

III. Approval Board Meeting Minutes

- a. July 24-25, 2019



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
DRAFT Public Board Meeting Minutes
July 24-25, 2019

DATES: July 24-25, 2019

LOCATION: Embassy Suites Anaheim North, Grand Ballroom
3100 E. Frontera St.
Anaheim, CA 92806

BOARD MEMBERS PRESENT: Gregory Lippe, Public Member, Acting President/Vice President
Allen Schaad, Licensee Member, Treasurer
Lavanza Butler, Licensee Member
Shirley Kim, Public Member (only July 24, 2019)
Ricardo Sanchez, Public Member
Maria Serpa, Licensee Member
Deborah Veale, Licensee Member
Albert Wong, Licensee Member

BOARD MEMBERS NOT PRESENT: Ryan Brooks, Public Member
Amjad Khan, Public Member
Valerie Muñoz, Public Member

STAFF PRESENT: Anne Sodergren, Interim Executive Officer
Laura Freedman, DCA Counsel
Kelsey Pruden, DCA Counsel
Desiree Kellogg, Deputy Attorney General
Christine Acosta, Supervising Inspector
MaryJo Tobola, Senior Enforcement and Administration Manager
Debbie Damoth, Administration Manager

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

Vice President Greg Lippe opened the meeting at 1:01 p.m. Mr. Lippe announced that Board President Victor Law resigned effective July 15, 2019. With his resignation, as the board's Vice President, Mr. Lippe advised he will now act as the Acting President until such time as the board conducts new elections.

Mr. Lippe provided the board's next scheduled meeting is September 13, 2019. With the board's approval, Mr. Lippe recommended adding the election of officers to the agenda of that meeting.

MOTION: Add elections for board president and board vice present to the board meeting agenda for September 13, 2019.

M/S: Veale/Butler

Support: 8

Oppose: 0

Abstain: 0

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Brooks | | | | x |
| Butler | x | | | |
| Khan | | | | x |
| Kim | x | | | |
| Lippe | x | | | |
| Muñoz | | | | x |
| Sanchez | x | | | |
| Schaad | x | | | |
| Serpa | x | | | |
| Veale | x | | | |
| Wong | x | | | |

Acting President Lippe provided that the board made a request to DCA for an update on the permanent executive officer recruitment currently under review with DCA. Mr. Lippe advised once an update is available, an announcement will be made.

Acting President Lippe advised the board's strategic plan establishes standing committees consisting of public and licensee members through which the board establishes its goals and organizes its activities. The committee structure provides an important venue for ensuring staff and members share information in crafting and implementing objectives. These meetings also provide an opportunity for stakeholder involvement and public comment is encouraged. Following committee meetings, the chairs from each of the respective committees provide reports to the full board as part of board meetings. Committee recommendations on policy decisions are referred to the full board as the final decision maker. As included on the agenda, during this meeting the board will receive reports from the chairperson of several of the board's committees.

Acting President Lippe provided the board will convene in closed session during the meeting. Mr. Lippe provided upon conclusion of closed session, the board will reconvene in open session to adjourn the meeting in open session. He added the board did not intend to webcast that portion of the meeting.

Board Members Present: Shirley Kim, Ricardo Sanchez, Albert Wong, Lavanza Butler, Greg Lippe, Maria Serpa, Debbie Veale and Allen Schaad. Quorum was established.

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

A member of the public with a pending application for a 503b outsourcing license expressed concern about licensing processing time and requested board members provide status updates on pending applications.

Former Board President Amy Gutierrez thanked the board members for their service and congratulated Greg Lippe on his new role as Acting President.

Jaspal Kumar of Proteus Digital Health requested being considered on a future agenda to share knowledge in digital medicine technology.

Joe Grasela from University Compounding Pharmacy requested the Enforcement Committee review the minimum penalty of revocation in the four categories of the disciplinary guidelines.

A member of the public requested the board consider a regulation to require ambulatory care surgery center to have pharmacists visit monthly rather than the current requirement of quarterly.

III. Approval of the May 7-8, 2019 Board Meeting Minutes

Motion: Approve the May 7-8, 2019, board meeting minutes with the changes noted to the May meeting minutes.

M/S: Sanchez/Wong

Dr. Serpa commented an area of correction under the Compounding Committee on page 28, the Chairperson referenced should be Serpa and not Schaad.

Support: 7 Oppose: 0 Abstain: 1

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Brooks | | | | X |
| Butler | X | | | |
| Khan | | | | X |
| Kim | | | X | |
| Lippe | X | | | |
| Muñoz | | | | X |
| Sanchez | X | | | |
| Schaad | X | | | |
| Serpa | X | | | |
| Veale | X | | | |
| Wong | X | | | |

IV. Approval of the June 21, 2019 Board Meeting Minutes

Motion: Approve the June 21, 2019, board meeting minutes.

M/S: Butler/Sanchez

Support: 6 Oppose: 0 Abstain: 2

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Brooks | | | | X |
| Butler | X | | | |
| Khan | | | | X |

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Kim | | | x | |
| Lippe | x | | | |
| Muñoz | | | | x |
| Sanchez | x | | | |
| Schaad | x | | | |
| Serpa | x | | | |
| Veale | | | x | |
| Wong | x | | | |

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

The board recognized Fredrick Meister, Philip Zia, Steven Thompson, and Joe Grasela for 40 years of service as a pharmacist.

Board Member Shirley Kim left at approximately 1:30 p.m.

VI. Enforcement Committee

a. Discussion and Consideration of Citation and Fine Program including Summary of Presentation

Chairperson Schaad reported the committee has dedicated time at several meetings to discuss several aspects of the board’s citation and fine program. He noted the chair report detailed several provisions of pharmacy law that govern the board’s citation and fine program including the board’s authority to issue citations as well as the factors to be considered in assessing an administrative fine.

Mr. Schaad continued the committee received an update on implementation of the board’s May 2018 guidance to staff wherein the committee suggested that staff consider using the abatement provisions, especially in cases where the violations involved medication errors. The presentation, including statistics, were detailed in the presentation included in the meeting materials.

Mr. Schaad provided the committee was advised that based on review of citations issued with an order of abatement, about 75% of licensees choose to follow the order and complete additional education whereas about 25% of licensees elect to merely pay the fine. Additionally, the top violations for the past quarter that resulted in the issuance of a citation are medication errors, followed by drug losses and record keeping violations. The presentation included summaries of some of the medication error violations. Mr. Schaad reported the information from the presentation will be included in the next issue of The Script. While there appears to be a significant drop in citations issued, this reduction is in large part because of staff vacancies and a resulting backlog.

Board Member Veale inquired if the licensees should be required to complete training. Interim Executive Officer Anne Sodergren provided board staff were following policy direction from the board to use training as an incentive. If the board preferred requiring training, the policy direction would need to be updated. Chairperson Schaad agreed to review at the committee level and report back to the board.

The board heard public comment asking of those that opted to pay the fine, how many repeated the same violation? Chairperson Schaad provided history is considered as part of the disciplinary guidelines.

b. Discussion and Consideration of Post Implementation Review of Inventory Reconciliation Requirements for Controlled Substances, Including Discussion and Consideration of Title 16, California Code of Regulations, Section 1715.65

Chairperson Schaad reported the board's inventory reconciliation requirements took effect in April 2018. Since that time the board has provided guidance documents including FAQs that are published on the board's website. During the meeting, the committee reviewed a sample of the types of questions that are received by board staff as well as the board approved FAQs on the implementation.

Mr. Schaad provided the committee noted that it seemed appropriate to complete a post implementation review of the regulation to determine if additional guidance or changes may be necessary to meet the board's policy goal of the regulation. After public comment, the committee suggested that clarification may be needed regarding the ADDS provisions in the regulation used in hospitals as well as the need for a possible definition of satellite. Further it was suggested that the board should consider if signatures need to be required for all pharmacists involved in inventory activities or if electronic records would suffice.

Mr. Schaad reported he will be working with board staff to make recommendations on additional FAQs and possible changes to the regulation language to clarify the board's expectations for reconciliation activities. The focus will be primarily on satellite locations within hospitals, physical counts of drugs in ADDS devices in hospitals as well as the signature requirements for all pharmacists involved in inventory activities.

Mr. Schaad noted the committee received public comment on the previously approved FAQs. Members of the public were requested to submit their comments in writing to allow for research in advance of our next committee meeting.

c. Discussion and Consideration of Reporting Drug Losses to the Board Pursuant to Title 16, California Code of Regulations, Section 1715.6

Chairperson Schaad reported both the state and federal requirement for reporting a drug loss. The board requires any drug loss to be reported, however under federal law, the DEA only requires the reporting of a significant drug loss.

Mr. Schaad noted both at committee and board meetings members have considered what if any changes should be made to the board's drug loss reporting requirement. The board has received previous advice that the same approach as the DEA cannot be pursued because of the requirements of the Administrative Procedures Act.

Mr. Schaad noted in the meeting materials are summary data regarding drug losses including types of losses that fall within the 1-100 dosage unit range. Mr. Schaad commented he will be working with staff to determine what if any changes should be made and will report back to the committee with recommendations for its consideration.

Ms. Veale requested comparison data to include losses the 1-100 dosage unit range.

Board Member Albert Wong requested adding to the future agenda items a requirement for any narcotic diversion to be reported to the police for possible prosecution of the PIC. Mr. Schaad advised there are impediments to implementation but can be added to a future agenda.

The board heard public comment requesting to factor in practice settings when considering what is defined as significant loss as well as possibly seeking a change in statute. Ms. Sodergren clarified the committee is exploring options on how best update the requirement.

d. Discussion and Consideration of Proposal to Establish an Alternative Disciplinary Process

Chairperson Schaad reported the committee previously received a presentation from CPhA regarding an alternative enforcement model. The committee did not agree with the CPhA proposal but requested that staff work on a possible alternative method.

Mr. Schaad noted the committee received a brief presentation from staff on the basic tenets of a possible enforcement model. As part of the presentation staff advised the committee that additional work would be necessary to implement such a proposal but requested feedback from the committee and board on the general concept and direction to confirm the basic framework is consistent with the board's intent and policy goal.

Ms. Veale inquired where stipulations were included in the proposal. Ms. Sodergren clarified there is no draft pleading in the enforcement model which creates an avenue to stipulation without denying due process. Additionally, there will be a memorialization of findings, but it will not be limited to the pleadings format.

