy workload as this is one area where licensing times are outside of the Board performance measures, although more updated information indicates there has been improvement since the meeting materials were released. Dr. Oh reported the Committee has been monitoring processing times and Dr. Oh has been working with the Executive Officer on this issue. Dr. Oh acknowledged the hard work the licensing staff perform each day. The workload was extensive for the number of staff. Staff vacancies and recruitment challenges continue to be contributing factors to these process times. Staff also experience challenges with applicants that provide incomplete or conflicting information during the application process. Full transparency by entities seeking licensure at the time application will aid staff significantly in reducing processing times.

Chairperson Oh noted the Committee received public comments from individuals suggesting that the Board develop a means to allow for the monitoring of the application process through an online system. Comments also indicated that inquiries submitted via email go unanswered which leads to frustration.

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

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

XVII. Organizational Development Committee Report

President Oh provided an update on items under the purview of the Organizational Development Committee.

a. Budget Update FY 2022/23

President Oh advised the new fiscal year began July 1, 2022. The Board's spending authorization for the new fiscal year was about $31.3 million which was a 2.5 percent increase from the prior year. The final budget figures for FY 2021/22 were now available and included in the meeting materials. The Board received approximately $36 million in revenue and expended about $29.5 million. The Board reverted about $1million back into its fund. A review of the fund condition prepared by the Department indicates that at the end of the fiscal year 2021/22, the Board has 4.9 months in reserve. As indicated in the meeting materials, under provisions of Pharmacy Law, the Board shall seek to maintain a reserve equal to approximately one year's operating expenditures. The fund condition projects a continued depletion of the Board's fund.

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

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

b. Board Member Attendance and Mail Vote Information

President Oh advised meeting materials contain Board Member attendance and mail vote records.

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

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

c. Personnel Update

President Oh advised as detailed in the meeting materials, the Board had several vacancies including a key leadership position. The vacancy count was higher as the Board received new positions July 1 but there were several of the inspector and licensing position with active recruitments underway. Dr. Oh reported working closely with the Executive Officer on recruitment challenges.

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

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

d. Discussion and Consideration of Possible Change to Business and Professions Code Section 440, Related to Fees

President Oh referred to the presentation the Board received earlier from Capitol Accounting Partners, LLC, including findings and recommendations on the fee audit. Dr. Oh referred to meeting materials providing some of the largest expenditure increases including increases in state distributed costs, enforcement related costs and personnel. Dr. Oh referred to meeting materials that included recommended fees for consideration. Dr. Oh noted the scope of the change in fees varied by licensed type with some fees being reduced, others not experiencing a current change in fees, while others were recommended to increase immediately. Dr. Oh referenced in the meeting materials fees assessed by other regulators that also license facilities, including the FDA. Dr. Oh pointed out an extremely large disparity between what the Board currently assessed as an application fee and renewal fee for an outsourcing facility compared to the fees assessed by the FDA. Comparing the audit findings to this information, the fees assessed by the FDA are more closely aligned with the costs the Board incurs for its regulation of such facilities. Dr. Oh advised any change to the Board's fee schedule must be done through legislation. If the Board determined it appropriate to make changes as either recommended in the meeting materials or otherwise, the Board would need to sponsor legislation.

Members were provided an opportunity to comment.

Member Serpa noted the Board was required to re-evaluate the fee schedule based on current funding levels. Dr. Serpa noted the Board doesn't take fee increases lightly but does consider the impact on the licensees during the process.

Member Chandler added it was a logical and straightforward approach to resolving the funding issue. Mr. Chandler inquired about the timeline. Dr. Oh advised the Board would hopefully solicit legislation starting next year and hopefully it would be effective the following year. Ms. Sodergren added if successful, there will need to be time to implement and it would be ideal to implement July 2024. Staff will engage with the legislature after policy direction is provided by the Board.

Member Crowley confirmed the temporary application was a facility license. Ms. Sodergren confirmed. Dr. Crowley appreciated the decrease in pharmacy technician application fees. Dr. Crowley was hoping that would encourage pharmacy technicians and interns to apply. Dr. Crowley noted if the higher end of the pharmacist renewal fee is implemented, the fees will have almost doubled in a five-year period adding newly graduated pharmacists are getting paid less than in the past. Ms. Sodergren provided a historical summary of the fee increases and explained the 10-year model was used. Dr. Crowley inquired about the cost of the transfer of intern hours. Ms. Sodergren explained the fee is for the cost to provide the service of transferring intern hours.

Member Patel noted an increase to the nonresident pharmacy application. Mr. Patel requested to have the pharmacy technician renewal kept as is and the deficit could be added to the institution (e.g., clinics, pharmacies, etc.) fees due to the shortage of pharmacy technicians.

Member Jha agreed with not increasing the fees for pharmacy technician or pharmacist.

President Oh was open to lowering pharmacy technician and pharmacist fees.

Member Serpa recommended discussing the previous fee audit where there was a comparison of what other professionals (e.g., dentists, licensed health care professionals, etc.) pay to look for equity across the health care professionals.

Member Crowley was interested in seeing fees overtime but noted pharmacists are in a unique position where the wages are decreasing over time.

President Oh inquired if the motion could be made broader. Ms. Sodergren advised information could be provided at the December 2022 Board Meeting. Dr. Crowley was in favor of additional discussion. Mr. Chandler recommended giving guidance to staff to allow for advocating for a sponsor in December. Dr. Oh agreed.

Motion: To pursue a statutory change to amend Business and Professions Code section 4400 to adjust fee levels to address

financial conditions of the Board in line with recommendations included in the meeting materials while allowing additional discussion on the pharmacy technician renewal and pharmacy renewal and to offset reductions with increases to institutional fees.

M/S: Chandler/Crowley

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

Support: 9 Oppose: 0 Abstain: 0 Not Present: 4

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

e. Future Meeting Dates

President Oh referenced meeting materials that included the meeting calendar for the remainder 2022 as well as dates for 2023 and noted a few changes were highlighted. Dr. Oh noted there could be additional meetings of the Enforcement and Compounding Committee and Standard of Care Committee.

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

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

XVII. Executive Officer Report

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

Ms. Sodergren advised the state of emergency for COVID-19 will end 2/28/23. The Board will begin messaging to licensees as well as use the Board's subscriber alert and website in addition with communication from DCA. Ms. Sodergren noted some broad waivers in effect detailed in the meeting materials such as the remote processing waiver that will remain in effect until March 2023. Ms. Sodergren reported a number of mobile pharmacies were issued consistent with the authority in BPC 4062. Board staff was reaching out to understand how those are being used.

b. Sunset Review

Ms. Sodergren recalled the Board requested there be an annual review of the status of the report. Ms. Sodergren reported meeting materials contain a portion of the report. Ms. Sodergren anticipated the next Sunset Report would be around the end of 2024 or early 2025.

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

Ms. Sodergren reported meeting materials contain the passing information for the CPJE/NAPLEX. Ms. Sodergren pointed to a slight increase in the CPJE pass rate.

d. Overview of Presentations and Outreach to Licensees and Consumers

Ms. Sodergren highlighted presentations done over the last quarter including prescription drug abuse training what a pharmacist should know in November 2022 and outreach activities.

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

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

The Board took a lunch break from approximately 12:00 p.m. to 1:00 p.m. Roll call was taken. Board Members present included: Maria Serpa, Licensee Member; Renee Barker, Licensee Member; Trevor Chandler, Public Member; Jessi Crowley, Licensee Member; Kartikeya "KK" Jha, Licensee Member; Jig Patel, Licensee Member; Ricardo Sanchez, Public Member; Nicole Thibeau, Licensee Member; and Seung Oh, Licensee Member. Quorum was established.

Member Koenig joined the meeting at approximately 1:20 p.m.

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

Administrative Law Judge Wim van Rooyen presided over the hearings. Petitions included:

a. Stephanie Ann Richards, RPH 82766

The Board took a break from approximately 1:44 p.m. to 1:54 p.m. Roll call was taken. Board Members present included: Maria Serpa, Licensee Member; Jig Patel, Licensee Member; Renee Barker, Licensee Member; Trevor Chandler, Public Member; Jessi Crowley, Licensee Member; Kartikeya "KK" Jha, Licensee Member; Kula Koenig, Public Member; Ricardo Sanchez, Public Member; Nicole Thibeau, Licensee Member; and Seung Oh, Licensee Member. Quorum was established.

b. Natalya Skye

XX. Closed Session Matters

Following completion of the open session at 3:32 p.m. the Board convened in closed session at 3:38 p.m. for the stated purposes indicated on the agenda. Due to technological limitations, adjournment for the day was not broadcast. The meeting adjourned at 4:30 p.m.

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Sacramento, CA 95833
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

Outsourcing Facility Self-Assessment

Sections 4129.1(b) and 4129.2(b) of the Business and Professions Code (BPC) and section 1750 of Title 16 of the California Code of Regulations (CCR) require any Outsourcing Facility licensed in the state of California to be compliant with federal current Good Manufacturing Practices (cGMP) and other federal laws as specified in Section 1750.**The assessment shall be performed before July 1 of every odd-numbered year by the facility's designated quality control person (as defined in CCR section 1750.1).** The designated quality control personnel must also complete a self-assessment within 30 days whenever: (1) a new outsourcing license has been issued; (2) there is a change in the designated quality control personnel; or (3) there is a change in the licensed physical location of the outsourcing facility. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

This self-assessment should be completed in its entirety, may be completed online, printed, initialed, signed and readily retrievable and available for Board inspection in the pharmacy as required by BPC section 4081. Do not copy a previous assessment. This is meant as a guide for Board requirements for filling a patient specific prescription to be furnished within and into the state of California by a licensed Outsourcing Facility.

Note: The licensed Outsourcing Facility can only dispense compounded drug preparations from its licensed location pursuant to a prescription within or into the state of California. Further, Outsourcing Facilities are not licensed pharmacies and may not provide or accept transferred prescriptions from pharmacies or other outsourcing facilities.

All references to the Business and Professions Code (BPC) are to Division 2, Chapter 9. All references to the California Code of Regulations (CCR) are to Title 16.

Each self-assessment must be kept on file in the facility for three years after it is performed.

Facility Name: _____

Address: _____ Phone: _____

Ownership: Sole Owner ☐ Partnership ☐ Corporation ☐ LLC ☐ Trust ☐

Other ☐ (please specify) _____

License #: _____ Exp. Date:_____ Date of Last FDA Inspection: _____

FDA EIN #: _____ Registration Date: _____ _____ DEA Number: _____

Name(s) of Designated Quality Control Personnel Responsible for Compliance (attach additional sheets if necessary): _____

Hours: Weekdays _____ Sat_____ Sun. _____ 24 Hours _____

Website address (optional): _____

_____
Initials

Facility Staff (Please include license type and license number where appropriate): (Please use additional sheets if necessary)

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____
11. _____
12. _____
13. _____
14. _____
15. _____
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19. _____
20. _____

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Initials

Please mark the appropriate box for each question. If "NO", enter an explanation on "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, you may add additional sheets.

Section I
Prescription Specific Regulations

Duties of a pharmacist in an Outsourcing Facility filling patient specific prescriptions

1. A pharmacist:

Yes No N/A

☐ ☐ ☐ 1.1 Transmits a valid prescription to another pharmacist; (BPC 4052[a][2])
☐ ☐ ☐ 1.2 Provides consultation, training, and education to patients about drug therapy disease management and disease prevention; (BPC 4052[a][8])
☐ ☐ ☐ 1.3 Receives a new prescription order from the prescriber; (BPC 4070[a]), (CCR 1793.1[a])
☐ ☐ ☐ 1.4 Consults with the patient; (BPC 4052[a][8], CCR 1707.2, CCR 1793.1[b])
☐ ☐ ☐ 1.5 Identifies, evaluates, and interprets a prescription; (CCR 1793.1[c])
☐ ☐ ☐ 1.6 Interprets the clinical data in a patient medication record; (CCR 1793.1[d])
☐ ☐ ☐ 1.7 Consults with any prescriber, nurse, health professional or agent thereof; (1793.1[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

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2. Patient Consultation

Yes No N/A

☐ ☐ ☐ 2.1 Pharmacists provide oral consultation: (BPC 4052[a][8], CCR 1707.2)
- ☐ 2.1.1 Whenever the prescription drug has not been previously dispensed to the patient;
- ☐ 2.1.2 Whenever a refill prescription drug is dispensed in a different dosage form, strength, or with new written directions;
- ☐ 2.1.3 Upon request;
- ☐ 2.1.4 Whenever the pharmacist deems it is warranted in the exercise of his or her professional judgment; and
- ☐ 2.1.5 All the above, unless a patient or patient's agent declines the consultation directly to the pharmacist.

☐ ☐ ☐ 2.2 The facility maintains patient profile information including allergies, date of birth or age, gender and other prescription and nonprescription drugs that the patient takes. (CCR 1707.1)
☐ ☐ ☐ 2.3 The pharmacist reviews a patient's drug therapy and medication record prior to consultation. (CCR 1707.3)
☐ ☐ ☐ 2.4 Consultation is performed in a manner that protects the patient's protected health care information and in an area suitable for confidential patient consultation and provided in accordance with nondisclosure obligations of Civil Code 56.10. (Civil Code 56.10, CCR 1714[a], 1764)

Yes No N/A

☐ ☐ ☐ 2.5 Appropriate drug warnings are provided orally or in writing. (BPC 4074, CCR 1744)
☐ ☐ ☐ 2.6 If prescription medication is mailed or delivered, the facility ensures that: (CCR 1707.2[b][1])
- ☐ 2.6.1 The patient receives written notice of his or her right to request consultation (CCR 1707.2 [b][1][A]);
- ☐ 2.6.2 The patient receives written notice of the hours of availability and the telephone number from which the patient may obtain oral consultation (CCR 1707.2 [b][1][B]);
- ☐ 2.6.3 A pharmacist is available to speak with the patient or patient's agent during any regular hours of operation, within an average of ten (10) minutes or less, unless a return call is schedule to occur within one business hour, for no fewer than six days per week, and for a minimum of 40 hours per week (CCR 1707.2 [b][1][C]).

