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

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

Date: January 8, 2025

Location: OBSERVATION AND PUBLIC COMMENT IN PERSON:
California Department of Consumer Affairs
1625 North Market Blvd., First Floor Hearing Room
Sacramento, CA 95834

PUBLIC PARTICIPATION AND COMMENT FROM A REMOTE LOCATION: WebEx

Board Members Present:
Seung Oh, PharmD, Licensee Member, President
Jessica Crowley, PharmD, Licensee Member, Vice President (via WebEx)
Trevor Chandler, Public Member, Treasurer
Renee Barker, PharmD, Licensee Member
Jeff Hughes, Public Member
Kartikeya "KK" Jha, RPh, Licensee Member (via WebEx)
Jason "J." Newell, MSW, Public Member
Satinder Sandhu, PharmD, Licensee Member
Maria Serpa, PharmD, Licensee Member

Board Members Not Present:
Indira Cameron-Banks, Public Member
Nicole Thibeau, PharmD, Licensee Member
Jason Weisz, Public Member

Staff Present:
Anne Sodergren, Executive Officer
Julie Ansel, Deputy Executive Officer
Corinne Gartner, DCA Staff Counsel
Shelley Ganaway, DCA Staff Counsel
Norine Marks, DCA Regulations Counsel
Jennifer Robbins, DCA Regulations Counsel
Sara Jurrens, Public Information Officer
Debbie Damoth, Executive Specialist Manager

January 8, 2025

I. Call to Order, Establishment of Quorum, and General Announcements (Including Possible Notifications, Actions, and Disclosures Pursuant to Government Code section 11123.2(j))

President Oh called the Board meeting to order at approximately 9:00 a.m. Dr. Oh provided information regarding emergency exit routes from the hearing room for the benefit of those attending the meeting in person. He also announced that the Enforcement and Compounding Committee meeting and the Communication and Public Education Committee meeting scheduled for January 9, 2025, were both cancelled. Dr. Oh further announced that the Board had released a subscriber alert that morning regarding the state of emergency for the Palisades fire in Los Angeles County, and that additional subscriber alerts would be sent if waivers were issued as a result of the state of emergency.

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

Roll call was taken. The following Board members were physically present in Sacramento: Trevor Chandler, Public Member; Renee Barker, PharmD, Licensee Member; Jeff Hughes, Public Member; J. Newell, MSW, Public Member; Satinder Sandhu, PharmD, Licensee Member; Maria Serpa, PharmD, Licensee Member; and Seung Oh, PharmD, Licensee Member. Jessi Crowley, PharmD, Licensee Member, and KK Jha, RPh, Licensee Member, participated via WebEx. Dr. Crowley and Mr. Jha each disclosed that no persons over 18 years old were present in the room with them as they participated in the meeting remotely via WebEx. A quorum was established.

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

President Oh reminded those present that the Board recognizes pharmacists who have been licensed for 40 or more years by posting the information on the Board's website and providing pharmacists with a certificate. President Oh invited pharmacists licensed for 40 years or more to identify themselves and be recognized by the Board. There were no pharmacists identifying themselves to be recognized for 40 years of service as a pharmacist. Dr. Oh thanked and congratulated pharmacists who had been licensed as a pharmacist for over 40-years. Dr. Oh thanked all pharmacy staff who worked in pharmacy serving the consumers of California.

III. Discussion and Possible Action Related to Proposed Regulations, Title 16, California

Code of Regulations, Repeal of Sections 1708.3, 1708.4, 1735 et seq., and 1751 et seq. and Addition of Sections 1735 et seq., 1736 et seq., 1737 et seq., and 1738 et seq. Related to Compounded Drug Preparations, Hazardous Drugs, and Radiopharmaceuticals, and Review of Comments Received During the 30-Day Comment Period

Dr. Oh advised that in response to the Board's 30-day comment period on the proposed regulations regarding sterile and nonsterile compounding, hazardous drugs, and radiopharmaceuticals, the Board continued to receive significant engagement from interested stakeholders. He recalled that during the September 2024 Board meeting, members requested additional education on this complex area of practice. He further noted that at the November 2024 Board meeting, consistent with the Board's request and as agendized, the Board received presentations on relevant legal requirements and background on compounding, and that the presentations are available on the Board's website.

