III. Approval Board Meeting Minutes

a. October 27-28, 2021, Board Meeting

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

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

Date: October 27-28, 2021

Location: Teleconference Public Board Meeting
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
Lavanza Butler, Licensee Member (October 27 only)
Shirley Kim, Public Member (October 28 only)
Ricardo Sanchez, Public Member
Nicole Thibeau, Licensee Member
Debbie Veale, Licensee Member
Jason Weisz, Public Member

Board Members Absent: Jose De La Paz, Public Member

Staff Present:
Anne Sodergren, Executive Officer
Eileen Smiley, DCA Staff Counsel
Sheila Tatayan, DCA Staff Counsel
Debbie Damoth, Administration Manager
Bob Dávila, Public Information Officer

October 27, 2021

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

President Oh called the Board Meeting to order at 12:30 p.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 observing or participating in the meeting that the meeting was being conducted consistent with the provisions of Government Code section 11133. Dr. Oh advised participants watching the webcast they could only observe the meeting. He noted anyone interested in participating in the meeting must join the WebEx meeting using the instructions posted on the Board's website.

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

Roll call was taken. Board Members present included: Maria Serpa, Jignesh Patel, Cheryl Butler, Ricardo Sanchez, Nicole Thibeau, Debbie Veale, Jason Weisz, Seung Oh. 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 comments. Steve Gray, requested discussion on AB 1533 section 20, related to Business and Professions Code section 4129. Dr. Gray noted that he has received calls on this provision and believes it is not clear.

Cori Hawks requested discussion on 503B outsourcing facilities and requested that the Board further discuss the provisions.

Dr. Serpa advised members that discussion is included on the agenda as part of the Enforcement Committee discussion scheduled for later in the meeting.

Mark Johnston, stated that in October 2020 he presented an issue related to implementation of Senate Bill 159 and noted that his understanding that that the Board decided not to agendize the issue because it was determined that a resolution should be decided by outside of the meeting between CVS health and the Executive, related to HIV testing.

Ms. Veale noted her intention to agendize a post implementation review of Senate Bill 159 as part of the Licensing Committee agenda.

No agenda items were recommended.

III. Approval Board Meeting Minutes

a. July 28-29, 2021, Board Meeting

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

Motion: Approve the July 28-29, 2021, minutes as presented in the meeting materials.

M/S: Veale/Sanchez

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

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

Board Member	Vote
Butler	Support
De La Paz	Not present
Kim	Not present
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibeau	Support
Veale	Support
Weisz	Support

b. September 3, 2021, Board Meeting

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

Motion: Approve the September 3, 2021 Emergency Meeting, minutes as presented in the meeting materials.

M/S: Patel/Butler

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

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

Board Member	Vote
Butler	Support
De La Paz	Not present
Kim	Not present
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibeau	Support
Veale	Support
Weisz	Support

c. September 23, 2021, Board Meeting

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

Motion: Approve the September 23, 2021, minutes as presented in the meeting materials.

M/S: Butler/Thibeau

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

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

Board Member	Vote
Butler	Support
De La Paz	Not present
Kim	Not present
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibeau	Support
Veale	Support
Weisz	Support

IV. Update from the Department of Consumer Affairs

President Oh welcomed Brianna Miller, Manager, Department of Consumer Affairs Board and Bureau Relations. Ms. Miller addressed the Board with an update from the Department of Consumer Affairs (DCA).

Ms. Miller discussed COVID-19 safety measures and telework provisions advising members that the department established a task force for long term telework.

Ms. Miller providing information about the state's testing and COVID-19 vaccine discussed requirements and noted that members must comply with the same provisions.

Remote meetings allowed through January 2022 indicating it is unclear if there are additional changes coming and discussed benefits of remote meetings including public engagement.

Member Veale questioned in person meetings moving forward and was advise given the dynamic nature of COVID additional changes for continued remote meetings may occur and reinforced

Members of the public were provided the opportunity to ask Ms. Miller questions; however, no questions were asked.

V. Enforcement and Compounding Committee Report

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

Dr. Serpa provided a summary of the October 20 Enforcement and Compounding Committee meeting. Members were advised that a significant portion of the committee meeting was dedicated to discussion of recently signed legislation impacting the practice of pharmacy.

Assembly Bill 107

Dr. Serpa advised members that Assembly Bill 107 related to veterans and military spouses. This measure will require the Board to issue a temporary license to practice within 30 days of the Board receiving the results of a fingerprint background check. The measure does require an applicant for a pharmacist license to take and pass the CPJE as a precursor to issuance of the temporary license.

Dr. Serpa referenced the meeting materials noting that the provisions take effect July 1, 2023, which will provide the Board time to complete necessary implementation activities. Dr. Serpa reviewed some of the implementation activities advised members that the Committee determined the Licensing Committee should be charged with development of the regulations necessary to implement the provisions. Debbie Veale, Chair of the Licensing Committee, agreed that the development of regulations is appropriate for the Licensing Committee.

Members of the public were provided the opportunity to provide public comment; however, none were provided.

Assembly Bill 527

Dr. Serpa advised members Assembly Bill 527 included the Board's sponsored provision to exempt specified non-narcotic combination product controlled substances from the California controlled substances schedule. Dr. Serpa noted that implementation efforts should be minimal and include education on the change.

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

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

Assembly Bill 1064

Dr. Serpa informed members that Assembly Bill 1064 expands authority to allow a pharmacist to independently initiate and administer any vaccine that has been approved or authorized by the FDA and received a recommendation by the Advisory Committee on Immunization Practices. Implementation efforts would focus primarily on education of the change.

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

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

Assembly Bill 1533

Dr. Serpa advised members Assembly Bill 1533 (our Sunset bill), contained a number of changes in Pharmacy Law.

Dr. Serpa noted that the measure extends the operations of the Board until January 1, 2026. Dr. Serpa advised members that the Committee agreed with staff's recommendation to review Sunset information on an annual basis.

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

Dr. Serpa informed members amendments to Section 4052 expand authority to pharmacists to initiate, adjust or discontinue drug therapy for a patient under a collaborative practice agreement and also expands authority for pharmacists to provide medication assisted treatment (MAT) pursuant to a state protocol. Implementation efforts will include the Board's development of a state protocol to facilitate implementation of the MAT authority. As part of the discussion, Debbie Veale

agreed that it was appropriate from the Licensing Committee to work on the state protocol. Members also noted that changes to expanded collaborative practice is in the best interest of consumers.

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

Dr. Serpa advised that Business and Professions Code section 4052.6 was amended to expand the authority for an advanced practice pharmacist to initiate, adjust, or discontinue drug therapy beyond health care facilities noting that implementation efforts will focus primarily on education about the provision and should reiterate the provisions for coordination for care and education with the diagnosing prescriber.

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

Dr. Serpa reported that Business and Professions Code sections 4110 and 4126.10 include changes necessary to implement provisions of the FDA MOU addressing certain distributions of compounded drugs. Specifically, pharmacy license renewal will include notification of compounding practices for distributing compounded human preparations as well as reporting requirements established in the MOU. Implement efforts will include updating renewal forms and data systems as well as the development of educational materials.

Dr. Serpa reported that during the Committee meeting members did not have any comments; however, public comment was received suggesting that provisions of the MOU could be delayed beyond October 2022 and it may be appropriate to consider exercising enforcement discretion relating to the reporting requirements. Dr. Serpa commented that no additional action is necessary at this time other than the implementation efforts detailed in the meeting materials.

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

Dr. Serpa advised members that Pharmacy Law was amended to allow outsourcing facilities licensed by the Board to dispense patient-specific compounded drug preparations under specified conditions, including that such dispensing shall comply with the same requirements of a pharmacy.

Implementation efforts will include development of education materials. It is anticipated that extensive education to outsourcing facilities will be required.

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

Dr. Serpa highlighted that Section 4161 was amended to create alternative pathways to licensure for nonresident third-party logistics providers. Implementation efforts will include updating application instructions and forms. Dr. Serpa noted that staff will also need to begin working with facilities granted temporary licenses to those entities currently under the Board's waiver process for purposes of distributing ventilators and vaccines into California. This work will need to be completed prior to the expiration of the temporary licenses to ensure continuity to the effective date of this new law, January 1, 2022.

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

Dr. Serpa advised members that Section 4210 alters application requirements for an advance practice pharmacist recognition to allow for qualification under a single pathway, if that pathway includes completion of a second criterion. This clarifies the requirements and eliminates the current confusing language. Implementation efforts will include updating application instructions and forms as well as development of educational materials. In addition, staff will review pending applications to determine if the changes in the requirements will impact applicant eligibility.

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

Dr. Serpa notified members that Business and Professions Code section 4232.5 was amended to require a pharmacist with authority to prescribe a controlled substance to complete an educational course on the risks of addiction to schedule II drugs. Implementation efforts will include updating the renewal application requirements via regulation. The regulation will give notice of the requirement and how an individual will demonstrate compliance. Dr. Serpa reported that the Committee determined that the Licensing Committee is well suited to complete this work and noted that the evaluation should include other areas related to CE requirements as well.