The board heard public comment requesting adding more than two board members to the process as well as an increase in the transparency and timeliness of the settlement terms. DCA Counsel Laura Freedman reminded the board that the board members who participate in the alternate enforcement process impacts later negotiations and decisions. Mr. Schaad requested the issue be returned to the Enforcement Committee for further development.

e. Discussion and Consideration of Draft Frequently Asked Questions Resulting from the Board's Ask An Inspector Program

Chairperson Schaad reported the committee deferred review of the draft FAQs, however members of the public were requested to submit their comments in writing to allow for research in advance of the next committee meeting.

f. Discussion and Consideration of Posting of an Individual Licensee's Address of Records on the Board's Website

Chairperson Schaad noted under California law, the address of record of board licensees is public information. With the exception for interns, this information is currently posted on the board's website since December 2003.

Mr. Schaad noted the committee received significant public comment about the potential risk to licensees when their address of record is made available on the board’s website. The committee questioned if it may be appropriate to remove the information from the board’s website, recognizing that by law the board would be required to release the information if requested. He added the committee determined it was appropriate to reassess the board’s policy and determine what, if any, changes can be made both at the policy level as well as from a technological standpoint.

The board heard public comment in support of removing individual licensee addresses from the board’s website.

Ms. Sodergren provided clarification if the board decides to remove addresses from the website for individual licensees and the board receives a request for a licensee’s address of record, the board is required to provide the address of record pursuant to the request. DCA Counsel Freedman clarified the address of record is not required to be a residence address. Additionally, Ms. Freedman advised if a member of the public requests an address of record for a licensee, there is no requirement for the member of the public to provide identification.

Motion: Remove all individual licensees’ addresses from the board’s website.

M/S: Butler/Veale

Support: 7

Oppose: 0

Abstain: 0

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Brooks | | | | x |
| Butler | x | | | |
| Khan | | | | x |
| Kim | | | | x |
| Lippe | x | | | |
| Muñoz | | | | x |
| Sanchez | x | | | |
| Schaad | x | | | |
| Serpa | x | | | |
| Veale | x | | | |
| Wong | x | | | |

g. Summary of Presentation on Board’s Jurisdiction in Enforcement Matters Regarding Pharmacies Operating Under Common Ownership or Management

Chairperson Schaad reported during the meeting, the committee heard a presentation on the board’s jurisdiction in enforcement matters regarding pharmacies operating under common ownership or management. As part of the presentation it was noted that because the board regulates at the site level, it is difficult to address a practice that is facilitated at the ownership level, noting that this is especially true for items such as policies and procedures.

Mr. Schaad noted the committee questioned if the solution is changing how to regulate the practice and if the committee should consider also issuing a license to the enterprise owner. Ultimately the committee determined that this issue requires further evaluation and discussion. It was suggested that it may be appropriate to evaluate the issue as part of the board’s Sunset Report.

Committee Recommendation (Motion): Recommend forwarding this issue to the Organizational Development Committee for development of an issue statement for inclusion into the Sunset Review.

Support: 7 Oppose: 0 Abstain: 0

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Brooks | | | | X |
| Butler | X | | | |
| Khan | | | | X |
| Kim | | | | X |
| Lippe | X | | | |
| Muñoz | | | | X |
| Sanchez | X | | | |
| Schaad | X | | | |
| Serpa | X | | | |
| Veale | X | | | |
| Wong | X | | | |

h. Discussion and Consideration of Citations as Non-Disciplinary Actions and Proposal to Amend Business and Professions Code Section 4314 to Include Provisions to that Effect

Chairperson Schaad reported the board routinely advised requesting parties that citations do not constitute discipline, however it appears that other regulators may apply a different meaning to the board’s action. While the board’s letter of admonishment provisions explicitly state that a letter of admonishment shall not be construed as a disciplinary action, there is no similar provision within the board’s existing citation statutes.

Mr. Schaad provided the committee considered a statutory proposal provided in meeting materials that would mirror the letter of admonishment provisions for citations. Specifically, the committee recommends to the board sponsorship of a statutory change to amend BPC section 4314.

Committee Recommendation (Motion): Recommend to the board to sponsor statutory change to amend BPC section 4314:

(a)The board may issue citations containing fines and orders of abatement for any violation of Section 733, for any violation of this chapter or regulations adopted pursuant to this chapter, or for any violation of Division 116 (commencing with Section 150200) of the Health and Safety Code, in accordance with Sections 125.9, 148, and 4005 and the regulations adopted pursuant to those sections.

(b)Where appropriate, a citation issued by the board, as specified in this section, may subject the person or entity to whom the citation is issued to an administrative fine.

(c) Notwithstanding any other provision of law, where appropriate, a citation issued by the board may contain an order of abatement. The order of abatement shall fix a reasonable time for abatement of the violation. It may also require the person or entity to whom the citation is issued to demonstrate how future compliance with the Pharmacy Law, and the regulations adopted pursuant thereto, will be accomplished. A demonstration may include, but is not limited to, submission of a corrective action plan, and requiring completion of up to six hours of continuing education courses in the subject matter specified in the order of abatement. Any continuing education courses required by the order of abatement shall be in addition to those required for license renewal.

(d) Nothing in this section shall in any way limit the board from issuing a citation, fine, and order of abatement pursuant to Section 4067 or Section 56.36 of the Civil Code, and the regulations adopted pursuant to those sections.

(e) The issuances of a citation pursuant to subdivision (a) shall not be construed as disciplinary action or discipline for purposes of licensure or the reporting of discipline for licensure.

Ms. Veale inquired if this would be included in the letters for citation. Ms. Sodergren explained adding this to statute will allow board staff to refer to statute when asked if a citation is considered disciplinary action. Currently, it is a policy decision to add to statute. A statement can be added to citations indicating the citation is not considered disciplinary action.

The board received public comment in support of this motion and to include orders of correction to be included. Chairperson Schaad requested it be added to the agenda future.

Support: 7

Oppose: 0

Abstain: 0

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Brooks | | | | X |
| Butler | X | | | |
| Khan | | | | X |
| Kim | | | | X |
| Lippe | X | | | |
| Muñoz | | | | X |
| Sanchez | X | | | |
| Schaad | X | | | |
| Serpa | X | | | |
| Veale | X | | | |
| Wong | X | | | |

i. Discussion and Consideration of Committee’s Strategic Goals

Chairperson Schaad reported the committee reviewed each goal and determined what if any additional action should be taken. The committee requested more data on violations for failure to provide patient consultation.

Mr. Schaad noted the committee recommends removal of Strategic Goal 2.6 “Collaborate with stakeholders to identify and expand resources for technicians who experience substance abuse to provide assistance in recovery,” from the Enforcement Committee Strategic Goals.

Committee Recommendation (Motion): Remove Strategic Goal 2.6 “Collaborate with stakeholders to identify and expand resources for technicians who experience substance abuse to provide assistance in recovery,” from the Enforcement Committee Strategic Goals.

Support: 7 Oppose: 0 Abstain: 0

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Brooks | | | | X |
| Butler | X | | | |
| Khan | | | | X |
| Kim | | | | X |
| Lippe | X | | | |
| Muñoz | | | | X |
| Sanchez | X | | | |
| Schaad | X | | | |
| Serpa | X | | | |
| Veale | X | | | |
| Wong | X | | | |

j. Discussion and Consideration of Board’s Enforcement Statistics

Chairperson Schaad provided the committee noted the continued reduction in investigation times. A review of case closure times for the past fiscal year indicate that 64 percent of the board’s field investigations were closed within one year, 31 percent were closed within 1-2 years and the remaining 5 percent were closed in over two years. This does not include cases that were referred to the Office of the Attorney General.

k. Future Committee Meeting Dates

Chairperson Schaad reported it is necessary to convene a meeting in advance of the November 5 board meeting. The date of September 25 has been identified as the next committee date. Once the date is confirmed the website will be updated with the information.

DCA Counsel Freedman provided additional information that an order of correction is not available as a public record pursuant to BPC 4083(g) and does not need to be added to a future agenda.

The board took a break at 2:42 pm and returned at 3:07 pm.

VII. Compounding Committee

a. Summary of a Presentation on the Proposed USP Chapter 825, Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging

Chairperson Maria Serpa reported the committee met twice since the last board meeting. On June 5, 2019, the committee continued education on application USP Chapters. Specifically, the June meeting focused on education of Chapter 825, Radiopharmaceuticals – Preparation, Compounding, Dispensing,

and Repackaging. Prior to the June 2019 committee meeting, several committee members had the opportunity to tour a radiopharmaceutical compounding facility. Dr. Serpa thanked PetNET for the tour and Paul Mahan, who provided the educational presentation to the committee. Dr. Mahan was a member of the expert panel responsible for developing the USP Chapter.

b. Discussion and Consideration of Proposed Amendments to Regulations Related to Pharmaceutical Compounding of Nonsterile Preparations

Chairperson Serpa reported this item is for discussion and action. During the July 2019 meeting, the committee considered draft regulations that may be necessary to provide clarity on the USP 795 Chapter as well as pursue regulations that are necessary to ensure safe processes and patient safety consistent with the board's consumer protection mandate. As a regulatory agency, the committee is developing a regulation proposal necessary for patient safety. USP represents the minimum national standard and the board should consider regulations beyond the minimum standard when patient safety is involved.

Dr. Serpa provided her recommendation to the committee and board that if the board determines regulations are necessary, promulgation of any regulations mirror the structure of the USP Chapters, including separate requirements for the various types of compounding preparations. She also clarified that rather than completing one rulemaking package that encompasses regulations for each of the USP Chapters, she recommended a separate regulation for each respective chapter as the chapters are finalized. This will allow for more immediate transition to the new chapters and regulations.

Dr. Serpa reported that the July 11 meeting was quite extensive and included significant public comment and collaboration. The regulation language proposed and reviewed at the board meeting represents language agreed to through consensus of the committee. Public comment was thoroughly considered, and in many instances, as a result of the public comment, changes were made.

Dr. Serpa acknowledged receipt of the comments submitted by CPhA in advance of the board meeting and noted that several of the comments included in the letter were considered by the committee on July 11th. Additionally, some of the written comments provided by CPhA reflected the language in its original form rather than the language that was amended through the consensus process during the July 11th meeting.

Dr. Serpa reminded the board members that as they discussed the proposed amendments to regulations related to pharmaceutical compounding of nonsterile preparations, the meeting materials included two documents for this discussion. One document was the regulation proposal being recommended for approval to initiate the rulemaking process. The second document included this same language, but also includes a brief statement of the necessity for the section.

California Code of Regulation (CCR) Section 1735 Compounding in Licensed Pharmacies.