Dr. Oh noted that the meeting materials included the modified text released for the 30-day comment period, comments received during the 30-day comment period, staff recommended responses to comments received, a letter from the Medical Board of California, and staff recommended second modified text dated January 8, 2025.

Dr. Oh thanked stakeholders for continuing to engage in the rulemaking process. He also thanked Members Serpa and Barker for reviewing the comments received and working with staff to provide recommendations for the Board's consideration today. Dr. Oh noted that he had reviewed the information and looked forward to the Board's discussion and action. Dr. Oh then asked Dr. Serpa to provide an overview of the recommended changes.

Dr. Serpa thanked stakeholders for their responses and noted that the comments and recommendations received were very helpful to the Board as it considers modifications to the proposed text. Dr. Serpa also thanked Dr. Barker for sharing her expertise and time.

Dr. Serpa reminded all present that the development of these regulations began in 2019 with a series of public meetings convened by the Enforcement and Compounding Committee and the Board. In November 2019, in light of the delays with USP, the Board released a Policy Statement to provide stakeholders with guidance on the applicability of the Board's compounding regulations and USP compounding chapters while appeals were pending before the USP Committee. Following the USP consideration of appeals and finalization of the chapters, the Enforcement and Compounding Committee resumed its efforts to review the Board's compounding regulations in January 2023, providing again numerous opportunities for stakeholders to participate in the Board's development of the proposed regulations.

Dr. Serpa provided a reminder that the Board has a statutory mandate to review Board regulations when USP is updated, and noted that although the Board started this review early, it was now well beyond the November 1, 2023, date that the updated USP chapters became compendial.

Dr. Serpa again thanked those who provided written comments to the proposed regulations. She expressed concern that some commenters appeared to be seeking changes to lessen the standards of existing law and noted that in considering all comments received, the Board must reflect on its consumer protection mandate.

Dr. Serpa reminded those present that the proposed regulations were to clarify or make more specific California compounding regulations in light of USP chapter updates that became effective November 1, 2023. The proposed regulations generally do not repeat federal law or USP standards but clarify the Board's standards for compounding along with the federal law and USP standards. She added as a further reminder that the proposed regulations have been reorganized to follow the organizational format of the USP chapters.

Dr. Serpa began her overview of the changes being recommended to the regulatory text in response to comments received with proposed Article 4.5 related to nonsterile compounding. She highlighted the following recommendations being offered by staff in response to comments received:

- Minor recommendations in section 1735, compounding definitions, to make clear that the pharmacist-in-charge (PIC) can serve as the designated person. It was also recommended that the definition of "essentially a copy" be further amended to clarify that a pharmacist is responsible for verifying and documenting the clinical significance determined by the prescriber.
- Modifications to section 1735.1(d) to allow an increase to a 14-day supply for veterinary patients. In addition, after discussion with the Board's veterinarian expert, staff recommend a change to 1735.1(e)(2) to reflect some of the provisions included in the Guidance for Industry #256 consistent with comments received. Also in this section, staff recommend including expanded conditions for health care facilities to compound a commercially available product under specific conditions, and the addition of new language related to facilities that limit compounding to combining a flavoring agent as specified, including a general exemption from the Board's nonsterile compounding requirements except where specified.
- Clarification is being recommended in section 1735.6(a) related to manufacturer specifications for use of equipment.
- A recommendation is made to remove the requirement in section 1735.7(c)(1) related to inclusion of the date and time of compounding for determining the beyond use date.

- Modification of section 1735.12(a) to remove the requirement for a written procedure for responding to out of range temperatures in some specified situations.
- Addition of new section 1735.15 specifically related to flavoring agents.

Members were provided an opportunity to comment. Members discussed ensuring section 1735.1(e)(1)(A) was consistent with federal law; specific changes that may need to be made to sections 1735.11(a)(2)(F) and 1735.12; UC Health's comments to these sections of the proposed regulations; and the new provisions regarding flavoring.