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

Dr. Serpa highlighted that the Board will be required to convene a working group of interested stakeholders to discuss whether moving to a standard of care model is feasible and appropriate. As included in the measure, the Board will be required to submit a report with recommendations to the Legislature by July 1, 2023 following completion of the workgroup. During the Committee meeting President Oh, who is a member of our Committee, noted that education on standard of care will be provided at the February Board Meeting and board members will be provided the opportunity to elect to participate in an ad hoc committee that will be created.

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

Dr. Serpa advised members that under the provisions established in Section 4317.5 the Board will have new fine authority to address repeated violations under specified conditions including that the violations occurred in community chain pharmacies operating under common ownership. The measure does provide for an opportunity for the pharmacy to cure a violation as long as the violation did not result in actual harm to any consumer or pose serious potential harm to the public.

Dr. Serpa indicated that implementation will include education about the provisions. The Enforcement and Compounding Committee we will be provided with data on implementation of this new fine as part of the annual presentation our Committee receives on the Board's citation and fine program.

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

Dr. Serpa noted that amendments to section 4427.65 expands the location where unit-dose automated drug delivery systems may be located noting that implementation will include education on the provisions.

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

Members of the public were provided with the opportunity to provide public comments. Danny Martinez, CPhA, commented that the Board has not yet entered the MOU. Dr. Serpa noted the Committee's recommendation to exercise enforcement discretion.

Steve Gray, emphasized the need for a timely decision on BPC 4129 before the law goes into effect.

Cori Hawks, request that the Board further discuss outsourcing and office use for 503Bs.

Dr. Serpa reiterated that extensive education materials will be provided about the new law related by outsourcing. Dr. Serpa offered to review the materials before they are released.

<u>Senate Bill 306</u>
Dr. Serpa noted that under the provisions of the measure a pharmacist will be allowed to dispense a medication without an individual name if the prescription includes "expedited partner therapy" or EPT. It will also require a pharmacist to provide a written notice that describes the right of an individual receiving EPT to consult with a

pharmacist about the therapy and potential drug interactions. Implementation efforts will focus primarily on education of the measure.

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

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

Senate Bill 310

Dr. Serpa notified members Senate Bill 310 creates a medication collection and distribution program that allows for patients to donate previously dispensed medication back to a participating practitioner or physician for redistribution to other patients of the same practitioner. Under the provisions of the measure the Board has the authority to request records to evaluate for compliance with the provisions and has the authority to prohibit a practitioner from participating in this program under specified conditions. Implementation will focus on education about the provisions as well as extensive education of identified Board staff to assure practitioners have appropriate policies and procedures, documentation of drug manufacturing requirements and to ensure appropriate patient protections exist. Data on this new program will be collected and reported to the Enforcement and Compounding Committee.

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

Members of the public were provided the opportunity to provide public comment. Dr. Gray indicated that a lot of education needs to be provided including to the participating practitioners.

Members were advised that the requirements related to registration do not reside with the Board but with an intermediary as specified in the measure.

Senate Bill 311

This measure requires health care facilities to allow a terminally ill patient to use medical cannabis under specified conditions. Late amendments to the measure specified that health care facilities permitting such use must comply with drug and medication requirements applicable to schedule II – IV drugs and shall be subject to enforcement actions by the California Department of Public Health.

Dr. Serpa referenced the late amendments that create conflicts within the measure itself. Specifically, the amendments to require the medicinal cannabis to comply with provisions related to scheduled II-IV medication creates a number of questions about the applicability of Board regulations including storage, inventory control, acquisition and the role of Pharmacy in these facilities.

Dr. Serpa advised members that the Committee discussed that it is appropriate to determine what the Board's role should be in resolving these conflicts along with other regulators and stakeholders. There are other challenges with this measure that may be outside of the Board's purview, but problematic for health systems, including concerns about federal implications to allowing the using of medicinal cannabis in health care facilities that could negatively impact their licensure, accreditations or reimbursement. During the meeting we noted that the measure does not reschedule medical cannabis. Dr. Serpa reported that the Committee received significant public comment on the many challenges with the bill.

Public comments included that discussions with the author's office appear to confirm that the intent of the measure was not to reschedule medical cannabis. The author clarified to interested parties that it was not the intent of the legislation to hold the pharmacy responsible and to ensure that was understood the author's office requested a letter be published in the Senate's daily journal. Comments also noted the several questions raised by the measure including questions of acquisition, disposition and inventory control. Further comments indicated that provisions of federal law prohibit the DEA from taking action against a hospital that allows the use of medical cannabis.

Dr. Serpa advised members that staff will report back to the committee with recommendations on communication and education on the measure.

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

Members of the public were provided an opportunity to provide public comment. Dr. Stein commented that medicinal cannabis was not rescheduled under the provisions of the measure.

Lori Hensic, Scripps Health, thanked the Committee and expressed support for the Board's focus on education, highlighting the concerns about a pharmacist's license that requires that the medical cannabis comply with other provisions of the law as specified.

Danny Martinez, shared similar concerns about the implications to a pharmacist.

<u>Senate Bill 362</u>
Dr. Serpa highlighted that Senate Bill 362 will prohibit a community chain pharmacy from using a quota to evaluate the performance of a pharmacist or pharmacy technician, noting that implementation efforts will include education about the provisions as well as the process for a pharmacist or pharmacy technician may use to file a complaint. Dr. Serpa indicated that it appears also appropriate to dedicate education efforts on information about whistleblower protections. Dr. Serpa reported

that the Committee will receive data on implementation of this new law and that during the Committee meeting, public comment was received from a representative from UFCW noting that UFCW looks forward to working with the Board on implementation efforts.

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

Members of the public were provided the opportunity to provide public comment. Rachel Stone, questioned if the Board has plans to assess fines for violation the law and was advised that the Board conducts investigations and determines the appropriate outcome based on the specific facts of the case.

Senate Bill 409

Dr. Serpa reminded members that Senate Bill 409 expands authority for pharmacists to provide CLIA-waived tests under specified conditions. Implementation will include education on the provisions. Also, the Board's Health Services Registry should be updated to include these additional patient care services.

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

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

b. Discussion and Consideration of Released Revised Proposed Changes to USP Chapters and the Board's Current Policy Statement.

Dr. Serpa transitioned to compounding matters noting that the first item for us to discuss is the recent release of the revised proposed changes to USP Chapters and the Board's current policy statement.

Dr. Serpa referenced the relevant law sections detailed in the meeting materials noting that under section 4127, the Board is required to review any formal revisions to USP Chapter 797 no later than 90 days after the revisions become official to determine whether amendments are necessary for Board regulations. Dr. Serpa reminded members that previous work to update compounding regulations was put on hold when USP paused their implementation date to look at additional changes to their proposed language.

Dr. Serpa noted that given the release of the newly revised proposed chapters, the Committee noted it is appropriate to resume our work on updating compounding regulations.

Dr. Serpa referenced the high-level comparison charts to USP 795 and 797 in the meeting materials prepared by staff and thanked staff for their efforts. Dr. Serpa noted

that the charts will assist members in its comparison of regulatory changes to the additional USP chapter updates. Dr. Serpa advised members that the next steps for the Committee we will be monitoring the USP process in finalizing the standards and restart stakeholder meetings on compounding in 2022.

Dr. Serpa referenced the draft policy statement that is included in the meeting materials and displayed on the slide. Members were provided the opportunity to provide comments on the recommended draft policy statement.

Motion (Committee recommendation): Recommend to the Board approval the draft policy statement.

> In light of the September 1, 2021 release by USP of proposed updates to USP General Chapters <795> and <797>, the California State Board of Pharmacy (Board) wishes to update its stakeholders on the anticipated next steps the Board will be taking and also remind stakeholders about the current status of legal requirements for pharmacies compounding drug preparations. It is the Board's understanding that USP published proposed revisions to USP General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations and General Chapter <797> Pharmaceutical Compounding – Sterile Preparations for public comment. It is the Board's understanding that comments may be submitted on or before January 31, 2022. Further, USP will host virtual Compounding Open Forum Series in January 2022.
>
> The Board understands that based on the appeals to the 2019 proposed revisions to Chapters <795> and <797>, further changes were made to these proposed chapters. Accordingly, the current Chapters <795> (last revised in 2014) and <797> (last revised in 2008) remain the official versions of USP standards. In addition, all licensees must adhere to all relevant sections of Pharmacy Law and regulations, including but not limited to the Board's current regulations – title 16, California Code of Regulations, section 1735 et. Seq (Article 4.5, Compounding); section 1751 et. Seq. (Article 7, Sterile Compounding); and section 1708.3 to section 1708.5 (related to radioactive drugs) – and Business and Professions Code section 4126.8 and other relevant state and federal provisions.
>
> It is the Board's understanding that USP is not offering any additional changes to Chapter <800> or Chapter <825>. Because Chapter <800> and Chapter <825> are not referenced in the current versions of Chapters <795> and <797>, Chapters <800> and <825> appear informational and not compendially applicable (or a required standard under USP) until the amendments in Chapters <795> and

<797> are finalized. Like USP, the Board encourages utilization of amended Chapter <800> in the interest of advancing public health before it becomes a required USP standard by USP adoption of revised Chapters <795> and <797>. States and other regulators with jurisdiction, also may incorporate USP chapters that are not compendially applicable (required USP standards) into their own statutes or regulations, or "through other steps in accordance with their own policy making processes" to apply or enforce chapters that are not yet required USP standards.