CORRECTIVE ACTION OR ACTION PLAN: _____

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3. Prescription Requirements

Yes No N/A

☐ ☐ ☐ 3.1 Prescriptions or electronic data transmission prescriptions are complete with all the required information and, if electronic, reduced to the required writing by a pharmacist. (BPC 4040, 4070)
☐ ☐ ☐ 3.2 Orally transmitted prescriptions are received and reduced to writing only by a Pharmacist. (BPC 4070[a], CCR 1717[c])
☐ ☐ ☐ 3.3 If a prescription is orally or electronically transmitted by the prescriber's agent, the pharmacist makes a reasonable attempt to verify that the prescriber's agent is authorized to do so, and the agent's name is recorded. (BPC 4071)
☐ ☐ ☐ 3.4 If orally transmitted, the pharmacist who received the prescription is identified by initialing the prescription, and if dispensed by another pharmacist, the dispensing pharmacist also initials the prescription. (CCR 1717[c], 1712)
☐ ☐ ☐ 3.5 The security, accuracy and confidentiality of electronically transmitted prescriptions are maintained. (BPC 4070[c], CCR 1717.4[h])
☐ ☐ ☐ 3.6 Facsimile prescriptions are received from a prescriber's office. (BPC 4040[c])
☐ ☐ ☐ 3.7 Internet prescriptions for patients (human or animal) in this state are only dispensed or furnished pursuant to a prior good faith examination. (BPC 4067[a])
☐ ☐ ☐ 3.8 Except for those prescriptions written under Health and Safety Code (HSC) sections 11159.2, 11159.3 and 11167.5, all written controlled substances prescriptions (Schedules II - V) are on California Security Prescription forms meeting the requirements of HSC 11162.1. (HSC 11162.1, 11164[a], 11167.5)
☐ ☐ ☐ 3.9 All controlled substance prescriptions are valid for six months and are signed and dated by the prescriber. (HSC 11164[a][1], 11166)
☐ ☐ ☐ 3.10 All controlled substance prescriptions that are e-prescribed conform to provisions of federal law. (21 CFR 1306.08, 1306.11, 1311.100)
☐ ☐ ☐ 3.11 The facility confirms compliance with the following: “No person shall dispense a controlled substance pursuant to a preprinted multiple check-off prescription blank. A person may dispense a dangerous drug that is not a controlled substance pursuant to a preprinted multiple checkoff prescription blank and may dispense more than one dangerous drug, that is not a controlled substance,

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Initials

pursuant to such a blank if the prescriber has indicated on the blank the number of dangerous drugs they have prescribed. 'Preprinted multiple checkoff prescription blank,' as used in this section means any form listing more than one dangerous drug where the intent is that a mark next to the name of a drug, i.e., a 'checkoff,' indicates a prescription order for that drug." (CCR 1717.3)

CORRECTIVE ACTION OR ACTION PLAN: _____

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4. Refill Authorization

Yes No N/A

☐ ☐ ☐ 4.1 Refill authorization from the prescriber for dangerous drugs or dangerous devices is obtained before refilling a prescription. (BPC 4063, 4064[a])

☐ ☐ ☐ 4.2 Prescriptions for dangerous drugs or devices are only filled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being. (BPC 4064)

☐ ☐ ☐ 4.3 Refills are documented. (CCR 1717)

☐ ☐ ☐ 4.4 Refills for Schedule II controlled substances are prohibited. (HSC 11200[c])

☐ ☐ ☐ 4.5 Refills for Schedule III and IV controlled substance prescriptions are limited to a maximum of 5 times within 6 months, and all refills taken together do not exceed a 120-day supply. (HSC 11200[a]-[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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5. Medication Errors related to a patient specific prescription

Yes No N/A

☐ ☐ ☐ 5.1 The facility has an established quality assurance program that documents medication errors attributable, in whole or in part, to the facility or its personnel. (BPC 4125, CCR 1711)

☐ ☐ ☐ 5.2 Quality assurance policies and procedures are maintained in the facility and are immediately retrievable. (CCR 1711[c])

☐ ☐ ☐ 5.3 The pharmacist communicates with the patient or patient's agent that a medication error has occurred, and the steps required to avoid injury or mitigate the error. (CCR 1711[c][2][A], 1711[c][3])

☐ ☐ ☐ 5.4 When a medication error has occurred (drug was administered to or by the patient or resulted in a clinically significant delay in therapy) the pharmacist communicates to the prescriber that a medication error has occurred. (CCR 1711[c][2][B], 1711[c][3])

☐ ☐ ☐ 5.5 Investigation of the medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])

Yes No N/A

☐ ☐ ☐ 5.6 In addition to all complaint and adverse drug reaction tracking compliant with the

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Initials

CFR, the record for quality assurance review for a medication error contains: (CCR 1711[e])

☐ 5.6.1 Date, location, and participants in the quality assurance review;
☐ 5.6.2 Pertinent data and other information related to the medication error(s) reviewed;
☐ 5.6.3 Findings and determinations; and
☐ 5.6.4 Recommended changes to policy, procedure, systems, or processes, if any.

☐ ☐ ☐ 5.7 The record of the quality assurance review is immediately retrievable in the facility and is maintained in the facility for at least one year from the date it was created. (CCR 1711[f])

CORRECTIVE ACTION OR ACTION PLAN: _____

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6. Erroneous or Uncertain prescriptions

Yes No N/A

☐ ☐ ☐ 6.1 If a prescription contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration, the pharmacist contacts the prescriber to obtain information needed to validate the prescription. (CCR 1761[a])

☐ ☐ ☐ 6.2 Pharmacists are aware of their corresponding responsibility to determine that a prescription written for a controlled substance was issued for legitimate medical purposes only. (HSC 11153)

☐ ☐ ☐ 6.3 Even after conferring with the prescriber, the pharmacist does not dispense a controlled substance prescription if they know or have objective reason to know that the prescription was not issued for a legitimate medical purpose. (CCR 1761[b], HSC 11153)

☐ ☐ ☐ 6.4 Internet prescriptions for controlled substances are only dispensed if in compliance with the Ryan Haight Online Pharmacy Consumer Protection Act of 2008. (21 USC 802, 829[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

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7. Labeling for a patient specific prescription

Yes No N/A

☐ ☐ ☐ 7.1 In addition to the requirements for labeling listed in the CFR, the prescription label contains all the required information specified in BPC 4076. (BPC 4076)

☐ ☐ ☐ 7.2 The prescription label is formatted in accordance with patient centered labeling requirements. (CCR 1707.5)

☐ ☐ ☐ 7.3 The beyond use date of a drug's effectiveness is accurately identified on the label. (BPC 4076[a][9])

☐ ☐ ☐ 7.4 The trade name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record and includes the statement "generic for __ " where the brand name is inserted, and the name of the

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Initials

manufacturer. In the professional judgment of the pharmacist, if the brand name is no longer widely used, the label may list only the generic name of the drug and the manufacturer's name may be listed outside the patient-centered area. (BPC 4076[a][1], CCR 1707.5[a][1][B], CCR 1717[b][2])

☐ ☐ ☐ 7.5 The federal warning label prohibiting transfer of controlled substances is on the prescription container. (21 CFR 290.5)

☐ ☐ ☐ 7.6 The label includes a physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules. (BPC 4076[a][11])

☐ ☐ ☐ 7.7 Whenever an opioid prescription drug is dispensed to patient for outpatient use, the facility prominently displays on the label or container or by a flag or other notification to the container, a notice that states, "Caution: Opioid. Risk of overdose and addiction." (BPC 4076.7)

☐ ☐ ☐ 7.8 When requested by a patient or patient representative, the facility provides translated directions for use, printed on the prescription container, label, or on a supplemental document. If the translated directions for use appear on the prescription container or label, the English-language version of the directions for use also appears on the container or label, whenever possible, and may appear on other areas of the label outside the patient-centered area. If it is not possible for the English-language directions to appear on the container or label, the English-language directions are provided on a supplemental document. (BPC 4076.6[a])

☐ ☐ ☐ 7.9 The pharmacist includes a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel. The label may be printed on an auxiliary label affixed to the prescription container. (BPC 4074[b], BPC 4076.7, CCR 1744[a])

☐ ☐ ☐ 7.10 The pharmacist includes a written label on the drug container to alert the patient about possible potentiating effects when taken in combination with alcohol. The label may be printed on an auxiliary label affixed to the prescription container. (CCR 1744[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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8. Furnishing and Dispensing

Yes No N/A

☐ ☐ ☐ 8.1 If the prescription is filled by a pharmacy technician, before dispensing, the prescription is checked for accuracy by a licensed pharmacist and that pharmacist initials the prescription label or records by their identity as the reviewing pharmacist in a computer system by a secure means. (BPC 4115, 4115.5[b][3], CCR 1712, 1793.7[a])

Yes No N/A

☐ ☐ ☐ 8.2 Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (15 USC 1473[b], 16 CFR 1700.15, CCR 1717[a])

☐ ☐ ☐ 8.3 Patient package inserts are dispensed with all estrogen medications.

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Initials

(21 CFR 310.515)

☐ ☐ ☐ 8.4 The facility provides patients with Black Box Warning Information in conformance with 21 CFR 201.57[c]. (21 CFR 201.57[c])

☐ ☐ ☐ 8.5 Medication guides are provided on required medications. (21 CFR, Part 208)

☐ ☐ ☐ 8.6 The facility furnishes dangerous drugs in compliance with BPC 4126.5 only to a patient pursuant to a prescription. (BPC 4126.5[a][5])

☐ ☐ ☐ 8.7 Controlled substance prescriptions are not filled or refilled more than six months from the date written. (HSC 11200[a])

☐ ☐ ☐ 8.8 Refills for Schedule III and IV controlled substance prescriptions are limited to a maximum of 5 times and in an amount, for all refills of that prescription taken together, not exceeding a 120-day supply. (HSC 11200[b])

☐ ☐ ☐ 8.9 The facility dispenses not more than a 90-day supply of a dangerous drug, excluding controlled substances, under the following provisions: (BPC 4064.5).

- ☐ 8.9.1 The prescription specifies an initial quantity of less than a 90-day supply followed by periodic refills; (BPC 4064.5[a])
- ☐ 8.9.2 The prescriber has not indicated "no change to quantity" or words of similar meaning; (BPC 4064.5[d])
- ☐ 8.9.3 The patient has completed an initial 30-day supply (this is not required where the prescription continues the same medication as previously dispensed in a 90-day supply); (BPC 4064.5[a][1], 4064.5[b])
- ☐ 8.9.4 The total quantity dispensed does not exceed the total quantity authorized on the prescription, including refills; (BPC 4064.5[a][2])
- ☐ 8.9.5 The prescriber has not specified on the prescription that dispensing the prescription in an initial amount, followed by periodic refills, is medically necessary; (BPC 4064.5[a][3])
- ☐ 8.9.6 The pharmacist is exercising their professional judgment; and (BPC 4064.5[a][4])
- ☐ 8.9.7 The pharmacist notifies the prescriber of the increase in quantity dispensed. (BPC 4064.5[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

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9. Confidentiality of Prescriptions

Yes No N/A

☐ ☐ ☐ 9.1 Patient information is maintained to safeguard confidentiality. (Civil Code 56 et seq.)

☐ ☐ ☐ 9.2 All prescriptions are kept confidential and only disclosed as authorized by law. (CCR 1764)

☐ ☐ ☐ 9.3 The facility ensures electronically transmitted prescriptions are received maintained and transmitted in a secure and confidential manner. (CCR 1717.4[h])

Yes No N/A

☐ ☐ ☐ 9.4 If electronically transmitted prescriptions are received by an interim storage device (to allow for retrieval at a later time), the facility maintains the interim storage device in a manner to prevent unauthorized access. (CCR 1717.4[d])

☐ ☐ ☐ 9.5 If the facility has established and utilizes common electronic prescription files to maintain required dispensing information, the system shall not permit disclosure

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of confidential medical information except as authorized by law. (CCR 1717.1)

☐ ☐ ☐ 9.6 Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101)

CORRECTIVE ACTION OR ACTION PLAN: _____

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10. Record Keeping Requirements in addition to compliance with cGMP

Yes No N/A

☐ ☐ ☐ 10.1 Completed self-assessments are kept on file in the facility and maintained for three years after completion. (CCR 1750.1[e])

☐ ☐ ☐ 10.2 All drug acquisition and disposition records (complete accountability) are maintained for at least three years. For any record maintained electronically, a hardcopy is able to be produced upon inspection and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records, including: (BPC 4081, 4105, 4169, 4333, CCR 1718)

- ☐ 10.2.1 Prescription records (BPC 4081[a])
- ☐ 10.2.2 Purchase Invoices for all prescription drugs (BPC 4081[b])
- ☐ 10.2.3 Purchase Invoices and sales records for non-prescription diabetic test devices dispensed pursuant to a prescription (BPC 4081[d])
- ☐ 10.2.4 Biennial controlled substances inventory (21 CFR 1304.11)
- ☐ 10.2.5 U.S. Official Order Forms (DEA Form 222) (21 CFR 1305.13)
- ☐ 10.2.6 Power of Attorney for completion of DEA 222 forms (21 CFR 1305.05)
- ☐ 10.2.7 Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

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11. Patient specific prescriptions may not be returned and reused by the facility.

Yes No N/A

☐ ☐ ☐ 11.1 Patient specific prescriptions are not returned and reused by the facility**.**

CORRECTIVE ACTION OR ACTION PLAN: _____

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Section II
Code of Federal Regulation Part 211 for all Outsourcing Facilities

Quality Systems, validation control, facility control and training

12. CFR Part 211, Subpart B, Organization and Personnel

Yes No N/A
☐ ☐ ☐ 12.1 Compliance with sections 211.22 through 211.34 in their entirety

Facility

13. CFR Part 211, Subpart C Buildings and Facilities

Yes No N/A
☐ ☐ ☐ 13.1 Compliance with Sections 211.42 through 211.58 in their entirety.

CORRECTIVE ACTION OR ACTION PLAN: _____

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Equipment

14. CFR Part 211, Subpart D Equipment

Yes No N/A
☐ ☐ ☐ 14.1 Compliance with sections 211.63 through 211.72 in their entirely.

CORRECTIVE ACTION OR ACTION PLAN: _____

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Compounding and manufacture of the product

15. CFR Part 211, Subpart E Control of Components and Drug Product Containers and Closures

Yes No N/A
☐ ☐ ☐ 15.1 Compliance with sections 211.80 through 211.94 in their entirety.

CORRECTIVE ACTION OR ACTION PLAN: _____

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16. CFR Part 211, Subpart F—Production and Process Controls

Yes No N/A
☐ ☐ ☐ 11.1 Compliance with sections 211.100 through 211.115 in their entirety.

CORRECTIVE ACTION OR ACTION PLAN: _____

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Initials

17. CFR Part 211, Subpart G—Packaging and Labeling Control

Yes No N/A

☐ ☐ ☐ 17.1 Compliance with sections 211.122 through 211.137 in their entirety.

CORRECTIVE ACTION OR ACTION PLAN: _____

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Distribution, storage,

18. CFR Section 211, Subpart H—Holding and Distribution

Yes No N/A

☐ ☐ ☐ 19.1 Compliance with sections 211.142 through 211.150

CORRECTIVE ACTION OR ACTION PLAN: _____

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Release of product for sale

19. CFR Section 211, Subpart I—Laboratory Controls

Yes No N/A

☐ ☐ ☐ 18.1 Compliance with sections 211.160 through 211.176 in their entirety.

CORRECTIVE ACTION OR ACTION PLAN: _____

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Record keeping

20. CFR Part 211, Subpart J—Records and Reports

Yes No N/A

☐ ☐ ☐ 20.1 Compliance with sections 211.180 through 211.198 in their entirety.

CORRECTIVE ACTION OR ACTION PLAN: _____

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Returns

21. CFR part 211, Subpart K—Returned and Salvaged Drug Products

Yes No N/A

☐ ☐ ☐ 21.1 Compliance with sections 211.204 through 211.208 in their entirety for products not sold pursuant to a patient specific prescription.

CORRECTIVE ACTION OR ACTION PLAN: _____

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Section III
DEA Controlled Substances Inventory, as applicable to your facility

22. Inventory:

Yes No N/A

☐ ☐ ☐ 22.1 Is completed biennially (every two years). (21 CFR 1304.11[c])
☐ ☐ ☐ 22.2 Schedule II inventory is separate from Schedule III, IV and V. (21 CFR 1304.04[h][1])
☐ ☐ ☐ 22.3 All completed inventories are available for inspection for three years. (CCR 1718)
☐ ☐ ☐ 22.4 Indicates on the inventory record whether the inventory was taken at the open of business or at the close of business. (21 CFR 1304.11 [a])
☐ ☐ ☐ 22.5 Separate Schedule II records are maintained. This includes Schedule II prescriptions, invoices, US official order forms, and inventory records. (21 CFR 1304.04[h])
☐ ☐ ☐ 22.6 Schedule III-V prescriptions are filed separately from all prescription records or are designated with a red "C." However, the red C requirement is waived if the facility uses an automated data processing or other record keeping system for identification of controlled substances by prescription number and the original prescription documents can be retrieved promptly. (21 CFR 1304.04[h][4])
☐ ☐ ☐ 22.6 Inventories and records for Schedule III-V controlled substances are filed separately or are designated in some manner that makes the required information readily retrievable from ordinary business records. (21 CFR 1304.04)
☐ ☐ ☐ 22.7 A U.S. Official Order Form (DEA Form 222) or electronic equivalent (CSOS) is utilized when ordering all Schedule II-controlled substances. When Schedule II Controlled substance orders are received by the facility, for each item received, the date and quantity received is indicated on the DEA Form 222. (21 CFR 1305.03, 1305.12, 1305.13, 1305.21, 1305.22[g])
☐ ☐ ☐ 22.8 When dispensed upon an "oral" order for a true emergency, a Schedule II prescription is provided by the prescriber by the 7th day following the transmission of the oral order. If not received, the facility reports failure to provide prescription document to the California Bureau of Narcotic Enforcement within 144 hours of the failure to provide the prescription. (HSC 11167[c]-[d])
☐ ☐ ☐ 22.9 The facility generates a controlled substances printout for refills of Schedule II-V prescriptions at least every three days (72 hours) which contains the signature of the dispensing pharmacist, or the facility maintains an alternate system to document the refilling of controlled substance prescriptions that complies with 21 CFR 1306.22.
☐ ☐ ☐ 22.10 Any controlled substances drug theft or significant loss is reported within one business day of discovery to the DEA (21 CFR 1301.74[c].)
☐ ☐ ☐ 22.11 A report is submitted to the Board within 30 days of the date of discovery of any loss of a controlled substance or any other significant drug losses as specified in Section 1715.6. (CCR 1715.6)
☐ ☐ ☐ 22.12 Pharmacists are creating initial prescription records and prescription labels by hand, or a pharmacist initials or signs prescription records and prescription labels by recording the identity of the pharmacist in a computer system by a secure means. This computer system does not permit the record to be altered after made and the record of the pharmacist's identity made in the computer system is immediately retrievable in the facility. (CCR 1712, 1717[b][1], 1717[f])

Yes No N/A

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☐ ☐ ☐ 22.13 All Schedule II through V controlled substances dispensing data is successfully transmitted within one working day from the date the controlled substance is released to the patient through the CURES System Administrator. [HSC 11165(d)])

☐ ☐ ☐ 22.14 The facility has designed and operates a system to identify suspicious orders and ensures the system complies with applicable Federal and State privacy laws. Upon discovering a suspicious order or series of orders, notify the DEA administration and the Special Agent in charge of DEA in their area. (21 USC 832[a])

CORRECTIVE ACTION OR ACTION PLAN: _____

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DESIGNATED QUALITY CONTROL PERSONNEL CERTIFICATION:

I, (please print) _____, Title _____ hereby certify that I have completed the self-assessment of this outsourcing facility of which I am the designated quality control person. Any deficiency identified herein will be corrected by _____(date). I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self-assessment form is true and correct.

