



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: April 19-20, 2023

Location: Public participation provided via WebEx

Board Members

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

Board Members Not Present: Indira Cameron-Banks, Public Member
 Jignesh Patel, Licensee Member, Treasurer
 Jason Weisz, Public Member

Staff Present: Anne Sodergren, Executive Officer
 Eileen Smiley, DCA Staff Counsel
 Noreen Marks, DCA Staff Counsel

April 19, 2023

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

President Oh called the Board Meeting to order at 1:00 p.m. Dr. Oh reminded all individuals present that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. Where protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. Dr. Oh advised all individuals the meeting was being conducted

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

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

Roll call was taken. Board Members present included: Maria Serpa, Licensee Member; Renee Barker, Licensee Member; Jessi Crowley, Licensee Member; KK Jha, Licensee Member; Ricardo Sanchez, Public Member; Nicole Thibeau, Licensee Member; and Seung Oh, Licensee Member. A quorum was established.

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

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

A psychiatrist on behalf of the California State Association of Psychiatrists commented about the continuation of prescribing issues for psychiatrists and their patients. The psychiatrist requested there be a motion and second to add this to a future agenda. President Oh noted Mr. Yoder previously provided public comment during the March Board Meeting. Members requested that staff solicit more information. Dr. Oh understood Ms. Sodergren was awaiting receipt of some requested information and would continue to keep Dr. Oh apprised.

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

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

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

IV. Approval of Board Meeting Minutes

a. President Oh referenced the draft minutes from the February 6-7, 2023, meeting.

Members were provided with an opportunity to comment.

Motion: Approve the February 6-7, 2023, minutes as presented in the meeting materials.

M/S: Sanchez/Crowley

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

Support: 7 Oppose: 0 Abstain: 0 Not Present: 6

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

b. President Oh referenced the draft minutes from the March 15, 2023, meeting.

Members were provided with an opportunity to provide comments.

Motion: Approve the March 15, 2023, minutes as presented in the meeting materials.

M/S: Crowley/Sanchez

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

Support: 7 Oppose: 0 Abstain: 0 Not Present: 6

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

V. Update from the Department of Consumer Affairs

President Oh introduced Yvonne Dorantes, Assistant Deputy Director, Board and Bureau Relations, to provide an update from the Department of Consumer Affairs (DCA).

Ms. Dorantes reported the DCA's Diversity, Equity, and Inclusion (DEI) Program established last year was working on updating the strategic planning process; increasing DEI training and development for DCA trainers and employees; and developing an informational DEI fact sheet. Ms. Dorantes advised the strategic planning process was updated and embedded in the DEI process to include a survey, DEI section, environment scan, video message and brief training video. DCA's SOLID Team will reach out to the Executive Officer to coordinate updating of the strategic plan this month. Ms. Dorantes advised DCA's SOLID trainers will complete a 50-hour DEI certification program through the University of Massachusetts which will expand the availability of courses offered to employees and noted there were currently three DEI courses available to staff beginning in June. Ms. Dorantes reported DCA's first DEI Fact Sheet was developed to be used as a tool.

Ms. Dorantes advised there were two DCA wide mandatory trainings for 2023 including sexual harassment prevention training and information security awareness. Ms.

Dorantes noted all appointed Board Members must take the 2-hour supervisory training. Ms. Dorantes noted Board Members with an assigned DCA email address must take the information security awareness training. Both trainings can be found at the DCA's LMS system. Ms. Dorantes noted training requirements can be found at www.dca.ca.gov at Board Member Resources Center Page under Required Training. Ms. Dorantes thanked Board Members and Executive Officers who helped DCA achieve Form 700 compliance.

Ms. Dorantes provided an update on the Bagley Keene Open Meeting Act and virtual meetings noting legislation was passed last year to extend the ability of state bodies to conduct public meetings virtually through 7/1/23. Ms. Dorantes noted absent of legislation allowing the extension of these provisions, DCA Board and Bureaus will not be allowed to conduct meetings virtually after 7/1/23. Ms. Dorantes reported DCA was aware of legislation introduced by Senator Laird (SB 544) that would remove certain teleconference requirements from the Open Meetings' Act; however, the bill didn't include an urgency clause and wouldn't take effect until 1/1/24. Ms. Dorantes noted Boards and Bureaus should be prepared to meet in person beginning 7/1/23.

Ms. Dorantes reported on January 5, 2023, a new federal law took effect that enables service members and their spouses who hold professional licenses in different states to practice in California within the same profession and discipline and at a similar scope of practice if they are required to relocate to California due to their military orders. Ms. Dorantes advised DCA has been collaborating with Agency on how best to implement and will share information as it becomes available. Ms. Dorantes advised should the Board receive an inquiry from a service member or spouse to please contact DCA Legal Affairs.

Ms. Dorantes advised DCA submitted its 2021/22 Annual Report to the Legislature and was available at www.dca.ca.gov. Ms. Dorantes reported the report has a new design and additional data (e.g., military licensing data).

Members were provided the opportunity to comment. President Oh thanked Ms. Dorantes for the update on SB 544 noting the July Board Meeting would be planned as a Sacramento in-person meeting with meetings through 2023 having a hybrid northern and southern California location.

Members Chandler and Koenig joined the meeting at approximately 1:20 p.m.

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

VI. Board Member Elections

President Oh advised as included in the Board of Pharmacy Board Member Procedure Manual, officers shall serve one-year term, effective June 1, and may be reelected for consecutive terms.

President Oh opened the nominations for the Office of President.

Nomination for President: Seung Oh

M/S: Crowley/Sanchez

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

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

President Seung Oh was re-elected as President.

President Oh accepted nominations for the Office of Vice President.

Nomination for Vice President: Jessi Crowley

M/S: Chandler/Sanchez

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

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

Member Jessi Crowley was elected as Vice President.

President Oh accepted nominations for the Office of Treasurer.

Nomination for Treasurer: Trevor Chandler

M/S: Crowley/Thibeau

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

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

President Oh looked forward to another year of great service and thanked Vice President Maria Serpa noting her leadership had been instrumental as Vice President for the past two years.

VII. Discussion and Consideration of Waiver of Pharmacy Law Provisions Consistent with the Authority in Business and Professions Code Section 4062 in Response to the Federal State of Emergency Related to COVID-19

President Oh referenced Business and Professions Code (BPC) section 4062 establishing the authority for the Board, during a declared federal, state, or local emergency, to waive provisions of Pharmacy Law or its regulations adopted pursuant to it, if in the Board's opinion, the waiver will aid in the protection of public health or the provision of care. Dr. Oh added the section further provides that the Board may elect to continue to waive application of any provision for up to 90 days following the termination of the declared emergency. Dr. Oh noted Governor Newsom terminated the declared state of emergency in California effective February 28, 2023. Board issued waivers still in effect based upon the end of the California state emergency will expire May 28, 2023.

President Oh recalled as part of the February 2023 Board Meeting, the Board voted to sponsor legislation to make permanent provisions for California licensed pharmacists to perform certain work remotely on behalf of a health care facility licensed pursuant to Health and Safety Code (HSC) section 1250 (Health Care Facility), from a location outside of the facility, including medication chart order reviews, as specified. The provisions were included in Assembly Bill 1557. Dr. Oh noted the measure was recently referred to the Assembly Appropriations Committee and now included an urgency

clause allowing the measure to become effective upon the signature of the Governor. Dr. Oh recalled the Board determined this action was necessary and appropriate to ensure continuity of patient care for inpatients by allowing for remote medication chart order review to meet CMS requirements. Dr. Oh added it was unlikely that AB 1557 would make it through the legislative process before the expiration date of the current waiver on May 28, 2023.

President Oh noted the meeting materials detail the Board's authority in BPC section 4062 provides that the Board may waive a provision of pharmacy law in response to a federal state of emergency and that unlike California's declaration, the federal declaration remains in effect. Dr. Oh reported the question before the Board was if the Board wanted to issue a new waiver based upon the COVID-19 federal declared emergency to aid in the protection of the public health or the provision of patient care. Dr. Oh added it was a very challenging issue and the Licensing Committee continues its work to assess the larger issue of remote processing for other environments. Dr. Oh noted that while he would be reporting later as part of the Licensing Committee report, Dr. Oh wanted to highlight pursuant to CCR 1717.1 that pharmacists already have the ability to work in a community pharmacy performing functions on behalf of another pharmacy if the pharmacies share a common electronic record. Dr. Oh added this was a common practice for community pharmacies. Dr. Oh noted that should the Board believe action was appropriate action was needed.

Members were provided an opportunity to comment.

Member Serpa commented this was very important to continue the process as it has been the practice and the understanding of the original intent even before the waiver in acute care facilities to meet federal guidelines through CMS. Dr. Serpa noted if the waiver wasn't approved in this format or a similar format, acute care facilities in California would not be able to meet federal guidelines.

President Oh agreed with Dr. Serpa noting it was necessary.

Member Chandler requested clarification on how the waiver would remedy the issue and if legislation would still be required. Mr. Chandler's understanding was that a legislative solution was required. Executive Officer Sodergren provided long term a legislative solution was necessary. Ms. Sodergren noted under the authority in BPC 4062, the Board has the authority to issue a waiver in response to a federal declared emergency which remained in effect for COVID. The provisions allowed for the Board if the Board deemed appropriate in the interest of ensuring continuity of patient care, the Board can extend the waiver 90 days beyond the end of the declaration. Ms. Sodergren provided the issue was before the Board for the Board to determine if a

waiver was needed while the legislation was being considered for continuity of care for patients. Mr. Chandler inquired if the motion would maintain status quo. Ms. Sodergren provided the motion as drafted would be consistent with what the law would be if AB 1557 was enacted. Ms. Sodergren clarified the current waiver was broader and covered additional practice sites. Mr. Chandler inquired if the waiver would be nullified if and when the federal emergency ended. Ms. Sodergren advised the Board has the authority to do a waiver up to 90 days beyond the declared emergency and with the current federal emergency ending mid-May (May 11th) if the Board decides, it could be an additional 90 days. Ms. Sodergren continued with the thought that with the urgency provision in the bill, the legislation will have had an opportunity to go through the process.

Motion: Consistent with the federal declared emergency issued in response to the COVID-19 public health crisis, the Board waives sections BPC 4071.1 for a period of 90 days following the end of the federal declared emergency. Conditions of the waiver include that the medication chart order review is performed by a California licensed pharmacist, on behalf of a health care facility licensed pursuant to Chapter 2 of Division 2 of the Health and Safety Code, from a location outside of the facility, verify medication chart orders consistent with federal requirements, as established in the health care facility's policies and procedures. The health care facility shall maintain a record of the pharmacist's verification on the medication chart order. Records shall be maintained consistent with the requirements in Business and Professions Code Sections 4081 and 4105.

M/S: Serpa/Thibeau

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

A representative of CSHP encouraged support of the waiver as it was critical for licensed health care facilities that require pharmacists to review the order before it can be administered.

The Board heard a comment stating that the US Department of Health and Human Services announced 4/14/23 a new amendment was planned to be issued under the current declaration of the Public Readiness and Emergency Preparedness (PREP) Act that will extend through 12/2024 as well as information on services and vaccines extended to the uninsured.

A pharmacist representative of Kaiser thanked the Board for the work on the remote work and expressed support for the motion.

A pharmacist representative of CVS Health commented on the pharmacists in specialty pharmacy who will lose their jobs because they can't return to the pharmacy (e.g., ailments, location, etc.) and added the waiver could be extended 90 days to help with continuity of care while replacements are hired and trained. If the waiver couldn't be updated, the representative asked if waivers could be issued by the Board President for the specialty pharmacies.

A pharmacist representative of the UCSD thanked the Board appreciating the approach taken and requested clarification for a number of the duties and functions.

A pharmacist thanked the Board and requested clarification on the duties and functions. The pharmacist requested the current waiver be extended as well.

Members were provided an opportunity to comment after public comment was received.

Member Thibeau asked if anything needed to be added to end the waiver if the legislation was passed. Dr. Thibeau asked for the difference of the current waiver and the proposed waiver to be explained.

Counsel Smiley confirmed the legislation was passed consistent with the motion, which was to mirror the pending legislation, the issue becomes moot with the urgency clause making it effective upon signature by the Governor.

Executive Officer Sodergren advised the current waiver in effect goes beyond what was currently established and the proposed language of the waiver is consistent with the Board's policy decisions at the February 2023 Board Meeting where the Board voted to sponsor legislation that was now included in AB 1557. Ms. Sodergren added the Board's current waiver was not limited to just medication chart order review and applied to settings other than health care facilities licensed pursuant to HSC section 1250. Ms. Smiley added the current waiver applies to pharmacists, pharmacist interns, and pharmacy technicians.

Member Barker asked for clarification on the settings allow in the proposed waiver. Ms. Sodergren provided as proposed the waiver would include health care facilities licensed pursuant to HSC section 1250 which do not include specialty pharmacies.

Member Thibeau requested clarification if the legislation would be limited to the language in the proposed motion and if the Board decided to move forward with the current motion in place, the narrower version would be approved. Ms. Sodergren clarified if the Board moved forward with the motion as drafted, the intent was for the provisions of the motion to become law through AB 1557. Ms. Sodergren advised there was no pending legislation beyond the provisions of the motion.

Members discuss the options of moving forward with the proposed motion versus amending the proposed motion to match the current waiver's provisions. The concern with the extending the current motion was that preparations for after the waiver ended may be stopped for 90 days.

Support: 8 Oppose: 0 Abstain: 0 Not Present: 5

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

VIII. Agenda Item VIII. Discussion and Consideration and Possible Action Related to Proposed Regulations to Amend title 16, California Code of Regulations Section 1715.1 and Automated Drug Delivery System Self-Assessment (Form 17M-112), Including Comments Received During the Public Comment Period

President Oh advised the history of this regulation change was included in the meeting materials and reminded Members as part of the February 2023 Board Meeting, in response to comments received during the 45-day comment period, the Board voted to make additional changes to the proposed regulation and release the matter for an additional 15-day comment period.

President Oh reported the Board received comments during this 15-day comment period for review and determination of appropriate action. Dr. Oh noted some of the comments received were previously considered by the Board and specifically addressed one of the repeat comments received by Kaiser related to the applicability of the self-assessment form. Dr. Oh provided this issue had been considered by several assigned counsels all of whom have repeatedly confirm that completion of the ADDS self-assessment form equally applies to an unlicensed ADDS.

President Oh stated he had reviewed the materials including the new comments received and staff's recommendations. Dr. Oh agreed with the recommendations offered by staff.

Members were provided the opportunity to comment. Members Serpa and Jha agreed with the changes.

Counsel Marks recommended reading the motion into the record. Ms. Marks recommended changing "Additionally, if no adverse comments are received" to "Additional, if no comments requiring Board response are received" to which Members Crowley and Serpa agreed to the change. Dr. Oh read the motion into the record.

Motion: Accept the Board staff recommended comment response, approve the staff recommended proposed text, and initiate a second 15-day public comment period. Additionally, if no comments requiring Board response are received during the second 15-day comment period, authorize the Executive Officer to take all steps necessary to complete the rulemaking and adopt the proposed regulation at Section 1715.1. Further, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

Title 16. Board of Pharmacy Modified Regulation Text

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

January 2023 changes are shown by ~~italicized double strikethrough~~ for deleted language and italicized wavy underline for added language.

April 2023 changes are show by double wavy underline for added language. [Changes are limited to Subdivisions (f) and (g)].

Proposal to amend §1715.1 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1715.1. Self-Assessment of an Automated Drug Delivery System by the Pharmacist-in-Charge.

- (a) The pharmacist-in-charge of each automated drug delivery system as defined under section 4119.11, 4187.5 or section 4427.3 of the Business and Professions Code (BPC) shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed ~~annually~~ before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
- (b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:
 - (1) A new automated drug delivery system license has been issued.
 - (2) There is a change in the pharmacist-in-charge, ~~and he or she becomes the new pharmacist-in-charge of an automated drug delivery system.~~
 - (3) There is a change in the licensed location of an automated drug delivery system to a new address.
- I A pharmacist-in-charge of an automated drug delivery system shall assess the system's compliance with current laws and regulations by using the components of Form 17M-112 (Rev ~~12/48223~~) entitled "Automated Drug Delivery System Self-Assessment". Form 17M-112 shall be used for all automated drug delivery systems and is hereby incorporated by reference.
 - (1) The pharmacist-in-charge shall provide identifying information about the underlying operating pharmacy including:
 - (A) Name and any license number(s) of the underlying pharmacy and their expiration date(s);
 - (B) Address, phone number, and website address, if applicable, of the underlying pharmacy;
 - I DEA registration number, expiration date, and date of most recent DEA inventory;
 - (D) Hours of operation of the pharmacy; and
I ADDS license number, address, and hours of operation.
 - (2) The pharmacist-in-charge shall respond "yes", "no", or "not applicable" (N/A) about whether the automated drug delivery system is, at the time of the self-assessment, in compliance with laws and regulations that apply to that pharmacy setting.
 - (3) For each "no" response, the pharmacist-in-charge shall provide a written corrective action or action plan to come into compliance with the law.
 - (4) The pharmacist-in-charge shall initial each page of the self-assessment with original handwritten initials in ink or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form.
 - (5) The pharmacist-in-charge shall certify on the last page of the self-assessment that ~~he or she has~~ they have completed the self-assessment

of the automated drug delivery system of which ~~he or she is~~ they are the pharmacist-in-charge. The pharmacist-in-charge shall also certify a timeframe within which any deficiency identified within the self-assessment will be corrected and acknowledge that all responses are subject to verification by the Board of Pharmacy. The certification shall be made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct with an original handwritten signature in ink or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form.

- (6) The automated drug delivery system owner shall certify on the final page of the self-assessment that ~~he or she~~ they have ~~has~~ read and reviewed the completed self-assessment and acknowledges that failure to correct any deficiency identified in the self-assessment could result in the revocation of the automated ~~dispensing drug delivery~~ system's license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California with an original handwritten signature in ink or digitally signed in compliance Civil Code Section 1633.2(h) on the self-assessment form.
- (d) Each self-assessment shall be completed in its entirety and kept on file in the underlying pharmacy for three years after it is performed. The completed, initialed, and signed original must be readily available for review during any inspection by the board.
- l Any identified areas of noncompliance shall be corrected as specified in the assessment.
- (f) The pharmacist-in-charge of a hospital using more than one unlicensed automated drug delivery system as authorized in BPC section 4427.2(i) may complete a single self-assessment of the hospital's compliance with federal and state pharmacy law for all automated drug delivery systems under the following conditions:
- (1) The mechanical devices used as part of the automated drug delivery system to store, dispense or distribute dangerous drugs are of the same manufacturer and controlled by the same software system on a single server; and
 - (2) The same policies and procedures required by Section 4427.2 of BPC are used.
 - (3) All mechanical devices for which the single consolidated self-assessment applies shall be listed with license number and expiration date as part of the self- assessment.
- (g) The pharmacist-in-charge of a licensed correctional pharmacy using more than one licensed automated drug delivery system at a single institution in compliance with federal and state pharmacy law may complete a single consolidated self-assessment for all automated drug delivery systems licensed to the correctional pharmacy under the following conditions:
- (1) The mechanical devices used as part of the automated drug delivery

system to store, dispense or distribute dangerous drugs are of the same manufacturer and controlled by the same software system on a single server;

- (2) The same policies and procedures required by Section 4427.2 of BPC are used; and
- (3) All mechanical devices for which the single consolidated self-assessment applies shall be listed with license number and expiration date as part of the self- assessment.