As required in Business in Professions Code section 4127(c), the Board's Enforcement and Compounding Committee intends to resume it discussion of the new proposed revised chapters. Although it is the Board's goal to seek conformity with USP where possible, consistent with the Board's consumer protection mandate and the authority granted to the Board by the Legislature in Business and Professions Code section 4126.8, it is anticipated that the Board's efforts may result in updates to its current regulations, including higher standards if deemed necessary for public protection. Information on meetings will be posted on the website and meeting materials made available in advance.

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

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

Board Member	Vote
Butler	Support
De La Paz	Not Present
Kim	Not Present
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibeau	Support
Veale	Support
Weisz	Support

c. Updates on FDA Actions Related to Human Compounding

Dr. Serpa noted that information contained in the meeting materials were included not only for the Board's information, but to inform stakeholders.

Dr. Serpa referenced the notice of extension released by the FDA relating to the MOU on Interstate Distribution of Compounded Drug Products. As included in the notice, the FDA is extending the period for a state to enter the MOU until October 27, 2022. This extension will allow the Board time to implement provisions, including those we considered earlier as part of our Assembly Bill 1533.

Further, Dr. Serpa advised members of the October 7 release by the FDA of a draft guidance document titled, Hospital and Health System Compounding Under Section 503 of the Federal Food, Drug, and Cosmetic Act Guidance for Industry. The guidance describes how the FDA intends to apply certain provisions of section 503 A to human drug products that are compounded by state-licensed pharmacies for distribution within a hospital or health-system.

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

Members of the public were provided the opportunity to provide public comment; however, none were provided.

d. Review and Discussion of Enforcement Statistics

Dr. Serpa noted that the enforcement statistics for the first quarter of the fiscal year were provided in the meeting materials.

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

Members of the public were provided the opportunity to provide public comment; however, none were provided.

The Board took a break from 2:01 p.m. to 2:16 p.m. Roll call was taken after the break. Members present included Maria Serpa, Jignesh Patel, Lavanza Butler, Nicole Thibeau, Debbie Veale, Jason Weisz, Seung Oh. Ricardo Sanchez returned at 2:18.

VI. Licensing Committee Report

Discussion and Consideration of Business and Professions Code section 4071.1, Board's Waiver to Facilitate Provisions for Remote Processing and Consideration of Possible Changes to Statute or Regulation to Establish Authority Under Specified Conditions.

Chairperson Veale reviewed the relevant provisions of the law noting that BPC section 4071.1 establishes the authority for a pharmacy to electronically enter a prescription or an order into a pharmacy's or hospital's computer from any location outside of the pharmacy or hospital with permission, under specified conditions.

Ms. Veale also noted that BPC section 4038 specifies that pharmacy technicians are wholly and exclusively permitted to practice only within a licensed pharmacy.

Chairperson Veale also reviewed the Board's current remote processing waiver stating that the Board's waiver provides that for the purposes of this waiver, "remote processing" means the entering of an order or prescription into a computer from outside of the pharmacy or hospital for a licensed pharmacy as defined in Business and Professions Code (BPC) sections 4029 and 4037.

The current waiver of provisions of BPC section 4071.1(a), also provide pharmacists performing remote processing may also receive, interpret, evaluate, clarify, and approve medication orders and prescriptions, including medication orders and prescriptions for controlled substances classified in Schedule II, III, IV or V. Under this waiver, remote processing may also include order entry, other data entry, performing prospective drug utilization review, interpreting clinical data, insurance processing, performing therapeutic interventions, providing drug information services, and authorizing release of medication for administration. The waiver does not include the dispensing of a drug or final product verification by remote processing.

Ms. Veale also reminded members that the Board's waiver further expands the provisions of BPC section 4071.1(a) to allow for remote processing by pharmacy technicians and pharmacy interns to include nondiscretionary tasks, including prescription or order entry, other data entry, and insurance processing of prescriptions and medication orders for which supervision by a pharmacist is provided using remote supervision via technology that, at a minimum, ensures a pharmacist is (1) readily available to answer questions of a pharmacy intern or pharmacy technician; and (2) verify the work performed by the pharmacy intern or pharmacy technician.

Ms. Veale noted that the Committee initiated its review to determine what, if any actions should be taken by the Board to change its current remote processing authorities.

Members were provided with a review of the approach taken in Virginia. Ms. Veale reviewed the provisions allowed for pharmacists under Virginia law which was also displayed on the meeting slide. Ms. Veale also reviewed the provisions that a pharmacy must comply with under Virginia law including requirements for policies and procedures and records requirements.

Ms. Veale reported that the Committee started its discussion considering if the Board should consider changes in the law to allow for remote processing. Ms. Veale noted that the discussion will occur over several meetings. Ms. Veale reported that Committee concluded that review of the issue is appropriate.

Ms. Veale noted that the Committee concluded that any change needs to separate out what is convenient versus was is safe for consumers.

The Committee concluded that the PIC should have explicit authority to determine when remote processing was appropriate and that provisions should be limited to California licensed entities. Further, Ms. Veale noted some items remain outstanding such as notification requirements. Ms. Veale advised members that staff will be providing legal information on what is currently provided, and to determine if the waiver resulted in investigations as well as review Virginia and Arizona to see if lessons can be learned from that state.

Members highlighted the benefits and opportunities to expand patient care. Members also noted the importance of being mindful to avoid unintended consequences.

Members of the public were provided with the opportunity to provide public comment; however, none were provided.

V. Discussion and Consideration of Requirements to Serve as a Pharmacist-in-Charge

Chairperson Veale provided a summary of the discussion including provisions of relevant law including that BPC section 4036.5 defines a "pharmacist-in-charge" as a pharmacist proposed by a pharmacy and approved by the board as the supervisor or manager responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

Ms. Veale reminded members that during its recent strategic planning session, the Board established a strategic objective to determine if application requirements for a PIC are appropriate to ensure sufficient knowledge, skills and abilities for individuals seeking to serve as a PIC.

Ms. Veale reviewed the policy questions considered by the Committee including:

1. Are there fundamental knowledge, skills, and abilities that are required for someone to serve as a PIC?
2. Should the Board require or provide a certain type of continuing education or other training as a precursor to assuming the role of a PIC?
3. Should the Board require an attestation from the proposed PIC acknowledging and confirming the legal requirements for a PIC?
4. Should there be a minimum number of hours a PIC should be required to work at the respective pharmacy?

Chairperson Veale advised members that the Committee concluded that some kind of training as a precursor to the PIC appeared appropriate as well as the requirement for some type of attestation. The Committee also concluded that there did not need

to be a minimum number of hours a PIC should be required to work at the respective pharmacy.

Members were provided with the opportunity to provide comments. Member Thibeau sought clarification if the proposal would encompass existing PICs and was advised that the Committee focused on requirements for new PICs versus current PICs. Member Thibeau suggested that the Board develop a subscriber alert dedicated to PICs.

Motion (Committee Recommendation): Recommend to the Board that the Licensing Committee pursue a training program for proposed PICs as well as a requirement for an attestation as a precursor to be appointed by a PIC.

Members of the public were provided the opportunity to provide public comments. Rachel Stone requested clarification if discussion about establishing a minimum number of hour a licensed pharmacists would need to work prior to be appointing a PIC and was advised that the Committee determine that was not appropriate

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

Board Member	Vote
Butler	Support
De La Paz	Not Present
Kim	Not Present
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibeau	Support
Veale	Support
Weisz	Support

c. Discussion and Consideration of Implementation Plan for Listening Sessions and Pharmacy Technician Summit

Chairperson Veale reminded members that as part of its July 2021 meeting, the Committee voted to convene a pharmacy technician summit. As a precursor to the summit, the Committee determined it appropriate to convene listening sessions, ideally throughout the state and during nontraditional business hours to make it easy for pharmacy technicians and pharmacists to participate in the meeting.

Ms. Veale highlighted that given the dynamic nature of the COVID pandemic, Chair Veale wanted to propose an alternative to allow the Committee to move forward while still balancing robust public engagement during the listening sessions. Chair Veale summarized the general proposed implementation plan for the various listening sessions as well as the potential questions that could be covered during the session.

Ms. Veale reviewed the policy questions considered during the Committee meeting that could be covered during the listening sessions with the questioning varying depending on the audience.