Signature _____ Date _____
(Designated Quality Control Personnel)

ACKNOWLEDGEMENT BY FACILITY OWNER OR OFFICER:

I, (please print) _____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment in the timeframe identified in the Designated Quality Control Personnel Certification above could result in the revocation of the outsourcing facility's license issued by the California State Board of Pharmacy.

Signature _____ Date _____
(Outsourcing Facility Owner or Officer)

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The following **Legal References** are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov (see *Laws and Regulations*), at the California State Law Library, or at other libraries or Internet web sites.

- Business and Professions Code, Division 1, Chapter 1 – General Provisions
- Business and Professions Code, Division 2, Chapter 1 – General Provisions
- Business and Professions Code, Division 2, Chapter 9 – Pharmacy
- California Code of Regulation, Title 16, Division 17 – California State Board of Pharmacy
- Civil Code, Division 1, Part 2.6, Chapter 2 – Disclosure of Medical Information by Providers
- Code of Federal Regulations, Title 16, Chapter II, Subchapter E, Part 1700 – Poison Prevention Packaging
- Code of Federal Regulations, Title 21, Chapter I, Subchapter C, Part 210 – Current Good Manufacturing Practice in Manufacturing, Processing, Packaging, or Holding of Drugs; General
- Code of Federal Regulations, Title 21, Chapter I, Subchapter C, Part 211 – Current Good Manufacturing Practice for Finished Pharmaceuticals
- Code of Federal Regulations, Title 21, Chapter II, Parts 1301, 1304, 1305, 1306, 1311
- Health and Safety Code, Division 10 – Uniform Controlled Substances Act
- Health and Safety Code, Division 104, Part 5 - Sherman Food, Drug, and Cosmetics Law
- United States Code, Title 21, Chapter 9, Subchapter V, Part A – Federal Food, Drug, and Cosmetic Act
- United States Code, Title 21, Chapter 13 – Drug Abuse Prevention and Control

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Attachment B

December 14, 2022,
Board Meeting

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

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

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

Date: December 14, 2022

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

Board Members Present:
Seung Oh, Licensee Member, President
Maria Serpa, Licensee Member, Vice President
Jignesh Patel, Licensee Member, Treasurer
Renee Barker, Licensee Member
Indira Cameron-Banks, Public Member
Trevor Chandler, Public Member
Jessica Crowley, Licensee Member
Jose De La Paz, Public Member
Kartikeya "KK" Jha, Licensee Member
Kula Koenig, Public Member
Nicole Thibeau, Licensee Member
Jason Weisz, Public Member

Board Members Not Present: Ricardo Sanchez, Public Member

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

December 14, 2022

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

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

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

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

Roll call was taken. Board Members present included: Maria Serpa, Licensee Member; Jig Patel, Licensee Member; Renee Barker, Licensee Member; Indira Cameron-Banks, Public Member; Trevor Chandler, Public Member; Jessi Crowley, Licensee Member; Jose De La Paz, Public Member; KK Jha, Licensee Member; Nicole Thibeau, Licensee Member; and Seung Oh, Licensee Member. A quorum was established.

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

Members of the public were provided with an opportunity to provide comment for items not on the agenda or agenda items for a future meeting.

The Executive Director of the Alliance for Quality Improvement and Patient Safety offered to provide a presentation about patient safety organizations.

Members were provided the opportunity to comment. Member Serpa inquired if appropriate. President Oh explained it would be addressed later in the agenda.

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

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

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

There were no pharmacists identifying themselves to be recognized for 40 years of service as a pharmacist. President Oh thanked and congratulated pharmacists who had been licensed as a pharmacist for over 40-years. Dr. Oh thanked all pharmacy staff who worked in pharmacy serving the consumers of California.

IV. Presentation by Institute for Safe Medication Practices (ISMP) on Medication Error Reporting

President Oh welcomed Dr. Rita Jew to provide a presentation on medication error reporting. Dr. Oh thanked Dr. Jew for the support and education ISMP provides to healthcare providers.

Dr. Jew reviewed the ISMP Medication Error Reporting Programs (MERP) for errors, vaccine errors, and consumer error programs. Dr. Jew reviewed what was done with the reports including investigating, informing, and preventing. Dr. Jew advised ISPM works with the organizations including US Food & Drug Administration (FDA), United States Pharmacopeia (USP), The Joint Commission, National Coordination Council for Medication Error Reporting and Prevention (NCC MERP), National Patient Safety Collaborative, and medical product industry.

Dr. Jew reported on the work with the US FDA including tall man lettering for look-alike drug names, FDA Barcode Rule, vincristine in minibag, and FDA Guidance: Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors. Dr. Jew provided an update on ISMP work related to PAXLOVID errors being reported to FDA and working with Pfizer to develop important prescribing and dispensing information.

Dr. Jew advised ISMP's contributions with USP could be found USP General Chapter <7> including the use of metric units; use of leading and terminal zeros; abbreviations of the work "units"; quantity and total volume expression; ratio expressions; potassium chloride concentrate labeling; neuromuscular blocking label; and expiration date labeling.

Dr. Jew advised ISMP's impact with The Joint Commission included elimination of "Rule of 6" for pediatric IV infusions; unsafe or do not use medical abbreviations; tall man (mixed case) lettering for look-alike drug names (EPINEPHrine/ePHEDrine); storage restrictions of concentrated potassium chloride implemented via NPSGs; and high-alert medications.

Dr. Jew advised ISMP's assistance provided about errors reported regarding potassium dilution and preventing catheter and tubing misconnections.

Dr. Jew reported ISMP's impact with Tylenol included influenced manufacturer recall due to confusing labels (2005); removal of concentrated acetaminophen 100 mg/mL

in pint bottles from market (2008); FDA safety alert on infant acetaminophen concentration (2011); and removal of 100 mg/mL drops from market.

Dr. Jew provided examples of labeling changes including multiple mix-ups reported between Prolia and Udenyca prefilled syringes; each packaged in similar green and white cartons, with the concentration listed in a green circle in the same location; and both products stocked in oncology and infusion centers, are refrigerated, and may be stored near each other.

Members were provided the opportunity to comment.

Member Crowley inquired if ISMP was working with manufacturers to help prevent labeling and boxing errors. Dr. Jew provided generic medications often want to look like the branded medication. Dr. Jew advised ISMP works with the manufacturers and FDA noting on the retail side it was not as effective to influence change due to lack of partners.

Member Thibeau commented it was good to see ISMP can take aggregate data from the errors to make facilitate change (trend watching, labeling, etc.).

Member Serpa requested Dr. Jew explain ISMP's proactive work in the newsletter and checklists sent to subscribers. Dr. Jew advised the mission was to get the errors and share information through the newsletter. Quarterly ISMP summaries are used to develop an action agenda to help people work through checklists and help to prevent errors from happening. The error reporting program allows ISMP to share the errors and identify that there are potential hazards to evaluate the system and prevent errors from happening.

Member Patel inquired about error reporting with ISMP to see if near miss incidents are included. Dr. Jew advised near misses are included and the most valuable data. Dr. Jew provided an example of a bulk bottles of potassium chloride used to prevent parental nutrition that is put into a glass container rather than IV bags. The glass bottles were discontinued and now it is put in bags that looks like an IV bag. If infused as an IV bag, it would kill someone in little time. ISMP received notifications because people want ISMP to help notify others of issues and develop a recommendation on how to avoid errors as well as work with manufacturers to develop new packaging which is successful.

Member Patel inquired how data from the evaluation and feedback to institutions was being utilized. Dr. Jew advised if there is a request for recommendation that is provided but not all errors receive a recommendation. ISMP can also provide a consultation if requested.

Member Patel noted error reporting was required but was a difficult task. Mr. Patel inquired if a pattern is seen of reduced report in incident was their feedback provided as well. Dr. Jew advised the feedback was not provided but ISMP was able to identify which organizations were reporting. Dr. Jew added during COVID, organizations with internal reporting mechanisms decreased but ISMP's reporting of errors increased.

Member Serpa provided how the information was handled by regulatory agencies and advised the information was taken from ISMP and then used to inquire if the national recommendations were followed. Typically, if ISMP was not followed, the entity was cited.

Member Patel inquired if ISMP can report HIPPA related information to a regulatory agency. Dr. Serpa advised ISMP works with the national guidelines and recommendation but didn't have access to aggregated data. Dr. Jew added nothing would be disclosed unless the reporter agrees for us to disclose where the error was happening.

Members of the public were provided the opportunity to comment.

A pharmacist commented ISMP was a great organization that saved many lives but noted that ISMP focuses work on labeling and packaging in the acute setting. The pharmacist recommended asking ISMP about their reporting process.

Dr. Jew added packing and labeling was a focus but there were many guidelines that are process focused including self-assessment for community and acute care setting. Dr. Jew noted ISMP has a community pharmacy newsletter and are doing work with the specialty pharmacies.

Member Crowley inquired if when ISMP was used in Canada if the free form was used or if there was a form created. Dr. Jew reported there were additional fields added. Dr. Jew noted the forms are free form to allow for capturing additional information but fields can be added.

Member Barker inquired since anyone can report to ISMP does ISMP only receive submissions from health systems or community retail setting. Dr. Jew provided reports are received from community setting as well as consumers from community settings. Dr. Jew confirmed the process was the same for each setting.

President Oh thanked Dr. Jew for the presentation.

The Board took a break from 9:57 a.m. to 10:10 a.m. Roll call was taken after the break. Members present included: Maria Serpa, Licensee Member; Jig Patel, Licensee Member; Renee Barker, Licensee Member; Indira Cameron-Banks, Public Member; Trevor Chandler, Public Member; Jessica Crowley, Licensee Member; Jose De La Paz, Public Member; KK Jha, Licensee Member; Nicole Thibeau, Licensee Member; Jason Weisz, Public Member; and Seung Oh, Licensee Member. A quorum was established.

V. Discussion and Consideration of Statutory Proposal to Establish Requirement for Reporting Medication Errors

Chairperson Thibeau provided the Board with a summary of the Committee's efforts and thanked fellow members, Vice-Chair Seung Oh, Jessica Crowley, Kula Koenig, and Jignesh Patel.

Chairperson Thibeau reminded participants of the thoughtful way the Committee has approached these complex issues. Dr. Thibeau advised the Committees initial meetings primarily focused on education of the issues medication error and workforce challenges. The Committee received presentations from the Institute for Safe Medication Practices, the National Association of State Boards of Pharmacy on Its Workforce Task Force Report, the American Pharmacist Association on the Well-being Index and Fundamental Responsibilities and Rights, as well as a presentation by the Nova Scotia College of Pharmacists on the Nova Scotia Workplace Conditions Strategic Work.

Chairperson Thibeau advised the Committee started evaluating policy issues to identify actions the Board can take to improve patient care and reduce medication errors consistent with the Board's consumer protection mandate. Dr. Thibeau advised as part of the September 2022 and November 2022 Committee meetings, the Committee discussed medication error reporting and if the Board should establish a mandatory reporting requirement. Dr. Thibeau referenced in the meeting materials, currently the reporting of medications errors was voluntary and there are very sources that accept such reporting.

Chairperson Thibeau advised the issue of medication errors was not new. A study referenced in prior meeting materials back from 2003 concluded that dispensing errors were a problem at a national level with about four errors per day in a pharmacy filling 250 prescriptions daily. In addition, the New Hampshire State Board of Pharmacy reviewed medication errors it received between February 2007 and July 2012 and published its results that include 40 percent of the errors involved dispensing the incorrect medication and 68 percent of the errors occurred when only one pharmacist was on duty. Dr. Thibeau noted limitations on the results included that the reporting of errors was not mandatory.

Chairperson Thibeau continued the practice of pharmacy has changed over the years. Such changes include pharmacies that may have integrated technology in the dispensing process and expanded authorization for pharmacists. More recent information published suggests that about 1.5 percent of all prescriptions in the community setting have a dispensing error. Dr. Thibeau advised while that percentage sounds low, given the number of prescriptions dispensed in California, the estimated number of dispensing errors was staggering.

Chairperson Thibeau noted as part of its assessment of this issue, the Committee first undertook consideration of several policy questions which were detailed in the meeting materials. The Committee reached consensus that the Board should establish a mandatory requirement to report medication errors. The Committee also indicated the need for some anonymity if the Board pursues such a requirement. The Committee agreed that the Board should not mandate use of a specific form; however, the Board should provide a template that could be used as a guideline for pharmacies. Dr. Thibeau noted at the end of the first discussion questions remained about who should receive the reports, the Board or a third- party organization.

Chairperson Thibeau advised the Committee continued its discussion during the November 2022 meeting. Dr. Thibeau referenced meeting materials providing summary information on different approaches taken to medication error reporting. In Pennsylvania, the Pennsylvania Patient Safety Authority was established as an independent state agency that collects reports of patient safety events from healthcare facilities. Reporting is mandatory under specified conditions including incidents of harm or potential for harm. The statewide mandatory reporting became effective in 2004 for hospitals, and other entities. The provisions do apply to community pharmacies. Dr. Thibeau provided in this example, it was a state agency receiving the reports. The reporting system included confidentiality and whistleblower protections.

Several entities were involved in the development and implementation of the reporting system, including ISMP. One of the primary outcomes of the system was quarterly publications.

Chairperson Thibeau reported another model reviewed by the Committee was used in Canada which was a collection of reported medication incidents submitted anonymously by community pharmacies for purposes of improving medication safety. ISMP Canada's National Incident Data Repository for Community Pharmacies was developed in 2008. In 2010, Nova Scotia was the first jurisdiction to implement a requirement for community pharmacies to anonymously report medication incidents for quality improvement. Since that time additional provinces have implemented mandatory reporting as well. Dr. Thibeau advised reporting to this system has contributed to improvements in practice through shared learning, medication safety and quality improvements and well as informing research and policy. Dr. Thibeau advised the Committee's recommendation was like the Canadian model.