Dr. Serpa provided the first section 1735(a)-(j) sets forth some of the general framework including the scope of compounding of nonsterile preparations in pharmacies. The proposed language represents the consensus reached during the committee meeting as well as nonsubstantive changes made following the meeting.

Dr. Serpa advised the board that the definition of compounding was limited to such action that occurs in a pharmacy as the board's jurisdiction does not extend to other areas where compounding may occur, such as a physician's office. The committee considered comments from several individuals. As part of the committee's discussion, areas of possible FAQs were identified to be helpful to the regulated public. Some changes sought by commenters would have violated federal law and as such were not incorporated.

Dr. Serpa advised the board, the CPhA letter referenced suggested changes in 1735(a)-(e) which were provided during the committee meeting and responded to during the meeting. For example, CPhA requested removal of 1735(c), however, the letter does not reflect that the language was changed during the meeting to apply to "reconstitution."

Ms. Veale inquired about CCR section 1735 (b) and (c) specific to changes about repackaging being considered compounding and adding flavors to medicines so kids will take the medicine as being defined as compounding. Supervising Inspector Christine Acosta clarified reconstitution in accordance with directions that have not been FDA approved are considered compounding. Dr. Acosta provided an example of compounding kits. Dr. Serpa added USP is clear on FDA approved documents but silent on documents not approved by FDA and so the committee provided guidance for when the information is not FDA approved. Dr. Acosta clarified that USP had identified that adding flavoring was considered compounding.

Section 1735.1. Introduction and Scope and Compounding Definitions.

Dr. Serpa explained this section provides the definitions that will be used to apply consistent understanding both in the application of the USP chapter as well as board regulations. The most notable change resulting from the committee meeting was the inclusion of the definition of potency, which was not part of the original proposal. The committee again received significant public comment and ultimately reached consensus

Ms. Veale requested clarification as to why definitions included in this section were not included in USP 795. Dr. Acosta explained for clarity, items referenced in USP were not repeated in the board's proposed draft regulations.

Section 1735.2. Personnel Training and Evaluation.

Dr. Serpa noted this section details the training and evaluation requirements. After considering public comment, the committee reached consensus. As part of the discussion, additional FAQs were identified related to the training requirements. The FAQ is necessary to draw the distinction between the USP requirements and those established in the regulation

Section 1735.3. Personal Hygiene and Garbing.

Dr. Serpa advised as the title suggested this section discusses personal hygiene and garbing requirements. There was significant discussion regarding the conditions under which someone should be prevented from entering the compounding area with certain conditions. After much discussion, the language was amended to allow for professional judgement as is reflected in the proposed language.

The committee also received public comment regarding which types of jewelry must be removed. Staff advised all present that the regulation language allows for a gowning and garbing accommodation in CCR section 1735.3(g). More detailed information is included in the draft minutes.

Section 1735.4. Building and Facilities

Dr. Serpa provided the committee's discussion on this section primarily focused around a provision the draft regulation provided intending to provide flexibility with when a compounding area could serve more than one purpose, if compounding was not performed daily. After consideration of concerns from the public, the provision was removed.

Dr. Serpa noted that the CPhA letter requests removal of the CCR section 1735.4 (c) requirement. This issue was not discussed during the committee meeting. Dr. Serpa stated she does not believe this change is necessary because the proposed regulation is not addressing cleaning a product, where a dishwasher would be acceptable. Rather it speaks to the rinsing of equipment, which is the activity that typically occurs following the cleaning. Rinsing removes the residue of the tap water for example. This section does not change any cleaning or dishwasher expectations.

Section 1735.5. Cleaning and Sanitizing.

Dr. Serpa advised the primary change to this section followed discussion that the board's emphasis should be on the documentation of cleaning. This was in response to public comment to which the committee responded that cleaning documentation is important. Dr. Serpa noted that the CPhA letter indicates that USP 795 is "pretty clear" on cleaning frequency and how it needs to occur. Dr. Serpa stated board regulations may at times need to exceed USP 795 to ensure safe practices and processes for patient protection. This was discussed and addressed during the meeting.

Section 1735.6. Equipment and Components.

Dr. Serpa reported the committee received significant comments on this section of the regulation. In its original form the proposed regulations required the use of a closed system processing device (containment ventilated enclosure - CVE) for any weighing, measuring, or other manipulations of components in a powder form. The committee noted that the requirement exceeded the USP requirement, which just requires **an assessment** to determine when such a device should be used, unless it involves hazardous drugs which would be covered under USP 800. Members of the committee reached consensus that such a requirement is not necessary, and the requirement was removed. As the chair of the committee Dr. Serpa requested staff arrange an informational training on the use of CVEs and how risk assessments should be performed if such information is available.

Dr. Serpa noted the CPhA letter requests changes to CCR section 1735.6 (c) some of which were discussed during the meeting and no changes made. However, the letter appropriately indicates that a component is not dispensed. As such, removal of the word "dispensed" will be removed from the proposed language. Dr. Serpa stated it was her intention to address this possible amendment to the proposal after the discussion on the remainder of the proposal. The

recommendation will be to remove the word from the stem of 1735.6 to read “Any component used to compound a CNSP shall be used and stored in accordance with all the following:...” Additionally, CCR section 1735.6 (e) was removed during the meeting.

Ms. Veale asked if CCR section 1735.6 (e) was removed. Dr. Serpa clarified there will be a nonsubstantive change to realign the renumbering/sequencing.

Section 1735.7. Master Formulation and Compounding Records.

Dr. Serpa reported this section transitions away from the terms “master formula” and “compounding logs” to conform with terms used by USP, “master formulation” and “compounding records.” The committee received significant comment regarding the proposed requirement for the master formulation document to include as part of it, the container closure system including the volume. While this was not changed during the committee meeting as part of our consensus building, staff conducted additional research on this issue and will be suggesting modification to this requirement. Dr. Serpa noted that changes were made to this section during the committee that make the recommendations offered by CPhA not applicable.

Section 1735.8. Release Inspections.

Dr. Serpa reported this section received no public comments during the committee meeting.

Section 1735.9. Labeling.

Dr. Serpa noted there may be some confusion between the term “label” and “labeling.” USP 795 provides definitions for both in the glossary. Public comment on this section was limited, but suggestion was made that we update the general prescription label requirement to include the route of administration. The committee noted that such a change went beyond the scope of the committee’s work but Dr. Serpa shared the comment in case the board is interested in another committee evaluating if such a change is appropriate.

Section 1735.10. Establishing Beyond-Use Dates.

Dr. Serpa reported public comment was limited on this section as well and noted it may be beneficial to develop an FAQ on this section.

Section 1735.11. Standard Operating Procedures.

Dr. Serpa stated public comment on this section was limited to a question regarding the need for the provision. The commenter was advised that the provision is current law.

Section 1735.12. Quality Assurance and Quality Control.

There were no committee or public comments on this section.

Section 1735.13. Packaging and Transporting.

Dr. Serpa stated the discussion primarily surrounded the delivery of a drug and how a pharmacy can be held responsible if a delivery company (e.g., mail carrier) mishandles a drug as part of the delivery process. The discussion did not result in any change to the language but was an opportunity to better understand the board's expectation. Dr. Serpa clarified the pharmacy is responsible for setting up processes but not held responsible for errors made by the mail carrier itself.

Dr. Serpa noted that the CPhA letter requests a cross reference to USP Chapter 659. Dr. Serpa clarified it would be inappropriate as the chapter relates to packaging and storage requirements within a pharmacy, not transportation and delivery.

Section 1735.14. Complaint Handling and Adverse Event Reporting.

Dr. Serpa reported there was no public or committee comment on this section.

Section 1735.15. Documentation.

Dr. Serpa noted the committee considered comments from the public regarding the value of documenting the time an edit occurs in a pharmacy record. The committee was advised that not all software systems provide the same and records can easily be deleted and altered without an audit trail, necessitating the need for a format of records that can not be edited after the fact.

Dr. Serpa reported having completed the review of the regulation proposal, the committee offered the recommendation for the board's consideration included in the meeting materials. Dr. Serpa inquired for the board's consideration of some additional changes to the proposed language as detailed in the chair report. She noted the changes were offered by staff based on further reflection of the comments received during the committee meeting. Dr. Serpa reported she reviewed the recommended changes and suggested the committee include them as part of the motion. Dr. Serpa reviewed the additional changes included in the chair report as the following:

CCR 1735.1

...

(j) "Potency" means an active ingredient strength typically within +/- 10% (or the range specified in USP) of the labeled amount.

CCR 1735.2

...

(a) Training, evaluation, and requalification of personnel involved in the preparation, verification, and or handling of CNSP preparations shall also contain at least the following:

- (1) Quality assurance and quality control procedures,
- (2) Container closure and equipment selection and
- (3) Component selection and handling

CCR 1735.6

...

(b) Any component used to compound a CNSP shall be used, stored, and dispensed, in

accordance with all the following:

- (1) United States Pharmacopeia (USP)- National Formulary (NF),
- (2) Food Drug and Cosmetic Act (FD&CA),
- (3) Food Drug Administration (FDA) issued Guidance Documents and Alerts, and
- (4) Manufacturers' specifications and requirements.

CCR 1735.7

...

(a) A CNSP shall not be compounded until the pharmacy has first prepared a written master

formulation document in compliance with USP Chapter 795 and the following:

- (1) Active pharmaceutical ingredient (API) or added substances identities and amounts shall include at least salt form and purity grade, if available.
- (2) Container–closure systems ~~shall include at least volume~~, and type for each container and closure to be used.
- (3) The reference source of the BUD assignment; each reference shall be fully available at the time of compounding and 3 years from each dispense.
- (4) Instructions for storage and handling of the compounded drug preparation.

1735.11 SOPs

In addition to the requirements in the USP Chapter 795 and referenced chapters

(a) Standard operating procedures (SOPs) shall:

- (1) Comply with Quality Assurance in Pharmaceutical Compounding USP Chapter 1163,
- (2) Include at least the SOPs listed in USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding, and
- (3)

(A) Include methods by which the supervising pharmacist will ensure the quality of compounded drug preparations.

(B) Include procedures for handling, compounding, and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdictional standards.

(C) Include the provisions used by a pharmacist to make the determination and approval, ~~by a pharmacist~~, of the ingredients and the compounding process for each preparation before compounding begins

Dr. Serpa inquired if other committee members agreed to the changes. Committee members Lippe and Schaad agreed.

Dr. Serpa reported she reviewed the recommended changes from the CPhA letter and suggested the committee include the recommendation to remove “dispensed” from CCR 1735.6 as part of the motion. Dr. Serpa reviewed the additional change as the following:

CCR 1735.6

...