Dr. Serpa continued with an overview of the changes being recommended to Article 4.6 regarding sterile compounding. She noted that many of the requirements in the proposed text exist in the Board's current regulations, and that the recommended text would actually establish greater flexibilities for pharmacies than what is currently allowed. Dr. Serpa again expressed concern that some commenters continue to appear to be seeking a lessening of the Board's current standards or changes that run afoul of federal law and national standards. She provided a reminder about the presentations on these topics that the Board received in January 2023 and November 2024 and added that these presentations were available for viewing on the Board's website. Dr. Serpa then highlighted the following recommendations being offered by staff in response to comments received:

- Minor recommendations in section 1736 to clarify that the PIC can serve as the designated person. It was also recommended that the definition of "essentially a copy" be further amended to clarify that a pharmacist was responsible for verifying and documenting the clinical significance determined by the prescriber.
- In section 1736.1:
    - Changes were recommended to subdivision (b) to provide additional flexibility to facilities to compound under immediate use provisions under specified conditions for up to 48 hours, and to provide additional flexibilities for a critical access hospital to perform such compounding for up to 120 hours.
    - In subdivision (d)(2) the proposed modified text extends the supply for an animal patient to a 7-day supply.
    - Changes were recommended similar to those made in the nonsterile article to include provisions of the Guidance for Industry #256 related to compounding for veterinary patients.
    - Changes were recommended for provisions for using nonsterile components in a sterile preparation.
    - Clarifications to provisions in subdivision (h) were also recommended.

Members were provided an opportunity to comment on the changes being recommended to sections 1736 and 1736.1. Members discussed UC Health's comment to section 1736.1(b). Members also agreed that section 1736.1(b)(3)

should be updated to include "after attempts to remediate pursuant to the facility's SOPs are unsuccessful."

Dr. Serpa then continued reviewing Article 4.6 and highlighted the following additional changes being proposed by staff in response to comments received:

- Minor changes to sections 1736.2 and 1736.3 to provide clarity on gloving requirements and provisions for transferring competencies between facilities.
- Staff recommended removal of the language related to classified and unclassified air and the requirement for dynamic interactions to be controlled through an HVAC system in section 1736.4(e).
- Additional clarifying language is proposed to be added to section 1736.13 regarding rate of infusion of admixed sterile products.
- Changes to section 1736.17(a)(2)(F) to provide clarification that the facility's SOPs did not need to require that the facility itself perform the specified testing; rather, a facility could rely upon such testing performed by other specified entities, if the testing results are provided to the facility.
- Removal of proposed text in section1736.21 related to compounding allergenic extracts was being recommended. Dr. Serpa notes that based on comments received and consideration of the proposed regulation text, it became apparent that the proposed language is not needed as the USP chapter does not allow for the compounding of a stock allergy solution.

Dr. Serpa concluded her overview of the changes being recommended to Article 4.6 in response to comments received by noting that there are no additional changes being proposed to the provisions addressing sterile compounding of 503A Category 1 bulk drug substances. She reiterated that the Board's goal is not to limit access to these products but rather to provide a clear and safe path forward to compound with these chemicals.

Members were provided the opportunity to comment. Members discussed the legal definition of "shall be typically maintained" in section 1736.4(c)(1); changes that might need to be made to section 1736.18(c) to be consistent with the counterpart provision in Article 4.5; adding a timeframe to maintain records of three years to section 1736.17(h); and changes that may need to be made to section 1736.20(b). Members also discussed UC Health's comments to the proposed regulatory text in these sections.

Dr. Serpa then proceeded to provide an overview of the changes being recommended to Article 4.7 related to hazardous drugs. She highlighted the following recommendations being offered by staff in response to comments received:

- Throughout the article, where the proposed modified text previously referenced requirements for "other manipulations" in the compounding of HDs, it was being recommended that this be limited instead to crushing or splitting tablets or opening capsules of antineoplastic hazardous drugs.