Chairperson Thibeau reported the last reporting model considered by the Committee was reporting to Patient Safety Organizations (PSOs) that collect and analyze data voluntarily reported by healthcare providers. The Agency for Healthcare Research and Quality (AHRQ) was responsible for regulating PSOs. Under the provisions of the federal law there were several entities excluded from serving as a PSO including a health insurance issuer, regulatory agencies, and entities that carry out inspections or audits for a regulatory agency. Dr. Thibeau noted there were several PSOs that appear to operate in California reflected in the meeting materials.

Chairperson Thibeau advised after considering the different approaches and the relevant policy questions, the Committee was recommending that the Board pursue a statutory proposal to establish a mandatory medication error reporting requirement. Dr. Thibeau referenced a copy of the draft language was included in the meeting materials.

Chairperson Thibeau reviewed the basic framework of the proposal. As drafted, a community pharmacy would be required to report all medication errors to the ISMP. Such reporting would need to occur no later than 14 days following discovery of the error. Under the proposal the reports would be deemed confidential and not subject to discovery or subpoena or other disclosure as specified. The pharmacy would be required to maintain records demonstrating compliance. The proposal would provide that a medication error report made would not be subject to discipline or other enforcement action by the Board based solely on the report.

Chairperson Thibeau advised the Committee determined it was necessary for medication errors to be reported to a single entity and that ISMP was the appropriate entity given its history and expertise. Dr. Thibeau advised the Committee's intention was to have one single entity to collect aggregate data.

Members were provided the opportunity to comment.

Member Patel commented as referenced in public comment, a public commentor requested a presentation on the Patient Safety Organization Act of 2005. Mr. Patel thought the presentation would be good so that the Board understands PSOs and agreement with federal law. Counsel Smiley noted the proposal had been generally reviewed.

Member Serpa was interested in reasoning for having a single entity and what discussions have been discussed with ISMP (e.g., need to have a contract, add data fields, etc.). Ms. Sodergren advised the work ISMP has done with Pennsylvania and Canada, ISMP has had experience in changing the reporting platform. Dr. Serpa recommended the language be changed to specifically refer to ISMP California to ensure errors were reported to the correct avenue.

Member Crowley highlighted the importance of having information in a single entity. Dr. Crowley was concerned if multiple entities were used, it would be difficult to aggregate data.

Member Chandler inquired the Committee's decision of multiple PSOs. Dr. Thibeau noted data in various formats would be difficult to ascertain the data. Mr. Chandler requested if ISMP was specified then the recommendation should be specific. Dr. Oh clarified the purpose was not to be punitive but recognizing Just Culture and understand what is going on in the pharmacies to share information to prevent errors. Dr. Thibeau noted based on the volume of prescriptions, change can positively impact the number of patients with data.

Member Koenig joined the meeting at 10:31 a.m.

Member Barker spoke in favor of having one entity to aggregate data. Dr. Barker clarified if this would be in addition to company required PSOs. Dr. Thibeau agreed and added this was to provide the Board the aggregate data so that the Board can hopefully make a large-scale intervention for patient safety in real time. Dr. Barker

inquired if California data would aggregate into the ISMP data as well as be available for California specific aggregated data.

Member Weisz inquired if there was discussion on uniformity of data. Dr. Thibeau noted this would be done in the future. Ms. Sodergren added the Board would do this in working with the legislature and stakeholders and then through regulation process. Mr. Weisz expressed concern of having ISMP specified in statute as the statute would have to change if there were any issues with ISMP. Dr. Crowley added one entity would allow for conformed and standard data.

Member Patel preferred having errors be reported to a PSO that must abide by the Patient Safety Act of 2005 and not a single entity. Dr. Thibeau added if PSOs were required those who do not use PSOs would have a PSO to report and favored a single entity. Ms. Sodergren added there could be challenges in getting information from a PSO under the patient safety act but it could be possible to get it form a PSO through a federal data bank.

Member Chandler spoke in support of having uniform single entity and wanted to make sure the language was clear. Mr. Chandler spoke in support of having a completely uniform repository for these entities.

Member Crowley advised one of the concerns was that some of the PSOs are associated to the chain retail pharmacies. Dr. Crowley viewed this as a potential conflict of interest with PSO being affiliated with chain pharmacy and impact on workforce.

Member Jha inquired if there would be more presentations and if the Board would have oversight in the aggregation of data, methodology, and how the data would be presented to the Board. Dr. Thibeau noted the Board would have to work with the entity. President Oh stated there would be more presentations to the Committee and full Board. Dr. Oh noted in the interest of time, the Board could begin the process while also hearing from PSOs at later meetings.

Member Barker inquired if the current PSO in California aggregated California information in total. Dr. Thibeau noted the Board doesn't have access to the data at this point if California data was aggregated.

Members of the public were provided with an opportunity to provide comments. Dr. Thibeau confirmed that Members received and reviewed comment submitted to the Board.

A representative of CPhA expressed support of the Committee yet expressed concern with the Board picking on entity to collect the data. The representative understood the desire for aggregate data and suggested standardizing the data needed. The representative thought there would be barriers for independent pharmacies and wanted the highest level of compliance as well as make it easier for pharmacies. If there is a desire to use one entity, a request for proposal process should be used and noted putting one entity into statute was problematic.

A representative from CVS Health inquired about hearing from a PSO prior to making the decision and adding remote pharmacist processing to a future agenda. The commenter added many states recognize PSOs and California could be the national leader by requiring the use of a PSO. The commenter inquired about fiscal impact and recommended sending it back to Committee.

A representative from UFCW spoke in strong support of proposal provided the Board wanted to move forward with the concept of implementation of mandatory reporting. If the Board wished to do it this year, the deadline for submitting a bill request will be January 20, 2023, and the last day to introduce a bill will be February 17, 2023, with the next Board Meeting being February 6, 2023. The concept was consistent with patient protection.

A pharmacist recommended amending the motion so that the Board could select through regulation the reporting entity, the reporting data, and the definition of an error. The Board also had experience with an entity being identified in statute and then having to change the statute through legislation. The Board could also require pharmacies to subscribe to ISMP. The commenter recommended using a request for proposal process to assist in determining costs.

A pharmacist representative from UC Health commented UC hospital pharmacies are required to have a medication error reduction plan (MERP) to reduce medication errors. The requirements apply to both hospital and retail pharmacies. ISMP was one of the external alerts they are required to examine as part of a MERP. The pharmacist commented in support of concept of increasing patient safety but expressed concern it would be a duplication of efforts in place already.

A representative of CRA/NACDS commented it would be beneficial to hear from PSO. The representative agreed with comments from CPhA and CVS Health and requested if community pharmacies were required to report medication errors, the errors can be reported to a PSO familiar with assisting community pharmacies as they assist pharmacy study medication errors and implement corrective actions to improve patient care and prevent errors in the future. The commenter continued as PSOs are

not a government program and reporting by pharmacies is voluntary under the Federal Patient Safety Act, requiring pharmacies to report to a single PSO with the aggregation of data could contradict the Federal Patient Safety Act. The representative recommended reviewing Virginia's policy.

A licensed pharmacist commented legislation should give the Board the ability to select the entity.

A representative from the Alliance for Quality Improvement and Patient Safety offered to provide a presentation to the Board on PSOs. The representative stated a concern for independent pharmacies who currently use a PSO but may not be able to afford both the ISMP and PSO. The representative noted it could be a harm to Californian consumers in that PSOs help independent pharmacies collect information, focus on their problems and improvement of problems.

Members were provided the opportunity to comment.

Member Serpa recommended moving forward so that an author could be secured with the change of "ISMP" to "entity approved by the Board."

Member Crowley agreed with open ended to continue discussion and remove concerns. Dr. Crowley also thought it was a good idea to consider a requirement to have all pharmacies subscribe to ISMP and noted the ISMP Canada was specific to community pharmacy settings.

Committee Recommendation (Motion): Pursue a statutory proposal to establish a mandatory medication error reporting requirement consistent with the language presented.

> **Proposed addition of Business and Professions Code Section 4113.1 Pharmacy Operations**
>
> Any community pharmacy licensed pursuant to this article shall report all medication errors to the Institute for Safe Medication Practices. Reporting shall be submitted no later than 14 days following discovery of the error. Such reports are deemed confidential and are not subject to discovery, subpoena, or disclosure pursuant to Chapter 3.5 (commencing with Section 6250) of Division of Title 1 of the Government Code. The pharmacy shall maintain records demonstrating compliance with this requirement for three years and shall make such records immediately available at the request of an inspector. A medication error report made pursuant to this section shall not be subject to discipline or other enforcement action by the Board based solely on the report;

however, if the Board receives other information regarding the medication error, that information may serve as basis for discipline or other enforcement by the Board.

Support: 0 Oppose: 11 Abstain: 1 Not Present: 1

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

President Oh inquired if specialty pharmacy should be included. Dr Serpa noted specialty pharmacy was a part of community pharmacy and recommend staying with the licensed pharmacy categories.

Motion: Pursue a statutory proposal to establish a mandatory medication error reporting requirement consistent with the language presented confirming that Community Pharmacy shall include any pharmacy with a PHY prefix and replacing "Institute for Safe Medication Practices" with "an entity approved by the Board."

Proposed addition of Business and Professions Code Section 4113.1 Pharmacy Operations

Any community pharmacy licensed pursuant to this article shall report all medication errors to the Institute for Safe Medication Practices. Reporting shall be submitted no later than 14 days following discovery of the error. Such reports are deemed confidential and are not subject to discovery, subpoena, or disclosure pursuant to Chapter 3.5 (commencing with Section 6250) of Division of Title 1 of the Government Code. The pharmacy shall maintain records demonstrating compliance with this requirement for

three years and shall make such records immediately available at the request of an inspector. A medication error report made pursuant to this section shall not be subject to discipline or other enforcement action by the Board based solely on the report; however, if the Board receives other information regarding the medication error, that information may serve as basis for discipline or other enforcement by the Board.

M/S: Serpa/Crowley

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

Members of the public were provided the opportunity to comment. A representative of CPhA suggested adding "third-party entity" to clarify it would be an entity outside of the enforcement process. A representative of UFCW commented in support of the revised motion.

Dr. Serpa confirmed the motion as presented.

Support: 11 Oppose: 0 Abstain: 1 Not Present: 1

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

The Board took a break from 1:26 am to 11:30 a.m. Roll call was taken after the break. Members present included: Maria Serpa, Licensee Member; Jig Patel, Licensee Member; Renee Barker, Licensee Member; Indira Cameron-Banks, Public Member; Trevor Chandler, Public Member; Jessica Crowley, Licensee Member; Jose De La Paz, Public Member; KK Jha, Licensee Member; Nicole Thibeau, Licensee Member; and Seung Oh, Licensee Member. A quorum was established.

VI. Discussion and Consideration of Statutory Proposal Related to Working Conditions

Chairperson Thibeau advised many of the issues and challenges faced by California were not unique noting the Committee had also considered enforcement authority exercised by other jurisdictions related to workplace conditions to learn about different approaches. Dr. Thibeau noted the Committee had previously learned that in Nova Scotia, legal provisions require that pharmacy managers ensure the staffing plan of the pharmacy was commensurate with the needs of the patients of the pharmacy. Further when staffing issues are related to errors, the Board can require the pharmacy owners and managers to show proof of how they insured that regulatory requirement had been met.

Chairperson Thibeau reported there were several other jurisdictions within the US that were evaluating working conditions including some establishing requirements to report unsafe working conditions, others have provisions to ensure sufficient personnel are scheduled to work, some have notification requirements requiring a pharmacy to notify patients if the pharmacy was experiencing significant delays or cannot dispense prescriptions in a timely manner.

Chairperson Thibeau advised in California, there were provisions establishing what can occur when a pharmacist was at lunch and requirements for a community chain pharmacy to ensure designated staff were available to assist a pharmacist when requested. Most recently there was a new requirement establishing a prohibition on workload quotas. Meeting materials included specific legal requirements for some other states which were reviewed and considered by the Committee. Several states included a requirement for the pharmacy to ensure sufficient staffing.

Chairperson Thibeau reported as part of the Committee's September 2022 meeting, Members spoke in support of the authorities from other jurisdictions including the provisions in Oklahoma. Members liked provisions that limited the number of working hours for pharmacists but noted that could be a challenge to implement due to variances in practice settings. Members considered the concept of establishing a staffing floor and considered who within a pharmacy should have the authority to establish appropriate staffing.

Chairperson Thibeau reported in November 2022, the Committee considered proposed statutory language developed following the September 2022 meeting. The Committee recommended that the Board pursue a statutory proposal. Dr. Thibeau

noted a summary of the various provisions was detailed in the meeting materials. Dr. Thibeau believed it was important to remind participants that this proposal was recommended to address contributing factors to medication errors which were previously identified as a significant consumer protection issue.

Committee Recommendation (Motion): Recommend to the Board pursuit of a statutory proposal to add and amend Business and Professions Code sections 4113.5, 4113, and 4301 consistent with the committee's discussion of the language as presented, with amendment to strike out ",after a reasonable attempt to reach the pharmacist-in-charge," in proposed BPC 4113(d).

Proposed Amendment to BPC 4113.5.

(a) A community pharmacy shall not require a pharmacist employee to engage in the practice of pharmacy at any time the pharmacy is open to the public, unless either another employee of the pharmacy or, if the pharmacy is located within another establishment, an employee of the establishment within which the pharmacy is located, is made available to assist the pharmacist at all times.

(b) This section shall not apply to any of the following:

(1) A hospital pharmacy, as defined in Section 4029 or 4056.

(2) A pharmacy located in a hospital facility, including, but not limited to, a building where outpatient services are provided in accordance with the hospital's license.

(3) A pharmacy owned or operated by a federal, state, local, or tribal government entity, including, but not limited to, a correctional pharmacy, a University of California pharmacy, or a pharmacy operated by the State Department of State Hospitals.

(4) A pharmacy owned by a person or persons who, collectively, control the majority of the beneficial interest in no more than four pharmacies in California.

(5) A pharmacy entirely owned and operated by a health care service plan that exclusively contracts with no more than two medical groups in the state to provide, or arrange for the provision of, professional medical services to the enrollees of the plan.

(6) A pharmacy that permits patients to receive medications at a drive-through window when both of the following conditions are met:

(A) A pharmacist is working during the times when patients may receive medication only at the drive-through window.

(B) The pharmacist's employer does not require the pharmacist to retrieve items for sale to patients if the items are located outside the pharmacy. These items include, but are not limited to, items for which a prescription is not required.

(7) Any other pharmacy from which controlled substances, dangerous drugs, or dangerous devices are not furnished, sold, or dispensed at retail.

(c) A violation of subdivision (a) is not subject to subdivision (a) of Section 4321.

(d) The board shall not take action against a pharmacy for a violation of this section if both of the following apply:

(1) Another employee is unavailable to assist the pharmacist due to reasonably unanticipated circumstances, including, but not limited to, illness, injury, family emergency, or the employee's termination or resignation.

(2) The pharmacy takes all reasonable action to make another employee available to assist the pharmacist.

(e) The pharmacist on duty may close a pharmacy if, in their opinion, the staffing at the pharmacy is inadequate to safely fill or dispense prescriptions or provide other patient care services in a safe manner without fear of retaliation.

(f) A pharmacy is always staffed with at least one clerk or pharmacy technician fully dedicated to performing pharmacy related services. Where staffing of pharmacist hours does not overlap sufficiently, scheduled closures for lunch time for all pharmacy staff shall be established and publicly posted and included on the outgoing phone message.

(g) This section shall not be construed to permit an employee who is not licensed under this chapter to engage in any act for which a license is required under this chapter.

Proposal to Amend BPC 4113.

(a) Every pharmacy shall designate a pharmacist-in-charge and, within 30 days thereof, shall notify the board in writing of the identity and license number of that pharmacist and the date he or she was designated.

(b) The proposed pharmacist-in-charge shall be subject to approval by the board. The board shall not issue or renew a pharmacy license without identification of an approved pharmacist-in-charge for the pharmacy.

(c) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. The pharmacist-in-charge shall have autonomy to make staffing decisions to ensure sufficient personnel are present in the pharmacy to prevent

fatigue, distraction or other conditions that may interfere with a pharmacist's ability to practice competently and safely.