Note: Authority cited: Sections 4119.11 and 4427.7, Business and Professions Code. Reference: Sections 4001.1, 4008, 4017.3, 4021, 4022, 4036, 4037, 4038, 4040, 4050, 4051, 4052, 4059, 4070, 4076, 4081, 4101, 4105, 4107, 4113, 4117.3, 4119.1, 4119.11, 4125, 4126, 4180, 4186, 4305, 4330, 4332, 4333, 4400, 4427, 4427.1, 4427.2, 4427.3, 4427.4, 4427.5, 4427.6, and 4427.7, Business and Professions Code; and Section 16.5, Government Code.

M/S: Crowley/Serpa

Members of the public were provided the opportunity to comment.

A pharmacist representative of CHSP commented in support of the motion.

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

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

The Board took a break from 2:10 p.m. to 2:20 p.m. Roll call was taken after the break. Members present included: Maria Serpa, Licensee Member; Renee Barker, Licensee

Member; Trevor Chandler, Public Member; Jessi Crowley, Licensee Member; Jose De La Paz, Public Member; Ricardo Sanchez, Public Member; Nicole Thibeau, Licensee Member; and Seung Oh, Licensee Member. A quorum was established.

IX. Discussion, Consideration and Possible Action Related to Proposed Regulations to Amend Title 16, California Code of Regulations Section 1707.6, Including Any Comments Received During the 45-Day Comment Period

President Oh advised the formal 45-day public comment period for the Board's Notice to Consumers regulation began February 24, 2023, and ended April 10, 2023. Dr. Oh referenced meeting materials including background information, a copy of the comment received, and Board staff's recommended response to the comment. Dr. Oh agreed with staff recommendation.

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

Motion: Accept the Board staff recommended comment response and adopt the regulation text as noticed on February 24, 2023. Additionally, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

**Title 16. Board of Pharmacy
Proposed Text**

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

§ 1707.6. Notice to Consumers.

(a) ~~In every pharmacy there shall be prominently posted, in a place conspicuous to and readable by a prescription drug consumer, a notice containing the text in subdivision (b).~~ Every pharmacy shall post a notice containing the text in subsection (b) and shall place the notice in a conspicuous place, physically accessible to a prescription drug consumer (consumer) so that the consumer can easily read the notice, and use the QR code displayed on the notice to obtain language translation of the notice. Such notice shall be posted at all locations where a consumer receives medication. Each pharmacy shall use the standardized poster-sized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval. As an alternative to a printed notice, the pharmacy may also or instead display the notice on a

video screen located in a place conspicuous to and readable by ~~prescription drug~~ consumers, so long as: (1) The video screen is at least 24 inches, measured diagonally; (2) The pharmacy utilizes the video image notice provided by the board; (3) The text of the notice remains on the screen for a minimum of 60 seconds; ~~and~~ (4) The video screen utilizes QR code technology for the consumer to access translation of the notice, with sufficient display time for consumers to access the QR code; and (5) No more than five minutes elapses between displays of any notice on the screen, as measured between the time that a one-screen notice or the final screen of a multi-screen notice ceases to display and the time that the first or only page of that notice re-displays. The pharmacy may seek approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

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

**NOTICE TO CONSUMERS
KNOW YOUR RIGHTS**

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

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

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

TALK TO THE EXPERT – SPEAK WITH YOUR PHARMACIST

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

- The patient name on the label is correct;
- The medication matches the description on the label;
- The name of the medicine and what it does;
- How and when to take the medication, for how long, and what to do if you miss a dose;

- Possible side effects and what you should do if they occur;
- Whether the medication will work safely with other medicines or supplements;
and
- What foods, drinks, or activities should be avoided while taking the medicine.

The address and contact information for consumers to send any complaints about the pharmacy:

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

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

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

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

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

This text shall be repeated in the top 16 languages spoken by limited-English-proficient individuals in California, as determined by the U.S. Department of Health and Human Services, Office for Civil Rights, and the California Department of Health Care Services.

~~This text shall be repeated in at least the following languages: Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, Tagalog, and Vietnamese.~~

Each pharmacy shall use the standardized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

The pharmacy may post this notice in paper form or on a video screen if the posted notice or video screen is positioned so that a consumer can easily point to

and touch the statement identifying the language in which ~~he or she requests~~ they request assistance. Otherwise, the notice shall be made available on a flyer or handout clearly visible from and kept within easy reach of each counter in the pharmacy where dangerous drugs are dispensed or furnished, available at all hours that the pharmacy is open. The flyer or handout shall be at least 8 1/2 inches by 11 inches.

(d) Every pharmacy shall either post or provide on the patient's written receipt a statement describing patients' rights per Business and Professions Code sections 733 and 4122.

Note: Authority cited: Sections 4005 and 4122, Business and Professions Code.
Reference: Sections 733, 4005, 4076.5 and 4122, Business and Professions Code.

M/S: Thibeau/Chandler

Member Jha returned to the meeting at approximately 2:21 p.m.

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

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

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

X. Organizational Development Committee Report

President Oh noted the Organizational Development Report was for information only. Dr. Oh reported the Board's authorized budget for the year was about \$31.3 million. The Board received about \$27 million in revenue for the first eight months of the fiscal year and estimated about \$19.5 million. Dr. Oh advised the Board's fund condition indicated that the Board fund will slowly decrease; however, at a slower rate than was provided in the Board's fee audit. This was believed to be due in part to the department provided fund condition did not currently reflect anticipated costs for a new IT solution.

President Oh advised Board Member attendance and mail vote information was included in the meeting materials. Dr. Oh stated being truly grateful to members for their time and commitment to protecting California Consumers.

President Oh reported the Board currently had 15 vacant staff positions with ongoing recruitments. Dr. Oh indicated receiving regular updates on recruitments as part of weekly meetings with the Executive Officer and monthly as part of the Organizational Development Meetings.

President Oh advised there was a draft 2024 schedule of meetings included in the meeting materials.

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

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

XI. Medication Error Reduction and Workforce Committee Report

Chairperson Thibeau provided the report on the Committee's efforts at its March 8, 2023, meeting. Dr. Thibeau thanked fellow Committee Members Vice-Chair Oh, Crowley, Koenig, and Patel.

- a. Summary of Presentation provided by the Alliance for Quality Improvement and Patient Safety, on Patient Safety Organizations.

Chairperson Thibeau reported throughout various Committee discussions, the Committee considered different approaches to address the issue of medication errors. Dr. Thibeau provided an example as learning about the Institute for Safe Medication Practices (ISMP) and its role in addressing medication errors

including providing free resources and information to licensees about best practices and its advocacy with the FDA to facilitate change.

Chairperson Thibeau added the Committee continued education on this issue, with a presentation by Peggy Binzer, the Executive Director with the Alliance for Quality Improvement and Patient Safety (Alliance) that is a professional association for patient safety organizations (PSOs). Dr. Thibeau reported Ms. Binzer provided some history on the creation of PSOs and the services they provided. Members were advised that pharmacy PSOs evaluate quality related events through a variety of means to minimize patient risk and prevent events from reoccurring. Ms. Binzer discussed the Alliance's National Safe Tables Program which was created in 2017 to create a national learning system to solve industry-wide problems and share best practices. Dr. Thibeau reported learning that PSOs compiled the top four most important issues. Ms. Binzer expressed her opinion regarding mandatory state reporting of medication errors and suggested that mandatory reporting to outside organizations will chill reporting. Part of the information shared from Ms. Binzer included anecdotal information that when a Just Culture is implemented, there is an enhancement in well-being and an increase in reporting from pharmacists. Dr. Thibeau highlighted this specifically because the Committee dedicated time to learning about Just Culture. Dr. Thibeau reported meeting materials contained the presentation slides and encouraged Members to review the livestream available on the Board's website.

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

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

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

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

Chairperson Thibeau reported the Committee had been monitoring information on the Pharmacist Well-Being Index, an online screening tool invented by the Mayo Clinic to assist licensees in assessing their well-being. Dr. Thibeau advised the screening tool was anonymous and available at no charge. Dr. Thibeau reported pharmacists identified as being at a risk of high distress are at a two-fold higher risk of medication errors. Dr. Thibeau noted the February state report

was included in the meeting materials where California was ranked 40. For comparison, in October 2022 California was ranked 43rd.

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

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

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

Chairperson Thibeau reported the Committee's final meeting as an ad hoc committee was scheduled for June 7, 2023.

XII. Closed Session Matters

Following completion of the open session at 2:36 p.m. the Board convened in closed session at 2:50 p.m. for the stated purposes indicated on the agenda. Closed session ended at 3:25 p.m.

XIII. Reconvene Open Session, to Adjourn for the Day

Due to technological limitations, adjournment for the day was not broadcast. The meeting adjourned at 3:25 p.m.

April 20, 2023

President Oh called the Board Meeting to order at 9:00 a.m. Dr. Oh reminded all individuals present that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. Where protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. Dr. Oh advised all individuals the meeting was being conducted via WebEx. Dr. Oh advised participants watching the webcast they could only observe the meeting. He noted anyone interested in participating in the meeting must join the WebEx meeting using the instructions posted on the Board's website. Department of Consumer Affairs' (DCA) staff provided general instructions for the WebEx Board Meeting for members of the public participating in the meeting.

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

XIV. Enforcement and Compounding Committee Meeting Report

Board President Oh thanked Members and staff for their work on the Enforcement and Compounding Committee.

Chairperson Serpa provided the Board with a summary of the Committee's efforts at its meetings during the past quarter. Dr. Serpa thanked fellow Members Vice-Chair Patel, Barker, Cameron-Banks, Oh, and Sanchez.

Chairperson Serpa advised the Committee has met several times to review new and revised USP Chapters related to radiopharmaceuticals, hazardous drugs, sterile and nonsterile compounding, and the Board's related regulations to determine what, if any changes were necessary based on the actions of USP. Dr. Serpa reported it has been a significant undertaking. Dr. Serpa thanked the Committee and stakeholders for participating in this process.

a. Summary of Presentations on US Pharmacopeia (USP) General Chapters

Chairperson Serpa reported as part of the Committee process, prior to considering proposed changes to Board regulations in the respective areas, members and stakeholders received an overview of each of the USP Chapters. Presentations were provided on USP Chapter 825 Regarding Radiopharmaceuticals, USP Chapter 795 Pharmaceutical Compounding –

Nonsterile Preparations, USP Chapter 797 Pharmaceutical Compounding – Sterile Preparations and USP Chapter 800 – Hazardous Drugs – Handling in Healthcare Settings. Supervising Inspectors Acosta, Kalantar and Panella-Spangler provided the summary presentations and served as subject matter experts during the discussion. Dr. Serpa noted the Board was fortunate to have experts available to share their knowledge with the Committee as the proposed regulations were discussed.

Chairperson Serpa advised the presentation slides were included in the meeting materials as well as FAQs for each of the USP Chapters. Dr. Serpa added the slides for USP 795 had been updated on the Board's website. Dr. Serpa encouraged licensees that have not yet considered the new and revised Chapters to begin doing so now as there were some significant changes becoming effective November 1, 2023.

Committee Members were provided the opportunity to comment on any of the presentations received over the four meetings; however, no comments were made.

Members were provided the opportunity to comment or ask questions on any of the presentations received over the four meetings; however, no comments were made.

Members of the public were provided the opportunity to comment or ask questions on any of the presentations received over the four meetings; however, no comments were made.

b. Discussion, Consideration and Possible Action on Proposed Changes to Regulations

Chairperson Serpa expressed excitement being at the point where the Board could move regulation language to initiate the rulemaking process in support of consumer protection. Dr. Serpa reported of these regulations were initially developed in 2019 but were suspended in response to USP's September 2019 announcement delaying the official date of revised Chapters 795 and 797 and new Chapter 825. Dr. Serpa advised the Board announced in its policy statement at the time encouraging licensees to move toward compliance with provisions of the revised chapters and encouraged utilization of Chapter 800 to advance public health. Dr. Serpa recalled USP Chapter 800 was not subject to appeals. Dr. Serpa noted as part of the Board's policy statement, the Board encouraged licensees to continue efforts to transition to proposed USP requirements to ensure the safety and efficacy of compounding drug

preparations and patient safety. Those stakeholders that elected to do so, should be well positioned to be compliant with the chapters when they become compendial November 1, 2023. Dr. Serpa thanked stakeholders that took proactive steps to implement the provisions to improve patient care.

Chairperson Serpa advised for the discussion and consideration at the meeting, the Board would review one revised and three proposed new articles covering various areas. Dr. Serpa indicated intending to review each article separately allowing member discussion and an opportunity to public comment and only after consideration of all four articles and related regulations were completed, Dr. Serpa recommended the Board take formal action if the Board determined such action was appropriate.

Chairperson Serpa believed it was important to share the process the Committee used to develop the regulations. Dr. Serpa recalled the proposed changes to regulations began in 2019 and those efforts were suspended at that time. Dr. Serpa advised the language developed in 2019 served as the starting point for the language before the Board. Dr. Serpa reported the Committee dedicated four meetings to reviewing the proposed language and during each meeting, the Committee provided significant opportunity for public comment on each section. Dr. Serpa added the Committee considered written comments received in advance of each meeting.

Chairperson Serpa intended to provide some summary comments on the respective articles and regulations, provide an opportunity for Committee members to provide comments, followed by an opportunity to the Board to discuss the proposed regulations, and then open up for public comments. Members were provided the opportunity to ask questions or voice concerns about the process. No comments were made.

Chairperson Serpa reminded participants this was the beginning of rulemaking process adding there would be additional opportunities to provide comments during the formal rulemaking process. Dr. Serpa suggested focusing on policy issues today and avoid wordsmithing to ensure necessary timeframes were met.

Chairperson Serpa added there were a myriad of state and federal laws that licensees must comply with, including relevant provisions of the Food Drug and Cosmetic Act, 503A provisions, USP Chapters, state statues, and Board regulations. Dr. Serpa noted it was important for licensees to remain mindful of all legal requirements, not just those established in Board regulations. Dr. Serpa provided the proposed regulations would not be restating federal requirements, nor would they be restating USP standards established in the respective

chapters. Dr. Serpa advised the Board's regulations were in addition to federal requirements, USP Chapters and California statutes consistent with the Board's authority and consumer protection mandate.

Chairperson Serpa reminded participants DCA Counsel Smiley provided an excellent overview of some related federal requirements for licensees compounding under the provisions of 503A. For licensees to compound in compliance with California requirements, they must ensure compliance with these federal requirements. Dr. Serpa encouraged licensees to review the presentation slides and overview Ms. Smiley provided to serve as an excellent reminder to licensees of federal requirements.

Chairperson Serpa started with the proposed changes to Article 4.5 and proposed revisions to regulation sections 1735 – 1735.14 related to nonsterile preparations. Consistent with the USP 795 Chapter, the proposed regulations mirror the structure of the USP Chapter and include:

- Section 1735 Compounding Definition
- Section 1735.1 Introduction and Scope
- Section 1735.2 Personnel Training and Evaluation
- Section 1735.3 Personnel Hygiene and Garbing
- Section 1735.4 Building and Facilities
- Section 1735.5 Cleaning and Sanitizing
- Section 1735.6 Equipment and Components
- Section 1735.7 Master Formulation and Compounding Records
- Section 1735.8 Release Inspections and Testing
- Section 1735.9 Labeling
- Section 1735.10 Establishing Beyond-Use Dates
- Section 1735.11 Standard Operating Procedures
- Section 1735.12 Quality Assurance and Quality Control
- Section 1735.13 CNSP Packaging and Transporting
- Section 1735.14 Documentation.

Chairperson Serpa advised the proposed language and comments were included in the meeting materials. Dr. Serpa reviewed the comments and did not recommend any changes. Dr. Serpa specifically addressed several comments that were submitted as part of the Committee Meeting and in advance of this meeting related to flavoring agents. As discussed during the Committee meeting, BPC section 4126.8 explicitly states that the compounding of drug preparations by a pharmacy shall be consistent with standards established in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary as specified. Dr. Serpa noted the Board may adopt regulations to impose additional standards for

compounding drug preparations. Dr. Serpa advised USP was a minimum operating standard in California and there was nothing in this section that provided the Board with the authority to consider a lesser standard than what is established in the USP Compounding Chapters.

Chairperson Serpa noted that many of the comments received appeared to be urging the Board to adopt a lesser standard than what is established in USP. Such action would run contrary to the Board's authority and would create conflict with federal law. California cannot adopt a lesser standard than those established in USP. Dr. Serpa stated it appeared based on her read of several of the comments submitted by consumers that they believe the Board is taking action to prohibit the use of flavoring agents. Dr. Serpa believed it was important to clarify there was nothing in the Board's proposed language that would prohibit the use of flavoring agents. Dr. Serpa noted the use of flavoring agents was allowed both under USP Compounding Chapter 795 as well as the Board's proposed regulations under requirements established. Pharmacies can continue adding flavoring agents as requested by patients. Such pharmacies will need to meet the USP and Board requirements the same as another nonsterile compounding activity. A pharmacy may choose to no longer offer flavoring agents to consumers; however, that is a business decision being made by the pharmacy. Dr. Serpa reiterated the Board and USP were NOT prohibiting the use of flavoring agents.

Chairperson Serpa added the Committee determined it appropriate to modify the language related to compounding of preparations for veterinary patients. These changes were reflected in section CCR section 1735.1(e).

Chairperson Serpa believed that the proposed language included in article 4.5 was appropriate, consistent with legal requirements within both 503A and California statute, and consistent with the Board's consumer protection mandate.

Committee Members were provided the opportunity to comment.

Member Chandler appreciated the thoroughness of the information.

Committee Members were provided the opportunity to comment on the proposed revised section 4.5 and the proposed language.

Member Crowley appreciated the thoroughness and that the public comments were addressed. Dr. Crowley noted doing non-sterile compounding in another state prior to coming to California and the concept of flavoring as a part of

compounding was something that standard in the past. Dr. Crowley noted it made sense in the past and made sense now. Dr. Crowley appreciated the time taken to make everything clear and the summary was well done.

Members of the public were provided the opportunity to comment.

The Board heard comments from representatives of California Community Pharmacy Coalition, FLAVORx, pharmacists, parents of children and members of the public. Representatives commented about the definition of compounding that no longer explicitly excludes flavoring. Representatives understood the Board couldn't have lower standards than USP and asked if the Board could examine other ways to ensure flavoring can be continued without being considered compounding. Representatives noted pharmacies will probably not offer flavoring if required to adhere to the requirements. Some representatives disagreed that the Board had no other choice and felt the Board could exclude flavoring from compounding rules by rule. Some commenters were not aware of safety issues with the current practice of flavoring. A representative provided examples of flavoring in Washington and Arizona. Parents raised concerns of their ability to get their children to take medicines without flavoring as did parents of children with disabilities. A pharmacist spoke against adopting USP as it was a written standard not a written regulation.