- In response to a request from CalOSHA, it was recommended that the Board's regulations include a reminder of safety and health requirements included in Title 8 Industrial Relations.
- It was recommended that section 1737.2 be restructured to accurately reflect the different responsible personnel in the various types of facilities licensed by the Board.
- It was recommended that provisions related to wipe sampling be reworded to more clearly state that wipe sampling was not required; however, the determination about whether wipe sampling was appropriate for a facility must be appropriately documented.
- It was recommended that section 1737.7(c) be changed to extend allowances for outer gloves for use when preparing multiple HD preparations of the same drug or preparing multiple HD preparations for a single patient. After consideration, it was determined that such a provision will not create a risk to patients and could provide for easier workflows for licensees and a lower cost.
- Section 1737.11 was proposed to be amended to add subdivision (c) to provide for additional flexibility in the labeling requirements for a compounded antineoplastic HD if it will be administered within a health care facility.
- It was recommended that provisions related to disposable preparation mats and handling of more than one HD preparation in a PEC also be further modified under similar conditions to those described in the outer gloving provisions.
- Section 1737.14 was proposed to be amended to provide clarity in the language. Subdivision (b) was reworded to make clear that necessary gloves must be offered to a patient. It was recommended that an exemption to this requirement be provided for compounded antineoplastics preparations that will be administered within a licensed health care facility.

Members were provided the opportunity to comment. In addition to recommending some technical/nonsubstantive changes, members also discussed refining the language in section 1737.14(b) to make it clear that the pharmacy does not need to provide the gloves for free.

Dr. Serpa continued with an overview of the changes being recommended to Article 4.8 related to radiopharmaceuticals. Dr. Serpa noted that very few comments were received related to these provisions, and that staff's recommended changes in response to comments received included:

- Removal of the prohibition on compounding in an SRPA in section 1738.5.
- Removal of some of the language initially proposed in section 1738.10(c).
- In section 1738.14(b), it was recommended that the required notification to the Board be extended from 72 to 96 hours.

Members were provided the opportunity to comment. Members discussed adding "hours" to section 1738.14(b) after "96."

Dr. Serpa concluded her remarks by discussing the timeline for the proposed regulations and the impact of delays on licensees. She noted that if the Board does not move forward quickly, the current regulatory package will expire, requiring the Board to start the process again. She emphasized that in her view, this would not be a productive use of the Board's time and would mean continued confusion for licensees. She then proposed a motion to approve the second modified text for noticing.

The Board took a break from 10:30 a.m. to 11:10 a.m. Roll call was taken. The following Board members were physically present in Sacramento: Trevor Chandler, Public Member; Renee Barker, PharmD, Licensee Member; Jeff Hughes, Public Member; J. Newell, MSW, Public Member; Satinder Sandhu, PharmD, Licensee Member; Maria Serpa, PharmD, Licensee Member; and Seung Oh, PharmD, Licensee Member. Jessi Crowley, PharmD, Licensee Member, and KK Jha, RPh, Licensee Member, participated via WebEx. Quorum was established.

Dr. Serpa stated that she wanted to clarify the motion she made before the break and asked that the specific changes to be made to the second modified text based on the Board's discussion be reviewed. Ms. Sodergren then provided a summary of the proposed changes based on the Board's discussion:

Article 4.5:

- Amend section 1735.1(e)(1)(A) so that it reads "in short supply at the time of compounding or within 60 days of the end of the shortage"
- Amend section 1735.11(a)(2)(F) to remove "and all adverse drug experiences"
- Amend section 1735.12(b) to remove "or the occurrence of an adverse drug experience"
- Amend section 1735.12(c) to remove "all adverse drug experience events," replace "by the pharmacist-in-charge" with "consistent with the facility's SOPs," and remove "or occurrence of an adverse drug experience event"

Article 4.6:

- Amend section 1736.1(b)(3) to add "after attempts to remediate pursuant to the facility's SOPs are unsuccessful"
- Amend section 1736.17(h) to add a three-year record retention requirement
- Amend section 1736.20(b) to add "modified" to the second sentence to read "modified or relied upon"

Article 4.7:

- Amend section 1737.5(d) to add "containment"

- Amend section 1737.14(b) to add "is exempt from this requirement" to the last sentence and to change verbiage to reflect the policy that the pharmacy is not required to provide gloves for free.

Article 4.8:

- No substantive changes

The changes having been reviewed, Dr. Serpa proceeded to restate the motion.

Motion: Accept the Board staff recommended responses to comments received during the 30-day comment period as presented. Approve the recommended second modified text as discussed by the Board for a 15-day comment period. Delegate to the Chair of the Enforcement and Compounding Committee to work with the staff to finalize the update consistent with the discussion and policy of the Board and to make technical or nonsubstantive changes as needed. Additionally, should additional comments be received during the comment period, delegate to Members Serpa and Barker authority to review the comments with staff to offer recommendations to the Board for consideration at a future meeting.