(d) The pharmacist-in-charge shall have the authority to close a pharmacy if workplace hazards, such as unsanitary conditions, temperatures deviate from appropriate drug storage conditions, or other conditions based on their professional judgement may create an unsafe environment for personnel or pharmacy staff. In the event the pharmacist-in-charge is not available, the pharmacist on duty, may close the pharmacy to the reasons previously cited.

(e) Every pharmacy shall notify the board in writing, on a form designed by the board, within 30 days of the date when a pharmacist-in-charge ceases to act as the pharmacist-in-charge, and shall on the same form propose another pharmacist to take over as the pharmacist-in-charge. The proposed replacement pharmacist-in-charge shall be subject to approval by the board. If disapproved, the pharmacy shall propose another replacement within 15 days of the date of disapproval and shall continue to name proposed replacements until a pharmacist-in-charge is approved by the board.

(~~e~~ f) If a pharmacy is unable, in the exercise of reasonable diligence, to identify within 30 days a permanent replacement pharmacist-in-charge to propose to the board on the notification form, the pharmacy may instead provide on that form the name of any pharmacist who is an employee, officer, or administrator of the pharmacy or the entity that owns the pharmacy and who is actively involved in the management of the pharmacy on a daily basis, to act as the interim pharmacist-in-charge for a period not to exceed 120 days. The pharmacy, or the entity that owns the pharmacy, shall be prepared during normal business hours to provide a representative of the board with the name of the interim pharmacist-in-charge with documentation of the active involvement of the interim pharmacist-in-charge in the daily management of the pharmacy, and with documentation of the pharmacy's good faith efforts prior to naming the interim pharmacist-in-charge to obtain a permanent pharmacist-in-charge. By no later than 120 days following the identification of the interim pharmacist-in-charge, the pharmacy shall propose to the board the name of a pharmacist to serve as the permanent pharmacist-in-charge. The proposed permanent pharmacist-in-charge shall be subject to approval by the board. If disapproved, the pharmacy shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a pharmacist-in-charge is approved by the board.

Proposal to Amend BPC 4301.
The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct includes, but is not limited to, any of the following:

(a) Procurement of a license by fraud or misrepresentation.

(b) Incompetence.

(c) Gross negligence.

(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

(h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a person holding a license under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.

(i) Except as otherwise authorized by law, knowingly selling, furnishing, giving away, or administering, or offering to sell, furnish, give away, or administer, any controlled substance to an addict.

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

(k) The conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any dangerous drug or alcoholic beverage, or any combination of those substances.

(l) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the

qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

(m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program.

(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter that would be grounds for revocation, suspension, or other discipline under this chapter. Any disciplinary action taken by the board pursuant to this section shall be coterminous with action taken by another state, except that the term of any discipline taken by the board may exceed that of another state, consistent with the board's enforcement guidelines. The evidence of discipline by another state is conclusive proof of unprofessional conduct.

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

(p) Actions or conduct that would have warranted denial of a license.

(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.

(r) The selling, trading, transferring, or furnishing of drugs obtained pursuant to Section 256b of Title 42 of the United States Code to any person a licensee knows or reasonably should have known, not to be a patient of a covered entity, as defined in paragraph (4) of subsection (a) of Section 256b of Title 42 of the United States Code.

(s) The clearly excessive furnishing of dangerous drugs by a wholesaler to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities. Factors to be considered in determining whether the furnishing of dangerous drugs is clearly excessive shall include, but not be limited to, the amount of dangerous drugs furnished to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities, the previous ordering pattern of the pharmacy, and the general patient population

to whom the pharmacy distributes the dangerous drugs. That a wholesaler has established, and employs, a tracking system that complies with the requirements of subdivision (b) of Section 4164 shall be considered in determining whether there has been a violation of this subdivision. This provision shall not be interpreted to require a wholesaler to obtain personal medical information or be authorized to permit a wholesaler to have access to personal medical information except as otherwise authorized by Section 56 and following of the Civil Code. For purposes of this section, "long-term care facility" has the same meaning given the term in Section 1418 of the Health and Safety Code.

(t) The acquisition of a nonprescription diabetes test device from a person that the licensee knew or should have known was not the nonprescription diabetes test device's manufacturer or the manufacturer's authorized distributor as identified in Section 4160.5.

(u) The submission of a reimbursement claim for a nonprescription diabetes test device to a pharmaceutical benefit manager, health insurer, government agency, or other third-party payor when the licensee knew or reasonably should have known that the diabetes test device was not purchased either directly from the manufacturer or from the nonprescription diabetes test device manufacturer's authorized distributors as identified in Section 4160.5.

(v) Actions or conduct that would subvert or tend to subvert the efforts of a pharmacist to comply with laws and regulations, or exercise professional judgement, including creating or allowing conditions that may interfere with a pharmacist's ability to practice with competency and safety or creating or allowing an environment that may jeopardize patient care.

(w) Actions or conduct that would subvert or tend to subvert the efforts of a pharmacist-in-charge to comply with laws and regulations, exercise professional judgement, or make determinations about adequate staffing levels to safely fill prescriptions of the pharmacy or provide other patient care services in a safe and competent manner.

(x) Actions or conduct that would subvert or tend to subvert the efforts of a pharmacist intern or and pharmacy technician to comply with laws or regulations.

(y) Establishing policies and procedures related to time guarantees to fill prescriptions within a specified time unless such guarantees are required by law or to meet contractual requirements.

Members were provided an opportunity to comment.

Member Chandler spoke in support of recommended proposed statutory changes to support pharmacists in their work to ensure patient safety.

Member Serpa appreciated the detail and completeness but had concerns especially after reading the public comment letters submitted to the Board. Dr. Serpa commented about BPC 4113.5 (f) regarding the pharmacy always was staffed with at least one pharmacy technician or one clerk. Dr. Serpa expressed concern about impact to patient access and pharmacy care if enacted. Dr. Serpa noted challenges with the new regulation CCR section 1714.3 that requires a pharmacy to have a second person in the store available within five minutes. Dr. Serpa added if there were challenges with the current regulation, the Board should try to enforce or educate rather than jump to this proposal that would limit access to patients. Dr. Serpa thought it would cause 24-hour pharmacies to close and rural pharmacies to limit hours to patients. Dr. Serpa added if the Board decides to go down this path, it should be very clear that this only applies when the pharmacy is open to the public.

Chairperson Thibeau appreciated the point about when the pharmacy is open to the public. Dr. Thibeau was concerned by letters but realized there was an assumption that there was no contingency plan in the pharmacy. Dr. Thibeau noted if someone is sick at the pharmacy, there are contingency plans in place. Dr. Thibeau reported the Committee had heard comments that pharmacists are pressured to not call in when they are sick and come in and work when they are sick.

President Oh explained the text provided in BPC 4113.5 (f) would show intent of the Board to the Legislature on where the Board would want the measure to go. Dr. Oh agreed with Dr. Serpa's concerns but thought the concerns could be resolved by amending it after the intent was conveyed to the Legislature. If the Legislature wanted to move forward, the language would be amended to remove duplication. Dr. Oh thought the proposal had good consensus and was balanced without being too extreme. Dr. Oh added it was obvious there was a problem and California needed to lead in this urgent issue with high standards for patients. Dr. Oh added he would be amenable to address concerns through exemptions (e.g., 24-hour or rural pharmacies) to balance concerns addressed.

Member Crowley agreed with Dr. Serpa's comment to clarify the pharmacist isn't alone when the pharmacy is open to the public. Dr. Crowley added pharmacists don't always have someone who is properly trained or people do not show up when needed which means the pharmacists aren't taking their breaks. Dr. Crowley agreed clarification was needed as (f) contradicts (a). Dr. Crowley added BPC 4113 (c) supported changing the pharmacist-in-charge having authority to the pharmacist on duty having autonomy for staffing conflicting incentives for lessening labor costs for owners/managers.

Member Jha expressed concern about patient access as access to pharmacies has already decreased over time and the Board needed to be mindful. Mr. Jha noted there would need to be a robust system to notify consumers and prescribers when a pharmacy is closed as well as a system that continues to accept electronic refills.

Member Barker expressed concern if the pharmacists are not getting their breaks or meals. Dr. Barker understood the pharmacy needs to be open but inquired if that cost was medication errors. Dr. Thibeau added closure would be the most extreme with other steps in between that a pharmacy can take (e.g., vaccines aren't administered that day, prescriptions only filled for people waiting, etc.). Mr. Chandler agreed with Dr. Barker's comment that pharmacists need to be taken care of or it will be more harmful to the pharmacists and consumers. Dr. Thibeau agreed it was a quality versus quantity issue to be addressed.

Member Patel agreed there were many steps to be taken before shutting down a pharmacy and it would be important for the language to spell out how limiting services could be done. Mr. Patel noted this would give the pharmacist the authority to cut down services before deciding to close the pharmacy especially related to rural locations, emergency situations, and severe weather. Dr. Thibeau noted it was important for pharmacists to be able to address their own health emergencies and being able to leave the pharmacy. Dr. Crowley provided an example during a protest outside of her pharmacy and not being able to close the pharmacy. When Dr. Crowley left for the day, the pharmacy was being boarded up.

Member Serpa expressed concern about changing proposals and moving forward too early. Dr. Serpa felt it was better to state what the Board wants with intent in the conversation but noted the risk of approving something that isn't necessarily agreed to but have as a starting place would be an interesting discussion for the Board. Dr. Serpa was concerned about the confusion and misinformation that would be conveyed to the public and legislature. Dr. Serpa appreciated Dr. Crowley's comment about giving the authority to the pharmacist-in-charge and pharmacist on duty.

President Oh commented the pharmacist-in-charge should have autonomy to encourage better scheduling. Dr. Oh would support the pharmacist-in-charge having the authority and in cases where the pharmacist on duty should also have the authority. Dr. Oh didn't think it should just be pharmacist on duty because it was too dynamic and last minute orientated. Dr. Thibeau stated the intent was for situations where the scheduling happens outside of the authority of the pharmacist.

Member Serpa commented the Board has a huge opportunity with CCR section 1714.3 to educate on how complaints can be filed. Dr. Serpa noted it wasn't the same topic but it was the same issue that could help.

Chairperson Thibeau confirmed Members received and reviewed written public comment received. Members of the public were provided the opportunity to comment.

A representative of CRA/NACDS commented with concerns about the proposal having significant and detrimental patient access noting it didn't consider many scenarios (e.g., pharmacy technician/clerk calls in sick or quits, etc.) that are outside of the pharmacist's control. The representative noted it would be problematic for pharmacies in rural areas where pharmacies are the main access point for care and it was difficult to recruit personnel for pharmacies. The representative noted concern about the pharmacist being able to close a pharmacy if the pharmacist felt staffing was insufficient to fill prescriptions or offer services which as written would have an enormous impact on patient safety. The representative thought it would result in the reduction of pharmacy hours which have already been reduced; 24-hour pharmacies would diminish; weekend hours could cease; and operating hours would shrink. The representative noted the proposal prohibits pharmacies from implementing requirements to fill prescriptions within a certain amount of time unless required by law which was duplicative from the prohibition on quotas.

A representative from CVS Health commented in opposition to the bill noting closing a pharmacy without notice was a much larger public safety concern than what was trying to be solved through the proposal. The representative noted a key component of public safety was access to care and adherence to medication regimens which could be interrupted if a patient arrives to refill medication to find the pharmacy closed where medication can't be refilled and the patient is unlikely to return before the medication runs out. The representative stated it was bad for public safety if a pharmacy was closed due to an increase in patients, a pharmacy technician called in sick, or a pharmacist determined staffing was inadequate. The representative urged the proposal to be sent back to Committee. The representative stated the administrative burden California has imposed through legislation/regulation will cause pharmacies to cease operating in California. The representative commented CVS was in the process of closing 900 unprofitable CVS pharmacies and numerous Quorum sterile compounding pharmacies across the nation noting that 10 percent of CVS pharmacies were in California. The representative noted it was impactful to California

residents. The representative stated each year CVS reduces hours open to the public including eliminating overnight shifts and shortening weekend hours due in part to administrative burden. In addition to the burden of a pharmacy technician or clerk working each slow hour a pharmacy is open, these hours may disappear resulting in more pharmacy closures, less 24-hour pharmacies, reduced weekend hours, and less hours for pharmacists to work. The representative stated the impact to access to care and public safety needed to be considered. The representative noted the proposal didn't have the same exemption as included in CCR section 4113.5 if an employee is unavailable to assist due to reasonably unanticipated circumstances (e.g., illness, injury, family emergency or employee termination/resignation).

A representative of UFCW commented adequate pharmacy staffing in chain stores was an urgent patient protection issue as noted in the meeting materials and in comments from pharmacists to UFCW. The representative noted it warranted the Board's urgent leadership and a legislative discussion this year. The representative spoke in support of the legislative staffing proposal mindful that the proposals are invitations to the legislature to discuss the critical issues under the Board's leadership.

A representative of CPhA commented in support of the autonomy of the pharmacist on duty to determine adequate staffing levels that would allow the pharmacists to honor their oath to provide patient care safely without any fear of retaliation. The representative comment in support of the Committee and Board's work and the attention to rectifying what has become an untenable situation for many California pharmacists in their workplace. The representative stated the proposal was complementary to their work with SB 362 to eliminate pharmacy quotas noting this was the next step to allow pharmacists to discharge their duties. The representative noted lessons could be learned from independent pharmacies who do not seem to run into these issues because they anticipate, plan, and prepare for these scenarios so that it is not as much of the sky is falling scenario as being painted.

A retired pharmacist who provided history on the no pharmacist left behind legislation which was controversial and had to be clarified in regulation. The pharmacist believed the proposal had very good language that clarified the intent about staff being available at all times and qualified to help the pharmacist. The pharmacist believed the concern that pharmacies will close was overstated as a lot of pharmacies have trouble competing because there are three to five pharmacies within a quarter mile of each other where the business plans have adapted to have short staffing to keep them in business. The representative noted there are labor codes that limit the hours of work and the days of the week that needs to be modified so the Board can enforce it.

Chairperson Thibeau thanked the public for their comments and provided Members an opportunity to comment.

Member Crowley recommended adding an additional sentence "if the pharmacist-in-charge is unavailable a pharmacist on duty may adjust staffing according to workload if needed." Dr. Oh was in support of the comment but noted the Board had to vote on the Committee's recommendation.

Support: 11 Oppose: 0 Abstain: 1 Not Present: 1

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

President Oh inquired how to address Dr. Crowley's suggestion. Counsel Smiley advised the motion could be amended or the intent could be discussed with the sponsors.

Motion: To add the language of "If a pharmacist-in-charge is unavailable, a pharmacist on duty may adjust staffing according to workload, if needed."

M/S: Crowley/Thibeau

Proposed Amendment to BPC 4113.5.
(a) A community pharmacy shall not require a pharmacist employee to engage in the practice of pharmacy at any time the pharmacy is open to the public, unless either another employee of the pharmacy or, if the pharmacy is located

within another establishment, an employee of the establishment within which the pharmacy is located, is made available to assist the pharmacist at all times.

(b) This section shall not apply to any of the following:

(1) A hospital pharmacy, as defined in Section 4029 or 4056.

(2) A pharmacy located in a hospital facility, including, but not limited to, a building where outpatient services are provided in accordance with the hospital's license.

(3) A pharmacy owned or operated by a federal, state, local, or tribal government entity, including, but not limited to, a correctional pharmacy, a University of California pharmacy, or a pharmacy operated by the State Department of State Hospitals.

(4) A pharmacy owned by a person or persons who, collectively, control the majority of the beneficial interest in no more than four pharmacies in California.

(5) A pharmacy entirely owned and operated by a health care service plan that exclusively contracts with no more than two medical groups in the state to provide, or arrange for the provision of, professional medical services to the enrollees of the plan.

(6) A pharmacy that permits patients to receive medications at a drive-through window when both of the following conditions are met:

(A) A pharmacist is working during the times when patients may receive medication only at the drive-through window.

(B) The pharmacist's employer does not require the pharmacist to retrieve items for sale to patients if the items are located outside the pharmacy. These items include, but are not limited to, items for which a prescription is not required.