Chairperson Serpa added this was not a new issue as it had been worked on since 2019. Dr. Serpa indicated this could be an area for an FAQ to pharmacies to encourage them to continue adding flavoring. Dr. Serpa noted the discussion for now was the regulations for compounding that include adding flavoring as a compounded process.

Members were provided an opportunity to comment.

Member Crowley commented on the public comment suggesting that non-compounding pharmacies would not be able to add flavoring but that was not Dr. Crowley's understanding and requested clarification. Supervising Inspector Acosta advised there was no separate licensure requirement with the Board of Pharmacy for a licensed pharmacy to do non-sterile compounding. Dr. Crowley thanked Dr. Acosta for providing the clarification. Dr. Crowley explained in her experience at a children's hospital that flavoring and adding flavoring was a very simple form of compounding with easy documentation. Dr. Crowley encouraged pharmacies to continue providing that service as it just meant the pharmacist would be documenting everything appropriately which was essential because when flavoring was added it does change the amount of distilled water to add to make sure the final concentration was the same. Dr.

Crowley added the documentation was required to know what manipulation was done to the product and it was essential to be in line with USP standards.

Chairperson Serpa recalled proposed article 4.6 relates to sterile compounding including the following:

- Section 1736 Sterile Compounding Definitions
- Section 1736.1 Introduction and Scope
- Section 1736.2 Personnel Training and Evaluation
- Section 1736.3 Personnel Hygiene and Garbing
- Section 1736.4 Facilities and Engineering Controls
- Section 1736.5 Certification and Recertification
- Section 1736.6 Microbiological Air and Surface Monitoring
- Section 1736.7 Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA
- Section 1736.8 Introducing Items into the SEC and PEC
- Section 1736.9 Equipment, Supplies and Components
- Section 1736.10 Sterilization and Depyrogenation
- Section 1736.11 Master Formulation and Compounding Records
- Section 1736.12 Release Inspections and Testing
- Section 1736.13 Labeling
- Section 1736.14 Establishing Beyond-Use Dates
- Section 1736.15 Use of Conventionally Manufactured Products as Components
- Section 1736.16 Use of CSPs as Components
- Section 1736.17 Standard Operating Procedures
- Section 1736.18 Quality Assurance and Quality Controls
- Section 1736.19 CSP Handling, Storage, Packaging, Shipping and Transport
- Section 1736.20 Documentation
- Section 1736.21 Compounding Allergenic Extracts

Chairperson Serpa noted given the significant risk to patients, the requirements for sterile compounding were more robust than for nonsterile compounding. Dr. Serpa referenced the proposed language and comments included in the meeting materials. Dr. Serpa added comments received before and at the Committee were reviewed and resulted in some changes to the original proposal language. Dr. Serpa noted the language proposed at the meeting was a result from input from staff and stakeholders. Dr. Serpa noted one set of comments, from Cedars Sinai was inadvertently included in the wrong attachment. Dr. Serpa reviewed the comments and believed one change in the proposed language was appropriate.

Chairperson Serpa highlighted the proposed language was providing clear requirements specifically related to a certificate of analysis (COA). The provisions related to the COA was a good example of the collaboration between the Committee and public comment. The language incorporated changes made during the Committee meeting to address public comments received.

Chairperson Serpa noted as proposed in section 1736.2(b), the language would allow for the aseptic qualifications from one premises to be used for another premises under specified condition adding this was a big change from the Board's current regulation requirements and provides better flexibility to licensees.

Chairperson Serpa highlighted as proposed in section 1736.4 the Board would begin stepping into a future requires for the use of interlocking pass-through doors. Dr. Serpa suggested in response to comments received, it may be appropriate to move the second sentence in 1736.4(e) to remove the language "No passive ceiling or wall penetration are allowed."

Chairperson Serpa highlighted provisions related to active pharmaceutical ingredients also referred to as API. In proposed section 1736.9. The language of the section required a COA that includes the grade of the material unless the component used was a commercially available drug product. Dr. Serpa added requiring the COA to include the grade of the material would ensure licensees understand the quality of the component and was consistent with the requirements established in Chapter 1080 for use of excipients.

Committee Members were provided the opportunity to comment on the proposed revised section 4.6 and the proposed language; however, no comments were made.

Members were provided the opportunity to comment on the proposed revised section 4.6 and the proposed language; however, no comments were made.

Members of the public were provided the opportunity to comment on the proposed revised section 4.6 and the proposed language.

A pharmacist commented section 1736 as presented provides licensees with clarification on which USP standards the Board wishes to enforce as requirements rather than best practices. The pharmacist appreciated the Committee collaborated with the public and the proposed amendment to section 1736.4 (e) regarding passive penetrations. The pharmacist added there

were several proposed requirements in section 1736 that would unduly increase the cost of compliance and the compounded medication preparations without clear improvements to quality and/or safety which will be passed on to the consumer and felt access to compounded preparations would be reduced.

A pharmacist representative of Kaiser thanked the Committee for taking recommendations on section 1736.1(d) regarding restrictions on when a compound should not be compounded. The representative added the Committee needed to provide empirical data to support the need for a regulations that exceeds the requirement of the chapter noting inspector observation was anecdotal. The representative recommended deleting sections including 1736.1(b), 1736.6(b), and 1736.9(d). The representative thought rather than chapters of USP being incorporated by reference, the information from the chapter should be included in the text.

Members were provided the opportunity to comment after public comment was received; however, no additional comments were made.

Chairperson Serpa referenced proposed article 4.7 relates to handling of hazardous drugs. Dr. Serpa reminded participants that USP 800 related to the handling of hazardous drugs was published in 2019 and had not changed adding it was not compendial until USP 797 regarding sterile compounding was compendial because they were interrelated. The proposed regulation sections included the following:

- Section 1737 Handling of Hazardous Drugs
- Section 1737.1 Introduction and Scope
- Section 1737.2 List of Hazardous Drugs
- Section 1737.3 Types of Exposure
- Section 1737.4 Responsibilities of Personnel Handling Hazardous Drugs
- Section 1737.5 Facilities and Engineering Controls
- Section 1737.6 Environmental Quality and Control
- Section 1737.7 Personal Protective Equipment (PPE)
- Section 1737.8 Hazard Communication Program
- Section 1737.9 Personnel Training
- Section 1737.10 Receiving
- Section 1737.11 Labeling, Packaging, Transport and Disposal
- Section 1737.12 Dispensing Final Dosage Form
- Section 1737.13 Compounding
- Section 1737.14 Administering
- Section 1737.15 Deactivation, Decontamination, Cleaning, and Disinfecting
- Section 1737.16 Spill Control

- Section 1737.17 Documentation and Standard Operating Procedures
- Section 1737.18 Medical Surveillance

Chairperson Serpa advised the language and comments received were included in the meeting materials. Dr. Serpa noted comments received at the Committee meeting were reviewed and resulted in some changes to the original proposed language. Dr. Serpa believed the language as presented was appropriate.

Committee Members were provided the opportunity to ask questions or comment on the proposed revised section 4.7 and the proposed language.

Members were provided the opportunity to ask questions or comment on the proposed revised section 4.7 and the proposed language.

President Oh requested staff explain how this chapter was relevant to community pharmacies and how the adoption of the chapter would affect community pharmacies who were not compounding.

Supervising Inspector Christine Acosta provided USP 800 in general was related to the handling of hazardous drugs and didn't only encompass compounding. Dr. Acosta advised most of the requirements were related to the handling of API or anti-neoplastic noting that not all retail location would handle these categories of drugs. Dr. Acosta added some may handle anti-neoplastic tablets or even 5FU cream which was an anti-neoplastic agent on Table 1. Dr. Acosta encouraged all pharmacies to read the Chapter and do an assessment of risk to see how the pharmacy will handle particular products. Dr. Acosta noted it would affect retail stores which may need to write a policy, outlining what hazardous drugs are being used and/or assessment of risk to determine how it will be handled.

President Oh recommended developing an FAQ if the regulations being approved today would affect that as it is not included in the self-assessment noting it would be important to clarify what will be looked for during inspections and to make sure community pharmacies are aware of additional requirements. Dr. Acosta advised as regulations are going through the process, inspectors start the communications with the licensees during inspections to help prepare for changes.

Members were provided the opportunity to ask questions or comment on the proposed revised section 4.7 and the proposed language; however, there were no comments made.

Members of the public were provided the opportunity to ask questions or comment on the proposed revised section 4.7 and the proposed language.

A pharmacist representative of Kaiser commented in support of the collaborative process and taking the feedback provided for many suggestions provided by Kaiser on sections 1735.5(a), 1737.7(a) and 1737.8(e). The representative indicated having issues and the lack of accompanying evidence with several sections including 1737.5(d), 1737.7(c), 1727.13(a), and 1737.13(b).

A pharmacist representative of Sutter Health commented in support of the collaboration and taking suggestions but had similar concerns as the Kaiser representative related to sections 1735.5(d), 1737 (c), and 1737 (e).

A pharmacist commented in support of standards being clarified and appreciated the collaboration. The pharmacist was concerned with the lack of evidence to support new requirements and agreed with the sections provided by representatives from Kaiser and Sutter Health and added section 1737.10.

Members were provided an opportunity to comment after public comment was received; however, no comments were received.

Members took a break from 10:21 a.m. to 10:30 a.m. Roll call was taken after the break. Members present included: Maria Serpa, Licensee Member; Renee Barker, Licensee Member; Trevor Chandler, Public Member; Jessi Crowley, Licensee Member; Jose De La Paz, Public Member; Ricardo Sanchez, Public Member; and Seung Oh, Licensee Member. A quorum was established.

Chairperson Serpa advised proposed article 4.8 related to radiopharmaceuticals and included the following proposed sections:

- Section 1737 Radiopharmaceuticals – Preparation, Compounding, Dispensing and Repackaging
- Section 1738.1 Introduction
- Section 1738.2 Radiation Safety Considerations
- Section 1738.3 Immediate Use of Sterile Radiopharmaceuticals
- Section 1738.4 Personnel, Qualifications, Training and Hygiene
- Section 1738.5 Facilities and Engineering Controls
- Section 1738.6 Microbiological Air and Surface Monitoring
- Section 1738.7 Cleaning and Disinfecting
- Section 1738.8 Assigning BUD
- Section 1738.9 Documentation
- Section 1738.10 Preparation

- Section 1738.11 Compounding
- Section 1738.12 Dispensing
- Section 1738.13 Repackaging
- Section 1738.14 Quality Assurance and Quality Controls

Chairperson Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate.

Committee Members were provided the opportunity to ask questions or comment on the proposed revised section 4.8 and the proposed language; however, no comments were made.

Members were provided the opportunity to ask questions or comment on the proposed revised section 4.8 and the proposed language; however, no comments were made.

Members of the public were provided the opportunity to ask questions or comment on the proposed revised section 4.8 and the proposed language; however, no comments were made.

Chairperson Serpa noted with an apparent consensus that the proposed language was appropriate to move forward with a possible motion to begin the formal rulemaking process. Dr. Serpa noted it was important to move forward with the action today to provide clarity to licensees as USP Chapters become compendial on November 1, 2023. Dr. Serpa recommended adding to the recommended motion to remove from 1736.4(e) the section that said, "no passive ceiling or wall penetrations are allowed." Dr. Serpa read the motion into record.

Motion: Approve the proposed regulatory text as proposed to amend article 4.5, related to nonsterile compounding and the regulation language as proposed, add article 4.6 related to sterile compounding and the text as proposed, add article 4.7 related to hazardous drugs and the regulation text as proposed, and add article 4.8 related to radiopharmaceuticals and the regulation text as proposed. Further, repeal article 7 related to sterile compounding and repeal sections 1708.3, 1708.4 and 1708.5 related to radioactive drugs. In addition, remove from the proposed text of 1736.4(e), "no passive ceiling or wall penetrations are allowed." Further, direct staff to submit the text to the Director of the Department of Consumer Affairs

and to the Business, Consumer Services and Housing Agency for review and if no adverse comments are received, authorize the Executive Officer to take all steps necessary to initiate the rulemaking process. Authorize the Enforcement Committee Chair and Executive Officer to make any nonsubstantive changes or clarifying changes necessary consistent with the Board's policy. If no comments received that the Board must respond during the 45-day comment period and no hearing is requested, authorize the Executive Officer to take all necessary steps to complete the rulemaking and adopt the proposed regulations as noticed.

[Note: A copy of the text is appended to these minutes.]

M/S: Serpa/Sanchez

Members of the public were provided the opportunity to comment. The Board heard comments from representatives of Pacific Compounding Pharmacy and Consultations, Kaiser, Hartley Medical Center in Long Beach and FLAVORx. Comments thanked the Committee and Board for the work on the compounding regulations but requested returning the regulation language back to Committee for a variety of reasons including too many regulations above USP Chapters; conflicting definitions; lack of evidence; and clarification that only documentation was required for flavoring.

Chairperson Serpa spoke in favor of moving the regulation forward to ensure Board regulations were not in conflict with the USP Chapters that become compendial on November 1, 2023.

Members were provided an opportunity to comment in response to public comment.

Member Crowley understood the changes being made to being compliant with the newest USP standards released and asked if there were regulations that would be stricter than USP. Dr. Serpa noted it was a complex question and added the Board's current regulations were stricter than what USP was proposing so in some situations the Board's proposed regulation was to keep the same regulatory standard in the current Board regulation. Dr. Serpa added in other situations it was to add clarity and additional information. Dr. Serpa noted globally the Board's current regulations did not meet the standard or structure of USP that becomes effective on November 1, 2023. Dr. Serpa noted it was important to mirror the standards and be closer to implementing regulations by

that date. Otherwise, it could be very complicated having conflicting and confusing regulations at the federal and state level. Dr. Acosta advised there were standards above USP in all four of the sections of proposed regulations (e.g., endotoxin testing be made available and reviewed prior to drug being released, etc.). Dr. Acosta cautioned if the Board doesn't move forward when the USP goes into effect and is enforceable on November 1, 2023, the Board's standards will have conflicts which will be difficult for licensees when moving forward now allows for both USP and Board regulations to hopefully go into effect around the same time.

Member Jha inquired about the flavoring component if now considered compounding will it be subject to potency testing as well for the compounded product or would there be a carve out. Dr. Acosta provided in the current law, there is a quality assurance requirement for some type of quality assurance testing and will be part of the repealed language. Dr. Acosta noted the flavoring would have to comply with all of the requirements of USP and Board 1735 regulations. Dr. Acosta didn't recall any requirements for a potency test but they will have to completely comply (e.g., training, cleaning, etc.) with all requirements.

Support: 8 Oppose: 0 Abstain: 0 Not Present: 5

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

- c. Discussion and Consideration of Draft Statutory Proposal to Amend Business and Professions Code Sections 4081 and 4105

Chairperson Serpa noted as part of the Committee's January 2023 meeting, the Committee considered a recommendation from staff to amended BPC sections 4081 and 4105 to address challenges staff are experiencing in obtaining records necessary to evaluate pharmacy operations for compliance with Pharmacy Law. Dr. Serpa advised the Committee requested staff prepare draft statutory language for consideration included in the meeting materials. Dr. Serpa added during the meeting, Committee Members spoke in support of the language. Dr. Serpa reported in response to public comment members spoke in support of also incorporating electronic records, if appropriate.

Committee Recommendation (Motion): Recommend approval of the proposed amendments to 4081 and 4105 as presented and allow for further amendment to the language to incorporate electronic records if appropriate.

Proposal to Amend Business and Professions Code section 4081

- (a) All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility, physician, dentist, podiatrist, veterinarian, laboratory, licensed correctional clinic, as defined in Section 4187, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.
- (b) The owner, officer, and partner of a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge, responsible manager, or designated representative-in-charge, for maintaining the records and inventory described in this section.
- (c) The pharmacist-in-charge, responsible manager, or designated representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge, responsible manager, or designated representative-in-charge had no knowledge, or in which he or she did not knowingly participate.
- (d) Pharmacies that dispense nonprescription diabetes test devices pursuant to prescriptions shall retain records of acquisition and sale of those nonprescription diabetes test devices for at least three years from the date of making. The

records shall be at all times during business hours open to inspection by authorized officers of the law.

(e) In addition to the records described in subdivision (a) records that must be maintained include staffing schedules, pharmacy personnel job duty statements, consultant reports, and policies and procedures related to pharmacy personnel and pharmacy operations.

Proposal to amend BPC 4105

(a) All records or other documentation required by this Chapter of the acquisition and disposition of dangerous drugs and dangerous devices to be maintained by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.

(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.

(d) (1) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hardcopy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(2) In the case of a veterinary food-animal drug retailer, wholesaler, or third-party logistics provider, any records that are maintained electronically shall be maintained so that the designated representative-in-charge or the responsible manager, or the designated representative on duty or the designated representative-3PL on duty if the designated representative-in-charge or responsible manager is not on duty, shall, at all times during which the licensed place of business is open for business, be able to produce a hardcopy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(e) (1) Notwithstanding subdivisions (a), (b), and (c), the board may, upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.

(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter.

(f) When requested by an authorized officer of the law or by an authorized representative of the board, the owner, corporate officer, or manager of an

entity licensed by the board shall provide the board with the requested records within three business days of the time the request was made.

The entity may request in writing an extension of this timeframe for a period not to exceed 14 calendar days from the date the records were requested. A request for an extension of time is subject to the approval of the board. An extension shall be deemed approved if the board fails to deny the extension request within two business days of the time the extension request was made directly to the board.

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

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

Members of the public were provided the opportunity to comment.

A pharmacist representative of Kaiser encouraged the Board to consider if it would be beneficial to allow for electronic storage of records regardless of the form in which they were made citing BPC section 4070(c) and Evidence Code section 1550 regarding the conditions the Board may want to specify to ensure electronic records cannot be changed. The representative added that allowing explicitly for electronic record storage could help inspectors doing their job.

Executive Officer Sodergren noted the Committee Recommendation provided the flexibility to incorporate the additional clarification specific to electronic records. Additionally in these changes, the Board's policy has been that the staff work with the Committee Chair to confirm finalized language is consistent with the Board policy.

Support: 8 Oppose: 0 Abstain: 0 Not Present: 5

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

- e. Discussion and Consideration of Proposed to Amend Title 16, California Code of Regulation Sections related to Compounding of Nonsterile and Sterile Preparations for Dispensing by Veterinarians for Animal Patients.

Chairperson Serpa advised the Board already discussed this issue as part of the discussion on the nonsterile and sterile compounding regulations.

- f. Review and Discussion of Enforcement Statistics

Chairperson Serpa advised the meeting materials included enforcement statistics. Dr. Serpa reported the Board initiated 2,686 investigations and closed 2,376 investigations. Outcomes varied and included the issuance of 141 letters of admonishment, 766 citations and referral of 181 cases to the AG's Office. Dr. Serpa highlighted 181 cases have been referred to the AG's Office. Dr. Serpa believed there was a misconception about the Board's disciplinary activities with some suggesting that the Board is always seeking to discipline a license. Dr. Serpa reported the referrals to the AG's Office were about 7.6 percent.