M/S: Serpa/Jha

Members were provided with the opportunity to comment. Members discussed the change to section 1735.12(c) to remove "adverse drug experiences" and the request from the California Medical Association to confirm that physicians are excluded from the scope of the proposed regulations. Ms. Sodergren noted the letter from the California Medical Board that was included in the meeting materials, which clarified that the Medical Board was the regulator who could take action against their licensees.

Members of the public participating from Sacramento were provided the opportunity to comment. The Board heard comments from representatives of CVS Health, Pacific Compounding Pharmacy, FlavorRx, Volunteer Fire Foundation, and CMA. Comments received expressed appreciation for the changes made to the proposed regulations; thanked the Board for taking the issue of flavoring seriously; urged the Board to make the pathway for compounding 503A Category 1 bulk drug substances such as glutathione less onerous; expressed continued concern about how the proposed regulations will apply to physicians; and requested specific changes to the regulatory text.

Members of the public participating via WebEx were then provided the opportunity to comment. The Board heard comments from members of the

public including pharmacists, patients, and pharmacy technicians, and from representatives of interested stakeholders including UC San Diego Health, UCLA Health, CVMA, Kaiser Permanente, Outsourcing Facility Association, APC, Scripps, Hartley Medical Center, Sutter Health, stopthebop, gotlongcovid, and Integrative Healers Action Network. Multiple comments thanked the Board for their ongoing efforts to collaborate with stakeholders. Other comments voiced opposition to the regulations in their entirety and asked the Board to vote down the motion; suggested the Board was not relying on scientific evidence; urged the Board to reduce barriers to access to 503A Category 1 substances such as methylcobalamin and glutathione; raised specific concerns about glove and passthrough requirements; expressed concern about adoption of the regulations being further delayed and the impact that would have on California sterile compounding pharmacies that ship into other states; questioned the requirement to prove clinical significance; and requested specific changes to the proposed regulatory text.

Members were provided the opportunity to comment after having heard public comment. Members discussed looking at the glove and passthrough issues again if the modified text was approved. Stakeholders were also encouraged to submit all comments in writing should there be a 15-day comment period, as this would allow for the Board to respond to all comments. Members also discussed the importance of remaining mindful that the proposed regulations cover a wide spectrum of compounding practices; whether language should be added to specifically exempt licensees of other healing arts boards; the negative impacts of further delays in finalizing the regulations; the pathway the proposed regulations provide to safely compound 503A Category 1 bulk drug substances; and the next steps in the regulatory process.

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

Board Member	Vote
Barker	Support
Cameron-Banks	Not Present
Chandler	Support
Crowley	Support
Hughes	Support
Jha	Support
Newell	Support
Oh	Support
Sandhu	Support
Serpa	Support
Thibeau	Not Present
Weisz	Not Present

The Board took a lunch break from 12:51 p.m. to 1:45 p.m. Roll call was taken. The following Board members were physically present in Sacramento: Trevor Chandler, Public Member; Renee Barker, PharmD, Licensee Member; Jeff Hughes, Public Member; J. Newell, MSW, Public Member; Satinder Sandhu, PharmD, Licensee Member; Maria Serpa, PharmD, Licensee Member; and Seung Oh, PharmD, Licensee Member. Jessi Crowley, PharmD, Licensee Member, and KK Jha, RPh, Licensee Member, participated via WebEx. A quorum was established.

IV. Discussion and Possible Action Related to Proposed Amendment to California Code of Regulations, Title 16, Section 1708.2 Related to Discontinuance of Business and Review of Comments Received During the 45-Day Comment Period

Dr. Oh recalled that in April 2024, the Board approved proposed regulation text to amend section 1708.2, related to the Board's discontinuance of business requirements. The 45-day comment period began November 15, 2024, and concluded December 30, 2024. The meeting materials included the proposed text released for the 45-day comment period, comments received, staff prepared responses to comments, and staff recommended modifications to the proposed text. Dr. Oh stated that he had reviewed the materials and agreed with the staff recommendations, including the recommendations to the proposed modified text.