1. What duties do you believe a pharmacy technician could perform beyond those currently authorized?
2. Should some functions allow for supervision by another technician (e.g., tech check tech)? If yes, please provide examples.
3. Do you believe as a pharmacy technician you have sufficient oversight by a pharmacist?
4. Do you believe you have appropriate on the job training, education (e.g., community college, etc.) to perform your duties safely, including in the following areas - - pharmacy operations, HIPAA compliance, compounding?
5. Do you believe the level or type of training depends on the functions you perform?
6. What are some of the biggest challenges you face?

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

Motion (Committee Recommendation): Recommend the Board allowing the convening of listening sessions via WebEx and providing an equal number of sessions for pharmacy technicians and pharmacists with questions intended for each audience. Grant authority to Chair and EO to schedule the sessions accordingly.

Members of the public were provided with the opportunity to provide public comment; however, none were provided.

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

Board Member	Vote
Butler	Support
De La Paz	Not Present
Kim	Not Present
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibeau	Support
Veale	Support
Weisz	Support

VII. Review and Discussion of Licensing Statistics

Ms. Veale referenced the quarterly licensing statistics for the first quarter of fiscal year 2021/2022 are provided as an attachment.

Chairperson Veale referenced the statistics provided in the materials and specifically spoke to processing times. Ms. Veale noted that the data reflects the time from when an application or deficiency response is received by the Board through to the time it is reviewed by licensing staff. The standard performance processing time is within 30 days for initial applications and is within 10 days for deficiency mail. The term "Current" means there are no items to review or staff is currently reviewing the items within 1-5 days for that specific license type.

Processing times are outside of the performance measures established by the Board. The Board's licensing unit has vacancies in various stages of recruitment as well as staff out on unexpected leave. Managers are working with staff to prioritize work. It is anticipated processing times will improve as vacancies are filled and staff return from unexpected leave. Appropriate resources are just part of the challenge. The issue of processing times is also impacted by the number of deficient applications which appear to be a significant percentage of the workload for some application types.

Ms. Veale highlighted some of the actions taken to reduce deficient applications noting that over 50 percent of the pharmacy technician applications received are deficient.

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

Members of the public were provided the opportunity to provide public comment; however, none were provided.

VII. Communication and Public Education Report

As the Chairperson for this committee, Member Sanchez provided the report. Mr. Sanchez noted that the Committee meeting scheduled earlier in the day was cancelled due to a lack of quorum. Full discussion on each of the topics is required during the meeting.

a. Discussion and Consideration of Recommended Changes to the Notice to Consumers Poster/Display and Suggested Revisions to California Code of Regulations, Division 17, Title 16 Section 1707.6

Chairperson Sanchez referenced the meeting materials include the relevant law and background material.

Chairperson Sanchez noted relevant law and background were included in the meeting materials. He reported the proposed language to modify CCR 1707.6 was drafted by staff based on direction from the Board at the July 28 Board meeting.

Chairperson Sanchez recalled California Code of Regulations (CCR) 1707.6 provides the text for the Notice to Consumers. He noted the regulation also requires pharmacies to provide a separate notice regarding availability of interpreter services; this is commonly known as the "Point to Your Language" notice.

Members considered the proposed language to modify CCR 1707.6 is in Attachment 1. Including the specific proposed amendments including:

- Subsection (a) would require pharmacies to place the Notice to Consumers in places that are conspicuous and physically accessible so consumers can scan a QR code to obtain a translation of the Notice.
- Subsection (b) would require the Notice to include a QR code that links consumers to a translation of the Notice in the top 16 languages spoken by Californians with limited English proficiency, as determined by the U.S. Department of Health and Human Services and the California Department of Health Care Services.
- Subsection (c) would require the "Point to Your Language" notice to be printed in the top 16 languages required in subsection (b). This would bring the regulation in line with current Medi-Cal requirements.
- Lastly, the proposed language would add a subsection (d) requiring pharmacies to either post or provide on the patient's written receipt a statement describing patients' rights per BPC 733 and BPC 4122.

Several policy questions were also considered as part of the Board's discussion. Members confirmed the appropriateness of the proposed language. Counsel advised members of the use of "tag lines". Members noted that consumers are unclear why a pharmacist provides consultation.

Motion: Initiate a Rulemaking to amend 1707.6 as presented with changes identified including the reordering of the first paragraph and amendment to the bullet related to the purpose of the medication. Authorized the EO to make nonsubstantive changes and work with the Committee Chair to finalize the language prior to initiation of the rulemaking.

Title 16. Board of Pharmacy
Proposed Text

Underline is text that will be added. ~~Strikethrough~~ is text that will be deleted.
Amend Section 1707.6 to Title 16 of the California Code of Regulations, to read as follows:

§ 1707.6. Notice to Consumers.

(a) ~~In every pharmacy there shall be prominently posted, in a place conspicuous to and readable by a prescription drug consumer, a notice containing the text in subdivision (b).~~ Every pharmacy shall post a notice containing the text in subsection (b) and shall place the notice in a conspicuous place, physically accessible to a prescription drug consumer (consumer) so that the consumer can easily read the notice, and use the QR code displayed on the notice to obtain language translation of the notice. Such notice shall be posted at all locations where a consumer receives medication. Each pharmacy shall use the standardized poster-sized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval. As an alternative to a printed notice, the pharmacy may also or instead display the notice on a video screen located in a place conspicuous to and readable by ~~prescription drug~~ consumers, so long as: (1) The video screen is at least 24 inches, measured diagonally; (2) The pharmacy utilizes the video image notice provided by the board; (3) The text of the notice remains on the screen for a minimum of 60 seconds; ~~and~~ (4) The video screen utilizes QR code technology for the consumer to access translation of the notice, with sufficient display time for consumers to access the QR code; and (5) No more than five minutes elapses between displays of any notice on the screen, as measured between the time that a one-screen notice or the final screen of a multi-screen notice ceases to display and the time that the first or only page of that notice re-displays. The pharmacy may seek approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

(b) The notice shall contain the following text~~:~~. It must also include a QR code that assists limited-English-proficient individuals and alerts consumers that the QR code may be used to obtain a translation of the notice. Consumers must be able to use the QR code to obtain translation of the notice in the top 16 languages spoken by limited-English-proficient individuals in California, as determined by the U.S. Department of Health and Human Services, Office of Civil Rights and the California Department of Health Care Services.

~~NOTICE TO CONSUMERS~~
KNOW YOUR RIGHTS

California law requires a pharmacist to speak with you upon your request, every time you get a new prescription, and every time you get a new prescription dosage form, strength, or written directions.

You have the right to ask for and receive from any pharmacy prescription drug labels in 12-point font.

Interpreter services are available to you upon request at no cost.

TALK TO THE EXPERT – SPEAK WITH YOUR PHARMACIST

Before you leave the pharmacy, CHECK ~~taking your medicine, be sure you know: the name of the medicine and what it does; how and when to take it, for how long, and what to do if you miss a does; possible side effects and what you should do if they occur; whether the new medicine will work safely with other medicines or supplements; and what foods, drinks, or activities should be avoided while taking the medicine. Ask the pharmacist if you have any questions.~~

- the patient name on the label is correct;
- the medication matches the description on the label;
- the name of the medicine and what it does;
- how and when to take the medication, for how long, and what to do if you miss a dose;
- possible side effects and what you should to do if they occur;
- whether the medication will work safely with other medicines or supplements; and
- what foods, drinks, or activities should be avoided while taking the medicine.

The address and contact information for consumers to send any complaints about the pharmacy:
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
(916) 518-3100
www.pharmacy.ca.gov.

~~*This* pharmacy must provide any medicine or device legally prescribed for you, unless it is not covered by your insurance; you are unable to pay the cost of a copayment; or the pharmacist determines doing so would be against the law or potentially harmful to health. If a medicine or device is not immediately available, the pharmacy will work with you to help you get your medicine or device in a timely manner.~~

~~*You* may ask this pharmacy for information on drug pricing and of generic drugs.~~

(c) Every pharmacy, in a place conspicuous to and readable by a prescription drug consumer, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, shall post or provide a notice containing the following text:

Point to your language. Interpreter services will be provided to you upon request at no cost.

This text shall be repeated in the top 16 languages spoken by limited-English-proficient individuals in California, as determined by the U.S. Department of Health and Human Services, Office of Civil Rights, and the California Department of Health Care Services.
~~This text shall be repeated in at least the following languages: Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, Tagalog, and Vietnamese.~~
Each pharmacy shall use the standardized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.
The pharmacy may post this notice in paper form or on a video screen if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which he or she requests assistance. Otherwise, the notice shall be made available on a flyer or handout clearly visible from and kept within easy reach of each counter in the pharmacy where dangerous drugs are dispensed or furnished, available at all hours that the pharmacy is open. The flyer or handout shall be at least 8 1/2 inches by 11 inches.
(d) Every pharmacy shall either post or provide on the patient's written receipt a statement describing patients' rights per Business and Professions Code sections 733 and 4122.
Note: Authority cited: Sections 4005 and 4122, Business and Professions Code. Reference: Sections 733, 4005, 4076.5 and 4122, Business and Professions Code.