Chairperson Serpa highlighted that the Board secured 6 interim suspension orders and had been granted 8 penal code 23 restrictions. In both instances the Board was successful in securing immediate public protection through these actions while the disciplinary case process continues which is core to the Board's mandate. Dr. Serpa noted the average days of investigations awaiting final closure was reported on the final chart for April 1, 2023, as 75 day it should have been 43 days.

Chairperson Serpa reported investigation times were also included. Dr. Serpa thanked supervising inspectors who have worked to reduce supervisor review time with two vacancies which was commendable. Dr. Serpa noted appreciation for their efforts. Dr. Serpa reminded during the July 2023 Board Meeting there would be a three-year comparison data which will help evaluate for trends.

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

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

XV. Licensing Committee Report

President Oh as Chairperson of the Licensing Committee thanked fellow Committee Members Patel, Cameron-Banks, Chandler, Crowley, and Weisz. Dr. Oh noted as there was not quorum for the Committee Meeting, any action will require a motion.

a. Discussion and Consideration of Provisions for Remote Processing

President Oh reminded to facilitate physical distancing early in the COVID-19 pandemic, the Board approved a waiver to extend the provisions for remote processing based on the Board's authority in BPC section 4062 and was limited in duration. Dr. Oh referenced meeting materials that contained extensive information on remote processing and the remote processing waiver that had been in effect for a majority of the pandemic. Dr. Oh highlighted the Board continues to receive comments suggesting that the Board has changed its legal interpretation of remote processing. Dr. Oh reminded participants that was not accurate as Counsel Ms. Smiley had repeatedly indicated, the Board's interpretation of the law has not changed as the Board was never asked to issue an interpretation of the provisions before the issuance of the first waiver. The Board's interpretation of the remote processing question arose from the structure of current permanent Pharmacy Law.

President Oh reported the Committee considered several concepts that could be included in a legislative proposal if the Board ultimately determined that such action was appropriate. Concepts were detailed in the chair report along with a summary of comments from members and the public. The Committee requested data from stakeholder regarding pharmacy personnel that were working remote. Dr. Oh thanked CVS for providing information and was hopeful that other stakeholders would also provide similar information requested.

Committee Members present at the Committee meeting were provided the opportunity to comment.

Member Crowley commented requesting how many pharmacies were actually benefiting from remote work in California and was hoping to get more information at some point.

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

Members of the public were provided the opportunity to comment.

A representative of the CCPC advised membership had been requested to provide feedback on what types of remote work was being used, how many pharmacists were working remotely, and how many of those working remotely were specialty versus community. The representative requested a statutory fix to allow remote processing to continue beyond the waiver and was hopeful that a 90-day extension could be extended for community pharmacy settings. The representative added as of May 28th some pharmacist members will lose their jobs.

A pharmacist representative of Kaiser appreciated the Board's engagement in discussing remote work. Based on past experience, Kaiser continued to believe the remote work processing waiver was the best framework for the statutory changes needed. The representative cited a 2022 McKinsey and Company found that certain traditionally underrepresented groups have a stronger than average preference for remote or hybrid work arrangements and encouraged the Board to consider inclusion implications of diversity, equity and inclusion (DEI) efforts related to Executive Order N1622. The representative expressed concerns and requested removal of the requirement that each pharmacist working remotely sign a consent acknowledging the Board may inspect their remote work location. The representative expressed concerns about having a pharmacist-in-charge (PIC) sign the determination under penalty of perjury that reliance on remote work would not be used as a means to or lead to reduced staffing levels in the pharmacy as conditions are dynamic and recommended removing restrictions on using laptops as it was a business decision.

President Oh noted there would be future discussions on this topic at future meetings.

b. Discussion and Consideration of Changes to the Board's sample CPA Related to Medication Assisted Treatment to Remove the Data 2000 Waiver Reference

President Oh reported in October 2020 the Board released a sample Collaborative Practice Agreement (CPA) for pharmacists to provide medication-assisted treatment (MAT) to patients with opioid use disorder in collaboration with a medical provider. Dr. Oh added with recent changes at the federal level, the sample agreement requires updating to remove reference to the DATA 2000 requirement as federal law no longer contains such a requirement. Dr. Oh reported agreement with the change. However, as the CPA was just a resource available for pharmacists, formal action by the board was not needed.

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

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

President Oh reported staff would work to update the agreement available on the Board's website to reflect this change.

c. Discussion and Consideration of Possible Regulations to Implement Government Code Section 16.5 Related to Digital Signatures and Development of Policy Statement to Facilitate Implementation of Digital Signatures on Applications and Other Notices.

President Oh advised background information was included in the meeting materials and noted there were provisions in the California law that allow for a public entity to accept digital signatures under specified conditions. Regulations further specify the two forms of acceptable technology, public key cryptography and signature dynamics. Dr. Oh reported reviewing the issue and noted agreement with the general policy offered by staff at the meeting. Dr. Oh added the draft policy statement was included and the need for regulations to permanently establish the provisions. Dr. Oh advised as there wasn't quorum at the Committee Meeting, the Committee could not act and a motion would be required if the Board would like to move forward to implement provisions for digital signatures. Dr. Oh reported public comment received in support of the staff recommendation. Dr. Oh advised the draft policy statement was included in the meeting materials.

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

Motion: Approve the draft policy statement to establish the requirements for digital signatures including the use of public key cryptography as the acceptable technology as provided in the meeting materials.

M/S: Chandler/Crowley

Members of the public were provided the opportunity to comment.

A pharmacist requested clarification if the public key cryptography was the only technology allowed in the public statement where other federal requirements accept other types of electronic signatures.

Support: 7 Oppose: 0 Abstain: 0 Not Present: 6

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

d. Discussion and Consideration of Licensing Statistics.

President Oh reported licensing statistics were updated to include data through March 2023. The Board received 10,403 initial applications as well as 358 requests for temporary licenses. The Board issued 6,289 permanent licenses and an additional 252 temporary licenses. Dr. Oh reported staff also provided updated process times. The Board recently filled the sole position responsible for processing pharmacy technician applications, a position that was vacated the end of November 2022. In the last week the processing time decreased to 72

days and anticipating it will continue to decrease. Dr. Oh reported there were several vacancies in Licensing. Dr. Oh advised similar to the improvements with the pharmacy technician program, as positions are filled and onboarding occurs, Dr. Oh anticipated similar improvements in other licensing programs. Dr. Oh thanked Licensing staff.

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

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

President Oh noted at the July meeting, the Committee will look forward to reviewing the statistics where the Committee will monitor the progress on processing times and review three-year comparison data on licensing workload.

XVI. Legislation and Regulation Committee Report

Chairperson Crowley reported on the Legislation and Regulation Committee Meeting from April 19, 2023, and thanked fellow Committee Members De La Paz, Chandler, Jha, Serpa, and Thibeau.

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

1. Assembly Bill 317 (Weber) Pharmacist Service Coverage

Chairperson Crowley reported Assembly Bill 317 would require a health care service plan and specified disability insurers that offer coverage for a service that is within the scope of practice of a pharmacist to pay or reimburse the cost of services performed by a pharmacy at an in-network or out-of-network pharmacy as specified. Dr. Crowley noted Licensing Committee received public comment from pharmacists detailing barriers to patient care stemming from a lack of reimbursement. Dr. Crowley added the measure was sponsored by the California Pharmacy Association and National Community Pharmacists Association.

Chairperson Crowley provided the Committee considered if the measure should be amended to indicate that pharmacists should be included and received comments in support of the measure with some of the public comments suggesting that amendments should be offered to include pharmacists. Dr. Crowley advised the Committee considered the possible

change, but ultimately noted that the Board's role focuses on consumer protection and recommended establishing a support position on the measure.

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

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

Members of the public were provided the opportunity to comment.

An ambulatory pharmacy manager with a health system in the Central Valley commented AB 317 was a well-intended bill to ensure pharmacist are paid for their cognitive services but noted the bill falls short by requiring payments to community pharmacies and not to the pharmacist who was providing services. The commenter recommended support if amended to align with other states' practices. DHCS recently started an MTM pharmacy services to provide payments for medical beneficiaries however the new system only applied to brick and mortar pharmacies and not health system pharmacies. This would codify only a small percentage of the public would benefit from the pharmacy services.

A pharmacist representative of CSHP commented by opening up to pharmacists, access to care is increased for the public and requested a position of support if amended by including pharmacists and not just pharmacies.

A representative of CPhA requested the Board concur with the Committee's recommendation of Support.

A recent Kaiser retiree clinical operations manager with 30 years' clinical experience commented on behalf of self and provided an overview of pharmacists working in ambulatory settings at Kaiser. The commenter noted a one-to-one link between reimbursement for pharmacists rather than pharmacy and meeting patient care needs and encouraged support for the bill.

A pharmacist commented the flaw in the bill was that it only reimburses the pharmacists' cognitive or clinical services when working in a pharmacy but not dispensing services. The pharmacist commented the bill could be modified to include both and advocated

for both to accommodate many different types of business models to provide additional care to patients. The commentor noted it would exclude pharmacists working in medical offices and clinics. The commentor encouraged a new motion to support the bill if amended to cover clinical practice services by pharmacists inside a pharmacy, on behalf of a pharmacy but also independent of a pharmacy (e.g., medical offices, clinics, etc.) where pharmacists have been providing the services for decades.

A pharmacy director of programs at Kern Medical in Bakersfield commented with an overview of their diabetic clinic who services 117,000 diabetics in a population of 900,000 with minimal staff and a1c's decreasing by 2 percent. Without amending the bill to say "pharmacist or a pharmacy clinic" would hamper ability to expand services to patient population. The commentor supported an amendment so pharmacy services could expand services which the bill would prevent.

A representative of the University of California commented noting the benefits of pharmacists working in an ambulatory clinical settings to manage patients with chronic diseases in clinics adding the biggest barrier was the financing and reimbursement. The commentor spoke in support of an amendment to the bill that would allow pharmacists to be reimbursed for services.

A commentor noted there were many pharmacists working in an ambulatory care setting assisting patients that wouldn't be included as currently written noting organizations are working with the author's office to support an amendment. The commentor thought the Board should consider supporting a modification to include all pharmacists in the bill.

The Board heard multiple comments in support of amending the bill to include all pharmacists in settings outside of a pharmacy.

Committee Recommendation (Motion): Support

Chairperson Crowley thanked the commentors and agreed that including pharmacists could actually improve patient access and encourage pharmacists to continue providing expanded services. Dr. Crowley opened Board Member comment after hearing public comment.

Member Serpa commented that the bill's sponsor heard all of the comments and can work with the author's office should they choose to

include pharmacists. Dr. Serpa noted the sponsor was requesting the Board support the bill and not support the bill if amended. Dr. Serpa thought the intent was to provide better services to patients to ensure pharmacists are available and being paid for their services.

Member Barker spoke in support of including all pharmacists not just pharmacists at a pharmacy and looked forward to Board discussion.

Member Barker requested clarification on the motion. Executive Officer Sodergren advised if the Board approved the support position, the letter of support would include the intent of the comments.

Support: 7 Oppose: 0 Abstain: 1 Not Present: 5

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

2. Assembly Bill 602 (Pellerin) California State Board of Pharmacy: Emergency Refills: Report

Chairperson Crowley advised Assemble Bill 602 was heard in committee on April 18, 2023, and passed through committee as a consent item. Dr. Crowley reported the measure would require the Board to report to the Legislature on or before February 28, 2025, the total number of times a pharmacist refilled a prescription for a dangerous drug without a prescriber's authorization. Additionally, the measure would require the Board to report the total number of complaints the Board receives alleging that a pharmacist failed to refill a prescription because the prescriber was unavailable and would require the Board to make a reasonable effort to determine how many of these complaints resulted

from pharmacist's failure to refill a prescription due to a lack of understanding of the authority vested in pharmacists to refill the prescription. Dr. Crowley noted during the Committee's discussion some of the implementation challenges raised in the meeting materials including the variability within pharmacy systems. Dr. Crowley advised the Committee was recommending a watch position on the measure. The Committee did not receive any public comment on the measure.

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

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

Members of the public were provided the opportunity to comment.

A pharmacist commented the bill would require a lot of documentation by pharmacists, pharmacies, and the Board of Pharmacy. The commentor wasn't able to identify the problem the bill was trying to solve and recommended an oppose position.

Committee Recommendation (Motion): Watch

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

Support: 8 Oppose: 0 Abstain: 0 Not Present: 5

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

The Board took a lunch break from 12:00 p.m. to 12:45 p.m. Roll call was taken. Members present included: Maria Serpa, Licensee Member; Renee Barker, Licensee Member; Trevor Chandler, Public Member; Jessi Crowley, Licensee Member; KK Jha, Licensee Member; Ricardo Sanchez, Public Member; and Seung Oh, Licensee Member. A quorum was established.

President Oh recognized Board Member Ricardo Sanchez for his years of service on the Board of Pharmacy since 2014 when appointed by Governor Brown. Dr Oh noted Mr. Sanchez served tirelessly in numerous roles mainly as Chairperson of the Communication and Public Education Committee. Dr. Oh added Mr. Sanchez's leadership, application of law enforcement background and devotion to public service truly helped the Board navigate tough cases. Dr. Oh noted Mr. Sanchez would be missed as this was his last meeting with the Board. Dr. Oh read the Resolution for Mr. Sanchez signed by the Director of the Department of Consumer Affairs and the President of the Board of Pharmacy. Mr. Sanchez thanked Dr. Oh adding time with the Board has been a great experience. Members thanked Mr. Sanchez for his service with the Board.

Member De La Paz joined the meeting at approximately 12:53 p.m.

3. Assembly Bill 663 (Haney) Pharmacy: Mobile Units

Chairperson Crowley reported Assembly Bill 663 would allow a mobile unit deployed as an extension of a county owned pharmacy, to carry controlled substances approved by the FDA for the treatment of opioid use disorder under specified conditions. The measure followed up on last year's provisions with creating the initial authority of the use of a mobile unit as an extension of a county owned pharmacy. The Committee agreed with the staff recommendation and recommended the Board establish a support position on the measure. The Committee did not receive public comment on this measure.

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

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

Members of the public were provided the opportunity to comment.

A representative of CCAP spoke in support of the legislation.

Committee Recommendation (Motion): Support

Support: 7 Oppose: 0 Abstain: 0 Not Present: 6

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

4. Assembly Bill 913 (Petrie-Norris) Pharmacy Benefit Managers

Chairperson Crowley reported Assembly Bill 913 would require the Board to license and regulate pharmacy benefits managers as specified and would require the Board to promulgate necessary regulations and prepare a report to the Legislature on or before August 1, 2025, and annually thereafter. Dr. Crowley reiterated from the previous day's Committee Meeting agreement with the comments from staff that implementation of the measure would be a significant undertaking but had the potential to address significant patient care challenges that currently exist. Dr. Crowley noted the measure would also address inequities that currently exist in pharmacy reimbursement models. Board staff had been advised that this measure had become a two-year bill. Dr. Crowley added during the Committee Meeting, there was significant discussion by members and the public. Some members noted agreement with the policy proposed noting the policy is in line with the Board's consumer protection mandate while other members expressed concern establishing a position on a bill that will likely change over the coming months could be problematic.

Chairperson Crowley added the Committee received significant public comment recommending that the Board take a support position noting

that one comment recommended that the Board watch the measure, and another commenter recommended the Board establish a support if amended position. Dr. Crowley reported after considering the matter and comments received, the Committee recommended a support position on the measure in its current form.

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

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

Members of the public were provided the opportunity to comment.

A representative of CPhA commented as the sponsor of the legislation thanked the Committee for the recommendation and requested the Board's support.

Committee Recommendation (Motion): Support

Members of the public were provided the opportunity to comment.

Support: 7 Oppose: 0 Abstain: 0 Not Present: 6

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

5. Assembly Bill 1060 (Ortega) Health Care Coverage: Naloxone Hydrochloride

Chairperson Crowley advised Assembly Bill 1060 would make legislative findings regarding the naloxone hydrochloride as a medicine that can counter overdose effects when administered timely to reduce opioid overdose deaths. The measure would prohibit health care service plans, health insurance plans, and Medi-Cal from imposing a cost-sharing requirement, including a co-payment or deductible, for coverage provided and shall require the plan to cover the costs of prescription or nonprescription naloxone hydrochloride.

Chairperson Crowley noted while the FDA had recently approved the purchase of naloxone over-the-counter, there was a lot unknown as to what the cost will be and what insurance will decide should someone get the medication as a prescription. Dr. Crowley added during the Committee discussion, the support of the measure was appropriate. Some members suggested that the measure should go even further and apply to all opioid antagonists to ensure upon approval new products, those products would similarly be covered under the provisions of the measure. The Committee received public comment in support of the measure. Dr. Crowley added following consideration of the measure and comments, the Committee recommended a support position.

Committee Members were provided the opportunity to comment.

Member Chandler spoke to the importance of the measure, the bill, and the motion for the health and safety of Californians.

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

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

Committee Recommendation (Motion): Support

Support: 8 Oppose: 0 Abstain: 0 Not Present: 5

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

6. Assembly Bill 1286 (Haney) Pharmacy

Chairperson Crowley reported Assembly Bill 1286 was the Board's patient medication safety bill. The measure was considered in Assembly Business and Professions Committee on April 18, 2023, and passed out of the committee. Dr. Crowley understood amendments were made to further define the conditions under which a pharmacy may be closed to state that it may be closed if based on the professional judgement of the PIC or pharmacist, as specified, determined that conditions present an immediate risk to the health and safety of patients, personnel, or pharmacy staff. Amendments would further specify that the pharmacy shall reopen as soon as reasonably possible upon abatement of issue. Another amendment made relates to the staffing floor being established in the measure. As amended, there would be explicit language that provided authority for a pharmacist on duty to waive the requirement for additional staff. Dr. Crowley noted as a member of the Medication Error Reduction and Workforce Committee being excited to see the Board's measure moving forward. Dr. Crowley added the provisions in the measure have the potential to significantly reduce medication errors and improve patient care. Dr. Crowley noted as this was a Board sponsored measure, the Committee did not take action.

Chairperson Crowley advised there was significant discussion during the meeting about the measure. Members noted excitement about the legislation and the positive impact the measure will have on patient care.

Discussion included concern about the closing of pharmacies. Members noted that the recent amendments address those concerns.

Chairperson Crowley reported some public comment received in support of the legislation with commenters thanking the Board for its leadership. Other commenters indicated support while requesting amendments to exempt pharmacies operated as part of a general acute hospital from the medication error reporting, while other comments requesting that the Board allow reporting to patient safety organizations (PSOs). The Committee also received comments in opposition to the measure indicating concerns with the staffing floor being established in the measure and pharmacy closure provisions. The Committee also received comment requesting that an alternative means be identified for a consulting pharmacist working on behalf of a surgical clinic be provided an alternative to the current renewal requirement. Dr. Crowley noted that as the legislation was currently pending, any changes to the legislation would occur through the legislative process.

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

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

Members of the public were provided the opportunity to comment.

A representative of the CCPC noted concerns with the pharmacist closure provision of the bill on staffing floor even with the recent amendments but was committed to engage.