(b) Any component used to compound a CNSP shall be used, and stored, ~~and dispensed~~, in accordance with all the following:

- (1) United States Pharmacopeia (USP)- National Formulary (NF),
- (2) Food Drug and Cosmetic Act (FD&CA),
- (3) Food Drug Administration (FDA) issued Guidance Documents and Alerts, and

(4) Manufacturers' specifications and requirements.

Dr. Serpa inquired if other committee members agreed to the changes. Committee members Lippe and Schaad agreed. Dr. Serpa reported with the agreement of Committee members Lippe and Schaad:

Committee Recommendation (Motion): To modify Article 4.5 and to

- Authorize to the board staff to initiate the formal rulemaking process with regard to the changes proposed and
- Authorize the executive officer to make changes to the language consistent with the policies indicated by the board.

Proposal to Repeal Article 4.5 Compounding including Sections 1735-1735.8.

Proposal to Add Article 4.5 as proposed with the following:

Article 4.5 Nonsterile Compounding in Pharmacies

1735. Nonsterile Compounding in Licensed Pharmacies

(a) For purposes of this article, compounding, occurs in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a patient specific prescription.

(b) Repackaging of a compounded nonsterile preparation (CNSP) shall be considered compounding and this article shall apply.

(c) Reconstitution in accordance with directions which have not been FDA approved are considered compounding and all requirements shall apply.

(d) No compounded non-sterile preparations (CNSPs) shall be compounded prior to receipt by a pharmacy of a valid patient specific prescription document where the prescriber has approved use of a compounded drug preparation either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription document prior to compounding. A signed and dated document between a prescriber and a pharmacy may serve as an understanding that all non-commercially available preparations will be compounded the identified patient.

(1) Except that a pharmacy may prepare and store a limited quantity of a CNSP in advance of receipt of a patient specific prescription document where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.

(e) No pharmacy or pharmacist shall compound a CNSP that:

(1) Is classified by the FDA as demonstrably difficult to compound;

(2) Appears on an FDA list of drugs that have been withdrawn or removed from the market because such drugs or components of such drug preparations have been found to be unsafe or not effective; or

(3) Is a copy or essentially a copy of one or more commercially available drug products, unless (A) the drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense, or (B) the compounding of that CNSP is justified by a specific, documented medical need made known to the pharmacist prior to compounding.

The pharmacy shall retain a copy of the documentation of the shortage or the specific

medical need in the pharmacy records for three years from the date of receipt of the documentation.

(4) Is made with any component not intended for use in a CNSP for the intended patient population.

(f) Prior to allowing any drug product preparation to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board (Incorporated by reference is “Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment” Form 17M-39 Rev. XX/XX.) as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations.

(g) In addition to CCR 1707.2, consultation shall be available to the patient and/or primary caregiver concerning proper use, storage, handling, and disposal of a CNSP and related supplies furnished by the pharmacy.

(h) Compounding with blood or blood components shall be done in compliance with Health and Safety Code section 1602.5.

(i) Storing, weighing, measuring, compounding, and/or performing other manipulation of an active pharmaceutical ingredient (API) or added substance deemed hazardous by Occupational Safety and Health (NIOSH) shall be done in compliance with CCR XXX and USP Chapter 800.

(j) Storing, weighing, measuring, compounding, and/or performing other manipulation of an antineoplastic under Occupational Safety and Health (NIOSH) shall be done in compliance with CCR XXX and USP chapter 800.

1735.1. INTRODUCTION AND SCOPE AND COMPOUNDING DEFINITIONS.

In addition to the definitions in the USP Chapter 795 and referenced chapters

(a) “Approved labeling” means the Food and Drug Administration’s (FDA) approved labeling which contains FDA approved information for the diluent, the resultant strength, the container closure system, and storage time.

(b) “Copy or essentially a copy” of a commercially available drug product includes all preparations that are comparable in active ingredients to commercially available drug products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a clinically significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.

(c) “Diluent” is a liquid with no pharmacological activity used in reconstitution, such as water or sterile water for injection.

(d) “Integrity” means retention of potency until the beyond use date provided on the label, so long as the preparation is stored and handled according to the label directions.

(e) “Repackaging” means the act of removing a product or preparation from its original primary container and placing it into another primary container, usually of smaller size without further manipulation, that is not pursuant to a prescription

(f) “Preparation” means a drug or nutrient compounded in a licensed pharmacy; the preparation may or may not be sterile.

(g) “Product” means a commercially or conventionally manufactured drug or nutrient evaluated for safety and efficacy by the FDA.

(h) “Quality” means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula document.

(i) "Strength" means amount of active ingredient per unit of a compounded drug preparation.

(j) "Potency" means an active ingredient strength typical within +/- 10% (or the range specified in USP) of the labeled amount.

1735.2 PERSONNEL TRAINING AND EVALUATION

In addition to the requirements in USP Chapter 795 and referenced chapters.

(a) Training, evaluation, and requalification of personnel involved in the preparation, verification, and/or handling of CNSP preparations shall also contain at least the following:

(1) Quality assurance and quality control procedures,

(2) Container closure and equipment selection and

(3) Component selection and handling

(b) A pharmacist responsible for or directly supervising and controlling compounding of CNSPs, shall demonstrate proficiency in skills necessary to ensure the integrity, potency, quality, and labeled strength of CNSP.

(c) Personnel who fails any aspect of training or demonstrated competency, shall not be involved in the compounding process until after successfully passing reevaluations in the deficient area(s) as detailed in the SOPs.

(d) The pharmacist-in-charge shall be responsible for all activities and decisions made or approved by the designated person(s).

(e) The pharmacy must document that any person assigned to provide training has obtained training and demonstrated competency in any area they will be providing training or observational review.

1735.3 PERSONAL HYGIENE AND GARBING

In addition to the requirements in the USP Chapter 795 and referenced chapters

(a) The supervising pharmacist shall evaluate compounding personnel experiencing any of the following: rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection or and other conditions to determine if such condition could contaminate a CNSP or the environment. The supervising pharmacist shall not allow personnel with potentially contaminating conditions to enter the compounding area.

(b) Prior to entry into the compounding area all hand, wrist, and other exposed jewelry or piercing shall be removed.

(c) A gown and face mask shall be used whenever a closed system processing device is required.

(d) Disposable garb shall not be shared by staff and shall be discarded after each shift and when soiled. Garb removed during a shift must be maintained in the compounding area.

(e) Non-disposable garb shall be cleaned with a germicidal detergent and sanitized with 70% isopropyl alcohol before re-use.

(f) Eye glasses shall be cleaned as part of hand hygiene and garbing per a facility standard operating procedures (SOPs).

(g) Any gowning or garbing accommodation made by the designated person shall be documented and a full assessment of the risk to the CNSPs and environment shall be included.

Documentation and assessment shall be done prior to accommodation taking place.

1735.4 BUILDING AND FACILITIES

In addition to the requirements in the USP Chapter 795 and referenced chapters

- (a) The handwashing stations and scrub sinks used for compounding, hand hygiene, or both, shall not be part of a restroom or water closet.
- (b) Compounding personnel must monitor temperatures in storage area(s) and compounding areas either manually at least once daily on days that the facility is open or by a continuous temperature recording device to determine whether the temperature remains within the appropriate range for the CNSPs or components. This shall be documented.
- (c) Purified water, distilled water, or reverse osmosis water shall be used for rinsing equipment and utensils.
- (d) No CNSP shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures or those required in USP chapter 795.

1735.5 CLEANING AND SANITIZING

In addition to the requirements in the USP Chapter 795 and reference chapters

- (a) Documentation of the cleaning and sanitizing of the compounding area include the personnel completing the cleaning and sanitizing and the cleaning and sanitizing agents used.
- (b) Decontamination, cleaning, disinfecting and sporicidal agents shall be used in accordance with manufacturers' specifications.

1735.6 EQUIPMENT AND COMPONENTS

In addition to the requirements in the USP Chapter 795 and referenced chapters

- (a) Any equipment used to compound CNSP shall be used in accordance with the manufacturer's specifications.
- (b) Any component used to compound a CNSP shall be used, and stored, ~~and dispensed~~, in accordance with all the following:
 - (1) United States Pharmacopeia (USP)- National Formulary (NF),
 - (2) Food Drug and Cosmetic Act (FD&CA),
 - (3) Food Drug Administration (FDA) issued Guidance Documents and Alerts, and
 - (4) Manufacturers' specifications and requirements.
- (c) Any API or added substance used to compound a CNSP shall be obtained from an FDA-registered supplier and shall be accompanied by a valid certificate of analysis (COA). This COA shall be in English and should all the requirements of USP Chapter 1080, Bulk Pharmaceutical Excipient- Certificate of Analysis. All COAs shall be readily retrievable for at least 3 years from last use in CNSP.

1735.7. MASTER FORMULATION AND COMPOUNDING RECORDS

In addition to the requirements in the USP Chapter 795 and referenced chapters.

- (a) A CNSP shall not be compounded until the pharmacy has first prepared a written master formulation document in compliance with USP Chapter 795 and the following:
 - (1) Active pharmaceutical ingredient (API) or added substances identities and amounts shall include at least salt form and purity grade, if available.
 - (2) Container–closure systems ~~shall include at least volume~~, and type for each container and closure to be used.
 - (3) The reference source of the BUD assignment; each reference shall be fully available at the time of compounding and 3 years from each dispense.
 - (4) Instructions for storage and handling of the compounded drug preparation.
- (b) Where a pharmacy does not routinely compound a particular drug preparation, the master formulation record for that preparation may be recorded on the prescription document itself.

This record shall be in compliance with USP 795 and 1735.7(a).

(c) A compounding record shall be a single document and shall include the requirements of USP chapters 795, and 800 as applicable, and the following:

(1) The date and time of preparation shall be the time when compounding started and when the assigned BUD starts.

(2) the assigned internal identification number shall be unique for each compounded drug preparation.

(3) the total quantity compounded shall include the number of units made and volume or weight of each unit.

(4) The identity of the compounder and pharmacist verifying the final drug preparation.

1735.8 RELEASE INSPECTIONS

In addition to the requirements in the USP Chapter 795 and referenced chapters A pharmacist performing, or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, so long as label instructions for storage and handling are followed once the preparation is dispensed.

1735.9 LABELING

In addition to the requirements in the USP Chapter 795 and referenced chapters

(a) A CNSP shall be labeled in compliance with USP Chapter 795 and shall include the following:

(1) Route of intended administration

(2) Name of compounding pharmacy and dispensing pharmacy (if different)

(b) Labeling shall also include:

(1) Any special handling instructions

(2) Any warning statements that are applicable

(3) Name, address, and phone number of the compounding facility if the CNSP is to be sent outside of the facility or healthcare system in which it was compounded

(c) Any CNSP dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required under Business and Professions Code section 4076 and Section 1707.5.