M/S: Veale/Weisz

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

Robert Stein, expressed concern with QR codes because not everyone has a phone with a QR code. Suggested that language in the first paragraph to include the language in a different sequence.

Steve Gray, agreed that language is the first paragraph in confusing. Further the third bullet that indicated "what it does" versus "purpose or what the medication is for"

Paige Tally, California Council for the advancement of pharmacy indicated that automated drugs in an APDS.

Keith Yoshizuka, agreed with comments expressed by Dr. Stein regarding QR codes.

Member comments spoke in support of the reordering of the language in the first paragraph. Direct staff to make the change as well as change to "purpose of the medication"

Members of the public were provided with the opportunity to provide public comment; however, none were provided.

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

Board Member	Vote
Butler	Support
De La Paz	Not Present
Kim	Not Present
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibeau	Support
Veale	Support
Weisz	Support

b. Update on Communication and Public Education Activities by Staff

1. The Script

Chairperson Sanchez advised member the current issue of the Script was published in September and is available on the Board's website. The next issue will include an annual update on new pharmacy laws and is expected to be published in early 2022.

2. Staff Outreach

Members were advised that Board inspectors and staff provided continuing education training via WebEx for about 400 pharmacists on prescription drug abuse and diversion on August 11, 2021. In addition, Executive Officer Anne Sodergren served as a panelist at two events for pharmacists listed in the meeting materials.

3. News Media

Chairperson Sanchez advised staff responded to news media inquiries as listed in meeting materials.

4. Conversion of Self-Assessment Profess to Online

Chairperson Sanchez advised staff responded to news media inquiries as listed in meeting materials.

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

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

VIII. Legislation and Regulation Committee

As the Chairperson for this committee, President Oh provided the report. Dr. Oh provided the committee did not meet this quarter.

President Oh detailed in the meeting materials and associated attachments, the Board has a number of regulations in various stages of promulgation. President Oh currently has one regulation undergoing Final review by the Office of Administrative Law and one regulation undergoing final review by the DCA. The Board also has three regulations undergoing pre-notice review.

Members were provided the opportunity to provide comments on the items within the Legislation and Regulation report; however, no comments were provided.

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

X. Organizational Development Committee Report

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

Budget Update

President Oh provided a summary of the Board's budget. The Board's spending authorization for the current fiscal year is $29.6 Million which is a 1.3% increase from the prior year.

Also included in the meeting materials is information on the prior year budget. The prior year spending authorization was $29.3 million. Based on final budget reports the Board received $34.4 million in revenue and expended $27.7 million. The largest sources of revenue and expenditure are provided in the meeting materials.

A review of the fund condition prepared by the Department indicates that at the end of the current fiscal year, it is projected the Board will have 4 months in reserve. As indicated in the meeting materials, under provisions of Pharmacy Law, the Board shall

seek to maintain a reserve equal to approximately one year's operating expenditures. We will continue to closely monitor our fund as projections indicate a slow depletion of the fund rather than moving to approach the one-year reserve called for in the law.

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

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

Board Member Attendance and Mail Vote Information
President Oh referenced Member attendance and mail vote information included in the meeting materials.

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

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

Personnel Update
As detailed in the meeting materials, the Board has a number of vacancies including several leadership and senior management positions. Recruitment for many of these positions is delayed because of budget concerns. President Oh advised members that he is working with the Executive Officer on the issue.

Strategic Plan Update
Members were reminded of the outcome of the strategic planning process in September noting that no changes were made to the Board's mission, vision or values. Further we voted to approve the strategic objectives for each of the respective areas. President Oh reminded members that he will be working with staff to finalize the language and action plans will be developed.

Meeting Calendar for 2021 and 2022
President Oh referenced the meeting calendar for the remainder of 2021 and 2022.

Members were provided with an opportunity to provide comments on respective agenda items; however none were provided.

Members of the public were provided with an opportunity to provide public comments on the agenda items; however, none were provided.

XI. Discussion and Consideration of Adoption of Board Approved Regulation, Title 16, California Code of Regulations Section 1704, Address Change Notification

President Oh advised members that an item for consideration is adoption of the Board's regulation, Section 1704 related to address change notification.

President Oh reminded members that the materials include the proposed text released for the 45-day comment period, the comments received during the comment period, and the staff prepared summarized comments and staff recommendations.

I agree with the staff's recommendation and would appreciate member comments. I would also entertain a motion to adopt the regulation. I note the meeting materials include possible adoption language.

MOTION: Accept the Board staff recommended comment responses and adopt the regulation language as noticed for 45-day comment on September 3, 2021. Additionally, delegate to the executive officer the authority to make technical or nonsubstantive changes as may be required by the Control agencies to complete the rulemaking file.

Title 16. Board of Pharmacy
Proposed Text

Proposed changes to the current regulation language are shown by ~~strikethrough~~ for deleted language and <u>underline</u> for added language.

Amend Section 1704 to Title 16 of the California Code of Regulations, to read as follows:

§ 1704. ~~Change of~~ <u>Providing</u> Addresse<u>s</u>.

<u>(a)</u> Each person holding a certificate, license, permit, registration or exemption to practice or engage in any activity in the State of California under any and all laws administered by the Board shall file a proper and current residence address with the Board at its office in Sacramento and shall within 30 days notify the Board at its said office of any and all changes of residence address, giving both the old and new address.

<u>(b) Each applicant or person holding a certificate, license, permit, registration or exemption to practice who has an electronic mail address shall provide to the Board that electronic mail address and shall maintain a current electronic mail address, if any, with the Board and shall within 30 days notify the Board of any change of</u>

electronic mail address, giving both the old and new electronic mail address.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4003, 4013, and 4100, Business and Professions Code.

M/S: Veale/Serpa

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

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

Board Member	Vote
Butler	Support
De La Paz	Not Present
Kim	Not Present
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibeau	Support
Veale	Support
Weisz	Support

XII. Executive Officer Report

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

Ms. Sodergren provide a brief update on the Board's response to COVID-19 including information of Board issued site-specific and broad waivers along with waivers issued by the Board. Ms. Sodergren advised members of updates to the Board's website to consolidate COVID-19 related information as well as the more formal actions taken to transition to telework.

b. Increase in NAPLEX Fees

Members were advised about upcoming increase in NAPLEX fees.

c. ACPE Standards Revisions Feedback Survey

Members were advised that the Accreditation Council for Pharmacy Education (ACPE) Board of Directors has issued a call for comments to all stakeholders as part of its work on the next revisions of the Accreditation Standards and Key Elements for the Professional Program in Pharmacy. The standards revision feedback survey is available through 2021.

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

Ms. Sodergren referenced the biannual examination reporting for the CPJE and NAPLEX.

d. Release of the New Detailed Content Outline for the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)

Information on the transition to a new detailed content outline was discussed, including the implementation steps.

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

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

XIII. Closed Session Matters

The Board recessed to closed session at approximately 4:10 p.m.

The Board adjourned from closed session at approximately 5:13 p.m.

The Board adjourned at approximately 5:13 p.m.

October 28, 2021

President Oh called the Board Meeting to order at 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 observing or participating in the meeting that the meeting was being conducted consistent with the provisions of Government Code section 11133. Dr. Oh advised participants watching the webcast could only observe the meeting. He noted anyone interested in participating in the meeting must join the WebEx meeting using the instructions posted on the Board's website.

DCA staff provided general instructions for the WebEx Board Meeting for members of the public participating in the meeting.

President Oh advised those participating in the teleconference the Board would convene in closed session after deliberating on the open session items, except adjournment.

Roll call was taken. Board Members present included Maria Serpa, Jignesh Patel, Shirley Kim, Ricardo Sanchez, Nicole Thibeau, Debbie Veale, Jason Weisz, and Seung Oh. A quorum was established.

XV. Presentation by Dr. Steve Chen, Associate Dean for Clinical Affairs, University of Southern California on California Right to Meds Collaborative

President Oh welcomed and introduced Dr. Steve Chen, Associate Dean for Clinical Affairs, University of Southern California on California Right to Meds Collaborative.

Dr. Chen provided a summary of his background and examples of his indigent patients. Dr. Chen reviewed statistics indicating disparities in quality of care.

Dr. Chen reviewed the Comprehensive Medication Management (CMM) as right choice of drug, right dose of drug, safety of medications, patients can use medication devises safely, and affordability of drugs. He noted it includes ongoing patient evaluation and monitoring.

Dr. Chen shared an example of working with USC/Alta med Center for Medicare and Medicaid Innovation where the focus of the project was patient targeting and management strategy including patient costs, frequent and recent acute care utilizers, 48 EHR-embedded triggers to detect high risk patients and doctor referrals. CMM was continued until patients reached goal and followed up with check ins every two months. Approximately 6,000 patients enrolled and provided profile information for

the patients. Dr. Chen reviewed medication-related problems identified through the program and highlighted the benefits of CMM.