(7) Any other pharmacy from which controlled substances, dangerous drugs, or dangerous devices are not furnished, sold, or dispensed at retail.

(c) A violation of subdivision (a) is not subject to subdivision (a) of Section 4321.

(d) The board shall not take action against a pharmacy for a violation of this section if both of the following apply:

(1) Another employee is unavailable to assist the pharmacist due to reasonably unanticipated circumstances, including, but not limited to, illness, injury, family emergency, or the employee's termination or resignation.

(2) The pharmacy takes all reasonable action to make another employee available to assist the pharmacist.

(e) The pharmacist on duty may close a pharmacy if, in their opinion, the staffing at the pharmacy is inadequate to safely fill or dispense prescriptions or provide other patient care services in a safe manner without fear of retaliation.

(f) A pharmacy is always staffed with at least one clerk or pharmacy technician fully dedicated to performing pharmacy related services. Where staffing of pharmacist hours does not overlap sufficiently, scheduled closures for lunch time for all pharmacy staff shall be established and publicly posted and included on the outgoing phone message.

(g) This section shall not be construed to permit an employee who is not licensed under this chapter to engage in any act for which a license is required under this chapter.

Proposal to Amend BPC 4113.

(a) Every pharmacy shall designate a pharmacist-in-charge and, within 30 days thereof, shall notify the board in writing of the identity and license number of that pharmacist and the date he or she was designated.

(b) The proposed pharmacist-in-charge shall be subject to approval by the board. The board shall not issue or renew a pharmacy license without identification of an approved pharmacist-in-charge for the pharmacy.

(c) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. The pharmacist-in-charge shall have autonomy to make staffing decisions to ensure sufficient personnel are present in the pharmacy to prevent fatigue, distraction or other conditions that may interfere with a pharmacist's ability to practice competently and safely. If a pharmacist-in-charge is unavailable, a pharmacist on duty may adjust staffing according to workload, if needed.

(d) The pharmacist-in-charge shall have the authority to close a pharmacy if workplace hazards, such as unsanitary conditions, temperatures deviate from appropriate drug storage conditions, or other conditions based on their professional judgement may create an unsafe environment for personnel or pharmacy staff. In the event the pharmacist-in-charge is not available, the pharmacist on duty, may close the pharmacy to the reasons previously cited.

(e) Every pharmacy shall notify the board in writing, on a form designed by the board, within 30 days of the date when a pharmacist-in-charge ceases to act as the pharmacist-in-charge, and shall on the same form propose another pharmacist to take over as the pharmacist-in-charge. The proposed replacement pharmacist-in-charge shall be subject to approval by the board. If

disapproved, the pharmacy shall propose another replacement within 15 days of the date of disapproval and shall continue to name proposed replacements until a pharmacist-in-charge is approved by the board.

(~~e~~ f) If a pharmacy is unable, in the exercise of reasonable diligence, to identify within 30 days a permanent replacement pharmacist-in-charge to propose to the board on the notification form, the pharmacy may instead provide on that form the name of any pharmacist who is an employee, officer, or administrator of the pharmacy or the entity that owns the pharmacy and who is actively involved in the management of the pharmacy on a daily basis, to act as the interim pharmacist-in-charge for a period not to exceed 120 days. The pharmacy, or the entity that owns the pharmacy, shall be prepared during normal business hours to provide a representative of the board with the name of the interim pharmacist-in-charge with documentation of the active involvement of the interim pharmacist-in-charge in the daily management of the pharmacy, and with documentation of the pharmacy's good faith efforts prior to naming the interim pharmacist-in-charge to obtain a permanent pharmacist-in-charge. By no later than 120 days following the identification of the interim pharmacist-in-charge, the pharmacy shall propose to the board the name of a pharmacist to serve as the permanent pharmacist-in-charge. The proposed permanent pharmacist-in-charge shall be subject to approval by the board. If disapproved, the pharmacy shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a pharmacist-in-charge is approved by the board.

Proposal to Amend BPC 4301.
The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct includes, but is not limited to, any of the following:

(a) Procurement of a license by fraud or misrepresentation.

(b) Incompetence.

(c) Gross negligence.

(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

(h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a person holding a license under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.

(i) Except as otherwise authorized by law, knowingly selling, furnishing, giving away, or administering, or offering to sell, furnish, give away, or administer, any controlled substance to an addict.

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

(k) The conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any dangerous drug or alcoholic beverage, or any combination of those substances.

(l) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

(m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled

substances or of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program.

(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter that would be grounds for revocation, suspension, or other discipline under this chapter. Any disciplinary action taken by the board pursuant to this section shall be coterminous with action taken by another state, except that the term of any discipline taken by the board may exceed that of another state, consistent with the board's enforcement guidelines. The evidence of discipline by another state is conclusive proof of unprofessional conduct.

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

(p) Actions or conduct that would have warranted denial of a license.

(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.

(r) The selling, trading, transferring, or furnishing of drugs obtained pursuant to Section 256b of Title 42 of the United States Code to any person a licensee knows or reasonably should have known, not to be a patient of a covered entity, as defined in paragraph (4) of subsection (a) of Section 256b of Title 42 of the United States Code.

(s) The clearly excessive furnishing of dangerous drugs by a wholesaler to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities. Factors to be considered in determining whether the furnishing of dangerous drugs is clearly excessive shall include, but not be limited to, the amount of dangerous drugs furnished to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities, the previous ordering pattern of the pharmacy, and the general patient population to whom the pharmacy distributes the dangerous drugs. That a wholesaler has established, and employs, a tracking system that complies with the requirements of subdivision (b) of Section 4164 shall be considered in determining whether there has been a violation of this subdivision. This provision shall not be interpreted to require a wholesaler to obtain personal medical information or be authorized to permit a wholesaler to have access to personal medical information except as otherwise authorized by Section 56 and following of the Civil Code. For purposes of this section, "long-term care facility" has the same meaning given the term in Section 1418 of the Health and Safety Code.

(t) The acquisition of a nonprescription diabetes test device from a person that the licensee knew or should have known was not the nonprescription diabetes

test device's manufacturer or the manufacturer's authorized distributor as identified in Section 4160.5.

(u) The submission of a reimbursement claim for a nonprescription diabetes test device to a pharmaceutical benefit manager, health insurer, government agency, or other third-party payor when the licensee knew or reasonably should have known that the diabetes test device was not purchased either directly from the manufacturer or from the nonprescription diabetes test device manufacturer's authorized distributors as identified in Section 4160.5.

(v) Actions or conduct that would subvert or tend to subvert the efforts of a pharmacist to comply with laws and regulations, or exercise professional judgement, including creating or allowing conditions that may interfere with a pharmacist's ability to practice with competency and safety or creating or allowing an environment that may jeopardize patient care.

(w) Actions or conduct that would subvert or tend to subvert the efforts of a pharmacist-in-charge to comply with laws and regulations, exercise professional judgement, or make determinations about adequate staffing levels to safely fill prescriptions of the pharmacy or provide other patient care services in a safe and competent manner.

(x) Actions or conduct that would subvert or tend to subvert the efforts of a pharmacist intern or and pharmacy technician to comply with laws or regulations.

(y) Establishing policies and procedures related to time guarantees to fill prescriptions within a specified time unless such guarantees are required by law or to meet contractual requirements.

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

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

Support: 11 Oppose: 0 Abstain: 1 Not Present: 1

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

The Board took a break from 12:30 p.m. to 1:00 p.m. Roll call was taken after the break. Members present included: Maria Serpa, Licensee Member; Renee Barker, Licensee Member; Indira Cameron-Banks, Public Member; Trevor Chandler, Public Member; Jessi Crowley, Licensee Member; Jose De La Paz, Public Member; KK Jha, Licensee Member; Nicole Thibeau, Licensee Member; Jason Weisz, Public Member; and Seung Oh, Licensee Member. A quorum was established.

VII. Discussion and Consideration of Statutory Proposal to Amend Board's Fee Schedule, Including Proposed Changes to Business and Professions Code Section 4400.

President Oh recalled during the October 2022 Board meeting, the Board received a presentation on the fee audit conducted by Capitol Accounting Partners, LLC, including findings and recommendations. The Board also discussed and voted to pursue a statutory change to adjust fee levels to address financial conditions of the Board in line with recommendations included while allowing for additional discussion on pharmacy technician renewal and pharmacist renewal and to offset reductions with increased facility fees.

President Oh provided the meeting materials included a brief history of the Board's prior fee increase including information on the last audit of fees completed in 2015. At that time the Board's authorized expenditures were $19.7 million. The Board's current authorized budget was over $31 million which was about a 57 percent increase. Dr.

Oh provided as a reminder, the Board's authorized expenditures was done through the legislative process.

President Oh advised this significant increase in authorized expenditures can be attributed to overall increases stemming from program growth, expansion of regulatory authority, and increases in costs incurred from other state agencies. Some of the largest expenditure increases included increases in state distributed costs, enforcement related costs and personnel.

President Oh reported included in the meeting materials were comparisons of other regulatory fees assessed by the California Department of Public Health, Medical Board of California, Dental Board of California, and others. Dr. Oh noted an extremely large disparity between what the Board currently assesses as an application fee and renewal fee for an outsourcing facility compared to the fees assessed by the FDA. Comparing the audit findings to this information, the fees assessed by the FDA were more closely aligned with the costs the Board incurs for its regulation of such facilities.

President Oh noted meeting materials included a summary chart detailing the new proposed fee ranges and the revised statutory language that incorporates changes requested by Members.

President Oh continued as presented, it is anticipated that the adjusted fee schedule would result in approximately $35.5 million annually in application and renewal fees allowing for a slower restoration of the Board's fund than what was recommended by the auditor. Dr. Oh noted as the Board had already voted to pursue the statutory change, Dr. Oh didn't believe formal action was necessary for authorizing sponsorship but would entertain a motion to approve the proposed fees established in the draft language if the Board believed such action was appropriate, specifically those related to the pharmacist and pharmacy technician renewal.

Motion: Approve the proposed fees established in the draft language (appended to the minutes) specifically changed related to the pharmacist and pharmacy technician renewal.

M/S: Chandler/De La Paz

Member Chandler researched the numbers provided in the report noting the approach and methodology made sense. Mr. Chandler noted the Board would be

charging what it costs for the Board while keeping the pharmacist and pharmacy technicians fees from increasing.

Member Serpa inquired about the ADDS renewal increase from $200 to almost $600 and how many facilities would have more than two machines. Dr. Serpa didn't want to create a safety issue for cost savings if the use of ADDS were discontinued due to the cost to renew. Ms. Sodergren indicated she would have to work with staff to get the information.

Member Jha voiced concerns about the renewal of ADDS as many small, medium, and large long-term care pharmacies deploy ADDS in various geographies to make medication available. Mr. Jha noted going back to the tacklebox e-kits would be a step backwards. Mr. Jha added using ADDS provides great access to a greater number of medications than a tacklebox e-kit as well as visibility, access, and control of access. Mr. Jha was concerned the cost may prohibit the proliferation of the ADDS and may reconsider putting ADDS into new facilities. Mr. Jha added ADDS helps to provide essential service to rural communities in nursing homes where pharmacies may be 3-4 hours away.

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

Support: 8 Oppose: 0 Abstain: 2 Not Present: 3

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

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

Administrative Law Judge Wim van Rooyen presided over the hearings. Petitions heard by members as a committee included:

a. Elaine Vu Nguyen, RPH 76448

Member Koenig joined the meeting at 1:35 p.m.

Member Thibeau left the meeting at 1:54 p.m.

b. Wassim A. Armanious, RPH 59305

Counsel Smiley announced pursuant to Government Code section 11126.3 subdivision (a) in addition to the closed session items listed on the agenda, the Board would also be meeting to discuss a recent case entitled Absolute Pharmacy LLC doing business as Absolute Pharmacy and Andreas Dieter Dettlaff versus the California State Board of Pharmacy and Anne Sodergren filed in Los Angeles Superior Court Case Number 22 STCP 04253.

IX. Closed Session

Open session concluded at approximately 3:37 p.m. The Board entered closed session at approximately 4:00 p.m. and ended closed session at 5:45 p.m. The Board Meeting concluded at approximately 5:45 p.m.

ARTICLE 23. Revenue and Renewal [4400 - 4409]
(Article 23 added by Stats. 1996, Ch. 890, Sec. 3.)

Proposed Amendment to 4400.
The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a pharmacy license shall be seven hundred fifty dollars ($750) and may be increased to two thousand dollars ($2,000) ~~five hundred twenty dollars ($520) and may be increased to five hundred seventy dollars ($570)~~. The fee for the issuance of a temporary pharmacy permit shall be one thousand six hundred dollars ($1,600) and may be increased to two thousand seven hundred forty dollars ($2,740) ~~two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325)~~.

(a)(1) The fee for a nonresident pharmacy license shall be two thousand four hundred twenty-seven dollars ($2,427) and may be increased to three thousand four hundred twenty-four dollars ($3,424). The fee for the issuance of a temporary nonresident pharmacy permit shall be two thousand dollars ($2,000) and may be increased to two thousand four hundred sixty-nine dollars ($2,469).(b) The fee for a pharmacy license annual renewal shall be ~~six hundred sixty-five dollars ($665) and may be increased to nine hundred thirty dollars ($930)~~ one thousand twenty-five dollars ($1,025) and may be increased to two thousand dollars ($2,000).

(b)(1) The fee for a nonresident pharmacy license annual renewal shall one thousand twenty-five dollars ($1,025) and may be increased to two thousand dollars ($2,000).

(c) The fee for the pharmacist application and examination shall be two hundred sixty dollars ($260) and may be increased to two hundred eighty-five dollars ($285)

(d) The fee for regrading an examination shall be ~~ninety dollars ($90) and may be increased to~~ one hundred fifteen dollars ($115) and may be increased to two hundred dollars ($200). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license shall be one hundred ninety-five dollars ($195) and may be increased to two hundred fifteen dollars ($215). The fee for a pharmacist biennial renewal shall be four fifty hundred dollars ($450) and may be reduced to three hundred sixty dollars ($360). ~~and may be increased to five hundred five dollars ($505).~~

(f) The fee for a wholesaler or third-party logistics provider license and annual renewal shall be one thousand dollars ($1,000) and may be increased to one thousand four hundred eleven dollars ($1,411) ~~seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820)~~. ~~The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225).~~ A temporary license fee shall be seven hundred fifteen dollars ($715) and may be increased to one thousand nine dollars ($1,009) ~~decreased to no less than five hundred fifty dollars ($550)~~.

(g) The fee for a hypodermic license shall be five hundred fifty dollars ($550) and may be increased to seven hundred seventy-five ($775) ~~one hundred seventy dollars ($170) and may be increased to two hundred forty dollars ($240)~~. The fee for a hypodermic license renewal shall be four hundred dollars ($400) and may be increased to five hundred sixty-one dollars ($561) ~~two hundred dollars ($200) and may be increased to two hundred eighty dollars ($280)~~.

(h)(1) The fee for application, investigation, and issuance of a license as a designated representative pursuant to Section 4053, as a designated representative-3PL pursuant to Section 4053.1, or as a designated representative-reverse distributor pursuant to Section 4053.2 shall be three hundred forty-five dollars ($345) and may be increased to four hundred eighty-five dollars ($485). ~~one hundred fifty dollars ($150) and may be increased to two hundred ten dollars ($210).~~

(2) The fee for the annual renewal of a license as a designated representative, designated representative-3PL, or designated representative-reverse distributor shall be three hundred eighty-eight dollars ($388) and may be increased to five hundred forty-seven dollars ($574) ~~two hundred fifteen dollars ($215) and may be increased to three hundred dollars ($300)~~.

(i)(1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be three hundred forty-five dollars ($345) and may be increased to four hundred eighty-five dollars ($485) ~~one hundred fifty dollars ($150) and may be increased to two hundred ten dollars ($210)~~.

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be three hundred eighty-eight dollars ($388) and may be increased to five hundred and forty-seven dollars ($547) ~~two hundred fifteen dollars ($215) and may be increased to three hundred dollars ($300)~~.