1735.10 ESTABLISHING BEYOND-USE DATES

In addition to the requirements in the USP Chapter 795 and referenced chapters

(a) Beyond use dates (BUDs) assigned with only a date shall expire at midnight at the end of date.

(b) No BUDs shall be assigned that exceed:

(1) The limits specified in USP Chapter 795,

(2) The chemical and physical properties of the drug and/or its formulation,

(3) The compatibility of the container–closure system with the finished preparation (e.g., leachables, interactions, and storage conditions), or

(4) Shortest remaining expiration date or BUD of any of the starting components.

(c)

(1) If the BUD of the CNSP is extended beyond the BUDs in USP Chapter 795, an aqueous CNSP, as defined by USP Chapter 795, shall be tested for antimicrobial effectiveness, in compliance with USP Chapter 51, Antimicrobial Effectiveness Testing.

(2) If a pharmacy chooses to use antimicrobial effectiveness testing results provided by an FDA-registered facility or published in peer-reviewed literature sources the full reference, including the raw data and testing method suitability, and shall be fully available at the time of compounding and three years from each dispense.

1735.11 SOPs

In addition to the requirements in the USP Chapter 795 and referenced chapters

(a) Standard operating procedures (SOPs) shall:

(1) Comply with Quality Assurance in Pharmaceutical Compounding USP Chapter 1163,
(2) Include at least the SOPs listed in USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding, and

(3)

(A) Include methods by which the supervising pharmacist will ensure the quality of compounded drug preparations.

(B) Include procedures for handling, compounding, and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdictional standards.

(C) Include the provisions used by a pharmacist to make the determination and approval, ~~by a pharmacist,~~ of the ingredients and the compounding process for each preparation before compounding begins

(b) Any pharmacy engaged in compounding non-sterile drug preparations shall maintain and follow written policies and procedures for compounding.

(c) The policies and procedures shall be reviewed, and such review shall be documented on an annual basis by the pharmacist-in-charge. The policies and procedures shall be updated whenever changes are implemented. Such changes shall be documented and disseminated to the appropriate staff prior to implementation.

1735.12 QUALITY ASSURANCE AND QUALITY CONTROL

In addition to the requirements in the USP Chapter 795 and referenced chapters

(a) The quality assurance program shall comply with Section 1711 and also include the following:

(1) A written procedure for scheduled action, such as a recall, in the event any compounded drug preparation is discovered to be outside the expected standards for integrity, potency, quality, or labeled strength.

(2) A written procedure for responding to out-of-range temperature variations within the medication storage areas where furnished drug is returned for redispensing.

(3) Compliance with USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding and shall include the integrated components and standard operating procedures.

1735.13 PACKAGING AND TRANSPORTING

In addition to the requirements in the USP Chapter 795 and referenced chapters

(a) There shall be a defined process and documented procedure to ensure temperature sensitive products will arrive at their desired destinations after transporting within the expected quality standards for integrity, potency, quality and labeled strength.

(b) Packaging materials shall protect CNSPs from damage, leakage, contamination, degradation, and adsorption while preventing inadvertent exposure to transport personnel.

(c) A pharmacist supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug preparation.

1735. 14 COMPLAINT HANDLING AND ADVERSE EVENT REPORTING

In addition to the requirements in the USP Chapter 795 and referenced chapters

(a) The pharmacy shall process recalls in compliance with Business and Professions Code section 4126.9.

(b) All complaints related to a potential quality problem with a compounded drug preparation and all adverse events shall be reviewed by the pharmacist-in-charge, this review shall be documented and dated. All complaints shall be handled in compliance with Business and Professions Code section 4126.9.

1735.15 DOCUMENTATION

In addition to the requirements in the USP Chapter 795 and referenced chapters

(a) Pharmacies shall maintain and retain all records required by this article and requirements in the USP chapters in the pharmacy in a readily retrievable form for at least three years from the date the record was last in effect. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).

(b) Records created shall be in an un-editable form. If edits are needed it must be tracked and the person making the edits along with date and time shall be documented. As used in the subdivision: Tracked is means the original documentation is readable and notes any changes made.

Dr. Serpa inquired if there were any board member comments. There were none.

Dr. Serpa inquired if there were any public comments on the motion.

The board heard comments that were previously discussed at the compounding committee. These topics were discussed at committee and the committee came to a consensus based upon the committee meeting. As a result, the topics did not need to be discussed again. These comments included: definition of 503A; definition of repackaging for 795; garbing review by designated person; removal of professional judgement for BUDs; flavoring to not be considered compounding; handling of prescriptions written for products not commercially available; for office use prescribing/supplying for physicians and veterinarians; volume of container closure systems; and continued approved uses of dishwashers and sanitizing agents.

The board heard comments via proxy for a member of the public who couldn't attend the meeting but wanted to comment on disposal of compounded medications; COA certificates required for FDA-approved products; and clarification on how to document a specific provision.

The board provided direction to staff to request clarification from USP on flavoring being considered as compounding. Additionally, the board provided direction to staff to research BPC 4052(a)(1) to see if California law needs to conform to federal law.

Ms. Veale requested clarification that the motion included working on language for authorization of compounded products; send a letter requesting clarification for flavoring; work with the California Veterinary Medical Board. Ms. Sodergren clarified part of the issues are direction from the board to staff.

Support: 7

Oppose: 0

Abstain: 0

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Brooks | | | | x |
| Butler | x | | | |

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Khan | | | | X |
| Kim | | | | X |
| Lippe | X | | | |
| Muñoz | | | | X |
| Sanchez | X | | | |
| Schaad | X | | | |
| Serpa | X | | | |
| Veale | X | | | |
| Wong | X | | | |

Dr. Serpa provided the next committee meeting is scheduled August 28 in Irvine, California.

The board adjourned at 5:09 p.m.

Thursday, July 25, 2019

Acting President Greg Lippe called the meeting to order at 9:04 a.m. Board members present: Ricardo Sanchez, Albert Wong, Lavanza Butler, Greg Lippe, Maria Serpa, Debbie Veale and Allen Schaad. Quorum was established.

VIII. Organizational Development Committee

Chairperson Lippe reported the committee had not yet met so he was providing information updates on general items.

a. Budget Report/Update

Chairperson Lippe reported fiscal year-end figures are not yet available for FY 2017/18. Further, year-end figures for FY 2018/19 cannot be produced until the prior fiscal year closes. Staff reported preliminary figures for FY 2018/19 in the meeting materials which indicate the board estimates it received about \$25.5 million in revenue. Preliminary expenditure figures are only available through May which indicate expenditures of \$20.2 million for the first 11 months of the year.

Mr. Lippe provided the board’s fund condition report prepared by the DCA was available in the meeting materials. He reported based on current information and projections, the board’s fund will be reduced to 0.4 months in reserve by the end of the fiscal year and then slowly starts to restore in subsequent years. This slow rebuild of the fund assumes the board’s fee regulation is approved and becomes effective next calendar year.

b. Board Member Attendance Information

Chairperson Lippe reported a summary of board member attendance for the last fiscal year was available in the meeting materials. He noted this information demonstrates the significant time commitment made by members of this board. Chairperson Lippe thanks the board members for their commitment to the board and its mission.

c. Discussion and Consideration of Committee Meetings and Board Meeting Dates and Locations for Fiscal Year 2019/20

Chairperson Lippe reported the meeting materials included the board and committee meetings currently scheduled for the remainder of the fiscal year. The schedule reflects the action taken during the May 2019 board meeting seeking to consolidate board meetings and committee meetings. Staff are finalizing some meeting locations as included in the meeting materials. This information will be updated on the board's website as well.

d. Discussion and Consideration of Designating all or Portions of the decision, *In the Matter of the Citation Against: Omnicare, Inc., Omnicare Holding Co., dba Omnicare of Cerritos, Case No CI 2014 63230; OAH Case No. 2017070407* as Precedential Pursuant to Government Code Section 11425.60

Chairperson Lippe stated staff is recommending that the board designate the decision in the Matter of the Citation Against Omnicare, Inc., as precedential. He reported a copy of the decision and a copy of the memo from DCA Counsel Kelsey Pruden are available. Mr. Lippe reported making this case precedential would clarify the legal requirements for supervising a pharmacy technician and that general awareness of a pharmacy technician's functions is not sufficient to meet the standard required by board regulation.

Board members expressed concern about further defining direct supervision and control by pharmacists on the premises at all times requiring eyes on and how this will impact other practice settings when the pharmacist is out on rounds, counseling or away from the pharmacy technician when the pharmacist can't have eyes on the pharmacy technician. The board agreed on the original case but are concerned for the interpretation that the processes where pharmacy technicians are trusted to do the work without direct supervision.

The board heard comments from the public in support of board comments on the decision to make this decision precedential. Specifically, concerns were heard around sterile compounding; temporary absence of the pharmacist; filling ADDS machines; and immediate vs direct supervision.

Based on the board member's concern in making this a precedential decision, no action was taken by the board.

e. Update on Implementation of the Acceptance of Credit Cards for Renewal Payments

Chairperson Lippe provided information on acceptance of credit card payments for renewals for six license types. Data provided in the meeting materials demonstrate that renewal payments received online continues to increase with almost 40 percent of renewal payments submitted online via credit cards in June 2019.

f. Sunset Report Update

Chairperson Lippe provided the board will be undergoing the Sunset Review process this fiscal year. To

date the board had not received the report template, but staff are working to collect data based on prior reporting data requirements.

g. Personnel Update

Chairperson Lippe stated the meeting material include the list of staff vacancies which are in varying stages of recruitment.

h. Update on the Relocation of Board Office

Chairperson Lippe reported the relocation of the board's office was completed over the last weekend in June 2019. Board services were limited on June 28 and July 1 but resumed July 2. Staff are working diligently to reduce delays caused by the move.

i. Update on Implementation of SB 1447 (Chapter 666, Statutes of 2018) Pharmacy: automated drug delivery systems.

Chairperson Lippe reported discussions on the legislation occurred at the committee and board level. To mitigate impact to patients currently receiving their medications through an ADDS, board staff started performing inspections in advance of the July 1 implementation date. Staff used information from the board's previous registration requirements to identify pharmacies currently operating ADDS.