Members were provided the opportunity to comment. Members agreed with the change from 30 days to 45 days to align with Business and Professions Code (BPC) section 22949.92.1 and with the addition of the exemption for inpatient hospital pharmacies, with one member recommending that the phrase "inpatient hospital pharmacy" be replaced with "general acute care hospital pharmacy". Members also discussed whether the regulation should expressly permit electronic notice; whether the PIC or the pharmacy owner should have the burden of certifying compliance with the regulation; and whether the requirement from BPC section 22949.92.1 to post a written notice of the closure in a conspicuous location at the entrance to the pharmacy should be added to the regulation.

Following the Board's discussion, Ms. Sodergren confirmed that changes to the proposed modified regulation text (in addition to staff-recommended changes still applicable following the Board's discussion) should also include amending (b)(4) to update that the owner is responsible, and the owner or PIC, if still available, shall certify compliance; amending (b)(5) to change "inpatient hospital pharmacy" to "general acute care hospital pharmacy"; and adding a new paragraph/subdivision to set forth the statutory requirement to post a

written notice of the closure (including the planned closure date) in a conspicuous location at the entrance of the establishment.

Motion: Accept the Board staff's recommended comment responses and modified text consistent with the Board's discussion, and notice the modified text for a 15-day comment period. Additionally, if no adverse comments are received during the 15-day comment period, authorize the executive officer to take all steps necessary to complete the rulemaking and adopt the proposed regulation at Section 1708.2 as noticed. Further, delegate to the executive officer the authority to make technical or nonsubstantive changes as may be required by the Control agencies to complete the rulemaking file.

Department of Consumer Affairs Title 16.
Board of Pharmacy

Modified Regulation Text Discontinuance of Business

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

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

Amend section 1708.2 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

(a) Any permit holder shall contact the ~~b~~Board prior to transferring or selling any dangerous drugs, devices, or hypodermics inventory as a result of termination of business or bankruptcy proceedings (individually or collectively referred to as a "closure") and shall follow official instructions given by the ~~b~~Board applicable to the transaction.

(b) In addition to the requirements in (a), a pharmacy that shall cease operations due to a closure (cessation or substantial cessation) shall complete the following:

(1) At least ~~30~~ 45 days in advance of the closure, provide written notice to patients that have received a prescription within the last year. At a minimum, this notice shall include:

(A) the name of the patient and if one exists and is known to the pharmacy, the name of the legal representative of the patient,

(B) the name and physical address of the pharmacy closure,

(C) the name of the pharmacy where patient records will be transferred and maintained, and

(D) information on how to request a prescription transfer prior to closure of the pharmacy.

(2) Reverse all prescriptions for which reimbursement was sought but the prescriptions are not picked up by patients,

(3) Provide the Board with a copy of the notice specified in subsection (b)(1), and

(4) The pharmacist-in-charge shall certify compliance with the requirements in this section. In the event the pharmacist-in-charge is no longer available, the owner must certify the compliance, along with a pharmacist retained to perform these functions.

(5) An inpatient hospital pharmacy that is owned by a health facility as defined in Section 1250 of the Health and Safety Code, and meets the requirements of Business and Professions Code section 22949.92(a)(1)(B)(iii), shall be exempt from the requirements of subdivision (b).

NOTE: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4080, 4081, 4113, 4332, ~~and~~ 4333, 22949.92, and 22949.92.1, Business and
Professions Code; and Section 11205, Health and Safety Code.

M/S: Crowley/Sandhu

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

Members of the public via WebEx were provided the opportunity to comment. A pharmacist representative from Kaiser Permanente commented that it was unclear where the Board landed on the issue of allowing the notice to be given electronically and encouraged the Board to provide flexibility and include language in the regulation text that would allow the notice to patients to be given in a form in which the pharmacy regularly communicates with its patients, which could include electronic communication.

Ms. Robbins confirmed that the addition of language (in line with the statutory requirement) regarding the form of communication (written/electronic) being consistent with the patient's preference was included in the Board's discussion and that the motion therefore didn't need to be amended in order for that change to be made to the proposed regulation text.