The Chief Pharmacy Officer of the University of California Health noted the Board's Medication Error Reduction and Workforce Committee received a report from the Executive Director with the Alliance for Quality Improvement and Patient Safety. In the report, the Executive Director discussed unintended consequences to State reporting including collecting events was just numbers and difficult to make meaningful improvements; mandatory reporting to outside organizations will chill reporting by pharmacists in fear of reprisal; moves the community back to a shame and blame environment which would be a step backward in creating a safety culture; small pharmacies may not be able to afford continuing to work with the PSA, PSO and meet State reporting requirements; loss of learning system; and resources do not make sense

given that pharmacies were already struggling with workforce shortages and poor economy. The commentor questioned if the mandated reporting would achieve the intended consequences.

A representative of CPhA commented having a support if amended position around the PSO issue but overall thought it was a wonderful piece of legislation and looks forward to working with the Board on the small issue.

7. Assembly Bill 1341 (Berman) Public Health: COVID-19 Testing and Dispensing Sites: Oral Therapeutics

Chairperson Crowley advised Assembly Bill 1341 would establish temporary authority, for a pharmacist to furnish COVID-19 therapeutics until January 1, 2025, under specified conditions. Dr. Crowley noted pharmacists had been performing these functions under a waiver issued by the Department of Consumer Affairs as well as provisions of the PREP Act. Dr. Crowley advised this measure was being considered April 19, 2023, as part of the Assembly Appropriations Committee.

Chairperson Crowley provided the Committee determined a support if amended position was appropriate, with the amendment to make the authority permanent. The Committee also received public comment in support of the measure and the Committee's recommendation.

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

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

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

Committee Recommendation (Motion): Support, if amended

Members of the public were provided the opportunity to comment.

Support: 7 Oppose: 0 Abstain: 0 Not Present: 6

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

8. Assembly Bill 1557 (Flora) Pharmacy: Electronic Prescriptions

Chairperson Crowley advised Assembly Bill 1557 was also a Board sponsored measure which would make permanent authority for a California licensed pharmacist to perform medication chart order reviews from a remote location within California on behalf of California licensed health care facilities licensed under Health and Safety Code section 1250, under specified conditions. Dr. Crowley reported as amended, the measure also includes an urgency provision and has received support from several organizations. Dr. Crowley added as the matter is Board sponsored, the committee did not act on this matter but noted the Committee received public comment in support of the measure.

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

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

Members of the public were provided the opportunity to comment.

A pharmacist spoke in support of the measure and cautioned on difference between words selected including “review” and “verify” to avoid confusion.

9. Assembly Bill 1619 (Dixon) Pharmacists: Drug Disclosures: Cannabis or Cannabidiol Interactions

Chairperson Crowley advised Assembly Bill 1619 had become a two-year bill.

10. Senate Bill 339 (Weiner) HIV Preexposure Prophylaxis and Postexposure Prophylaxis

Chairperson Crowley reported Senate Bill 339 would authorize a pharmacist to furnish up to a 90-day course of PrEP or beyond, under specified conditions. The measure would require the Board to adopt emergency regulations by July 1, 2024, and it would require health plans and health insurers to cover PrEP and PEP including medications furnished and tests ordered by pharmacists as specified. Dr. Crowley advised the bill addresses some of the challenges discussed during the Licensing Committee's recent post-implementation discussion on pharmacist-provided PrEP and PEP. Dr. Crowley noted it updates the law to allow for flexibility in treatment by removing the specified type of PrEP authorized to be furnished and provides a means by which a pharmacist can continue to provide care beyond the 90-days under specified conditions, including that a patient receives testing and follow-up care consistent with the CDC guidelines. Dr. Crowley reported the measure would be considered in the Senate Health Committee hearing on April 26, 2023.

Chairperson Crowley advised the measure received broad support from a number of organizations but has opposition from the American College of Obstetrician and Gynecologists and California Medical Association. Dr. Crowley reported during the meeting, Members noted support of the measure indicating that there are real gaps in care and other states have eclipsed California is expanding access. Dr. Crowley recalled public comment was also received in support of the measure as well as a suggestion that the Board should establish a support if amended position requesting that the measure be amended to provide pharmacists with the authority to order tests specified in subsection (f)(1) of the language. Dr. Crowley advised following consideration of the measure; the Committee was recommending a support position.

Committee Members were provided the opportunity to comment.

Member Chandler spoke in support of the measure and motion noting every diagnosis of HIV/AIDS in California is a travesty and as many barriers

for both prevention and reaction should be removed. Mr. Chandler noted this was a commonsense action that could be taken to fight back against the epidemic in California and the nation. Mr. Chandler added California had established a leadership position on HIV/AIDS prevention and response but have since lost that leadership to states like Washington and Colorado noting this was an important step to reestablish leadership.

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

Members of the public were provided the opportunity to comment.

A representative of CPhA spoke as the sponsor of the measure and thanked the Legislation and Regulation Committee for the support of the measure requesting the Board's approval of the Committee's recommendation.

A pharmacist representative from CSHP commented in support of the measure. The representative noted previously approved Board sponsored legislation to perform tests for infectious disease provided authority for pharmacists to order the tests.

Committee Recommendation (Motion): Support

Support: 7 Oppose: 0 Abstain: 0 Not Present: 6

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

11. Senate Bill 345 (Skinner) Health Care Services: Legally Protected Health Care Services

Chairperson Crowley advised Senate Bill 345 would prohibit a Board from suspending, revoking, or denying a license of a person based solely because the licensee provided legally protected activity as defined. Legally protected activities include the exercise of rights related to reproductive health care services or gender-affirming health care services. Dr. Crowley noted during the meeting members voiced concern with actions being taken in other states and the need for the Board to support the measure as a means to convey its policy in the area. Members noted that the services covered in the measure were essential for patient care. Public comment suggested that the Board should establish a support if amended position to ensure pharmacists are covered while other public comment suggested that the Board currently automatically disciplines a licensee that is disciplined in another jurisdiction. It was clarified that the Board does not take automatic action based on discipline in another jurisdiction, rather the Board evaluates an issue to determine if action is appropriate and if so, follows the process required in the law. Dr. Crowley reported following consideration of the matter, the Committee was recommending a support position.

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

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

Members of the public were provided the opportunity to comment.

A pharmacist representative of CSHP requested that pharmacists be added to the list of health care providers protected while providing legally authorized tasks and duties in the state of California that may have been prohibited in other states.

Committee Recommendation (Motion): Support

Support: 7 Oppose: 0 Abstain: 0 Not Present: 6

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

12. Senate Bill 427 (Portantino) Health Care Coverage: Antiretroviral Drugs, Devices and Products

Chairperson Crowley advised Senate Bill 427 would prohibit prior authorization or step therapy for medications approved for the prevention of AIDS/HIV under specified conditions. The measure would allow for prior authorization or step therapy if at least one therapeutically equivalent version was covered without prior authorization or step therapy. Dr. Crowley reported during the meeting members noted agreement with the policy goal of the measure, but did not believe it went far enough. Members noted that the requirement should be expanded to include more than a single therapeutic. Dr. Crowley reported the Committee was recommending a support if amended position.

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

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

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

Committee Recommendation (Motion): Support if amended

Support: 7 Oppose: 0 Abstain: 0 Not Present: 6

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

13. Senate Bill 524 (Caballero) Pharmacists: Testing and Treatment

Chairperson Crowley reported as amended, Senate Bill 524 would establish authority for a pharmacist, until January 1, 2034, furnish specified medications based upon test results received for specified illness, conditions, or diseases. Specified illnesses include SARS-CoV-2, Influenza, Streptococcal pharyngitis, sexually transmitted infection, and conjunctivitis. It would require the Board to develop standardized procedures and protocols with the Medical Board of California. It would also require a pharmacy or health care facility in which a pharmacist was providing such treatment to provide an area designated to maintain privacy and confidentiality. It would require documentation to the extent possible, of the testing services provided in a record system maintained by the pharmacy. The measure would specify the provisions established were covered under Medi-Cal.

Chairperson Crowley added the measure recently passed out of the Senate Business, Professions and Economic Development Committee and was scheduled to be heard in the Senate Health Committee on April 25, 2023. Several entities support the measure including the California Pharmacists Association. The measure was sponsored by the California Community Pharmacy Coalition (CCPC), which is a project of the California Retailers Association. Dr. Crowley noted there were several city governments that were supportive of the measure. Dr. Crowley noted there was opposition to this measure including opposition from the

Chairperson Crowley noted there was significant discussion on this measure during the Committee meeting. Dr. Crowley summarized that members agreed patients would be well served by pharmacists performing these services; however, members also expressed significant concern with working conditions in community pharmacies and if conditions currently would promote quality access to care. Dr. Crowley shared personal experiences currently working in this environment and challenges that create risk to patients when pharmacists are going in and out of providing patient care services while balancing other duties. Dr. Crowley believed the proposed authorizations covered in this measure were appropriate and consistent with a pharmacist's knowledge, skills and abilities but was not confident that pharmacists working in community chain pharmacies currently have appropriate staff support to provide these services in the best interest of patients while also balancing all of the other workload pharmacists currently have. Dr. Crowley reported members agreed that expansion of care, especially in rural communities was needed. Some members suggested that staffing issues need to be addressed first and noted that the Board's measure, AB 1286 would address the staffing challenges. Members noted that the legislation itself did not create a mandate to perform the services but indicated that from a practical standpoint, employers could require it.

Chairperson Crowley reported the Committee also received significant public comment including from the CCPC as the sponsor of the measure. They noted that the measure was about healthcare access and indicated they were willing to work with the Board on concerns in the hopes the Board can come to a support position. Other comments spoke in support of the measure and one commenter noted the challenges with one of the provisions in the measure requiring the Board to secure approval from the Medical Board on required protocols. Dr. Crowley noted members also received public comment from UFCW indicating their established position was an oppose unless amended position with amendments to require an additional pharmacist at the pharmacy to provide the services. Dr. Crowley reported after considering all of the comments and discussion, the Committee was recommending a watch position on the measure allowing the Board to monitor the progress of AB 1286. Members noted that as part of the communication to the author's office regarding the established position it would be appropriate to convey that the Board supports the concept of the measure and policy but cannot support the measure at this time because of working

conditions that currently exist placing patients at risk.

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

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

Members of the public were provided the opportunity to comment.

A representative from the CCPC commented as the sponsor of the measure that it was a healthcare access measure given the amount of healthcare professional shortage areas designated in California. The representative noted that while many don't live by hospitals or physicians, many live by community pharmacies where patients can receive many healthcare services from the pharmacist. This measure would give an increased access to health care to many Californians. The representative noted the measure had been pared down in response to opposition to include COVID-19 and four other conditions. The measure also indicated privacy requirements were added for patients receiving treatment and a statewide protocol for training. The representative expressed hope in the Board coming to a support position on the measure and willingness to work with the Board on any concerns.

A pharmacist representative of CSHP urged the Board to take a support position on the measure as it broadly expands patient access to primary care.

The Board received a comment of supporting the measure as it increased access to care for many patients. The commenter noted AB 317 would allow for payment of services that could fund additional positions in the pharmacy.

A representative of UFCW WSC didn't disagree with the intent of the measure to provide health care access but concerns included pharmacists currently not being able to have adequate staffing to complete workload and do not have autonomy over workflow decisions. The services and treatment plans under the proposal take time where the pharmacist consistently has to break workflow. The Board sponsored AB 1286 was not complete and still going through the legislative process. The representative advised they were requesting an amendment and were currently opposing unless amended that would require an additional

pharmacist in the pharmacy to provide only the clinical services authorized by the measure.

A pharmacist commented in support of the intent of the bill noting that other states have moved to this for these conditions and reduced the inappropriate prescribing of antibiotics. The commentator noted with the move to standard of care, the Board no longer needs the Medical Board agree to every standardized procedure and protocol.

A representative of CVS Health urged the Board to support the bill and move forward with expanding the practice of pharmacy and increasing health care access.

Members were provided an opportunity to comment after public comment.

Member Serpa commented based on testimony to rethink the position taken. Previous discussion included support of the concept but concern with pharmacists being overworked which need to be considered but the overall goal of the bill was positive. Dr. Serpa suggested changing the Board's position to support if amended and have amendments be there to provide the safety and support that was needed.

Member Jha agreed with Dr. Serpa noting the need to decouple the expansion of practice of pharmacy with the valid concern of staffing and pharmacist availability.

Member Chandler commented having a supportive amended position on this measure without AB 1286 in place would be an issue. While the intent of the bill to provide flexibility was important, Mr. Chandler supported the current position of watch given the staffing issue hasn't been resolved.

Member Serpa noted safeguards could be added to prevent negative consequences. Member Jha noted all of the current services pharmacists were currently providing were contingent on environment being conducive to doing the job.

Chairperson Crowley noted being torn on the measure in agreeing access is important but having concern for conditions pharmacists were working. Dr. Crowley expressed concern for providing suboptimal care in rural and specifically inner cities where there are marginalized communities like Black, Latino, and Indigenous communities who are

already receiving statistically suboptimal care from what can be seen in health care. Dr. Crowley noted one comment was made that the goal of the measure was to help provide patients a way to get tested and treatment in minutes which was Dr. Crowley's concern as there was already a lot of pressure on the retail chain pharmacists.

Committee Recommendation (Motion): Watch

Support: 5 Oppose: 2 Abstain: 0 Not Present: 6

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

14. Senate Bill 544 (Laird) Bagley-Keene Open Meetings Act: Teleconferencing

Chairperson Crowley advised Senate Bill 544 would create permanent authority for remote Board Meetings underspecified conditions. Dr. Crowley noted the measure would be heard in the Senate Judiciary Committee April 25, 2023. Members spoke in support of the measure and noted that the measure creates equity by allowing all individuals to participate. The Committee did not receive any public comment on the measure. Dr. Crowley reported following consideration of the measure, the Committee was recommending a support position.

Committee Members were provided the opportunity to comment.

Member Chandler appreciated the comments from the public at the Committee Meeting highlighting the accessibility for people with mobility or neurodivergence issues and supported this measure.

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

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

Committee Recommendation (Motion): Support

Support: 7 Oppose: 0 Abstain: 0 Not Present: 6

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

15. Senate Bill 826 (Rubio) Crimes: Criminal History Information: Subsequent Arrest

Chairperson Crowley reported Senate Bill 826 would establish a process for the Board to receive subsequent arrest notifications from the FBI. Dr. Crowley reiterated comments from the Committee Meeting in agreeing with the comments included in the meeting materials including acknowledging the inequities that exist in the criminal justice system; however, given the Board's consumer protection mandate, support of the measure was appropriate. The Committee did not receive any public comment on the measure and recommended a support position.

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

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

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

Committee Recommendation (Motion): Support

Support: 7 Oppose: 0 Abstain: 0 Not Present: 6

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

16. Senate Bill 873 (Bradford) Prescription Drugs: Cost Sharing

Chairperson Crowley advised Senate Bill 873 would require the cost sharing savings of a prescription drug, based on rebates received, to be calculated at the point of sale as specified, by requiring the health care service plan or insurer to provide the information to the dispensing pharmacy. Dr. Crowley reported the measure was considered April 19, 2023, as part of the Senate Health Committee hearing.

Chairperson Crowley advised the Committee noted agreement with the concept but expressed concern that with more specificity in the measure to explicitly state that pharmacy benefit managers were responsible for calculating this information for pharmacies, it could foster conditions for

claw backs by PBMs. Public comment also suggested that the measure in its current form was unclear regarding which entity is responsible for making the determination at the point of sale.

Chairperson Crowley noted the following consideration of the issue and comments, the Committee was recommending a support of amended position with amendments to require more specificity regarding the obligations of the PBM to provide the necessary cost sharing information for the pharmacist to use.

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

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

Members of the public were provided the opportunity to comment.

A pharmacist commented in seeing a logistical problem in requiring point of sale if the rebate is dependent on the market share at the end of a quarter.

Committee Recommendation (Motion): Support, if amended

Support: 7 Oppose: 0 Abstain: 0 Not Present: 6

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

- b. Discussion and Consideration of Board Approved Regulations Undergoing Pre-Notice Review by the Department of Consumer Affairs or Business, Consumer Services and Housing Agency
 - 1. Proposed Regulation to Add Title 16 CCR Section 1706.6 Related to Military Spouses and Partners Temporary Licensure
 - 2. Proposed Regulation to Amend Title 16 CCR Section 1709.1 Related to the Designation of Pharmacist-in-Charge
 - 3. Proposed Regulation to Add Title 16 CCR Section 1750 & 1750.1 Related to Outsourcing Facilities
 - 4. Proposed Regulation to Amend Title 16 CCR Section 1746.3 Related to Opioid Antagonist
- c. Discussion and Consideration of Board Approved Regulations – Board Staff Reviewing Comments Provided by the Department of Consumer Affairs or Business, Consumer Services and Housing Agency
 - 1. Proposed Regulation to Amend Title 16 CCR Section 1760 Related to the Disciplinary Guidelines
- d. Discussion and Consideration of Board Approve Regulations – Board Staff Drafting Rulemaking Documents
 - 1. Proposed Regulation to Amend Title 16 CCR Section 1732.5 and Add Section 1732.8 Related to Continuing Education
 - 2. Proposed Regulation to Amend Title 16 CCR Section 1708.2 Related to Discontinuance of Business
 - 3. Proposed Regulation to Add Title 16 CCR Section 1746.6 Related to Medication Assisted Treatment Protocol
 - 4. Proposed Regulation to Amend Title CCR Section 1711 Related to Quality Assurance
- e. Update on Board Authorized Section 100 Regulations – Board Staff Drafting Section 100 Documents
 - 1. Proposed Regulation to Amend Title 16 CCR Sections 1715 and 1785 Related to the Community Pharmacy, Hospital Pharmacy, and Dangerous Drug Distributor Self-Assessment Forms

Chairperson Crowley noted the regulation items were for information only and detailed in the meeting material. Dr. Crowley noted the Board had four regulations undergoing pre-notice review by the Department of Consumer Affairs or Business, Consumer Services and Housing Agency. Staff were also reviewing the comments provided by DCA related to the Board's proposed changes to its disciplinary guidelines as well as drafting regulation documents for five regulation packages,

including one regulation package to update self-assessment forms via the Section 100 process.

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

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

XVII. Executive Officer Report

a. Changes to CURES System

Ms. Sodergren advised there would be changes in the CURES System. The Department of Justice (DOJ) will be releasing information. The Board strongly encourages licensees to monitor the DOJ website as the version of ASAP will be changing August 2024.

b. Update on Presentations Provided During the Quarter

Ms. Sodergren reported the Board has been giving presentations to the graduating classes to help candidates understand the licensing process and common pitfalls to avoid in the application, testing, and licensing process. Ms. Sodergren had the opportunity to present the Board's efforts related to medication errors at a patient safety conference in March 2023.

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

Ms. Sodergren recalled every six months the passing rate for the CPJE is provided at the Board Meeting. Ms. Sodergren noted in comparison to the data from last year, the CPJE has had an increase in the pass rate of about 14 percentage points where the NAPLEX pass rate had gone down 10.4 percentage points.