(j)(1) The application fee for a nonresident wholesaler or third-party logistics provider license issued pursuant to Section 4161 shall be one thousand dollars ($1,000) and may be increased to one thousand four hundred eleven dollars ($1,411) ~~seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820)~~.

~~(2) For nonresident wholesalers or third-party logistics providers that have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225).~~ A temporary license fee shall be seven hundred fifteen dollars ($715) and may be increased to one thousand nine dollars ($1,009). ~~decreased to no less than five hundred fifty dollars ($550).~~

(3) The annual renewal fee for a nonresident wholesaler license or third-party logistics provider license issued pursuant to Section 4161 shall be ~~seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820)~~ one thousand dollars ($1,000) and may be increased to one thousand four hundred eleven dollars ($1,411).

(k) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars ($40) per course hour.

(l) The fee for an intern pharmacist license shall be one hundred seventy-five dollars ($175) and may be increased to two hundred and forty-five dollars ($245) ~~one hundred sixty-five dollars ($165) and may be increased to two hundred thirty dollars ($230)~~. The fee for transfer of intern hours or verification of licensure to another state shall be one hundred twenty dollars ($120) and may be increased to one hundred sixty-eight dollars ($168) ~~twenty-five dollars ($25) and may be increased to thirty dollars ($30)~~.

(m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be seventy-five dollars ($75) and may be increased to one hundred dollars ($100) ~~thirty-five dollars ($35) and may be increased to forty-five dollars ($45)~~.

(o) The fee for processing an application to change information on a premises license record shall be three hundred ninety-five dollars ($395) and may be increased to five hundred fifty-seven dollars ($557). ~~one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).~~

———(o)(1) The fee for processing an application to change a name or correct an address on a premises license record shall be two hundred six dollars ($206) and may be increased to two hundred eighty-two dollars ($282).

———(o)(2) The fee for processing an application to change a pharmacist-in-charge, designated representative-in-charge, or responsible manager on a premises license record shall be two hundred fifty dollars ($250) and may be increased to three hundred fifty-three dollars ($353).

(p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(q) The fee for any applicant for a clinic license shall be six hundred twenty dollars ($620) and may be increased to eight-hundred seventy-three dollars ($873). ~~five hundred twenty dollars ($520) for each license and may be increased to five hundred seventy dollars ($570).~~ The annual fee for renewal of the license shall be four hundred dollars ($400) and may be increased to five hundred sixty-one dollars ($561) ~~three hundred twenty-five dollars ($325) for each license and may be increased to three hundred sixty dollars ($360)~~.

(r) The fee for the issuance of a pharmacy technician license shall be one hundred twenty dollars ($120) and may be increased to one hundred sixty-five dollars

($165). ~~one hundred forty dollars ($140) and may be increased to one hundred ninety-five dollars ($195).~~ The fee for renewal of a pharmacy technician license shall be one hundred ~~fifty~~ eighty dollars ($180) and may be reduced to one hundred twenty-five dollars ($125). ~~be increased to one hundred ninety-five dollars ($195).~~

(s) The fee for a veterinary food-animal drug retailer license shall be ~~four hundred thirty-five dollars ($435) and may be increased to~~ six hundred ten dollars ($610) and may be increased to eight hundred twenty-five dollars ($825). The annual renewal fee for a veterinary food-animal drug retailer license shall be ~~three hundred thirty dollars ($330) and may be increased to~~ four hundred sixty dollars ($460) and may be increased to five hundred sixty-one dollars ($561). The fee for the temporary license shall be five hundred twenty dollars ($520) and may be increased to seven hundred thirty-two dollars ($732).

(t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be ~~thirty-five dollars ($35) and may be increased to forty-five dollars ($45)~~ fifty dollars ($50) and may be in increased to one hundred dollars ($100).

(u) The fee for issuance of a sterile compounding pharmacy license or a hospital satellite compounding pharmacy shall be three thousand eight hundred seventy - five dollars ($3,875) and may be increased to five thousand four hundred sixty-six dollars ($5,466). ~~one thousand six hundred forty-five dollars ($1,645) and may be increased to two thousand three hundred five dollars ($2,305).~~ The fee for a temporary license shall be one thousand sixty-five dollars ($1,065) and may be increased to one thousand five hundred three dollars ($1,503). ~~five hundred fifty dollars ($550) and may be increased to seven hundred fifteen dollars ($715).~~ The annual renewal fee of the license shall be four thousand eight-five dollars ($4,085) and may be increased to five thousand seven hundred sixty-two dollars ($5,762) ~~one thousand three hundred twenty-five dollars ($1,325) and may be increased to one thousand eight hundred fifty-five dollars ($1,855)~~.

(v) The fee for the issuance of a nonresident sterile compounding pharmacy license shall be eight thousand five hundred dollars ($8,500) and may be increased to sixteen thousand five hundred two dollars ($16,502). ~~two thousand three hundred eighty dollars ($2,380) and may be increased to three thousand three hundred thirty-five dollars ($3,335).~~ The annual renewal of the license shall be ~~two thousand two hundred seventy dollars ($2,270) and may be increased to three thousand one hundred eighty dollars ($3,180)~~ eight thousand five hundred dollars ($8,500) and may be increased to seventeen thousand forty dollars ($17,040). In addition to paying that application fee, the nonresident sterile compounding pharmacy shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant. The fee for a temporary license shall be

one thousand five hundred dollars ($1,500) and may be increased to two thousand dollars ($2,000).

(w) The fee for the issuance of an outsourcing facility license shall be twenty-five thousand dollars ($25,000) and may be increased to thirty-five thousand two hundred fifty-six dollars ($35,256) ~~two thousand two hundred seventy dollars ($2,270) and may be increased to up to three thousand one hundred eighty dollars ($3,180) by the board~~. The fee for the renewal of an outsourcing facility license shall be twenty-five thousand dollars ($25,000) and may be increased to forty-one thousand three hundred sixty-six dollars ($41,366) ~~one thousand three hundred twenty-five dollars ($1,325) and may be increased to up to one thousand eight hundred fifty-five dollars ($1,855) by the board~~. The fee for a temporary outsourcing facility license shall be ~~seven hundred fifteen dollars ($715)~~ four thousand dollars ($4,000) and may be increased to five thousand six hundred forty-two dollars ($5,642).

(x) The fee for the issuance of a nonresident outsourcing facility license shall be twenty-eight thousand five hundred dollars ($28,500) and may be increased to forty-two thousand three hundred eighteen dollars ($42,318). ~~two thousand three hundred eighty dollars ($2,380) and may be increased to up to three thousand three hundred thirty-five dollars ($3,335) by the board.~~ The fee for the renewal of a nonresident outsourcing facility license shall be twenty-eight thousand five hundred dollars ($28,500) and may be increased to forty-six thousand three hundred fifty-three dollars ($46,353) ~~two thousand two hundred seventy dollars ($2,270) and may be increased to up to three thousand one hundred eighty dollars ($3,180) by the board~~. In addition to paying that application fee, the nonresident outsourcing facility shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4129.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant. The fee for a temporary nonresident outsourcing license shall be four thousand dollars ($4,000) and may be increased to five thousand six hundred forty-two dollars ($5,642).

(y) The fee for the issuance of a centralized hospital packaging license shall be three thousand eight hundred fifteen dollars ($3,815) and may be increased to five thousand three hundred eighteen dollars ($5,318) ~~eight hundred twenty dollars ($820) and may be increased to one thousand one hundred fifty dollars ($1,150)~~. The annual renewal of the license shall be two thousand nine hundred twelve dollars ($2,912) and may be increased to four thousand one hundred seven dollars ($4,107) ~~eight hundred five dollars ($805) and may be increased to one thousand one hundred twenty-five dollars ($1,125)~~.

(z) The fee for the issuance of a license to a correctional clinic pursuant to Article 13.5 (commencing with Section 4187) ~~that is not owned by the state~~ shall be six hundred twenty dollars ($620) and may be increased to eight hundred seventy-

three dollars ($873). ~~five hundred twenty dollars ($520) and may be increased to five hundred seventy dollars ($570).~~ The annual renewal fee for that correctional clinic license shall be four hundred dollars ($400) and may be increased to five hundred sixty-one dollars ($561) ~~three hundred twenty-five dollars ($325) and may be increased to three hundred sixty dollars ($360)~~.

(z)(1) The fee for the issuance of an ADDS license to a correctional clinic pursuant to Article 13.5 (commencing with Section 4187) shall be five hundred dollars ($500) and may be increased to seven hundred five dollars ($705). The annual renewal fee for the correctional clinic ADDS shall be four hundred dollars ($400) and may be increased to five hundred sixty-one dollars ($561).

(aa) ~~Beginning on and after July 1, 2019, t~~The fee for an ADDS license shall be five hundred twenty-five dollars ($525) and may be increased to seven hundred forty-one dollars ($741) ~~two hundred dollars ($200) and may be increased to two hundred fifty dollars ($250)~~. The fee for the annual renewal of the license shall be four hundred fifty-three dollars ($453) and may be increased to six hundred thirty-nine dollars ($639) ~~two hundred dollars ($200) and may be increased to two hundred fifty dollars ($250)~~.

(ab) The application and initial license fee for a remote dispensing site pharmacy application shall be one thousand seven hundred thirty dollars ($1,730) and may be increased to two thousand four hundred forty dollars ($2,440). The fee for the annual renewal shall be one thousand twenty-five dollars ($1,025) and may be increased to two thousand dollars ($2,000). The fee for a temporary license shall be eight hundred ninety dollars ($890) and may be increased to one thousand one hundred ninety-nine dollars ($1,199).

(ab) The application and initial license fee to operate EMSADDS shall be one hundred fifty dollars ($150) and may be increased to three hundred eighty dollars ($380) per machine. The fee for the annual renewal shall be two hundred dollars ($200) and may be increased to two hundred seventy-three dollars ($273). The license fee may not be transferred to a different location if the EMSADDS is moved. The application and renewal fee for a licensed wholesaler that is also an emergency medical services provider agency shall be eight hundred ten dollars ($810) and may be increased to one thousand one hundred forty-three dollars ($1,143).

(ac) The fee for application and issuance of an initial license as a designated paramedic shall be three hundred fifty dollars ($350) and may be increased to four hundred ninety-four dollars ($494). The fee of biennial renewal shall be two hundred dollars ($200) and may be increased to two hundred ninety-two dollars ($292).

(ad) The fee for an application for an advanced practice pharmacist license and renewal of advanced practice pharmacist license shall be three hundred dollars ($300) and may be increased to four hundred eighteen dollars ($418).

(ae) This section shall become operative on ~~July 1, 2021~~ January 1, 2025.

Proposed Amendment to 4119.01.

(a) Notwithstanding any other law, a pharmacy, or a licensed wholesaler that is also an emergency medical services provider agency, may restock dangerous drugs or dangerous devices into an emergency medical services automated drug delivery system (EMSADDS) that is licensed by the board under this section. Dangerous drugs and dangerous devices stored or maintained in an EMSADDS shall be used for the sole purpose of restocking a secured emergency pharmaceutical supplies container as authorized in subdivision (b) of Section 4119. The EMSADDS may be used only if all of the following conditions are met:

(1) The emergency medical services provider agency obtains a license from the board to operate the EMSADDS. As a requirement for licensure, the EMSADDS shall be located on the premises of a fire department headquarters, a fire station, or at an emergency medical services provider agency's location. A separate license shall be required for each location.

(A) As part of its license application, the emergency medical services provider agency shall provide: the address where the EMSADDS will be located; the name of the medical director responsible for overseeing the emergency medical services provider agency; the name of any designated pharmacist or licensed designated paramedic who is responsible for performing the duties as required under this section; the policies and procedures detailing the provisions under which the EMSADDS will operate; and the name and license number of the pharmacy or emergency medical services provider agency wholesaler that will furnish the dangerous drugs and dangerous devices through the EMSADDS.

~~(B) The application and initial license fee to operate EMSADDS shall be one hundred dollars ($100) per machine. The license shall be renewed annually. The license fee may not be transferred to a different location if the EMSADDS is moved. The penalty fee for failure to renew an EMSADDS license shall be thirty-five dollars ($35).~~

~~(C) The application and renewal fee for a licensed wholesaler that is also an emergency medical services provider agency shall be seven hundred eighty dollars ($780).~~

(2) Each EMSADDS shall collect, control, and maintain all transaction information necessary to accurately track the movement of drugs into and out of the system for purposes of security, accuracy, and accountability.

(3) The medical director and designated pharmacist, or the medical director and the licensed designated paramedic, shall develop, adopt, and maintain policies and procedures detailing the provisions under which the EMSADDS will operate. At a minimum, the policies and procedures shall address (A) inventory controls, (B) training, (C) storage and security of the dangerous drugs and dangerous devices, and (D) safeguards to limit access to the EMSADDS to authorized staff only.

(4) The licensed EMSADDS operator shall limit access to the EMSADDS only to employees of the operator who are licensed by the state and as authorized in this section.

(A) An EMSADDS may only be restocked by the medical director, a pharmacist, or a licensed designated paramedic, each of whom may possess and transport dangerous drugs or dangerous devices for that purpose. The transport of dangerous drugs or dangerous devices for restocking into an EMSADDS shall be done in a secured manner to prevent theft or unauthorized access, and shall be done under conditions appropriate to meet storage and handling requirements of the dangerous drugs or dangerous devices. While the dangerous drugs or dangerous devices may be transported, representatives shall not store a dangerous drug or dangerous device at an unlicensed location.

(B) Only a medical director, a pharmacist, or a paramedic may remove dangerous drugs or dangerous devices from an EMSADDS to fill a secured emergency pharmaceutical supplies container. This access shall be observed by a second person who is also a paramedic, a pharmacist, or a medical director. Both the individual who removes dangerous drugs or dangerous devices from the EMSADDS and the observer shall record their participation in the removal of the dangerous drugs or dangerous devices via their signatures or use of biometric identifiers. The restocking of the secured emergency pharmaceutical supplies container from the EMSADDS shall occur at the licensed location of the EMSADDS.

(C) A medical director, a pharmacist, or a licensed designated paramedic may remove outdated dangerous drugs or dangerous devices from an EMSADDS. Any outdated dangerous drugs or dangerous devices shall be provided to a licensed reverse distributor for destruction.

(5) Every EMSADDS operator shall perform monthly inventory and inventory reconciliation functions. The medical director, designated pharmacist, or licensed designated paramedic shall perform a reconciliation and prepare a written report based on written policies and procedures developed to maintain the security and quality of the dangerous drugs and dangerous devices. The written inventory reconciliation report shall include all of the following:

(A) A physical count of all quantities of dangerous drugs and dangerous devices stored in the EMSADDS.

(B) A review of all dangerous drugs and dangerous devices added into and removed from each EMSADDS since the last monthly inventory.

(C) A comparison of subparagraphs (A) and (B), and identification of any variances.

(D) A review of all individuals who accessed the EMSADDS since the last inventory and identification of unauthorized individuals accessing the EMSADDS or suspicious activity.

(E) Identification of possible causes of shortages and overages.

(6) The medical director and designated pharmacist, or medical director and licensed designated paramedic, shall be jointly responsible for monthly review of the inventory reconciliation report, the training, storage, and security of dangerous drugs and dangerous devices, and the restocking of the EMSADDS.

Any inventory losses from an EMSADDS shall be reported to the board within seven days from identification of the loss.

(7) In order for an individual to perform the functions of a licensed designated paramedic described in this section, that individual shall be licensed by the board pursuant to Section 4202.5. A paramedic who only restocks a secured emergency pharmaceutical supplies container from an EMSADDS need not be licensed with the board.

(8) A record of each access to the EMSADDS, as well as all records used to compile an inventory reconciliation report, shall be maintained at the operator's location for at least three years in a readily retrievable form. The records shall include the identity of every individual who accessed the system or witnessed such access; the date of each access; and the drug, dosage, form, strength, and quantity of dangerous drugs or dangerous devices added or removed.

(b) A violation of any of the provisions of this section shall constitute unprofessional conduct and provides the board the authority to take action against the EMSADDS operator's license.