Dr. Chen shared reviewed the IHI Breakthrough Series Collaborative Process sued with a focus on training with ongoing support. He shared other key components include stringent pharmacy vetting process, partners with CDC, working with data platform with continuous quality improvement, and preparing to thrive in the pay-for-value world. A best practices model was developed and shared.

Dr. Chen shared the LA Care Pilot Right Meds Collaborative Pharmacies and FQHCs. He noted preliminary impact results where the focus was uncontrolled diabetes with A1C greater than 9 percent. After five months decreases in A1C were seen at an average of 2.6 percent.

Members were provided the opportunity to discuss the presentation. Member Veale advised members that she has attended the training and noted that it is very well done. Members also discussed how to engage in the program.

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

Administrative Law Judge Timothy Aspinwall presided over the following petition hearings:

a. Jurupa Valley Pharmacy, PHY 57522
b. Ekta M. Patel, RPH 63609
c. Toni Walker, RPH 33235

The Board took a break from 9:57 a.m. to 10:15 a.m. Roll call was taken after the break. Members present included Seung Oh, Maria Serpa, Jignesh Patel, Shirley Kim, Ricardo Sanchez, Nicole Thibeau, Debbie Veale, and Jason Weisz. A quorum was established.

The Board took a break from ?? a.m. to ?? a.m. Roll call was conducted visually through WebEx camera participation. Members present included Maria Serpa, Jignesh Patel, [anne check the video]

XVIII. Adjournment

The Board recessed to closed session at approximately 11:34 p.m.

The Board adjourned from closed session at approximately 12:13 p.m.

The Board adjourned at approximately 12:13 p.m.

III. Approval Board Meeting Minutes

b. December 2, 2021, Board Meeting

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

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

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

Date: December 2, 2021

Location: Teleconference Public Board Meeting
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,
Jose De La Paz, Public Member
Lavanza Butler, Licensee Member
Ricardo Sanchez, Public Member
Nicole Thibeau, Licensee Member
Jason Weisz, Public Member
Debbie Veale, Licensee Member

Board Members Absent: Shirley Kim, Public Member

Staff Present:
Anne Sodergren, Executive Officer
Eileen Smiley, DCA Staff Counsel
Sheila Tatayon, DCA Staff Counsel

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

The meeting was called to order at 9:03 a.m. President Oh reminded everyone that the meeting was being conducted consistent with the provisions of Government Code section 11133. Provisions for providing public comment throughout the meeting were reviewed.

DCA staff provided instructions for providing public comment throughout the meeting.

President Oh advised those participating in the teleconference the Board would convene in closed session after deliberating on the open session items, except adjournment.

Roll call was taken. Board Members present included Maria Serpa, Jignesh Patel, Jose De La Paz, Ricardo Sanchez, Nicole Thibeau, Debbie Veale, Jason Weisz, and Seung Oh. A quorum was established.

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

During the meeting members of the public were provided the opportunity to provide public comment on items not on the agenda. Paul Cummings, commented on the Board's probation program. He completed probation and thanked the Board and Inspector Simari. He appreciates the Board giving pharmacists a second chance and noted that probation works and helped him become a better pharmacist. Mr. Cummings noted that it was difficult to find employment while on probation.

Dr. Simonian works with pharmacists promoting the safe use of cannabis including education. Dr. Simonian indicated that guidelines have been developed to assist with the provisions of Senate Bill 311 and requested that this topic be placed on a future agenda item.

Members were surveyed to determine if any of the items should be placed on a future agenda. Member De La Paz, requested that Senate Bill 311 be placed on a future agenda for the enforcement committee. It was seconded by Nicole Thibeau.

Member Butler joined the meeting at 9:15.

MOTION: Schedule discussion on Senate Bill 311 related to education on the use of cannabis at a future Enforcement Committee meeting.

M/S: De La Paz/Thibeau

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

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

Board Member	Vote
Butler	Support
De La Paz	Support
Kim	Not present
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibeau	Support
Veale	Support
Weisz	Support

President Oh reminded members of the creation of an ad hoc committee to consider standard of care.

III. Presentation by Dr. Rita Shane on Quality Improvement Study Conducted on Senate Bill 1254

Dr. Shane provided background and history on the issue including the process to collect medical history and the problems with incomplete medication lists. SB 1254 the bill became effective January 1, 2019.

Following enactment, Dr. Shane conducted a study to determine the number of medication errors identified and intercepted as a result of the change. Dr. Shane reviewed the methodology for the quality improvement study. Eleven organizations participated in the study. The study used the NCC MERP wheel was used to ensure consistency with the reporting of the types of errors.

Dr. Shane noted that 2, 273 medication histories were documented with a total of 15,850 errors noted. Dr. Shane highlighted data including 94 percent of the medication histories had at least one error and 54 percent of the patients who had a potential serious or life-threatening error.

Dr. Shane provided examples of the types of errors avoided through the use of the medication reconciliation process.

Dr. Shane noted that California is the only state that has implemented such a requirement. Dr. Shane shared cost savings stemming from the errors averted.

Members were provided the opportunity to ask questions. Members noted the impressive outcomes and cost impacts. In response to a question, Members were advised of a study underway at Cedars evaluating medication errors avoided through pharmacist review at the time of discharge.

Members of the public were provided the opportunity to provide public comments. Dr. Gray suggested that very few hospitals have implemented Senate Bill 1254 and inquired what needs to be done to strengthen enforcement.

Public comment included an inquiry about if the results will be published.

IV. Discussion and Consideration of Results of Workforce Survey

Members received a presentation on the results of the workforce survey from Ms. Sodergren and Dr. Tracy Montez. (A copy of the presentation slides is available on the Board's website as part of the meeting materials.)

Dr. Montez noted the benefits of surveys in that they can reach a broad group of individuals; however, the surveys are typically self-report and the accuracy of the information is dependent on the responses and the overall response rate.

Members were provided with summary demographic data on survey respondents. Members were reminded that the survey was designed to assess the working conditions in community pharmacies in California, noting that over 2,900 pharmacists that completed the survey reported working in a chain community pharmacy, 407 reported working for an independent pharmacy and over 900 reported working in another setting. The remainder of the data reviewed would be limited to respondents that identified as working in either a chain community pharmacy or independent community pharmacy. Further, some data responses were further broken down by staff pharmacists versus those that work as a pharmacist-in-charge.

As part of the presentation, Dr. Montez highlighted findings that were statistically significant. Examples included responses to Question 18 "Do you believe you have sufficient time to provide adequate screening prior to the administration of an immunization" where 78 percent community chain pharmacists reported they did not have sufficient time, whereas 56 percent of independent community pharmacists reported yes to having sufficient time. Further a statistically significant finding included the responses to the question, "Does your primary worksite employer use workload metrics in specified areas?" which reveal chain pharmacies are more likely to use workload metrics than independent pharmacies.

Survey results also indicate that in response to the question, "Do you believe you have sufficient time to provide appropriate patient consultation?" again revealed a statistically significant finding with community chain pharmacists report they do not have sufficient time while, 68 percent of pharmacists working in an independent pharmacy reported they did have sufficient time. Results also indicated that in response to the question, "Do you believe the pharmacy staffing in your primary worksite is appropriate to ensure adequate patient care?" 91 percent of pharmacists working in a community chain pharmacist responded no, while 68 percent of pharmacists working in an independent community pharmacy responded yes.

Member Butler requested to be placed on the new ad hoc committee. Member Thibeau stated appreciation for how the information was presented and requested to be placed on the medication error reduction committee.

Members of the public were provided an opportunity to provide public comment. Dr. Gray suggested that PIC for the independent pharmacy should be assessed to determine if they are also the owner. He also questioned what is included in "chain."

Keith Yoshizuka, CSHP, applauded the Board for looking into this issue.

Following public comment, the meeting was in recess from about 10:35 a.m. to 10:45 a.m.

Upon return, roll call was taken. Members present included: Jignesh Patel, Cheryl Butler, Jose De La Paz, Nicole Thibeau, Debbie Veale, Jason Weisz, Maria Serpa, Ricardo Sanchez and Seung Oh.

V. Discussion and Consideration of Application and Enforcement of Business and Professions Code section 688 Related to Forwarding of Controlled Substance Prescriptions, Including Potential Statutory Amendments.

President Oh referenced the meeting materials and reminded members e-prescribing requirements become effective January 1, 2022. As part of its implementation efforts the Board has provided education on the requirements, including development of frequently asked questions which are posted on the Board's website.

Recently, as part of public comment, the Board received a request to further discuss the provisions related to unfilled schedule II-V controlled substances prescriptions and the requirements to transfer or forward such electronic prescriptions.

President Oh advised members of the development of a statutory change that could be one means to address the concerns raised. Dr. Oh referenced the DEA released a proposed rule related to the transfer of electronic prescriptions for scheduled controlled substances between pharmacies. Dr. Oh noted that this rule could address some of the challenges that have been expressed from stakeholders and members. .