Members were provided an opportunity to comment. Member Chandler inquired about the trends between the CPJE and NAPLEX. Ms. Sodergren provided the CPJE's content and processes were outlined in statute where the NAPLEX is provided at a national level by the NABP. Ms. Sodergren added by law there can't be a crossover of topics between the two examinations. Ms. Sodergren advised the staff was aware of and watching trends.

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

President Oh thanked Ms. Sodergren for her hard work. President Oh announced Member Kula Koenig decided to resign from the Board of Pharmacy due to too much time

commitments. Dr. Oh stated Ms. Koenig's energy will be missed. Dr. Oh added this was Member Ricardo Sanchez's last meeting. Dr. Oh announced DCA Counsel Eileen Smiley would be leaving. Dr. Oh noted Ms. Smiley was assigned to the Board during a busy time at the beginning of the COVID-19 public health emergency. Dr. Oh thanked Ms. Smiley for her thoughtful counsel to the Board through extremely complex issues and wished her much success. Ms Smiley stated it had been a pleasure working with Ms. Sodergren and the Board Members.

Ms. Smiley noted the Board finished closed session items on April 19, 2023. The Board would not be meeting in closed session to discuss Agenda Item XVIII and the Board would not be discussing subpart C on either April 19-20, 2023.

President Oh adjourned the meeting at 2:13 p.m.

**Article 4.5 draft regulation text
related to nonsterile compounding**

Title 16. Board of Pharmacy Proposed Regulation

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

Amend title of Article 4.5 and Repeal sections 1735, 1735.1, 1735.3, 1735.4, 1735.5, 1735.6, 1735.7, and 1735.8 of Article 4.5, adopt a new title for and amend section 1735.2, adopt new titles and sections 1735, 1735.1, 1735.3, 1735.4, 1735.5, 1735.6, 1735.7, 1735.8, 1735.9, 1735.10, 1735.11, 1735.12, 1735.13, and 1735.14 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

Article 4.5 Nonsterile Compounding in Pharmacies

1735. Compounding in Licensed Pharmacies

~~(a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:~~

- ~~(1) Altering the dosage form or delivery system of a drug~~
- ~~(2) Altering the strength of a drug~~
- ~~(3) Combining components or active ingredients~~
- ~~(4) Preparing a compounded drug preparation from chemicals or bulk drug~~

~~substances~~

~~(b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s), nor does it include the sole act of tablet splitting or crushing, capsule opening, or the addition of flavoring agent(s) to enhance palatability.~~

~~(c) The parameters and requirements stated by Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile compounding are stated by Article 7 (Section 1751 et seq.).~~

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

1735. Compounding Definitions.

In addition to the definitions contained in United States Pharmacopeia (USP) General Chapter 795 titled *Pharmaceutical Compounding – Nonsterile Preparations* "USP Chapter 795" for the purposes of this article, the following definitions apply to this article and supplement the definitions provided in USP Chapter 795.

- (a) “Approved labeling” means the Food and Drug Administration’s (FDA) approved labeling in accordance with sections 201.56 and 201.57 of title 21, Code of Federal Regulations that contains FDA approved information for the diluent, the resultant strength, the container closure system, and storage time.
- (b) “Essentially a copy” of a commercially available drug product means all preparations that include the same API(s) as the 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) Designated person(s) means one or more individuals assigned by the pharmacist-in-charge to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of the compounded nonsterile preparations (“CNSP”) for the purposes of this article). Nothing in this definition allows for the designated person to exceed the scope of their issued license. When the designated person is not a pharmacist, the Pharmacist-in-Charge (PIC) must review all practices related to the operations of the facility that require professional judgement.
- (d) “Diluent” means a liquid with no pharmacological activity used in reconstitution, such as purified water or sterile water for injection.
- (e) “Integrity” means retention of strength until the beyond use date provided on the label when the preparation is stored and handled according to the label directions.
- (f) “Quality” means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, or the absence of active ingredients other than those listed on the label, or the absence of inactive ingredients other than those listed on the master formulation record as specified in USP Chapter 795.
- (g) “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, when the act is not done pursuant to a prescription.
- (i) “Strength” means amount of active ingredient per unit of a compounded drug preparation.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

1735.1. Compounding Definitions

~~(a) "Ante-area" means an area with ISO Class 8 or better air quality where personnel hand hygiene and garbing procedures, staging of components, and other high-particulate-generating activities are performed, that is adjacent to the area designated for sterile compounding. It is a transition area that begins the systematic reduction of particles, prevents large fluctuations in air temperature and pressures in the cleanroom, and maintains air flows from clean to dirty areas. ISO Class 7 or better air quality is required for ante areas providing air to a negative pressure room.~~

~~(b) "Beyond use date" means the date, or date and time, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes).~~

~~(c) "Biological Safety Cabinet (BSC)" means a ventilated cabinet for compounding sterile drug preparations, having an open front with inward airflow for personnel protection, downward HEPA filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection. Where hazardous drugs are prepared, the exhaust air from the biological safety cabinet shall be appropriately removed by properly designed external building exhausting. This external exhaust should be dedicated to one BSC or CACI.~~

~~d) "Bulk drug substance" means any substance that, when used in the preparation of a compounded drug preparation, processing, or packaging of a drug, is an active ingredient or a finished dosage form of the drug, but the term does not include any intermediate used in the synthesis of such substances.~~

~~e) "Cleanroom or clean area or buffer area" means a room or area with HEPA filtered air that provides ISO Class 7 or better air quality where the primary engineering control (PEC) is physically located.~~

~~1) For nonhazardous compounding a positive pressure differential of 0.02 to 0.05-inch water column relative to all adjacent spaces is required.~~

~~2) For hazardous compounding at least 30 air changes per hour of HEPA filtered supply air and a negative pressure of between 0.01 to 0.03 inches of water column relative to all adjacent spaces is required.~~

~~(f) "Compounding Aseptic Containment Isolator (CACI)" means a unidirectional HEPA-filtered airflow compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where hazardous drugs are prepared, the~~

exhaust air from the isolator shall be appropriately removed by properly designed external building exhaust. This external exhaust should be dedicated to one BSC or CACI. Air within the CACI shall not be recirculated nor turbulent.

~~(g) "Compounding Aseptic Isolator (CAI)" means a form of isolator specifically designed for nonhazardous compounding of pharmaceutical ingredients or preparations while bathed with unidirectional HEPA filtered air. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Air within the CAI shall not be recirculated nor turbulent.~~

~~h) "Controlled cold temperature" means 2 degrees to 8 degrees C (35 degrees to 46 degrees F).~~

~~(i) "Controlled freezer temperature" means -25 degrees to -10 degrees C (-13 degrees to 14 degrees F) or at a range otherwise specified by the pharmaceutical manufacturer(s) for that product.~~

~~(j) "Controlled room temperature" means 20 degrees to 25 degrees C (68 degrees to 77 degrees F).~~

~~(k) "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.~~

~~(l) "Daily" means occurring every day the pharmacy is operating, except when daily monitoring of refrigerator and freezer temperature are required, then daily means every 24 hours.~~

~~m) "Displacement airflow method" means a concept which utilizes a low pressure differential high airflow principle to maintain segregation from the adjacent ante area by means of specific pressure differentials. This principle of displacement airflow shall require an air velocity of 40 ft per minute or more, from floor to ceiling and wall to wall, from the clean area across the line of demarcation into the ante area. The displacement concept may not be used to maintain clean area requirements for sterile compounds which originate from any ingredient that was at any time non-~~

~~sterile, regardless of intervening sterilization of the ingredient, or for hazardous compounds.~~

~~(n) "Dosage unit" means a quantity sufficient for one administration to one patient.~~

~~(o) "Equipment" means items that must be calibrated, maintained or periodically certified.~~

~~p) "First air" means the air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.~~

~~(q) "Gloved fingertip sampling" means a process whereby compounding personnel lightly press each fingertip and thumb of each hand onto appropriate growth media, which are then incubated at a temperature and for a time period conducive to multiplication of microorganisms, and then examined for growth of microorganisms.~~

~~r) "Hazardous" means all anti-neoplastic agents identified by the National Institute for Occupational Safety and Health (NIOSH) as meeting the criteria for a hazardous drug and any other drugs, compounds, or materials identified as hazardous by the pharmacist in charge.~~

~~(s) "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.~~

~~(t) "Lot" means one or more compounded drug preparation(s) prepared during one uninterrupted continuous cycle of compounding from one or more common active ingredient(s).~~

~~(u) "Media fill test" means a test used to measure the efficacy of compounding personnel in aseptic techniques whereby compounding procedures are mimicked using a growth-based media and then the resulting preparation is evaluated for sterility. The media fill test must mimic the most complex compounding procedures performed by the pharmacy.~~

~~(v) "Non-sterile to sterile batch" means any compounded drug preparation containing two (2) or more dosage units with any ingredient that was at any time non-sterile, regardless of intervening sterilization of that ingredient.~~

~~(w) "Parenteral" means a preparation of drugs administered in a manner other than through the digestive tract. It does not (x) "Personal protective equipment" means clothing or devices that protect the employee from exposure to compounding ingredients and/or potential toxins and minimize the contamination of compounded~~

preparations. These include shoe covers, head and facial hair covers, face masks, gowns, and gloves.

~~y) "Potency" means active ingredient strength within +/- 10% (or the range specified in USP37NF32, 37th Revision, Through 2nd Supplement Effective December 1, 2014) of the labeled amount. Sterile injectable products compounded solely from commercially manufactured sterile pharmaceutical products in a health care facility licensed under section 1250 of the Health and Safety Code are exempt from this definition. For those exempt, the range shall be calculated and defined in the master formula.~~

~~(z) "Preparation" means a drug or nutrient compounded in a licensed pharmacy; the preparation may or may not be sterile.~~

~~aa) "Prescriber's office" or "prescriber office" means an office or suite of offices in which a prescriber regularly sees patients for outpatient diagnosis and treatment. This definition does not include any hospital, pharmacy, or other facility, whether or not separately licensed, that may be affiliated with, adjacent to, or co-owned by, the prescriber's practice environment.~~

~~ab) "Primary Engineering Control (PEC)" means a device that provides an ISO Class 5 or better environment through the use of non-turbulent, unidirectional HEPA filtered first air for compounding sterile preparations. Examples of PEC devices include, but are not limited to, laminar airflow workbenches, biological safety cabinets, sterile compounding automated robots, compounding aseptic isolators, and compounding aseptic containment isolators.~~

~~ac) "Process validation" means demonstrating that when a process is repeated within specified limits, the process will consistently produce preparations complying with predetermined requirements. If any aspect of the process is changed, the process would need to be revalidated.~~

~~(ad) "Product" means a commercially manufactured drug or nutrient evaluated for safety and efficacy by the FDA.~~

~~(ae) "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.~~

~~(af) "Segregated sterile compounding area" means a designated space for sterile to-sterile compounding where a PEC is located within either a demarcated area (at least three foot perimeter) or in a separate room. Such area or room shall not contain and shall be void of activities and materials that are extraneous to sterile compounding.~~

~~The segregated sterile compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors, in a location with high traffic flow, or in a location that is adjacent to construction sites, warehouses, or food preparation. The segregated sterile compounding area shall not have a sink, other than an emergency eye-washing station, located within three feet of a PEC. The segregated sterile compounding area shall be restricted to preparation of sterile-to-sterile compounded preparations. include topical, sublingual, rectal or buccal routes of administration.~~

~~(1) The BUD of a sterile drug preparation made in a segregated sterile compounding area is limited to 12 hours or less as defined by section 1751.8(d).~~

~~(2) When the PEC in the segregated sterile compounding area is a CAI or a CACI and the documentation provided by the manufacturer shows it meets the requirements listed in section 1751.4(f)(1)-(3), the assigned BUD shall comply with section 1751.8(a-b) or (d).~~

~~(ag) "Strength" means amount of active ingredient per unit of a compounded drug preparation~~

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

1735.1. Introduction and Scope

In addition to the standards in the USP Chapter 795, the preparation of CNSP shall meet the following requirements of this article.

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

(b) Repackaging of a conventionally manufactured drug product shall be not considered compounding but must be compliant with USP Chapter 1178, *Good Repackaging Practices*.

(c) Reconstitution of a conventionally manufactured drug product in accordance with directions that have not been Food and Drug Administration (FDA) approved in accordance with 21 U.S.C.A Section 355 is considered compounding and this article applies.

(d) Notwithstanding subdivision (a), a limited quantity of CNSP may be prepared and stored in advance of receipt of a patient specific prescription document where, and solely in such quantity, as is necessary to ensure continuity of care individual patients based on a documented history of prescriptions for those patient populations.

(e) A reasonable quantity of a compounded drug preparation may be furnished to a veterinary office for use by the veterinarian that is sufficient:

- (1) for administration or application to veterinary patients solely in the veterinarian's office
- (2) for furnishing of not more than 7-day supply, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing;

(f) In addition to prohibitions and requirements for compounding established in federal law, no CNSP shall be prepared that:

(1) Is 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 Drug Shortages Database that are in short supply at the time of compounding and at the time of dispense, or

(B) the compounding produces a clinically significant difference of the medical need of an identified individual patient, as determined:

(1) by the prescribing practitioner,

(2) the compounding pharmacist, and

(3) the dispensing pharmacist(s).

(C) Documentation describing the conditions in (1)(A) & (1) (B) is maintained in a readily retrievable format

(2) Is made with any component not suitable for use in a CNSP for the intended patient population, unless allowable under Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA).

(g) Prior to allowing any CNSP to be compounded within a pharmacy, the pharmacist-in-charge shall complete a self-assessment consistent with the requirements established in section 1715.

(g) In addition to the provisions provided in Section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning proper use, storage, handling and disposal of the CNSP and related supplies furnished.

(h) CNSPs with human whole blood or human whole blood derivatives shall be prepared in compliance with Health and Safety Code section 1602.5.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4105, 4126.8 and 4169, 4301, 4306.5 and 4332 of the Business and Profession Code.

1735.2. Compounding Limitations and Requirements; Self-Assessment

~~(a) Except as specified in (b) and (c), no drug preparation shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient 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 prior to compounding.~~

~~(b) A pharmacy may prepare and store a limited quantity of a compounded drug preparation in advance of receipt of a patient-specific prescription 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.~~

~~(4) That the pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded medication and the nature of the prescriber's practice; and~~

~~(5) With regard to any individual prescriber to whom the pharmacy furnishes, and with regard to all prescribers to whom the pharmacy furnishes, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug preparation; and~~

~~(6) Does not exceed an amount the pharmacy can reasonably and safely compound.~~

~~(d) No pharmacy or pharmacist shall compound a drug preparation 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 drugs 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 that 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, and the compounding of that drug preparation 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 and the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.~~

~~(e) A drug preparation shall not be compounded until the pharmacy has first prepared a written master formula document that includes at least the following elements:~~

~~(1) Active ingredients to be used.~~

~~(2) Equipment to be used.~~

~~(3) The maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination.~~

~~(4) Inactive ingredients to be used.~~

~~(5) Specific and essential compounding steps used to prepare the drug.~~

~~(6) Quality reviews required at each step in preparation of the drug.~~

~~(7) Post compounding process or procedures required, if any.~~

~~(8) Instructions for storage and handling of the compounded drug preparation.~~

~~(f) Where a pharmacy does not routinely compound a particular drug preparation, the master formula record for that preparation may be recorded on the prescription document itself.~~

~~(g) The 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 after the preparation is dispensed.~~

~~(h) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.~~

~~(i) Every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.~~

~~(1) For non-sterile compounded drug preparation(s), the beyond use date shall not exceed any of the following:~~

~~(A) the shortest expiration date or beyond use date of any ingredient in the compounded drug preparation,~~

~~(B) the chemical stability of any one ingredient in the compounded drug preparation;~~

~~(C) the chemical stability of the combination of all ingredients in the compounded drug preparation,~~

~~(D) for non-aqueous formulations, 180 days or an extended date established by the pharmacist's research, analysis, and documentation,~~

~~(E) for water-containing oral formulations, 14 days or an extended date established by the pharmacist's research, analysis, and documentation, and~~

~~(F) for water-containing topical/dermal and mucosal liquid and semisolid formulations, 30 days or an extended date established by the pharmacist's research, analysis, and documentation.~~

~~(G) A pharmacist, using his or her professional judgment may establish an extended date as provided in (D), (E), and (F), if the pharmacist researches by consulting and applying drug specific and general stability documentation and literature; analyzes such documentation and literature as well as the other factors set forth in this subdivision, and maintains documentation of the research, analysis and conclusion. The factors the pharmacist must analyze include:~~

- ~~(i) the nature of the drug and its degradation mechanism,~~
- ~~(ii) the dosage form and its components,~~
- ~~(iii) the potential for microbial proliferation in the preparation,~~
- ~~(iv) the container in which it is packaged,~~
- ~~(v) the expected storage conditions, and~~
- ~~(vi) the intended duration of therapy.~~

~~Documentation of the pharmacist's research and analysis supporting an extension must be maintained in a readily retrievable format as part of the master formula.~~

~~(2) For sterile compounded drug preparations, the beyond use date shall not exceed any of the following:~~

- ~~(A) The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug product preparation,~~
- ~~(B) The chemical stability of any one ingredient in the sterile compounded drug preparation,~~
- ~~(C) The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and~~
- ~~(D) The beyond use date assigned for sterility in section 1751.8.~~

~~(3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following:~~

- ~~(A) Method Suitability Test,~~
- ~~(B) Container Closure Integrity Test, and~~
- ~~(C) Stability Studies~~

~~(4) In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.~~

~~(5) Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.~~

~~(j) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug preparation.~~

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

~~(l) Packages of ingredients, both active and inactive, that lack a supplier's expiration date are subject to the following limitations:~~

~~(1) such ingredients cannot be used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy.~~

~~(2) such ingredients cannot be used for any sterile compounded drug preparation more than~~

~~(1) year after the date of receipt by the pharmacy.~~

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

1735.2. Personnel Training and Evaluation

In addition to the standards in the USP Chapter 795, the preparation of CNSP shall meet the following requirements of this article.

(a) In addition to the training required by USP Chapter 795 training and competencies procedures for all personnel who compound or have direct oversight of personnel performing compounding, verifying, and/or handling a CNSP shall also address the following topics:

(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, the compounding of CNSPs, shall demonstrate proficiency in skills necessary to ensure the integrity, strength, quality, and labeled strength of a CNSP as described in the facilities SOPs as referenced in section 1735.11.

(c) A “reasonable quantity” that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision

(a)(1), means that amount of compounded drug preparation that:

(1) Is sufficient for administration or application to patients solely in the prescriber's office, or for furnishing of not more than a 120-hour supply for veterinary medical practices, solely to the prescriber's own veterinary patients seen as part of regular treatment in the prescriber's office, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted prior to furnishing.

(d) Compounding personnel or persons with direct oversight over personnel performing compounding, who fail any aspect of ongoing training and evaluation shall not be involved in compounding or oversight of the preparation of a CNSP until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs.

(e) Any person assigned to provide the training specified in this section shall have demonstrated competency in the skills in which the person will provide training or observe and measure competency described in the facilities SOPs as referenced in section 1735.11. Documentation must be maintained demonstrating compliance.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301, 4306.5 and 4332 of the Business and Profession Code.