Proposed Amendment to 4119.11.

(a) A pharmacy located in the state may provide pharmacy services to the patients of a "covered entity," as defined in Section 256b of Title 42 of the United States Code, through the use of an automated patient dispensing system located on the premises of the covered entity or on the premises of medical professional practices under contract to provide medical services to covered entity patients, which need not be the same location as the pharmacy, if all of the following conditions are met:

(1) The pharmacy obtains a license from the board to operate the automated patient dispensing system at the covered entity or affiliated site. As part of the application, the pharmacy shall provide the address at which the automated patient dispensing system shall be placed and identify the covered entity. A separate license shall be required for each location and shall be renewed annually concurrent with the pharmacy license. ~~The application and renewal fee shall be three hundred dollars ($300) and may be increased to five hundred dollars ($500). The board is authorized to lower the renewal fee to not less than two hundred dollars ($200) if a lower fee level will provide sufficient resources to support the regulatory activities~~.

(2) The pharmacy providing the pharmacy services to the patients of the covered entity, including, unless otherwise prohibited by any other law, patients enrolled in the Medi-Cal program, shall be under contract with that covered entity as described in Section 4126 to provide those pharmacy services through the use of the automated patient dispensing system.

(3) Drugs stored in an automated patient dispensing system shall be part of the inventory of the pharmacy providing pharmacy services to the patients of the covered entity and drugs dispensed from the automated patient dispensing system shall be considered to have been dispensed by that pharmacy.

(4) The pharmacy shall maintain records of the acquisition and disposition of dangerous drugs stored in the automated patient dispensing system separate from other pharmacy records.

(5) The pharmacy shall be solely responsible for the security, operation, and maintenance of the automated patient dispensing system.

(6) The pharmacy shall provide training regarding the operation and use of the automated patient dispensing system to both pharmacy and covered entity personnel using the system.

(7) The operation of the automated patient dispensing system shall be under the supervision of a licensed pharmacist acting on behalf of the pharmacy providing services to the patients of the covered entity. The pharmacist need not be physically present at the site of the automated patient dispensing system and may supervise the system electronically.

(8) Notwithstanding Section 4107, the board may issue a license for the operation of an automated patient dispensing system at an address for which it has issued another site license.

(9) The board, within 30 days after receipt of an application for an automated patient dispensing system license, shall conduct a prelicensure inspection at the proposed location of the automated patient dispensing system. Relocation of the automated patient dispensing system shall require a new application for licensure. Replacement of an automated patient dispensing system shall require notice to the board within 30 days.

(10) The automated patient dispensing system license shall be canceled by operation of law if the underlying pharmacy license is not current, valid, and active. Upon reissuance or reinstatement of the underlying pharmacy license, a new application for an automated patient dispensing system license may be submitted to the board.

(11) A pharmacy that holds an automated patient dispensing system license shall advise the board in writing within 30 days if use of the automated patient dispensing system is discontinued.

(b) For purposes of this section, the following definitions shall apply:

(1) An "automated drug delivery system" (ADDS) means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An ADDS shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

(2) An "automated patient dispensing system" (APDS) is an ADDS for storage and dispensing of prescribed drugs directly to patients pursuant to prior authorization by a pharmacist.

(3) An "automated unit dose system" (AUDS) is an ADDS for storage and retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions.

(c) (1) An automated patient dispensing system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

(2) Transaction information shall be made readily available in a downloadable format for review and inspection by individuals authorized by law. These records shall be maintained by the pharmacy for a minimum of three years.

(d) Drugs from the automated patient dispensing system may be dispensed directly to the patient, if all of the following requirements are met:

(1) The pharmacy shall develop, implement, and annually review written policies and procedures with respect to all of the following:

(A) Maintaining the security of the automated patient dispensing system and the dangerous drugs and devices within that automated patient dispensing system.

(B) Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the automated patient dispensing system and for which patients.

(C) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including those delivered via the automated patient dispensing system.

(D) Describing assignment of responsibilities to, and training of, pharmacy personnel, and other personnel using the automated patient dispensing system at the location where the automated patient dispensing system is placed, regarding maintenance and filing procedures for the automated patient dispensing system.

(E) Orienting participating patients on the use of the automated patient dispensing system, notifying patients when expected prescription medications are not available in the automated patient dispensing system, and ensuring that patient use of the automated patient dispensing system does not interfere with delivery of drugs and devices.

(F) Ensuring delivery of drugs and devices to patients expecting to receive them from the automated patient dispensing system if the automated patient dispensing system is disabled or malfunctions.

(2) The automated patient dispensing system shall only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drugs and devices from an automated patient dispensing system and whose use of the automated patient dispensing system meet the criteria pursuant to paragraph (1).

(3) The automated patient dispensing system shall have a means to identify each patient and only release the identified patient’s drugs and devices to the patient or the patient’s agent.

(4) A pharmacist shall perform all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation.

(5) Drugs shall be dispensed from the automated patient dispensing system only upon authorization from a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions.

(6) All prescribed drugs and devices dispensed from the automated patient dispensing system for the first time shall be accompanied by a consultation conducted by a pharmacist licensed by the board via a telecommunications link that has two-way audio and video.

(7) The automated patient dispensing system shall include a notice, prominently posted on the automated patient dispensing system, that provides the name, address, and telephone number of the pharmacy that holds the automated patient dispensing system license for that automated patient dispensing system.

(8) The labels on all drugs dispensed by the automated patient dispensing system shall comply with Section 4076 of this code and with Section 1707.5 of Title 16 of the California Code of Regulations.

(9) Any complaint, error, or omission involving the automated patient dispensing system shall be reviewed as part of the pharmacy's quality assurance program pursuant to Section 4125.

(10) The board shall not issue a pharmacy more than 15 licenses for automated patient dispensing system units under this section. Consistent with Section 4001.1, the board may adopt regulations to reduce the number of automated patient dispensing system licenses that may be issued to a pharmacy.

(11) The pharmacy holding the license for the automated patient dispensing system shall maintain the policies and procedures developed pursuant to paragraph (1) for three years after the last date of use of that automated patient dispensing system.

(e) Access to the automated patient dispensing system shall be controlled and tracked using an identification or password system or biosensor. A system that is accessed via a password system shall include a camera that records a picture of the individual accessing the machine. Picture records shall be maintained for a minimum of 180 days.

(f) The automated patient dispensing system shall make a complete and accurate record of all transactions that will include all users accessing the system and all drugs added to, or removed from, the system.

(g) The stocking of an automated patient dispensing system shall be performed by a pharmacist. If the automated patient dispensing system utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers as defined by the United States Pharmacopeia, the stocking system may be done outside of the facility and be delivered to the facility, if all of the following conditions are met:

(1) The task of placing drugs into the removable pockets, cards, drawers, similar technology, or unit of use or single dose containers is performed by a pharmacist,

or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

(2) The removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container.

(3) The pharmacy, in conjunction with the covered entity, has developed policies and procedures to ensure that the removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are properly placed into the automated patient dispensing system.

(h) Review of the drugs contained within, and the operation and maintenance of, the automated patient dispensing system shall be done in accordance with law and shall be the responsibility of the pharmacy. A pharmacist shall conduct the review on a monthly basis, which shall include a physical inspection of the drugs in the automated patient dispensing system, an inspection of the automated patient dispensing system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

(i) A pharmacy holding an automated patient dispensing system license shall complete a self-assessment, performed pursuant to Section 1715 of Title 16 of the California Code of Regulations, evaluating the pharmacy's compliance with pharmacy law relating to the use of the automated patient dispensing system. All information regarding operation, maintenance, compliance, error, omissions, or complaints pertaining to the automated patient dispensing system shall be included in the self-assessment.

(j) The pharmacy shall comply with all recordkeeping and quality assurance requirements pursuant to this chapter, and shall maintain those records within the pharmacy holding the automated patient dispensing system license and separately from other pharmacy records.

Proposed Amendment to BPC 4128.2.

(a) In addition to the pharmacy license requirement described in Section 4110, a centralized hospital packaging pharmacy shall obtain a specialty license from the board prior to engaging in the functions described in Section 4128.

(b) An applicant seeking a specialty license pursuant to this article shall apply to the board on forms established by the board.

(c) Before issuing the specialty license, the board shall inspect the pharmacy and ensure that the pharmacy is in compliance with this article and regulations established by the board.

(d) A license to perform the functions described in Section 4128 may only be issued to a pharmacy that is licensed by the board as a hospital pharmacy.

(e) A license issued pursuant to this article shall be renewed annually and is not transferrable.

(f) An applicant seeking renewal of a specialty license shall apply to the board on forms established by the board.

(g) A license to perform the functions described in Section 4128 shall not be renewed until the pharmacy has been inspected by the board and found to be in compliance with this article and regulations established by the board.

~~(h) Until July 1, 2017, the fee for issuance or annual renewal of a centralized hospital packaging pharmacy license shall be six hundred dollars ($600) and may be increased by the board to eight hundred dollars ($800).~~

Proposed Amendment to BPC 4161.

(a) A person located outside this state that (1) ships, sells, mails, warehouses, distributes, or delivers dangerous drugs or dangerous devices into this state or (2) sells, brokers, warehouses, or distributes dangerous drugs or devices within this state shall be considered a nonresident wholesaler or a nonresident third-party logistics provider.

(b) A nonresident wholesaler or nonresident third-party logistics provider shall be licensed by the board prior to shipping, selling, mailing, warehousing, distributing, or delivering dangerous drugs or dangerous devices to a site located in this state or selling, brokering, warehousing, or distributing dangerous drugs or devices within this state.

(c) (1) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler or nonresident third-party logistics provider from or through which dangerous drugs or dangerous devices are shipped, sold, mailed, warehoused, distributed, or delivered to a site located in this state or sold, brokered, warehoused, or distributed within this state. Each place of business may only be issued a single license by the board, except as provided in paragraph (2). A license shall be renewed annually and shall not be transferable.

(2) A nonresident wholesaler and a nonresident third-party logistics provider under common ownership may be licensed at the same place of business provided that all of the following requirements are satisfied:

(A) The wholesaler and the third-party logistics provider each separately maintain the records required under Section 4081.

(B) Dangerous drugs and dangerous devices owned by the wholesaler are not commingled with the dangerous drugs and dangerous devices handled by the third-party logistics provider.

(C) Any individual acting as a designated representative for the wholesaler is not concurrently acting as a designated representative-3PL on behalf of the third-party logistics provider. Nothing in this subparagraph shall be construed to prohibit an individual from concurrently holding a license to act as a designated representative and to act as a designated representative-3PL.

(D) The wholesaler has its own designated representative-in-charge responsible for the operations of the wholesaler and the third-party logistics provider has its own responsible manager responsible for the operations of the third-party logistics provider. The same individual shall not concurrently serve as the responsible manager and the designated representative-in-charge for a

wholesaler and a third-party logistics provider licensed at the same place of business.

(E) The third-party logistics provider does not handle the prescription drugs or prescription devices owned by a prescriber.

(F) The third-party logistics provider is not a reverse third-party logistics provider.

(G) The wholesaler is not acting as a reverse distributor.

(d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler or a nonresident third-party logistics provider, on renewal of a nonresident wholesaler or nonresident third-party logistics provider license, or within 30 days of a change in that information:

(1) Its agent for service of process in this state.

(2) Its principal corporate officers, as specified by the board, if any.

(3) Its general partners, as specified by the board, if any.

(4) Its owners if the applicant is not a corporation or partnership.

(e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.

(f) A nonresident wholesaler or nonresident third-party logistics provider shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.

(g) A nonresident wholesaler or nonresident third-party logistics provider shall maintain records of dangerous drugs and dangerous devices sold, traded, transferred, warehoused, or distributed to persons in this state or within this state, so that the records are in a readily retrievable form.

(h) A nonresident wholesaler or nonresident third-party logistics provider shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler or nonresident third-party logistics provider in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler or nonresident third-party logistics provider license in this state shall include a license verification from the licensing authority in the applicant’s state of residence. The board may waive the home state licensure requirement for a nonresident third-party logistics provider if the board inspects the location and finds it to be in compliance with this article and any regulations adopted by the board or the applicant provides evidence of its accreditation by the Drug Distributor Accreditation program of the National Association of Boards of Pharmacy. The nonresident third-party logistics provider shall reimburse the board for all actual and necessary costs incurred by the board in conducting an inspection of the location, pursuant to subdivision (v) of Section 4400.

(i) (1) The board shall not issue or renew a nonresident wholesaler license until the nonresident wholesaler identifies a designated representative-in-charge and notifies

the board in writing of the identity and license number of the designated representative-in-charge.

(2) The board shall not issue or renew a nonresident third-party logistics provider license until the nonresident third-party logistics provider identifies a responsible manager and notifies the board in writing of the identity and license number of the designated representative-3PL who will be the responsible manager.

(j) The designated representative-in-charge shall be responsible for the compliance of the nonresident wholesaler with state and federal laws governing wholesalers. The responsible manager shall be responsible for the compliance of the nonresident third-party logistics provider's place of business with state and federal laws governing third-party logistics providers. A nonresident wholesaler or nonresident third-party logistics provider shall identify and notify the board of a new designated representative-in-charge or responsible manager within 30 days of the date that the prior designated representative-in-charge or responsible manager ceases to be the designated representative-in-charge or responsible manager.

(k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. ~~A temporary license fee shall be five hundred fifty dollars ($550) or another amount established by the board not to exceed the annual fee for renewal of a license to compound sterile drug products.~~ When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. Neither for purposes of retaining a temporary license, nor for purposes of any disciplinary or license denial proceeding before the board, shall the temporary licenseholder be deemed to have a vested property right or interest in the license.

(l) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

Proposed Amendment to BPC 4202.5.

(a) The board may issue a designated paramedic license to an individual if he or she holds a license as a paramedic in this state and meets the criteria of this section.

(b) The board shall conduct a criminal background check of the applicant to determine if the applicant has committed acts that would constitute grounds for denial of licensure, pursuant to this chapter or Chapter 2 (commencing with Section 480) of Division 1.5.

(c) The board may suspend or revoke a license issued pursuant to this section on any ground specified in Section 4301.

(d) A license issued under this section is dependent on the validity of the holder's paramedic license and shall be automatically suspended if the individual's

paramedic license is expired, revoked, or otherwise invalidated by the issuing authority.

~~(e) The fee for application and issuance of an initial license as a designated paramedic shall be one hundred forty dollars ($140) for a two-year license. The biennial renewal shall be one hundred forty dollars ($140). The penalty fee for failure to renew an authorized paramedic license shall be sixty-five dollars ($65).~~

Proposed Amendment to BPC 4210. Advanced Practice Pharmacist License

(a) A person who seeks recognition as an advanced practice pharmacist shall meet all of the following requirements:

(1) Hold an active license to practice pharmacy issued pursuant to this chapter that is in good standing.

(2) (A) Satisfy any two of the following criteria:

(i) Earn certification in a relevant area of practice, including, but not limited to, ambulatory care, critical care, geriatric pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pediatric pharmacy, pharmacotherapy, or psychiatric pharmacy, from an organization recognized by the Accreditation Council for Pharmacy Education or another entity recognized by the board.

(ii) Complete a postgraduate residency through an accredited postgraduate institution where at least 50 percent of the experience includes the provision of direct patient care services with interdisciplinary teams.

(iii) Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.

(B) For purposes of this paragraph, if, as a condition of completion of one of the required criteria fulfillment of a second criterion is also required, that completion shall be deemed to satisfy this paragraph.

(3) File an application with the board for recognition as an advanced practice pharmacist.

(4) Pay the applicable fee to the board.

(b) An advanced practice pharmacist recognition issued pursuant to this section shall be valid for two years, coterminous with the certificate holder’s license to practice pharmacy.

~~(c) The board shall adopt regulations establishing the means of documenting completion of the requirements in this section.~~

~~(d) The board shall, by regulation, set the fee for the issuance and renewal of advanced practice pharmacist recognition at the reasonable cost of regulating advanced practice pharmacists pursuant to this chapter. The fee shall not exceed three hundred dollars ($300).~~