Ms. Veale suggested that the Board needs to simplify the language.

Dr. Serpa noted that the issue is a national issue and the amount of time and effort required to effectuate the change. Dr. Serpa suggested it may be pre-mature especially given the changes that are happening at the national level. Dr. Serpa suggested holding off for a few months.

Member Butler questioned if a pharmacy will have the ability to transfer a prescription and asked if holding off will impact her ability to have a prescription transferred.

Member Thibeau requested clarification on the proposal. Ms. Smiley reiterated the requirements of the law, the current problem, the solution being offered, as well as, the need for the transition period.

Members of the public were provided the opportunity to provide public comment. Danny Martinez, CPhA, indicated he does not believe there is a need for the transition period.

Lindsay Gullihorn, CRA and NACDS, thanked the Board for considering this issue, indicated support for the legislative fix, and suggested an urgency measure may be necessary noting that enforcement discretion is necessary while the statutory change is underway.

Steven Gray, indicated that one portion of the provision would eliminate the ability to transfer the request if there is not an NCPDP standard developed, even if the prescription was an oral prescription.

John Gray, Kaiser, appreciated the Board's consideration and suggested that the Board provide clarity for the time point. Dr. Gray offered language and spoke in support of the one-year delay and requested inclusion of an urgency provision in the language.

Keith Yoshizuka, CSHP, noted appreciation the Board's progressive position in a number of areas, but suggests that the Board should consult with the New York Board of Pharmacy as that entity may be able to provide some language.

Mark Johnston, CVS Health, noted appreciation for the Board's effort.

MOTION: Pursue a statutory change to BPC 688(g) with a one-year delay following the necessary change in law or standards. Delegate to EO and President to finalize the language and work through the statutory process.

M/S: Veale/Patel

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

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

Board Member	Vote
Butler	Support
De La Paz	Support
Kim	Not present
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibeau	Support
Veale	Support
Weisz	Abstain

VI. Discussion and Consideration of Adoption of Board Approved Regulation, Title 16, CCR Section 1715.65, Inventory Reconciliation and Discussion and Consideration of Public Comments Received during the 45-day Comment Period.

President Oh referenced the meeting materials for the regulation and commented in appreciation of the detailed responses to the comments received along with the relevant statutory provisions.

President Oh acknowledged all had the opportunity to review the meeting materials including the comments received and staff recommendations. Dr. Oh advised Ms. Tatayon and Ms. Smiley were present to answer any legal questions on the language, comments received, and staff recommendations developed in response to comments.

President Oh stated after reviewing the comments, he agreed with the recommendations of staff. Members were provided the opportunity to provide comment; however, no comments were made.

Dr. Serpa commented to the rest of the Board that this regulation is complex and that it has been in discussion. Dr. Serpa noted agreement with the proposed language. Dr. Serpa moved and Cheryl seconded with the motion and language as presented.

Member Veale, stated appreciation for the clean-up done on the language and suggested from a construction standpoint if (a)(3)(b) may be in the wrong place. Ms. Tatayon discussed how the language is constructed and how it is appropriate.

Dr. Serpa noted that the intent in (3)(B) was to require the reconciliation report for any loss.

Member Veale expressed concern with the requirement for signature. Further Ms. Veale sought clarification on (e) and (h). Dr. Serpa noted that outside of the hospital

setting, there are different requirements because there could be an unknown discrepancy necessitating the need for the physical count.

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

John Gray, Kaiser, suggested the terms acquisition and disposition needs to be defined and indicated that misapplication could occur.

Dr. Yoshizuka expressed concerns with the additional work that this regulation would require.

Paige Talley, California Council for the Advancement of Pharmacy, noted appreciation for Member Veale's comment that all ADDSs be included in the provision and request future consideration for other ADDS in other settings.

Mark Johnston, requesting a one-year delay. He restatement the comments submitted and administrative burdens.

Motion:

Accept the Board staff recommended comment responses, approve the staff recommended modified regulation language, and initiate a 15-day public comment period. Additionally, if no adverse comments are received during the 15-day comment period, authorize the Executive Officer to take all steps necessary to complete the rulemaking and adopt the proposed regulations at Section 1715.65 as noticed. Further, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

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

Modified changes to the current proposed language are shown by ~~double strikethrough~~ for deleted language and double underline for added language.

Amend Section 1715.65 to Title 16 of the California Code of Regulations, to read as follows:

§ 1715.65. Inventory Activities and Inventory Reconciliation Reports of Controlled Substances.

(a) Every pharmacy, and every clinic licensed under sections 4180 or 4190 of the Business and Professions Code, shall perform periodic inventory activities and prepare inventory reconciliation ~~functions~~ reports to detect and prevent the loss of federal controlled substances. Except as provided in subdivisions (f) and (g),

inventory reconciliation reports shall be prepared on the following ongoing basis:
(1) For federal Schedule II controlled substances, at least once every three months.
(2) For products containing the following substances in the following strengths per tablet, capsule, other unit, or specified volume, at least once every 12 months:
(A) Alprazolam, 1 milligram/unit.
(B) Alprazolam, 2 milligrams/unit.
(C) Tramadol, 50 milligrams/unit.
(D) Promethazine/codeine, 6.25 milligrams of promethazine and 10 milligrams of codeine per 5 milliliters of product.
(3)(A) For any controlled substance not covered by paragraph (1) or (2), an inventory reconciliation report shall be prepared for identified controlled substances lost no later than three months after discovery of the ~~any~~ loss of that controlled substance. This report shall be completed if the loss is discovered either by the inventory activities required by subparagraph (B), or in any other manner. The report shall cover the period from the last physical count of ~~the~~ that controlled substance before the loss was discovered through the date of discovery. At a minimum, any pattern(s) of loss(es) identified by the pharmacist in charge shall require an inventory reconciliation report for each pattern of loss identified, as defined by the pharmacy's policies and procedures. Any reportable loss, as specified in section 1715.6, shall also require an inventory reconciliation report.
(B) Inventory activities for each controlled substance not covered by paragraph (1) or (2) shall be performed at least once every two years from the performance of the last inventory activities. For purposes of this section, "inventory activities" means inventory and all other functions ~~necessary~~ sufficient to identify loss~~es~~ of ~~the~~ controlled substances. The functions sufficient to identify loss outside of the inventory reconciliation process shall be identified within the pharmacy's policies and procedures.
(b) The pharmacist-in-charge of a pharmacy or ~~consultant~~ consulting pharmacist for a clinic shall review all inventory activities performed and inventory reconciliation reports ~~taken~~ prepared pursuant to this section, and establish and maintain secure methods to prevent losses of federal controlled ~~drugs~~ substances. Written policies and procedures shall be developed for performing the inventory activities and preparing the inventory reconciliation reports required by this section.
(c) ~~A pharmacy or clinic shall compile an~~ An inventory reconciliation report ~~of all federal Schedule II controlled substances at least every three months. This compilation~~ prepared pursuant to this section shall ~~require~~ include all of the following:
(1) A physical count, not an estimate, of all quantities of ~~federal Schedule II~~ each federal controlled ~~substances~~ substance covered by the report that the pharmacy or clinic has in inventory, except as provided in subdivision (h). The

biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section. An individual who performs the inventory required by this paragraph shall sign and date the inventory or the report in which it is included as provided in subdivision (e)(1);

(2) A review of all acquisitions and dispositions of each federal ~~Schedule II~~ controlled ~~substances~~ substance covered by the report since the last inventory reconciliation report covering that controlled substance;

(3) A comparison of (1) and (2) to determine if there are any variances;

(4) ~~All~~ Identification of all records used to compile ~~each inventory reconciliation~~ the report, which shall be maintained in the pharmacy or clinic ~~for at least three years in a readily retrievable form~~ pursuant to subdivision (e)(2); ~~and~~

(5) Identification of each individual involved in preparing the report; and

~~(5)~~ (6) Possible causes of overages ~~shall be identified in writing and incorporated into the inventory reconciliation report~~.

(d) A pharmacy or clinic shall report in writing identified losses and known causes to the board within 30 days of discovery unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovery. If the pharmacy or clinic is unable to identify the cause of the loss, further investigation shall be undertaken to identify the cause and actions necessary to prevent additional losses of federal controlled substances.

(e)(1) ~~The~~ An inventory reconciliation report shall be dated and signed by ~~the individual(s) performing the inventory, and countersigned by~~ the pharmacist-in-charge or professional director (if a clinic) ~~and~~, in addition to any signature required by subdivision (c)(1). An individual may use a digital or electronic signature or biometric identifier in lieu of a physical signature under this section if, in addition, the individual physically signs a printed statement confirming the accuracy of the inventory or report. The signature shall be dated, and the signed and dated statement shall be retained on file pursuant to paragraph (2).