1735.3. Recordkeeping of Compounded Drug Preparations

~~(a) For each compounded drug preparation, pharmacy records shall include:~~

~~(1) The master formula document.~~

~~(2) A compounding log consisting of a single document containing all of the following:~~

~~(A) Name and Strength of the compounded drug preparation.~~

~~(B) The date the drug preparation was compounded.~~

~~(C) The identity of any pharmacy personnel engaged in compounding the drug preparation.~~

~~(D) The identity of the pharmacist reviewing the final drug preparation.~~

~~(E) The quantity of each ingredient used in compounding the drug preparation.~~

~~F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply.~~

~~(i) Exempt from the requirements in this paragraph (1735.3(a)(2)(F)) are sterile — in a single lot for administration within seventy-two (72) hours to a patient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for “Redispensed CSPs” found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference.~~

~~(G) A pharmacy assigned unique reference or lot number for the compounded drug product preparation.~~

~~H) The beyond use date or beyond use date and time of the final compounded drug, expressed in the compounding document in a standard date and time format.~~

~~I) The final quantity or amount of drug preparation compounded for dispensing.~~

~~(J) Documentation of quality reviews and required post-compounding process and procedures.~~

~~(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.~~

~~(c) Active ingredients shall be obtained from a supplier registered with the Food and Drug Administration (FDA). All other chemicals, bulk drug substances, and drug products used to compound drug preparations shall be obtained, whenever possible, from FDA-registered suppliers. The pharmacy shall acquire and retain certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the FDA. Any certificates of purity or analysis acquired by the pharmacy shall be matched to the corresponding chemical, bulk drug substance, or drug products received.~~

~~(d) Pharmacies shall maintain and retain all records required by this article 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).~~

~~Authority cited: Sections 4005, 4127, and 4169, Business and Professions Code.
Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.~~

1735.3. Personnel Hygiene and Garbing

The requirements of this section apply to nonsterile compounding in addition to the standards established by USP Chapter 795.

- (a) Prior to admitting any personnel into a compounding area, 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 medical conditions to determine if such condition could contaminate a CNSP or the environment ("contaminating conditions"). After such evaluation and determination the supervising pharmacist shall not allow personnel with potentially contaminating conditions to enter the compounding area.
- (b) A gown and face mask shall be used whenever a closed system processing device is required.
- (c) 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.
- (d) Gloves shall be wiped or replaced before beginning a CNSP that has different components.
- (e) Non-disposable garb shall be cleaned with a germicidal cleaning agent and sanitized with 70% isopropyl alcohol before re-use.
- (f) Any garbing accommodations provided by the designated person shall be documented and the record shall include the name of the individual granted the accommodation, date granted and description of the reasons for granting the accommodation. The record shall be retained in accordance with Business and Professions Code section 4081.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

1735.4. Labeling of Compounded Drug Preparations

(a) Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least:

- ~~(1) Name of the compounding pharmacy and dispensing pharmacy (if different);~~
- ~~2) Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed IV solutions, the intravenous solution utilized shall be included;~~
- ~~(3) Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;~~
- ~~(4) The beyond use date for the drug preparation;~~
- ~~(5) The date compounded; and~~
- ~~6) The lot number or pharmacy reference number.~~

~~(b) Any compounded drug preparation 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 California Code of Regulations, title 16, section 1707.5.~~

~~(c) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include, on the container label or on a receipt provided to the patient, a statement that the drug has been compounded by the pharmacy.~~

~~(d) Prior to dispensing drug preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a), (b), and (c) shall be labeled with at least the name of the compounding pharmacy and dispensing pharmacy, if different, the name(s) of the active ingredient(s), strength, volume or weight of the preparation, pharmacy reference or lot number, and beyond use date, and shall not be subject to minimum font size requirements. Once dispensed, outer packaging must comply with 1735.4(a) – (c).~~

~~(e) All hazardous agents shall bear a special label which states “Chemotherapy – Dispose of Properly” or “Hazardous – Dispose of Properly.”~~

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

1735.4. Building and Facilities

The requirements of this section apply to nonsterile compounding in addition to the standards established by USP Chapter 795.

(a) A sink used for compounding or hand hygiene shall not be part of a restroom or water closet.

(b) Purified water, distilled water, or reverse osmosis water shall be used for rinsing equipment and utensils.

(c) 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 law or the facilities SOPs

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301, 4306.5 and 4332 of the Business and Profession Code.

1735.5. Compounding Policies and Procedures

~~(a) Any pharmacy engaged in compounding shall maintain written policies and procedures for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action.~~

~~(b) 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 in policies and procedures are implemented.~~

~~(c) The policies and procedures shall include at least the following:~~

- ~~1) Procedures for notifying staff assigned to compounding duties of any changes in policies.~~
- ~~2) A written plan for recall of a dispensed compounded drug preparation where subsequent demonstrates the potential for adverse effects with continued use. The plan shall ensure that all affected doses can be accounted for during the recall and shall provide steps to identify which patients received the affected lot or compounded drug preparation(s).~~
- ~~3) Procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in , and for training on these procedures as part of the staff training and competency evaluation process.~~
- ~~(4) Procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process.~~
- ~~(5) Documentation of the methodology used to validate integrity, potency, quality, and labeled strength of compounded drug preparations. The methodology must be appropriate to compounded drug preparations.~~
- ~~(6) Documentation of the methodology and rationale or reference source used to determine appropriate beyond use dates for compounded drug preparations.~~

~~(7) Dates and signatures reflecting all annual reviews of the policies and procedures by the pharmacist-in-charge.~~

~~8) Dates and signatures accompanying any revisions to the policies and procedures approved by pharmacist-in-charge.~~

~~9) Policies and procedures for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.~~

~~10) Policies and procedures regarding ensuring appropriate functioning of refrigeration devices, refrigeration device temperatures, and actions to take regarding any out of range temperature variations within the pharmacy.~~

~~(11) Policies and procedures for proper garbing when compounding with hazardous products. — shall include when to utilize double shoe covers.~~

~~Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4127, and 4301, Business and Professions Code~~

1735.5. Cleaning And Sanitizing

The requirements of this section apply to nonsterile compounding in addition to the standards established by USP Chapter 795.

(a) In addition to the documentation requirements in USP Chapter 795, the facility's documentation of each occurrence of the cleaning and sanitizing of the compounding area shall include a record of the identity of the person completing the cleaning and sanitizing as well as the product name of the cleaning and sanitizing agents used.

(b) Any cleaning or sanitizing agents used by the facility to meet the requirements in this article shall be used in accordance with manufacturers' specifications.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

1735.6. Compounding Facilities and Equipment

~~(a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounding of compounded drug preparations. This shall include records of maintenance and cleaning of the facilities and equipment. Where applicable, this shall also include records of certification(s) of facilities or equipment.~~

~~(b) Any equipment used to compound drug preparations shall be stored, used, maintained, and cleaned in accordance with manufacturers' specifications.~~

~~c) Any equipment that weighs, measures, or transfers ingredients used to compound drug preparations for which calibration or adjustment is appropriate shall be calibrated prior to use, on a schedule and by a method determined by the manufacturer's specifications, to ensure accuracy. Documentation of each such calibration shall be recorded in a form which is not alterable and these records of calibration shall be maintained and retained in the pharmacy.~~

~~(d) Any pharmacy engaged in any hazardous drug compounding shall maintain written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs.~~

~~(e) Hazardous drug compounding shall be completed in an externally exhausted physically separate room with the following requirements:~~

~~(1) Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hours or less or when non-sterile products are compounded; and~~

~~2) Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and~~

~~(3) A) For sterile compounding, each BSC or CACI shall also be externally exhausted.~~

~~(B) For nonsterile compounding, a BSC, a CACI, or other containment ventilated enclosure shall be used and shall either use a redundant HEPA filter in series or be externally exhausted.; For purposes of this paragraph, a containment ventilated enclosure means a full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through high-efficiency particulate air (HEPA) filtration and to prevent their release into the work environment.~~

~~Each PEC in the room shall also be externally vented; and~~

~~4) All surfaces within the room shall be smooth, seamless, impervious, and non-shedding.~~

~~(f) Where compliance with the January 1, 2017 amendments to Article 4.5 or Article 7, requires physical construction or alteration to a facility or physical environment, the board or its designee may grant a waiver of such compliance for a period of time to permit such physical change(s). Application for any waiver shall be made by the licensee in writing, and the request shall identify the provision(s) requiring physical construction or alteration, and the timeline for any such change(s). The board or its designee may grant the waiver when, in its discretion, good cause is demonstrated for such waiver.~~

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

1735.6. Equipment And Components

The requirements of this section apply to nonsterile compounding in addition to the standards established by USP Chapter 795.

(a) Any equipment used to compound a CNSP shall be used in accordance with the manufacturer's specifications.

(b) Any component used to compound a CNSP shall be used and stored in accordance with all federal laws and regulations and industry standards including the manufacturers' specifications and requirements.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

1735.7. Training of Compounding Staff

~~(a) A pharmacy engaged in compounding shall maintain documentation demonstrating that personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating that all personnel involved in compounding are trained in all aspects of policies and procedures. This training shall include but is not limited to support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacist and all others whose jobs are related to the compounding process.~~

~~(b) The pharmacy shall develop and maintain an ongoing competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.~~

~~(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug preparation.~~

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

1735.7. Master Formulation and Compounding Records

The requirements of this section apply to nonsterile compounding in addition to the standards established by USP Chapter 795.

- (a) A CNSP shall not be compounded until the facility has first prepared a written master formulation record in compliance with USP Chapter 795 and identified in that document the following additional elements:
- (1) When a source is referenced to support the assigned beyond-use date (BUD); each source referenced shall be readily retrievable at the time of compounding and shall be maintained for three years from the date each CNSP is dispensed.
 - (2) Instructions for storage and handling of the CNSP.
- (b) Where a facility 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 comply with USP Chapter 795 standards and this section.
- (c) A compounding record (CR) shall be a single document. The document shall satisfy the compounding record requirements in USP Chapter 795, as well as the following:
- (1) The date and time of preparation. The time of preparation is the time when compounding the CNSP started, which also determines when the assigned BUD starts.(2) The manufacturer, lot number, and expiration date for each component.
 - (3) The assigned internal identification number shall be unique for each CR.
 - (4) The total quantity compounded shall include the number of units made and the volume or weight of each unit.
 - (5) The identity of each person performing the compounding, that has direct oversight of compounding, and pharmacist verifying the final drug preparation.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

1735.8. Compounding Quality Assurance

- ~~(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug preparations.~~
- ~~(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.~~

~~(c) The quality assurance plan shall include written standards for qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled strength, including the frequency of testing. All qualitative and quantitative analysis reports for compounded drug preparations shall be retained by the pharmacy and maintained along with the compounding log and master formula document. The quality assurance plan shall include a schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis.~~

~~(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug preparation is ever discovered to be outside minimum standards for integrity, potency, quality, or labeled strength.~~

~~(e) The quality assurance plan shall include a written procedure for responding to out-of-range temperature variations within the pharmacy and within patient care areas of a hospital where furnished drug is returned for redispensing.~~

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

1735.8. Release Inspections and Testing

The requirements of this section apply to nonsterile compounding in addition to the standards established by USP Chapter 795.

A pharmacist performing or supervising the nonsterile compounding is responsible for the integrity, quality, and labeled strength of a CNSP until the beyond-use date indicated on the label provided the patient or the patient's agent follows the label instructions provided on the CNSP for storage and handling after receiving the CNSP.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4036.5, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

1735.9. Labeling

The requirements of this section apply to nonsterile compounding in addition to the standards established by USP Chapter 795.

(a) A CNSPs label shall also include the following:

(1) Route of intended administration, and

(2) Name of compounding facility and dispensing facility (if different).

(b) A CNSPs Labeling shall also include:

- (1) Any special handling instructions,
- (2) Any applicable warning statements, and
- (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 by Business and Professions Code section 4076 and section 1707.5.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

1735.10. Establishing Beyond-Use Dates

The requirements of this section apply to nonsterile compounding in addition to the standards established by USP Chapter 795.

(a) Beyond-use dates (BUDs) assigned with only a date shall expire at 11:59 p.m. on that date.

(b) A CNSP's BUDs shall not exceed:

- (1) The chemical and physical stability data of the active pharmaceutical ingredient (API) and any added component in the preparation,
- (2) The compatibility and degradation of the container–closure system with the finished preparation (e.g., possible leaching, interactions, and storage conditions),
- (3) The shortest remaining expiration date or BUD of any of the starting components, or,
- (4) The potential for microbial proliferation in the CNSP.

(c) If a licensee chooses to use antimicrobial effectiveness testing results provided by an current FDA-registered drug establishment or outsourcing facility or published in current peer-reviewed literature sources, the reference (including the raw data and testing method suitability), shall be readily retrievable in accordance with Business and Professions Code section 4081 in its entirety for three years from the last date the CNSP was dispensed.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

1735.11. Standard Operating Procedures (SOPs)

The requirements of this section apply to nonsterile compounding in addition to the standards established by USP Chapter 795.

(a) The facility's standard operating procedures (SOPs) for nonsterile compounding shall be followed and shall:

- (1) Comply with USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding.
- (2) In addition to the SOPs required in USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding, SOPs must also be developed to describe the following:
 - (A) Methods by which the supervising pharmacist will ensure the quality of compounded drug preparations.
 - (B) Procedures for handling, compounding, and disposal of infectious materials. The written SOPS shall describe the facility protocols for cleanups and spills in conformity with local health jurisdictional standards.
 - (C) The methods a pharmacist will use to determine and approve the ingredients and the compounding process for each preparation before compounding begins.
 - (D) The method for complying with any other requirements specifically required to be addressed in the facility's SOPS as described in this article.

(b) The SOPs shall be reviewed on an annual basis by the pharmacist-in-charge. Such review shall be documented by the pharmacist-in-charge consistent with the facility's SOPs. The SOPs shall be updated any time changes are made to compounding processes, facility changes or other changes occur that impact the CNSP. Such SOP changes shall be disseminated to the affected staff prior to implementation.

(c) Failure to follow written SOPs shall constitute a basis for enforcement action.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

1735.12. Quality Assurance And Quality Control

The requirements of this section apply to nonsterile compounding in addition to the standards established in USP Chapter 795.

(a) The quality assurance program shall also comply with section 1711 and the standards contained in USP Chapter 1163, entitled *Quality Assurance in Pharmaceutical Compounding*. In addition, the program shall include in its SOPs 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, quality, or labeled strength.

(2) A written procedure for responding to out-of-range temperature variations within the medication storage areas where a furnished drug may be returned for furnishing to another patient.

(b) The Board shall be notified in writing within 72 hours of the facility's receipt of a complaint of a potential quality problem or the occurrence of an adverse drug event involving a CNSP.

(c) All complaints related to a potential quality problem with a CNSP and all adverse events shall be reviewed by the pharmacist-in-charge within 72 hours of receipt of the complaint or occurrence of the adverse event. Such review shall be documented and dated as defined in the SOPs.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

1735.13. CNSP Packaging and Transporting

The requirements of this section apply to nonsterile compounding in addition to the standards established by USP Chapter 795.

There shall be written procedures recorded in the facility's SOPs (as described in Section 1735.11) describing validated processes for storage, shipping containers and transportation of temperature sensitive CNPSs to preserve quality standards for integrity, quality and labeled strength.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

1735.14. Documentation

The requirements of this section apply to nonsterile compounding in addition to the standards established by USP Chapter 795.

(a) Records shall be maintain as required by USP Chapter 795 or this article, in a readily retrievable form, for at least three years from the date the record was created or relied upon to meet the requirements of this article. 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.

(b) Records created shall be created and maintained in a manner to provide an audit trail for revisions and updates of each record document. Prior versions of each record must be maintained in a readily retrievable format and include the changes to the document, identification of individual who made the change, and the date of each change

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4105, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

**Article 4.6 draft regulation text
related to sterile compounding**

Title 16. Board of Pharmacy

Proposed Regulation

Repeal Article 7 and sections 1751-1751.12 of Article 7 and add new titles and sections 1736- 1736.21, to Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1736 Sterile Compounding Definitions

The definitions in in this section shall be applicable to this Article and supplement the definitions provided in USP Chapter 797.

(a) "Compounding personnel" means any person involved with any procedure, activity or oversight of the compounding process.

(b) "Designated person(s)" means one or more individuals assigned by the pharmacist-in-charge to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of the compounded sterile preparations ("CSP" for the purposes of this article). Nothing in this definition allows for the designated person to exceed the scope of their issued license. When the designated person is not a pharmacist, the Pharmacist-in-Charge (PIC) must review all practices related to the operations of the facility that require professional judgement.

(c) "Diluent" means a liquid with no pharmacological activity used in reconstitution, such as sterile water for injection.

(d) "Designated compounding area or compounding area" means a restricted location with limited access designated for the preparation of CSP, where only activities and items related to compounding are present.

(e) "Essentially a copy" of a commercially available drug product means all preparations that include the same API(s) , as the 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.

(f) "Integrity" means retention of potency until the beyond use date provided on the label, when the preparation is stored and handled according to the label directions.

(g) "Quality" means the degree to which the components and preparation meets the intended specifications, complies with relevant law and regulation, and means the absence of harmful levels of contaminants, including but not limited to filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, or the absence of inactive ingredients other than those listed on the master formula record as specified in USP 797.

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

Note: Authority cited: Sections 4001.1, 4005, 4126.8, 4127 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4127, 4301 and 4332 of the Business and Profession Code.

1736.1 Introduction and Scope.

This article applies to compounded sterile preparations (CSP)s as defined in United States Pharmacopeia (USP) General Chapter 797 (Chapter 797), titled *Pharmaceutical Compounding – Sterile Preparations*. In addition to the standards in the USP Chapter 797, the preparation of a CSP shall meet the following requirements of this article.

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

(b) CSPs for direct and immediate administration as provided in the Chapter shall only be done in those limited situations where the failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need. Documentation for each such CSP shall include identification of the CSP, compounded date and time, number of units, the patient's name and patient's unique identifier and the circumstance causing the immediate need. Such documentation may be available in the patient's medical record and need not be redocumented by the compounding staff if already available

(c) Notwithstanding subdivision (a) a limited quantity of CSP may be prepared and stored 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 individual patients based on a documented history of prescriptions for those patient populations.

(d) A reasonable quantity of a compounded drug preparation may be furnished to a veterinary office for use by the veterinarian that is sufficient:

(1) for administration or application to veterinary patients solely in the veterinarian's office

(2) for furnishing of not more than a 120-hour supply, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing;

(a) With the exception of a topical ophthalmics where up to a 28 days supply may be furnished to veterinarian's office for individual patient. Such topical ophthalmics shall be compliant with USP 797 section 14.5, Multiple-Dose CSPs .

(e) In addition to prohibitions and requirements for compounding established in federal law, no CSP shall be prepared that:

(1) Is essentially a copy of one or more commercially available drug products, unless:

(A) that drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA Drug Shortages Database that are in short supply at the time of compounding and at the time of dispense, or

(B) the compounding produces a clinically significant difference of the medical need of an identified individual patient, as determined:

(1) by the prescribing practitioner,

(2) the compounding pharmacist, and

(3) the dispensing pharmacist(s).