Mr. Lippe stated as staff moved forward with implementation, several challenges with regulatory compliance became apparent. To ensure continuity of patient care, and with the approval of the former President and Chairperson Lippe, a subscriber alert was released providing an extension for compliance with the new licensing requirements.

Mr. Lippe provided the number of ADDS licensed increased since the preparation of the meeting materials. There are currently 345 ADDS licensed. Staff continues to work with licenses to remedy deficiencies.

Ms. Veale inquired on the number of pending applications. Ms. Sodergren noted that not all ADDs were maintaining registration, so it is difficult to assess who is not licensed. Ms. Sodergren added the board will focus on education at the beginning of the registration process.

The board received a request for clarification for the registration requirements of ADDs used by physicians for prescriber office use in a non-board licensed facility. DCA Counsel Freedman provided an ADDs license can only be licensed to a pharmacy.

j. Report of Multi-Year Comparisons of Licensing and Enforcement Statistics

Chairperson Lippe noted a decrease in overall investigation time, down 17 percent over the past three years as well as the significant increase in the number of citations issued with a proof of abatement. He also noted a slight decrease in the number of licensees on probation with the board as well as a slight decline in the overall number of licenses revoked. Mr. Lippe reported there was an increase in the number of pharmacists whose licenses were revoked. Mr. Lippe also noted a significant drop in the number of citations issued. The Enforcement Committee reported that this decrease was due to staff vacancies and Mr. Lippe believes it could also be due to the work that he and the former Board

President did in conducting post-issuance reviews of closed cases to ensure the focus on education and not penalty. DCA Counsel Freedman confirmed the cases were closed and review was done after the cases were closed.

The board received comment from the public inquiring if the it was the board’s intention to continue the practice. Chairperson Lippe responded affirmative.

IX. Communication and Public Education Committee

Chairperson Sanchez provided a summary and report of the Communication and Public Education Committee Meeting held July 24, 2019.

a. Discussion and Consideration of Policy on Subscriber Alerts

Chairperson Sanchez reported the board currently has specific email lists (known as “listservs”) for communicating via subscriber alerts with licensees. The board does not have specific lists for communicating with the general public or other non-licensees. At the May 7 committee meeting, staff suggested creating new types of email lists for sending subscriber alerts to the public. The committee directed staff to report back with a plan for new email lists and to consider whether the board should set policy on how subscriber alerts are targeted or give staff discretion to make those decisions.

Mr. Sanchez advised staff proposed creating a new email list for the public to be used for sending subscriber alerts about board and committee meetings, consumer information, press releases, and other types of general news from the board. This would help to reduce the volume of subscriber alerts being sent to licensees and help more effectively communicate with non-licensees.

Mr. Sanchez noted the committee discussed adding a new email list for the public and another new email list for receiving all types of subscriber alerts. Staff recommended the executive officer have discretion to create additional listservs as needed and to determine which types of subscriber alerts are appropriate for each email list. This flexibility would result in better targeting of messages and less volume for licensees. The committee adopted the following recommendation to the board:

Committee Recommendation (Motion): Delegate to the executive officer the ability to expand the board’s listservs to provide more flexibility in communicating with various groups and avoid overloading any listserv with subscriber alerts.

Support: 7 Oppose: 0 Abstain: 0

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Brooks | | | | X |
| Butler | X | | | |
| Khan | | | | X |
| Kim | | | | X |
| Lippe | X | | | |
| Muñoz | | | | X |
| Sanchez | X | | | |
| Schaad | X | | | |

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Serpa | x | | | |
| Veale | x | | | |
| Wong | x | | | |

b. Discussion and Consideration of Proposal to Create Online Search Tool for Pharmacies Providing Health Care Services

Chairperson Sanchez noted the board is committed to informing consumers about new pharmacy services to meet their needs. For example, the board has created a webpage that consumers can search to find locations of drug take-back collection bins. Staff proposed collecting similar information on the board’s website that consumers could search to find pharmacies offering other types of new health care services such as hormonal contraception, naloxone, vaccinations, and travel medications.

These listings would be voluntary. The board would invite pharmacies that want to be listed on the website to provide information about their types of services, location, hours, etc., and to also notify the board of any changes. Additionally, staff suggested possibly providing links on the board’s website to other websites that also provide listings of pharmacies that provide hormonal contraception and naloxone. The committee indicated a preference for a single comprehensive listing on the board’s website rather than links to various lists on other websites. The committee adopted the following recommendation to the board:

Committee Recommendation (Motion): Direct staff to evaluate the possibility of creating a list of California pharmacies providing health care services for posting on the board’s website and the resources that would be necessary to implement the list.

Dr. Serpa requested clarification if the committee determined internal or external lists would be used. Ms. Veale clarified the committee wanted to start with voluntary internal lists. Public Information Officer Bob Dávila noted the committee’s intent was to have an internal list that the board would maintain control of the content. This addressed Dr. Serpa’s concern.

The board received request for clarification if associations can submit on behalf of members. Ms. Sodergren clarified that the vision is an online portal where people are able to add the information into the portal for themselves.

The board received comments in favor of the motion requesting voluntary be added to the motion as well as adding pharmacies and pharmacists.

The committee members agreed to amend the following motion to add “voluntary” and add “pharmacies and pharmacists.”

Amended Committee Recommendation (Motion): Direct staff to evaluate the possibility of creating a voluntary list of California pharmacies and pharmacists providing health care services for posting on the board’s website and the resources that would be necessary to implement the list.

Support: 7 Oppose: 0 Abstain: 0

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Brooks | | | | X |
| Butler | X | | | |
| Khan | | | | X |
| Kim | | | | X |
| Lippe | X | | | |
| Muñoz | | | | X |
| Sanchez | X | | | |
| Schaad | X | | | |
| Serpa | X | | | |
| Veale | X | | | |
| Wong | X | | | |

c. Discussion and Consideration of Proposed Brochure about Pharmacy Inspections

Chairperson Sanchez provided board staff have been working on an information brochure about pharmacy inspections. The brochures will be posted online so that pharmacies can know in advance what to expect during an inspection. In addition, inspectors will hand out brochures when they arrive for an inspection.

Mr. Sanchez noted a copy was provided in meeting materials. DCA Counsel pointed out that text has been changed to reflect that citations and letters of admonishment are not disciplinary actions, and there is no formal hearing process for letters of admonishment.

Mr. Sanchez added the committee requested adding to the brochure reasons why pharmacies are inspected – for example, some are routine inspections, while others may be related to a complaint. The committee also requested wording emphasizing an inspection is an opportunity for licensee education and highlighting the process.

d. Discussion and Consideration of the Committee’s Strategic Goals

Chairperson Sanchez reported the board finalized its strategic plan in 2016. The plan includes eight strategic goals for communication and public education. These goals were provided in the committee report in the board meeting materials.

Mr. Sanchez noted at the committee meeting July 24, 2019, staff presented a brief status report on each goal for the committee to review and provide comments, suggestions or direction for additional progress. The committee urged continued progress and made no changes to the strategic plan goals.

Mr. Sanchez noted the committee asked what efforts have been made to collect mobile numbers from all licensees for text messaging to improve communications, as specified in goal 4.3. staff noted that legislation was adopted requiring licensees to register their email addresses with the board but not mobile numbers. The committee asked staff to recommend changes to refresh the “Notice to Consumers” poster and “Point to your language” notice in accordance with goal 4.7, which relates to revising consumer-facing materials to improve consumer awareness of their rights and how to take their medications.

e. Update on Communication and Public Education Activities by Board Staff

PIO Dávila reported staff is working on the next issue of The Script. Publication is expected this summer. Staff developed a tip sheet to help consumers plan and prepare for possible evacuation from their homes during a declared disaster. The tips sheet has been approved by legal counsel and will be posted on the board's website. Mr. Dávila provided a list of inquiries received from news reporters was provided in the meeting materials.

Mr. Dávila reported more than 80 pharmacists attended the board's CE forum on drug abuse and drug diversion on July 20 in Marin County. The board has hosted 12 of these events since March 2017. He also reported the total number of pharmacists who have completed the board's CE webinars on pharmacy law, ethics and naloxone training as of June 30, 2019:

- Law – 13,754
- Ethics – 3,359
- Naloxone – 2,023.

Dr. Wong requested the committee would like information provided on the board's website to warn licensees on the consequences of driving under the influence and the impact on the license. The issue was forwarded to the committee for review.

f. Future Meeting Dates

The committee's next meeting will be November 5, 2019.

The board took a break at 10:20 a.m. and resumed at 10:35 p.m.

Interim Executive Officer Sodergren reported to the board as a follow up to Organizational Development Committee report that there were 274 ADDs applications pending. Of the 274 pending applications, 174 of those applicants were sent a deficiency letter identifying outstanding items required to be provided in order to be issued a license.

Ms. Sodergren advised the board that the service ticket to remove the individual licensees' address of record from the board's website was submitted to DCA's Office of Information Services.

X. Legislation and Regulation Committee

Chairperson Lippe provided an update on the Legislation and Regulation Committee Meeting held July 24, 2019.

- a. Discussion and Consideration of Implementation of Business and Professions Code Section 4113.5 (SB 1442, Statutes 2018) Regarding Pharmacist Assistance and Possible Regulations to Clarify Statutory Language**

Chairperson Lippe reported recently enacted legislation (Senate Bill 1442, Statutes of 2018) added BPC Section 4113.5 regarding pharmacist assistance. Since enactment, the board has received public comments at committee and board meetings indicating that pharmacy employers may not be complying with the law as intended. At the May 2019 meeting, the board considered a Petition for Rulemaking to Implement Business and Professions Code Section 4113.5, Regarding Pharmacist Assistance. Following discussion during that May 2019 meeting, the board referred the development of regulation language to the Legislation and Regulation Committee.

Mr. Lippe advised the committee reviewed a draft regulation proposal seeking to address public comments previously received and provided in meeting materials. He noted the proposed language seeks to address some primary areas of the statute that appear to require further clarification via regulation:

1. Definition of “make available to assist”
2. Background requirements for the designated personnel
3. Policies and procedures

Mr. Lippe reported the committee received significant public comment on the proposal and most comments seemed to indicate that the approach being offered was workable. The committee heard comments that expressed concern with the documentation requirement and that it may be to laborious. It was suggested that requiring documentation of exceptions when assistance was not available may be more appropriate. Others stated the proposed documentation requirements are appropriate.

The committee also heard comments regarding the proposed 5-minute response time. Some commenters suggested replacing a specific response time with “reasonable time” but concern was raised about such language. It was suggested that it may be appropriate to consider comments received during the rulemaking on this topic before making changes to the language.