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

Board Member	Vote
Barker	Support
Cameron-Banks	Not Present
Chandler	Support
Crowley	Support
Hughes	Support
Jha	Support
Newell	Support
Oh	Support
Sandhu	Support
Serpa	Support
Thibeau	Not Present
Weisz	Not Present

V. Discussion and Possible Action Related to Proposed Amendment to California Code of Regulations, Title 16, Section 1711 Related to Quality Assurance Programs and Review of Comments Received during the 15-Day Comment Period

Dr. Oh reminded those present that in January 2023, the Board approved proposed regulation text to amend section 1711, related to quality assurance (QA) programs. Dr. Oh further recalled that as part of the Board's Medication Error Reduction and Workforce Committee, this ad hoc committee had taken a deep dive into the issue of medication errors, and that one of action item identified was the need to update the Board's QA regs that have largely remained unchanged for two decades.

Dr. Oh noted that the Board's 45-day comment period closed on September 23, 2024, and that during the November 6-7, 2024 Board meeting, following consideration of the comments received, the Board voted to further modify the proposed text and initiate a 15-day comment period. He continued that, as noted in the meeting materials, the Board received comments during the comment period. The meeting materials included several items including the proposed regulation text released for the 15-day comment period, comments received during the 15-day public comment period, staff recommended responses, and possible motion language.

Dr. Oh stated that he had reviewed the materials and had a concern about the requirement in (e)(2)(D) to track the number of patient consultations given, noting that it can be challenging for some pharmacies to precisely track this metric.

Members were provided the opportunity to comment. Members discussed estimated versus actual number of consultations and agreed to changing (e)(2)(D) to require the estimated number of patient consultations given.

Motion: Accept the Board staff's recommended comment responses, modify the regulation text in subdivision (e)(2)(D) to allow for an estimate of the number of consultations, and notice the modified text for a second 15-day comment period. Additionally, if no adverse comments are received during the second 15-day comment period, authorize the executive officer to take all steps necessary to complete the rulemaking to adopt the proposed regulation at section 1711 as noticed. Further, delegate to the executive officer the authority to make technical or nonsubstantive changes as may be required by the Control agencies to complete the rulemaking file.

Department of Consumer Affairs
Title 16. Board of Pharmacy

Proposed Modifications to Regulation Text
Quality Assurance Programs

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

Modified regulation text to the proposed regulation text is indicated with a ~~double strikethrough~~ for deletions and a double underline for additions.

Amend section 1711 to Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows**:**

§ 1711. Quality Assurance Programs.

(a) Each pharmacy shall establish or participate in an established quality assurance program that documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.
(b) For purposes of this section, “medication error” means any variation from a prescription or drug order not authorized by the prescriber, as described in ~~S~~section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.

(c)(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.

(2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible:

(A) Communicate to the patient or the patient's agent the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.

(B) Communicate to the prescriber the fact that a medication error has occurred.

(3) The communication requirement in paragraph (2) of this subdivision shall only apply to medication errors if the drug was administered to or by the patient, or if the medication error resulted in a clinically significant delay in therapy.

(4) If a pharmacist is notified of a prescription error by the patient, the patient's agent, or a prescriber, the pharmacist is not required to communicate with that individual as required in paragraph (2) of this subdivision.

(d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.

(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:

(1) The date, location, and participants in the quality assurance review;

(2) The pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c)~~;~~, including:

(A) The date and approximate time or date range when the error occurred if known or can be determined. If it cannot be determined, the pharmacy shall note “unknown” in the record.

~~(B) The names of staff involved in the error.~~

(~~C~~B) The use of automation, if any, in the dispensing process.

(~~D~~C) The type of error that occurred. To ensure standardization of error reporting, the pharmacies’ policies and procedures shall include the category the pharmacy uses for identifying the types of errors.

(~~E~~D) An outpatient pharmacy report must also document the ~~The~~ volume of workload completed by the pharmacy staff on the date of the error, if known, including clinical functions. If the date of the error is unknown, the average volume of workload completed daily shall be documented. For errors that occur in a community pharmacy, at a minimum the volume of workload records shall include the number of new prescriptions dispensed, the number of refill prescriptions

dispensed, the number of vaccines administered, and number of patient consultations given~~, and any other mandatory activities required by the pharmacy employer~~. Prescriptions filled at a central fill location and dispensed at the pharmacy must be documented separately from other prescriptions filled at the pharmacy.