(2) The report, and all records used to compile the report, shall be readily retrievable in the pharmacy or clinic for three years. ~~A countersignature is not required if the pharmacist-in-charge or professional director personally completed the inventory reconciliation report.~~

(f) A new pharmacist-in-charge of a pharmacy shall complete an inventory reconciliation report ~~as identified in subdivision (c)~~ for all federal controlled substances described in paragraphs (1) and (2) of subdivision (a) within 30 days of becoming pharmacist-in-charge. Whenever possible, an outgoing pharmacist-in-charge should also complete an inventory reconciliation report ~~as required in subdivision (c)~~ for those controlled substances.

(g) ~~For~~ Notwithstanding the periodic reporting requirements specified in paragraphs (1) and (2) of subdivision (a), inpatient hospital pharmacies~~,~~ shall prepare an inventory reconciliation report or reports covering the federal controlled substances described in paragraphs (1) and (2) of subdivision (a) on

~~a separate~~ quarterly ~~inventory reconciliation report shall be required for federal Schedule II~~ basis. The report or reports shall include controlled substances stored within the pharmacy ~~and for~~, within each pharmacy satellite location, and within each drug storage area in the hospital under the pharmacy's control.
(h) ~~The pharmacist-in-charge of~~ If an inpatient hospital pharmacy ~~or of a pharmacy servicing onsite or offsite~~ uses an automated drug delivery ~~systems~~ system (ADDS), inventory in the ADDS may be accounted for under subdivision (c)(1) using means other than a physical count. ~~shall ensure that:~~
~~(1) All controlled substances added to an automated drug delivery system are accounted for;~~
~~(2) Access to automated drug delivery systems is limited to authorized facility personnel;~~
~~(3) An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed; and~~
~~(4) Confirmed losses of controlled substances are reported to the board.~~

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4008, 4037, 4080, 4081, 4101, 4104, 4105, ~~4105.5,~~ 4110, 4113, ~~4119.1,~~ 4180, 4181, 4182, 4186, 4190, 4191, 4192 and 4332, Business and Professions Code; and Section 1261.6, Health and Safety Code.

M/S: Serpa/Butler

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

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

Board Member	Vote
Butler	Yes
De La Paz	Yes
Kim	Not present
Oh	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes
Thibeau	Yes
Veale	Yes
Weisz	Yes

VII. Discussion and Consideration of Adoption of Board Approved Regulation, Title 16, CCR Section 1746.5 Vaccine Administration of Public Comments Received during the 45-day Comment Period.

President Oh referenced the meeting materials for the regulation and commented in appreciation of the detailed responses to the comments received along with the relevant statutory provisions.

President Oh acknowledged all had the opportunity to review the meeting materials including the comments received and staff recommendations. Dr. Oh advised Ms. Tatayon and Ms. Smiley were present to answer any legal questions on the language, comments received, and staff recommendations developed in response to comments.

President Oh stated after reviewing the comments, he agreed with the recommendations of staff. Members were provided the opportunity to provide comment; however, no comments were made.

The public was provided with the opportunity to provide public comment; however, none were provided.

Motion: Accept the Board staff recommended comment responses and adopt the regulation language as noticed on October 8, 2021. Additionally, authorize the Executive Officer to take all steps necessary to complete the rulemaking and delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

To Amend Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

Legend: Insertions are Underlined; Deletions are ~~Stricken~~

§ 1746.4. Pharmacists Initiating and Administering Vaccines.
(a) A pharmacist initiating and/or administering any vaccine pursuant to section 4052 or 4052.8 of the Business and Professions Code shall follow the requirements specified in subdivisions (b) through (f) of this section.
(b) Training: A pharmacist who initiates and/or administers any vaccine shall keep documentation of:
(1) Completion of an approved immunization training program, and
(2) Basic life support certification.
This documentation shall be kept on site and available for inspection.

(c) Continuing Education: A pharmacist must complete one hour of ongoing continuing education focused on immunizations and vaccines from an approved provider once every two years.
(d) Notifications: At the request of a patient, ~~A~~ a pharmacist shall notify, each patient's primary care provider of any vaccine administered to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. Primary care provider notification must take place within 14 days of the administration of any vaccine. If a patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall advise the patient to consult an appropriate health care provider of the patient's choice. A pharmacist shall notify each pregnant patient's prenatal care provider, if known, of any vaccine administered to the patient within 14 days of the administration of any vaccine.
(e) Immunization Registry: A pharmacist shall report, in accordance with section 4052.8, subdivision (b)(3), of the Business and Professions Code, the information described in section 120440, subdivision (c), of the Health and Safety Code within 14 days of the administration of any vaccine. A pharmacist shall inform each patient or the patient's guardian of immunization record sharing preferences, detailed in section 120440, subdivision (e), of the Health and Safety Code.
(f) Documentation: For each vaccine administered by a pharmacist, a patient vaccine administration record shall be maintained in an automated data processing or manual record mode such that the information required under section 300aa-25 of title 42 of the United States Code is readily retrievable during the pharmacy or facility's normal operating hours. A pharmacist shall provide each patient with a vaccine administration record, which fully documents the vaccines administered by the pharmacist. An example of an appropriate vaccine administration record is available on the Board of Pharmacy's website.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052, 4052.8 and 4081, Business and Professions Code; Section 120440, Health and Safety Code; and Section 300aa-25, Title 42, United Stats Code.

M/S: Veale/Butler

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

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

Board Member	Vote
Butler	Support
De La Paz	Support
Kim	Not present
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibeau	Support
Veale	Support
Weisz	Support

VIII. Discussion and Consideration of Adoption of Board Approved Regulation, Title 16, CCR Section 1715.6, Reporting Drug Losses to Address Comments from the Office of Administrative Law

President Oh referenced the meeting materials for the regulation and commented in appreciation of the detailed responses to the comments received along with the relevant statutory provisions. Dr. Oh provided background on the issue and noted that staff prepared the recommended text to address the concerns expressed by OAL.

Dr. Oh advised Ms. Tatayon and Ms. Smiley were present to answer any legal questions on the language, comments received, and staff recommendations developed in response to comments.

Dr. Serpa noted the minor modifications and spoke in support.

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

Motion: Approve the recommended modified regulation language and initiate a 15-day public comment period. Additionally, if no adverse comments are received during the 15-day comment period, authorize the Executive Officer to adopt the proposed regulations at Section 1715.6 as noticed and take all steps necessary to complete the rulemaking. Further, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

Proposed changes to the current regulation language are shown by ~~strikethrough~~ for deleted language and <u>underline</u> for added language.

Modified changes to the proposed regulation language are shown by ~~double strikethrough~~ for deleted language and <u>double underline</u> for added language.

Amend Section 1715.6 to Title 16 of the California Code of Regulations, to read as follows:

§ 1715.6. Reporting Drug Loss.

(a) The owner shall submit ~~report~~ to the Board a report containing the information in subdivision (b) ~~within~~ no later than thirty (30) days after the date of discovery of the following:

(1) ~~any~~ Any loss of ~~the~~ a controlled substance~~s, including their~~ in one of the following categories that causes the aggregate amount of unreported losses discovered in that category, on or after the same day of the previous year, to equal or exceed:

(A) For tablets, capsules, or other oral medication, 99 dosage units.

(B) For single-dose injectable medications, lozenges, film, such as oral, buccal and sublingual, suppositories, or patches, 10 dosage units.

(C) For injectable multi-dose medications, medications administered by continuous infusion, or any other multi-dose unit not described in subparagraph (A), two or more multi-dose vials, infusion bags, or other containers.

(2) Any loss of a controlled substance, regardless of the amount, attributed to employee theft, in addition to the reporting requirements and time frames mandated by Business and Professions Code section 4104.

(3) Any other significant loss as determined by the pharmacist-in-charge, including but not limited to losses deemed significant relative to the dispensing volume of the pharmacy.

(b) All reports under this section shall specify the identity, amount~~s~~ and strength~~s~~ of each controlled substance lost, and date of discovery of the loss, for all losses that have made the report necessary.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4104, and 4332, Business and Professions Code.

M/S: Serpa/Veale

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

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

Board Member	Vote
Butler	Support
De La Paz	Support
Kim	Not present
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibeau	Support
Veale	Support
Weisz	Support

Roll call taken at 1:03. Members present included: Maria Serpa, Jignesh Patel, Cheryl Butler, Jose De Le Paz, Ricardo Sanchez, Nicole Thibeau, Debbie Veale, Jason Weisz, Seung Oh

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

Administrative Law Judge Heather Rowan presided over the following petition hearings:

a. James Poon, RPH 74515
b. Jessica Jin Hee Park, RPH 71655
c. Saifuddin Hatim Raniwala, RPH 49936

The Board took a break from 2:26 p.m. to 2:35 p.m. Roll call was taken after the break. Members present included Seung Oh, Maria Serpa, Cheryl Butler, Jignesh Patel, Jose De La Paz, Ricardo Sanchez, Nicole Thibeau, Debbie Veale, and Jason Weisz. A quorum was established.

X. Closed Session Matters

The Board recessed into closed session at approximately 3:35 p.m.

XI. Adjourn

The Board adjourned after closed session at approximately 4:15 p.m.