Further commenters spoke in opposition to establishing the requirement that designated employees should be able to perform the tasks “other non-licensed pharmacy personnel” may perform under the provisions of CCR 1793.3 and offered that “minimally trained in pharmacy operations” may be more appropriate. The committee disagreed with the approach offered.

Other comments suggested that the provisions to provide pharmacist assistance should expand to other pharmacies such as hospitals that are currently exempt from the underlying statutory provisions.

After consideration of the comments, the committee offered the following recommendation:

Committee Recommendation (Motion): Recommend approval of this proposed rulemaking to include approval of the proposed addition of Section 1714.3, Community Pharmacy Staffing and initiate the formal rulemaking process. Further, delegate to the executive officer the authority to make any non-substantive changes and clarifying changes consistent with the board’s policy direction upon recommendations of the control agencies.

Ms. Veale inquired if the committee should refine the language before moving forward. Chairperson Lippe and Committee Member Butler agreed with moving forward with this motion.

The board heard comments in support of the language proposed as being better and more eloquent than the original proposal.

The board also heard comments in support of referring the language back to committee to vet out items of disagreements including documentation and impacts to patient safety to a subsection of pharmacy.

Support: 6 Oppose: 1 Abstain: 0

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Brooks | | | | X |
| Butler | X | | | |
| Khan | | | | X |
| Kim | | | | X |
| Lippe | X | | | |
| Muñoz | | | | X |
| Sanchez | X | | | |
| Schaad | X | | | |
| Serpa | X | | | |
| Veale | | X | | |
| Wong | X | | | |

b. Discussion and Consideration of Board Sponsored Legislation

Chairperson Lippe provided the committee discussed board-sponsored legislation.

1. AB 690 (Aguiar-Curry) Pharmacies: Relocation: Remoted Dispensing Site Pharmacy: Pharmacy Technician: Qualifications

Mr. Lippe reported as amended July 1, 2019, this measure includes the board’s provision that would establish the limited exemption to the license transferability requirements for a pharmacy required to relocate because of damage caused by a declared disaster. This measure also includes the requirements for a pharmacy technician working in a remote dispensing site pharmacy. This portion of the measure is not board sponsored. Mr. Lippe noted as amended the measure increased the number of hours of experience a pharmacy technician must have to work in a remote dispensing site pharmacy. As amended it will require 2,000 hours. The measure is on the Senate Third Reading file.

2. AB 973 (Irwin) Pharmacies: Compounding

Mr. Lippe provided this measure was amended May 13, 2019. If enacted, this measure will clarify that the compounding of drug preparations by a pharmacy must be prepared consistent with the relevant compounding chapters of the United States Pharmacopeia-National Formulary. This measure is pending consideration by the Senate Appropriations Committee.

The board heard comments requesting the board seek amendments later in the legislative cycle to allow for the board to retain authority to remove items from USP if in the best interest of the people of California. Mr. Lippe inquired if the board could do this legally. DCA Counsel Freedman indicated under California law, statutes could be amended but questioned if there was a federal law that would prevent it. Ms. Sodergren responded this is a board sponsored measure and wouldn't recommend seeking an amendment at this time in the legislative cycle. Ms. Sodergren recommended identifying if this is feasible before taking action. Dr. Serpa spoke in support of keeping the current process and not seeking a change at this time.

3. SB 569 (Stone) Controlled Substances: Prescriptions: Declared Local, State or Federal Emergency

Mr. Lippe reported as amended July 2, 2019, this measure would authorize a pharmacist, during a declared local, state, or federal emergency to fill a prescription for a controlled substance on a prescription form that does not conform with security prescription form requires under specified conditions. As amended, the patient must demonstrate to the pharmacist their inability to access medications and provides that proof of residency within an evacuation area is an acceptable manner. Further the amendments provide that a CII prescription cannot be provided for more than a seven-day supply and prohibit the refill of a prescription provided under these provisions. This measure is awaiting consideration and action by the Assembly Appropriations Committee.

4. SB 655 (Roth) Pharmacy

Mr. Lippe provided as amended April 11, 2019, this measure would update several provisions of pharmacy law including alignment of application and renewal requirements and other technical cleanup provisions relating to the following areas:

- Validity period for pharmacy examination scores
- Pharmacy technician trainee provisions
- Advanced practice pharmacist renewal requirements
- Reverse distributor provisions
- Government-owned facility fees

This measure was referred to the Assembly consent calendar.

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

Chairperson Lippe updated the board on measures that impact the practice of pharmacy or the board's jurisdiction.

1. AB 387 (Gabriel) Task Force: Adverse Drug Events: Prescriptions

Mr. Lippe provided as Amended July 2, 2019, this measure creates the Prescription Labeling and Adverse Drug Event Advisory Task Force to study and make recommendations on how to increase medication adherence and decrease adverse drug events. The board had a Support

position on the prior version of this bill that would have provided for the purpose of the medication to be included on the prescription. Staff noted some concerns with this measure in the analysis, including the deadline to complete the mandated report submission of September 2, 2020, as well as the provision of the bill that requires the board to cover all costs associated with the measure within existing resources. The measure is awaiting action by the Senate Appropriations Committee.

Mr. Lippe noted during the committee meeting, the committee discussed staff concerns as well as public comment regarding the broad nature of the measure. Based on the concerns expressed and consideration of the issues, the committee is recommending that the board change its position to Oppose Unless Amended.

Committee Recommendation (Motion): Recommend the board change its position on AB 387 (Gabriel) to Oppose Unless Amended.

Ms. Veale inquired why the Oppose Unless Amended position was recommended. Mr. Lippe clarified the committee’s view was that the deadline of September 2020 was burdensome and the broadness of the legislation. Ms. Sodergren added the committee heard public comment for concern of the broadness of the task force.

Support: 7 Oppose: 0 Abstain: 0

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Brooks | | | | X |
| Butler | X | | | |
| Khan | | | | X |
| Kim | | | | X |
| Lippe | X | | | |
| Muñoz | | | | X |
| Sanchez | X | | | |
| Schaad | X | | | |
| Serpa | X | | | |
| Veale | X | | | |
| Wong | X | | | |

2. AB 528 (Low) Controlled Substances: CURES Database

Mr. Lippe advised as amended July 3, 2019, the measure would require expanding reporting requirements to also include Schedule V drugs and would reduce the reporting period to CURES to within one business day. The committee noted yesterday that the measure will also create a reporting requirement for veterinarians. During the May 2019 board meeting, the board established a support if amended position.

Mr. Lippe reported the committee recommended the board change its position to support primarily because of two key provisions, the inclusion of C-Vs and the reduced reporting period both of which were provisions in a board sponsored measure last year that died in committee. The measure is currently with Senate Rules.

Mr. Lippe provided during discussion, the committee was asked to place an item on a future agenda to discuss the challenges with cancelling a prescription reported to CURES when the medication is not provided to the patient.

Committee Recommendation (Motion): Recommend the board change its position on AB 528 (Low) to Support.

Ms. Veale inquired about the change. Ms. Sodergren provided it now includes Schedule 5.

The board heard public comments about implementation time and noted the bill doesn't involve the Department of Justice but allows the board discretion to transition. Mr. Lippe provided transition periods are allowed for enforcement.

Support: 7 Oppose: 0 Abstain: 0

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Brooks | | | | X |
| Butler | X | | | |
| Khan | | | | X |
| Kim | | | | X |
| Lippe | X | | | |
| Muñoz | | | | X |
| Sanchez | X | | | |
| Schaad | X | | | |
| Serpa | X | | | |
| Veale | X | | | |
| Wong | X | | | |

3. AB 690 (Aguiar-Curry) Remote Dispensing Site Pharmacy: Pharmacy Technician: Qualifications

This measure was not discussed.

4. AB 1076 (Ting) Criminal Records: Automatic Relief

Mr. Lippe reported as amended July 11, 2019, this measure would require the DOJ to review summary criminal history information and identify individuals who are eligible for automatic relief by having their arrest and criminal records withheld from disclosure. It would also require the DOJ to provide automatic relief to eligible persons. In the staff analysis, recent amendments restore the ability of certain entities licensed under the Health and Safety Code (child care licensing entities, residential care licensing entities, and community care facility licensing entities) to consider and act on criminal convictions. Regrettably this restoration of authority does not include the board. The measure is currently awaiting consideration and action by the Senate Appropriations Committee. Mr. Lippe advised as the board's amendments were not accepted the committee's recommendation is to change the board's position to an Oppose position.

Committee Recommendation (Motion): Recommend the board change its position on AB 1078 (Ting) to Oppose.

Support: 7

Oppose: 0

Abstain: 0

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Brooks | | | | X |
| Butler | X | | | |
| Khan | | | | X |
| Kim | | | | X |
| Lippe | X | | | |
| Muñoz | | | | X |
| Sanchez | X | | | |
| Schaad | X | | | |
| Serpa | X | | | |
| Veale | X | | | |
| Wong | X | | | |

5. AB 1131 (Gloria) Medi-Cal: Comprehensive Medication Management

Mr. Lippe reported as amended June 24, 2019, this measure would establish that comprehensive medication management (CMM) services are covered by Medi-Cal and would require CMM services to include a care plan that would encompass and identify medication therapy problems. The measure would establish the minimum criteria to receive CMM services and would require the Department of Health Care Services to establish reimbursement rates for pharmacists providing such services. This measure is awaiting consideration by the Senate Appropriations Committee. The committee is not recommending any change in the board’s current support position.

6. AB 1264 (Petrie-Norris) Medical Practice Act: Dangerous Drugs: Appropriate Prior Examination

Mr. Lippe advised as amended June 25, 2019, this measure would specify that an appropriate prior examination does not require a synchronous interaction between a patient and licensee, provided the licensee complies with the appropriate standard of care. Neither the committee nor board has previously considered this measure. The measure appears to be providing clarification on how a prescriber can use alternative technologies such as mobile apps to ascertain information from a patient to determine if a prescription medication is appropriate. This measure is currently on the Senate Third Reading File. Mr. Lippe stated he personally did believe the board should take a position on this bill unless they have concerns about consumer protection.

The board heard public comment providing background about the bill’s original intent for appropriate prior examination with respect to self-administered contraception class of medication and has been subsequently amended to include general prescribing statute. The concern brought to the board is that it could be opened up to internet prescribing and encouraged an Oppose or Oppose Unless Amended position. No motion was made.

7. SB 159 (Wiener) HIV Preexposure and Postexposure Prophylaxis

Mr. Lippe reported as amended July 1, 2019, this measure would authorize a pharmacist to furnish preexposure and postexposure prophylaxis in specified amounts and under specified conditions. Under the provisions of the bill the board would be required to promulgate regulations, including emergency regulations consistent with the CDC guidelines. The measure is currently awaiting consideration and action by the Senate Appropriations Committee.