(3) The findings and determinations generated by the quality assurance review; and~~,~~

(4) Recommend changes to pharmacy policy, procedure, systems, or processes, if any. The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program. Documentation of the steps taken to prevent future errors shall be maintained as part of the quality assurance report.

(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least ~~one~~ three years from the date the record was created. Any quality assurance record related to the use of a licensed automated drug delivery system must also be submitted to the ~~b~~Board within 30 days of completion of the quality assurance review and any facility with an unlicensed automated drug delivery system must report the quality assurance review to the Board at the time of annual renewal of the facility license.

(g) The pharmacy's compliance with this section will be considered by the ~~b~~Board as a mitigating factor in the investigation and evaluation of a medication error.

(h) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section.

NOTE: Authority cited: Sections 4005 and 4125, Business and Professions Code~~; and Section 2 of Chapter 677, Statutes of 2000~~. Reference: Sections 4125 and 4427.7, Business and Professions Code.

M/S: Crowley/Hughes

Members of the public in Sacramento were provided the opportunity to comment. A representative from CCPC commented that these reports should not be made to the Board and urged the Board to change the regulation to require reporting to a Board-approved entity.

Members clarified that the QA regulations do not require reporting to the Board, except in the case of QA records related to the use of ADDS.

Members of the public via WebEx were provided the opportunity to comment. A representative of UCLA Health commented that even an

estimated number of patient consultations may not be available as this is typically not something pharmacies track.

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

Board Member	Vote
Barker	Support
Cameron-Banks	Not Present
Chandler	Support
Crowley	Support
Hughes	Support
Jha	Support
Newell	Support
Oh	Support
Sandhu	Support
Serpa	Support
Thibeau	Not Present
Weisz	Not Present

VI. Report on Appointment to Research Advisory Panel of California pursuant to Health and Safety Code Section 11480

Dr. Oh advised that Health and Safety Code Section 11480 establishes the Research Advisory Panel of California to review and authorize research projects into the nature and effects of cannabis and hallucinogenic drugs. Dr. Oh further stated that this item was added to the agenda to advise members that he recently appointed Dr. Kelly Lee, PharmD. to serve as the Board's new representative on the panel. Historically, the Board's appointment to the panel has served until retirement; however, Dr. Oh appointed Dr. Lee for a three-year period, and as part of the appointment, he requested an annual presentation to the Board to ensure that, moving forward, the Board has an understanding of the work completed by the panel.

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

Members of the public participating in Sacramento and via WebEx were provided the opportunity to comment; however, no comments were made.

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

Dr. Oh announced the Board would now accept public comment for items not on the agenda and provided instructions on how the public could provide comments. Dr. Oh also confirmed that members had received the written comments received related to this agenda item.

Members of the public participating in Sacramento were provided the opportunity to comment.

The Board heard comments from a member of the public requesting that the Board add a future agenda item about the problems of vaccines administered by pharmacies.

A former Public Information Officer from CDPH commented that vaccines were killing and harming people of color at a higher rate and requested that a discussion of this issue be added to a future agenda.

Members of the public participating via WebEx were then provided the opportunity to comment.

A representative of CSHP requested a future agenda item for the consideration of retraining of pharmacy inspectors who perform inspections for sterile compounding.

A pain patient advocate commented that the previous agenda item regarding the injunctive relief provisions of the national opioid settlement has not been adequately addressed and urged the Board to take action on this issue.

Members were provided the opportunity to comment.

Enforcement and Compounding Committee Chair Dr. Serpa advised that the concerns raised by the commenter regarding the injunctive relief provisions of the opioid settlement was an ongoing issue being monitored and will be on a future committee agenda item.

Dr. Serpa requested that Executive Officer Sodergren correct the record regarding the training of the Board's inspectors. Ms. Sodergren explained that Board inspector staff receive a significant amount of ongoing training in sterile compounding.

VIII. Closed Session Matters

Open session concluded at approximately 2:44 p.m. The Board entered closed session at approximately 2:56 p.m.

IX. Reconvene in Open Session to Adjourn for the Day

The Board reconvened into open session and adjourned the meeting at 3:10 p.m.