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

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

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 health care organizations work 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).~~