Mr. Lippe reported the committee received comments noting that it is an important public health measure. The board previously held a Support position. The committee does not recommend a change in our current position.

The board heard public comment in support of the Support position and encouraged education if the bill is passed.

8. SB 601 (Morrell) State Agencies: Licenses: Fee Waiver

Mr. Lippe advised as amended June 27, 2019, this measure would provide authority for the board to establish a process for an individual or business to seek a reduction in fees, if such an individual or entity was displaced or affected by a declared disaster. This measure is currently awaiting consideration and action by the Assembly Appropriations Committee. The committee previously established a Support position and the committee did not recommend any change.

9. SB 650 (Rubio) Unused Medications: Cancer Medication Recycling

Mr. Lippe noted as amended July 8, 2019, this measure would require the board to establish a Cancer Medication Advisory Committee to identify the best mechanisms to enable the transfer of unused cancer medications to individuals in need of financial assistance. When the committee last discussed this measure, the committee did not take a position. The measure has since been amended. The measure is currently awaiting consideration and action by the Assembly Appropriations Committee.

The committee discussed that while the policy goal of the measure is notable, the general practice of recycling medications that have been in the control of patients may not be the best way to assist patients that need financial assistance to obtain cancer medication. Mr. Lippe recommended that the committee seek amendments to empower the task force to research the best solutions to aid cancer patients in need of financial assistance with receiving ready access to affordable medications rather than limiting the scope as the legislation currently provides. After discussion and consideration, the committee recommends establishing an Oppose Unless Amended position to address the concerns raised during the discussion.

Committee Recommendation (Motion): Recommend the board establish its position on SB 650 (Rubio) as Oppose Unless Amended.

Support: 7

Oppose: 0

Abstain: 0

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Brooks | | | | X |
| Butler | X | | | |
| Khan | | | | X |
| Kim | | | | X |
| Lippe | X | | | |
| Muñoz | | | | X |
| Sanchez | X | | | |
| Schaad | X | | | |
| Serpa | X | | | |
| Veale | X | | | |
| Wong | X | | | |

Regulations Portion

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

Mr. Lippe provided the board had one regulation package currently under post adoption review, the proposed Regulations to Amend Title 16 CCR Section 1749 Related to the Board’s Fee Schedule. The board adopted the regulation during its June 21, 2019 meeting. The rulemaking was submitted for final review on June 24, 2019.

e. Discussion and Consideration of Board Approved Regulations Undergoing Preparation of Post Adoption Documents by Board Staff for Final Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency

Mr. Lippe reported the board’s regulation to update the Naloxone Fact Sheet was adopted during the board’s June meeting as well. Staff are in the process of finalizing the rulemaking prior to submission to the department to initiate final review. Staff have advised this should be completed by mid-August.

f. Discussion and Consideration of Board Approved Regulations Undergoing Pre-Notice Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency

Mr. Lippe reported the board has a number of regulations undergoing prenotice review. Within the meeting materials is a summary of each regulation as well as the current status. Regulations without any update in activity for 30 days are noted in red ink and full timelines are included in the attachment.

Mr. Lippe stated at committee he was troubled by the number of regulations that have been in the same pending status since 2018. He would like to ask staff to work with DCA to determine what steps can be done to address what appears to be back log. It would appear to be a fair expectation to see progress with many of these regulations by the September 2019 Board Meeting. Mr. Lippe suggested the board request an update on regulations at each board meeting, including petitioner meetings until such time as this issue is addressed.

Ms. Veale agreed the time spent in pre-review prevents the board from making any changes as the regulations are waiting to be processed. Ms. Sodergren advised the regulations could be pulled back or dealt with during the rulemaking process. Ms. Sodergren provided the department has established a regulations unit that will assist with the processing time.

Ms. Veale expressed concern for the processing time of the future rulemaking for pharmacists left working alone. Mr. Lippe provided the statute exists. Ms. Sodergren added the regulation will add clarity to the statute. DCA Counsel Freedman added the motions for rulemaking authorize the executive officer to make changes consistent with the board's policy which would allow for changes to be made if laws are changed.

g. Discussion and Consideration of Committee's Strategic Goals

Mr. Lippe reported during the committee meeting, the committee reviewed the strategic goals for our committee.

3.1 Educate the board on national pharmacy initiatives impacting consumers and the future of pharmacy (e.g., pharmacists, pharmacy, technicians, distributors, etc.) to strategize the board's efforts in alignment with where the profession is going to be in 2020.

In the past, Ms. Herold would provide updates from national meetings she attended. Since her retirement, board staff have not had the opportunity to attend the NABP.

3.2 Support legislative and regulation proposals from board approval to enactment to effectuate the goals of the board.

Mr. Lippe provided a status on this goal for this fiscal year the board is sponsoring 4 legislative proposals. Further the board currently has 14 regulation packages in various status of promulgation.

3.3 Advocate for or against legislation that impacts the board's mandate for consumer protection.

Mr. Lippe updated the board with a status that during the legislative year, the board established support positions on 9 measures and oppose positions on 3 measures.

3.4 Establish a systemized, ongoing review process for board regulations to improve and maintain clear and relevant regulations.

Mr. Lippe provided board staff and counsel are working to improve the quality of regulation packages including ensuring regulation language is clear, consistent, and necessary.

The committee was in support of the current goals and are not recommending any changes.

h. Future Committee Meeting Dates

Chairperson Lippe reported the committee's next meeting will be November 5, 2019.

XI. Update from the Department of Consumer Affairs

The Department of Consumer Affairs provided a written update distributed at the meeting to board members and the public.

The board recessed to closed session at 11:39 a.m.

The board reconvened in open session at 1:16 p.m. and adjourned the meeting at 1:17 p.m.

III. Approval Board Meeting Minutes

b. September 13, 2019



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

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



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

Date: September 13, 2019

Location: California State Board of Pharmacy
2720 Gateway Oaks Drive
Board of Pharmacy Hearing Room, First Floor
Sacramento, CA 95833

Board Members

Present: Gregory Lippe, Public Member, Acting President/Vice President
Allen Schaad, Licensee Member, Treasurer
Ryan Brooks, Public Member
Shirley Kim, Public Member
Maria Serpa, Licensee Member
Deborah Veale, Licensee Member

Board Members

Not Present: Lavanza Butler, Licensee Member
Valerie Muñoz, Public Member
Ricardo Sanchez, Public Member
Albert Wong, Licensee Member

Staff Present:

Anne Sodergren, Interim Executive Officer
Laura Freedman, DCA Staff Counsel
Kristina Jarvis, Deputy Attorney General
Julie Ansel, Chief of Enforcement
MaryJo Tobola, Senior Enforcement and Administration Manager

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

Acting President Greg Lippe called the meeting to order at approximately 9:00 a.m. Mr. Lippe advised that the board may be unable to establish or maintain a quorum. As a result, some items may be taken out of order or may not be able to be addressed unless a quorum can be established for a portion of the meeting. Mr. Lippe advised at the start of the meeting, the board does not have a quorum.

Mr. Lippe provided pursuant to Business and Professions Code section 4309 and board policy,

members will consider disciplinary matters as a committee of the board unless a quorum is reached.

Roll call was taken. Board Members Present: Allen Schaad, Shirley Kim, Deborah Veale, Maria Serpa and Greg Lippe. A quorum was not established.

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

Mark Rouse, a pharmacist since 1984, began to comment on a complaint investigation. DCA Counsel Freedman explained the board members would not be able to hear about a complaint that was filed as it could be considered ex parte communication. If the complaint is further processed, it would be presented to the board. Ms. Freedman recommended following up with Enforcement Staff. Interim Executive Officer referred Mr. Rouse to Chief of Enforcement Julie Ansel.

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

There were no 40-year pharmacists in attendance.

IV. Board Officer Elections

Due to lack of quorum, the board was unable to address this agenda item.

V. Discussion and Consideration of Request from American University of Health Sciences, School of Pharmacy, for Board Recognition Pursuant to Title 16, California Code of Regulations Section 1719

Due to lack of quorum, the board was unable to address this agenda item.

The board took a break at approximately 9:14 a.m. and resumed at approximately 9:30 a.m.

Roll call was taken after the break. Board members present include: Board Members Present: Allen Schaad, Shirley Kim, Deborah Veale, Ryan Brooks, Maria Serpa and Greg Lippe. A quorum was not established.

VI. Petitions for Reinstatement of Licensure, Early Termination, or Other Reduction of Penalty

Administrative Law Judge Heather Rowan presided over the following petitions for reduction of penalties.

- a. Jennifer Hoerrner, RPH 52366
- b. Rashmi Mediratta, RPH 57047

VII. Closed Session Matters

The board recessed to closed session at approximately 12:15 p.m.

IX. Reconvene Open Session

The board returned to open session at approximately 1:06 p.m.

X. Adjournment Upon Conclusion of Business

Acting President Lippe adjourned the meeting at 1:07 p.m.

III. Approval Board Meeting Minutes

c. October 3, 2019



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

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



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

Date: October 3, 2019

PRIMARY LOCATION (MEMBERS/STAFF): California State Board of Pharmacy
 2720 Gateway Oaks Drive, Room 105
 1st Floor Hearing Room
 Sacramento, CA 95833

ADDITIONAL TELECONFERENCE LOCATIONS (MEMBERS):

6410 Palos Verdes Dr South
 Rancho Palos Verdes, CA 90275

2280 Ward Avenue, 1st floor
 Simi Valley, CA 93065

550 Montgomery, 10th floor,
 Tweed Room
 San Francisco, CA 94111

388 9th Street, Suite 108
 Oakland, CA 94607

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

The board was unable to establish quorum and the board meeting was cancelled.

III. Approval Board Meeting Minutes

d. October 14, 2019



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

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



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

Date: October 14, 2019

PRIMARY LOCATION (MEMBERS/STAFF): California State Board of Pharmacy
2720 Gateway Oaks Drive, Room 105
1st Floor Hearing Room
Sacramento, CA 95833

ADDITIONAL TELECONFERENCE LOCATIONS (MEMBERS):

6410 Palos Verdes Dr South
Rancho Palos Verdes, CA 90275

2280 Ward Avenue, 1st floor
Simi Valley, CA 93065

15330 Amar Road, Suite A
La Puente, CA 91744

1695 Eastshore Highway, Main Conference Room
Berkeley, CA 94710

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

The board was unable to establish quorum and the board meeting was cancelled.