(C)) Documentation describing the conditions in (1)(A) & (1) (B) is maintained in a readily retrievable format

(2) Is made with any component not suitable for use in a CSP for the intended patient population, unless allowable under Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA).

(3) Is made with a non-sterile component for which a conventionally manufactured sterile product is available and appropriate for the intended CSP.

(4) Where sterilization is required, it cannot be sterilized within the licensed location.

(f) Prior to allowing any CSP to be compounded within a pharmacy, the pharmacist-in-charge shall complete a self-assessment consistent with the requirements established in section 1715.

(g) In addition to the provisions provided in Section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning proper use, storage, handling and disposal of the CSP and related supplies furnished.

(h) CSPs with human whole blood or human whole blood derivatives shall be done in compliance with Health and Safety Code section 1602.5.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and

1736.2 PERSONNEL TRAINING AND EVALUATION

The requirements of this section apply to sterile compounding in addition to the standards in USP Chapter 797.

(a) In addition to the training required by USP 797, training and competency procedures for all personnel who compound or have direct oversight of compounding personnel training shall also address the following topics:

- (1) Quality assurance and quality control procedures,
- (2) Container closure and equipment selection,
- (3) Component selection and handling, and
- (4) Sterilization techniques, when applicable.

(b) Aseptic manipulation competency initial training and competency and ongoing training and competency documentation shall include the Primary Engineering Control (PEC's) type and PEC unique identifier used during the evaluation. Aseptic manipulation competency evaluation and requalification shall be performed using the same procedures, type of equipment, and materials used in aseptic compounding. Aseptic qualifications from one premises may be used for another premises if all of the following conditions are met:

1. The SOPs related to compounding are identical
2. The SEC facility designs are sufficiently similar to accommodate the use of the same SOPs.
3. The PECs are of the same type and sufficiently similar to accommodate the use of the same SOPs describing use and cleaning.

(c) Aseptic manipulation ongoing training and competency shall occur each time and for each staff member involved in an event where the quality assurance program yields an unacceptable result as defined in the SOPs referenced in section 1736.17 that may indicate microbial contamination of CSPs due to poor practices. Aseptic manipulation ongoing training and competency procedures shall be defined in the facilities SOPs.

(d) Compounding personnel or persons with direct oversight over personnel performing compounding, who fail any aspect of the aseptic manipulation ongoing training and competency evaluation shall not be involved in compounding or oversight of the preparation of a CSP until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs. A person with only direct oversight over personnel who fails any aspect of the aseptic manipulation ongoing training and competency evaluation, may continue to provide only direct oversight for no more than 14 days while applicable aseptic manipulation ongoing training and competency evaluation results are pending.

(e) Any person assigned to provide the training specified in this section shall have demonstrated competency in the skills in which the person will provide training or observe and measure competency described in the facilities SOPs as referenced in section 1736.17. Documentation must be maintained demonstrating compliance.

Note: Authority cited: Sections 4001.1, 4005, 4126.8, 4127 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4114, 4115, 4127, 4301 and 4332 of the Business and Profession Code.

1736.3 PERSONNEL HYGIENE AND GARBING

The requirements of this section apply sterile compounding in addition to the requirements in USP Chapter 797.

(a) The pharmacist overseeing compounding shall not allow personnel with potentially contaminating conditions to enter the compounding area.

(b) The pharmacist overseeing compounding shall not allow personnel to enter the compounding area with visible non-removable piercings that increase the risk of contamination of CSP.

(c) Garb shall be donned in an anteroom or immediately outside the segregated compounding area (SCA). Donning and doffing garb shall not occur in the anteroom at the same time unless the facility's SOP define specific processes that must be followed to prevent contamination.

(d) Restricted access barrier system (RABS) and pharmaceutical isolator sleeves and gloves shall be changed according to both the manufacturer's recommendations and the facility's SOP.

(e) Any garbing accommodations provided by the designated person shall be documented and the record shall include the name of the individual granted the accommodation, date granted and description of the reasons for granting the accommodation. The record shall be retained in accordance with Business and Professions Code section 4081.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

1736.4 FACILITIES AND ENGINEERING CONTROLS

The requirements of this section apply to sterile compounding in addition to the requirements in USP Chapter 797.

(a) A sink used for compounding or hand hygiene shall not be part of a restroom or water closet.

(b) If an SCA is used:

(1) Except for walls, the SCA's visible perimeter shall be at least 1 meter from all sides of the PEC or in a separate room.

(2) Surfaces within the SCA shall be smooth, impervious, free from cracks and crevices, and non-shedding so they can be easily cleaned and disinfected and to minimize spaces in which microorganisms and other contaminants can accumulate.

(c) (1) Designated compounding area(s) shall typically be maintained at a temperature of 20° Celsius or cooler and also provide comfortable conditions for compounding personnel attired in the required garb.

(2) The temperature shall be monitored in each room of the designated compounding area each day that compounding is performed, either manually or by a continuous recording device.

(d) Where a pass-through is installed in a secondary engineering control after [OAL insert effective date], the doors must be interlocking. An existing secondary engineering control that has a pass-through that is not an interlocking device, may continue to be used if the SOPs document that two doors may not be opened at the same time.

(e) Except as provided in (d) dynamic interactions between areas and rooms with classified air shall be controlled through a heating, ventilation, and air condition (HVAC) system. No passive ceiling or wall penetrations are allowed.

(f) No CSP shall be compounded if the compounding environment fails to meet criteria specified in the law or the facilities SOPs.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

1736.5 CERTIFICATION AND RECERTIFICATION

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) Testing and certification of all classified areas shall be completed by a

qualified technician knowledgeable with certification methods and procedures outlined within the Controlled Environment Testing Association (CETA)'s Certification Guide for Sterile Compounding Facilities as specified in this section. Testing shall be performed in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003, Revised 2022), which is hereby incorporated by reference.

(b) CETA standard(s) used to perform certification testing in all classified areas shall be recorded on report issued by the certifying technician.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

1736.6 MICROBIOLOGICAL AIR AND SURFACE MONITORING

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) SOPs shall specify steps to be taken when the microbiological air and surface monitoring action levels are exceeded including the investigative and corrective actions, allowable activities, and resampling procedures.

(b) At a minimum every 6 months, air and surface sampling results shall be identified to at least the genus level, regardless of the CFU count to trend for growth of microorganisms. Professional judgement and SOPs shall be used to determine the appropriate action necessary to remedy identified trends. Investigation must be consistent with the deviation and must include evaluation of trends.

(c) Environmental sampling shall be done in compliance with the most recent edition of the Controlled Environment Testing Association (CETA)'s Certification Application Guide USP <797> Viable Environmental Sampling & Gowning Evaluation (CAG-009, Revised October 2022), which is hereby incorporated by reference.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

1736.7 CLEANING, DISINFECTING, AND APPLYING SPORICIDAL DISINFECTANTS AND STERILE 70% IPA

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) Any cleaning, disinfecting, and sporicidal disinfectants used by the facility to meet the requirements in this article shall be used in accordance with manufacturers' specifications

(b) Reusable cleaning supplies, not for use in the PEC, shall not be stored within 1 meter of the PEC.

(c) In addition to the documentation requirements in USP Chapter 797, the facility's documentation of each occurrence of the cleaning, disinfecting, and applying of sporicidal disinfectants in the compounding area shall include a record of the identity of the person completing the cleaning and sanitizing as well as the product name of the cleaning and sanitizing agents used.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

1736.8 INTRODUCING ITEMS INTO THE SEC AND PEC

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

SOPs shall specify the process and products to be used on any equipment and other items entering from an unclassified area into the clean side of the anteroom, entering a PEC, and entering the SCA. These SOPs will define at a minimum, what product is to be used, the dwell time required, and how dwell time will be monitored and documented.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

1736.9 EQUIPMENT, SUPPLIES, AND COMPONENTS

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) All equipment and supplies used to compound CSP shall be used, in accordance with manufacturers' specifications and shall be surface

compatible.

(b) Incubators used by the facility shall be cleaned, maintained, calibrated, and operated in accordance with manufacturers' specifications. For incubators without specific manufacturers' specifications, cleaning shall take place at least every 30 days and calibration shall take place at least every 12 months. SOPs shall specify the frequency and process of cleaning, maintenance, and calibration, including when incubation of samples is taking place such that samples are not compromised. All cleaning, maintenance, and calibration shall be documented and dated as defined in the SOPs.

(c) Any component used to compound a CSP shall be used and stored in accordance with all federal laws and regulations and industry standards including the manufacturers' specifications and requirements.

(d) All API and excipient components used to compound a CSP shall be manufactured by an FDA-registered facility, be accompanied by a Certificate of Analysis (COA) and suitable for use in sterile pharmaceuticals. A COA which includes the compendial name, the grade of the material, and the applicable compendial designations on the COA must be received and evaluated prior to use, unless components are commercially available drug products. API and excipient components provided without this data shall not be used in a CSP

(1) When the COA is received from a supplier, it must provide the name and address of the manufacturer .

(e) When a bulk drug substance, or API, is used to compound a CSP, it shall comply with a USP drug monograph, be the active substance of an FDA approved drug, or be listed 21 CFR 216, unless authorized by a public health official in an emergency use situation for a patient specific compounded sterile preparation.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

1736.10 STERILIZATION AND DEPYROGENATION

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) Dry heat depyrogenation shall be done in compliance with USP Chapter 1228.1, Dry Heat Depyrogenation.

(b) Sterilization by filtration shall be done in compliance with USP Chapter 1229.4, Sterilizing Filtration of Liquids.

(1) Filter dimensions and the CSP to be sterilized by filtration shall permit the sterilization process to be completed without the need for replacement of the filter during the process.

(c) Steam sterilization shall be done in compliance with USP Chapter 1229.1, Steam Sterilization by Direct Contact.

(d) Dry heat sterilization shall be done in compliance with USP Chapter 1229.8, Dry Heat Sterilization.

(e) No compound of a CSP from nonsterile components shall be prepared when the licensed location cannot also sterilize the CSP as described in this section.

(f) Sterilization of supplies and/or container–closure systems shall be done in compliance with USP Chapter 1229, Sterilization of Compendial Articles.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

1736.11 MASTER FORMULATION AND COMPOUNDING RECORDS

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) A CSP shall not be compounded until the facility has first prepared a written master formulation record in compliance with USP Chapter 797 and identified in that document the following additional elements:

(1) When a source is referenced to support the assigned beyond-use date (BUD); each source referenced shall be readily retrievable at the time of compounding and shall be maintained for three years from the date each CSP is dispensed.

(2) Instructions for storage and handling the compounded drug preparation.

(b) Where a facility 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 comply with USP Chapter 797 and this section.

(c) A compounding record (CR) shall be a single document. The document shall satisfy the requirements of USP Chapter 797, as well as the following:

(1) The date and time of preparation. The time of preparation is the time when compounding the CSP started, which also determines when the assigned BUD starts.

(2) The assigned internal identification number shall be unique for each CR.

(3) The manufacturer, lot number, and expiration date shall be recorded for each component for CSPs.

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

(5) The identity of each person performing the compounding, that has direct oversight of compounding, and pharmacist verifying the final drug preparation.

(6) When applicable, endotoxin level calculations and results.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4081, 4114, 4115, 4126.8, 4169 and 4127, Business and Professions Code.

1736.12 RELEASE INSPECTIONS AND TESTING

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) A pharmacist performing, or supervising sterile compounding is responsible for the integrity, quality, and labeled strength of a CSP until the beyond use date indicated on the label provided the patient or the patient's agent follows the label instructions provided on the CSP for storage and handling after receiving the CSP.

(b) Validation of an alternative method for sterility testing shall be done in compliance with USP Chapter 1223, Validation of Alternative Microbiological Methods and shall document the method-suitability for each CSP formulation for which the alternate method is used.

(c) Injectable CSP's made from nonsterile components regardless of Category, must be tested to ensure that they do not contain excessive bacterial endotoxins, as established in USP Chapter 85, Bacterial Endotoxins. Results must

be reviewed and documented in the compounding record prior to release.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

1736.13 LABELING

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) A CSP label shall also include the following:

- (1) Route of intended administration, and
- (2) the solution utilized, if applicable and
- (3) Instructions for administration.

(A) For admixed CSPs, the rate of infusion, or range of rates of infusion as prescribed, or the duration, when the entire CSP shall be administered

- (4) Name of compounding facility and dispensing facility (if different).

(b) Any CSP dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076, 4114, 4115, 4123, 4126.8, and 4127, Business and Professions Code.

1736.14 ESTABLISHING BEYOND-USE DATES

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) A CSP's beyond-use date (BUD) shall not exceed:

(1) The chemical and physical stability data of the active pharmaceutical ingredient and any added substances in the preparation,

(2) The compatibility of the container–closure system with the finished preparation (e.g., possible leaching, interactions, and storage conditions),

(3) The shortest remaining expiration date or BUD of any of the starting components.

(b) A CSP labeled with a BUD with only a date shall expire at 11:59 p.m. on that date.

(c) Prior to dispensing a CSP that requires sterility and endotoxin testing for BUD determination, test results shall be received. Results must be within acceptable limits. Test results must be retained as part of the compounding record.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

1736.15. USE OF CONVENTIONALLY MANUFACTURED PRODUCTS AS COMPONENTS

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) A single-dose container entered or punctured outside of an ISO Class 5 area, must be discarded immediately.

(b) A single-dose container entered or punctured inside of an ISO class 5 area must be discarded within 12 hours.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

1736.16. USE OF CSPS AS COMPONENTS

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) A compounded stock solution intended for use in a CSP must comply with all provisions of this article including Category 1, Category 2, or Category 3.

(b) Nothing in this section shall prohibit the use of a CSP obtained from a California licensed outsourcing facility.

1736.17 Standard Operating Procedures (SOPS)

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) The facility's standard operating procedures (SOPs) for sterile compounding shall be followed and shall:

(1) Comply with USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding.

(2) In addition to the SOPs required in USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding, SOPs must also be developed to describe the following:

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

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

(C) The methods a pharmacist will use to determine and approve the ingredients and the compounding process for each preparation before compounding begins.

(D) The method for complying with any other requirements specifically required to be addressed in the facility's SOPS as described in this article.

(b) The SOPs shall specify the steps to be taken if a classified area(s) fails to meet the specified ISO classification including the investigative and corrective actions, allowable activities, and retesting procedures.

(c) The SOPs shall be reviewed on an annual basis by the pharmacist-in-charge. Such review shall be documented by the pharmacist-in-charge consistent with the SOPs. The SOPs shall be updated to reflect changes to compounding processes, facility changes or other changes that impact the CSP. Such SOP changes shall be disseminated to the affected staff prior to implementation.

(d) Failure to follow written SOPs shall constitute a basis for enforcement action.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

1736.18 QUALITY ASSURANCE AND QUALITY CONTROL

The requirements of this section apply to sterile compounding in addition to the standards established in USP Chapter 797.

(a) The quality assurance program shall comply with section 1711 and the standards contained in USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. In addition, the program shall 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, quality, or labeled strength.

(2) A written procedure for responding to out-of-range temperature variations within the medication storage areas where a furnished drug may be returned for furnishing to another patient.

(b) Recalls and adverse reporting must be completed in compliance with relevant provisions of law.

(c) In addition to subsection (b), all complaints related to a potential quality problem with a CSP and all adverse events shall be reviewed by the pharmacist-in-charge within 72 hours of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8, 4127, 4127.2, and 4127.11, Business and Professions Code.

1736.19 CSP HANDLING, STORAGE, PACKAGING, SHIPPING, AND TRANSPORT

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) There shall be written procedures for qualification of storage, shipping containers and transportation of temperature sensitive CSPs to preserve quality standards for integrity, quality and labeled strength.

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

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

1736.20 DOCUMENTATION

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) Records shall be maintained as required by USP Chapter 797 or this article, in a readily retrievable form, for at least three years from the date the record was created or relied upon. 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.

(b) Records created shall be created and maintained in a manner to provide an audit trail for revisions and updates of each record document. Prior versions of each record must be maintained in a readily retrievable format and include the

changes to the document, identification of individual who made the change, and the date of each change.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4081, 4105, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

1736.21 COMPOUNDING ALLERGENIC EXTRACTS

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) Any allergenic extract compounding shall take place in a dedicated PEC. No other CSP may be made in this PEC.

(b) Compounding of allergenic extracts are limited to patient-specific prescriptions and the conditions limited to Category I and Category 2 CSPs as specified in USP 797.

(c) Any stock solution made shall comply with the requirements established in USP 51, Antimicrobial effectiveness testing and container closure integrity tests consistent with USP Chapter 1207, Sterile Product Packaging – Integrity Evaluation. Compounding records are required for stock solutions.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

**Article 4.7 draft regulation text
related to hazardous drugs**

**Title 16. Board of Pharmacy
Proposed Regulation**

**Proposal to Add Article 4.7 and add new titles and section 1737 – 1737.18 to Division 17 or Title 16 of the California Code of Regulations to read as follows:
Article 4.7 Hazardous Drugs**

1737 Handling of Hazardous Drugs

In addition to the standards established by United States Pharmacopeia (USP) General Chapter 800 (USP Chapter 800), titled *Hazardous Drugs – Handling in Healthcare Setting* shall meet the requirements of this Article.

A licensee performing non-sterile and sterile HD compounding shall comply with this article in addition to Article 4.5 and Article 4.6.

1737.1 Introduction and Scope

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

In addition to providing consultation in compliance with section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning on handling and disposal of an HD or related supplies furnished.

1737.2 List of Hazardous Drugs

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) Designated person" is a single individual approved by the pharmacist-in-charge to be responsible and accountable for the performance and operation of the facility and personnel as related to the handling of hazardous drugs. Nothing in this definition allows for the designated person to exceed the scope of their issued license. When the designated person is not a pharmacist, the Pharmacist-in-Charge (PIC) must review all practices related to the operations of the facility that require professional judgement.

(b) If an assessment of risk is performed as allowed in USP Chapter 800, it shall be performed or approved and documented at least every 12 months by the designated person and the pharmacist-in-charge, professional director of a clinic, or designated representative-in-charge, as applicable.

(c) The facility's list of HDs must be reviewed and approved by the designated person and the pharmacist-in-charge, professional director of a clinic, or

designated representative-in-charge, as applicable. Approval shall be documented at least every 12 months.

1737.3 Types of Exposure

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

Each entity shall ensure that all employees are aware of the types of risks of HD exposures that may occur as documented in the Chapter. This shall be documented in SOPs and training documents.

1737.4 Responsibilities of Personnel Handling Hazardous Drugs

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

The Pharmacist-in-charge, designated representative-in-charge, or professional director, as applicable shall be responsible for all activities and decisions made or approved by the designated person.

1737.5 Facilities and Engineering Controls

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) When a containment primary engineering control (C-PECs), used for nonsterile and sterile HDs is placed in the same room, biannual certification must document that the room can continuously maintain ISO 7 classification throughout the nonsterile compounding activity. Specific standard operating procedures (SOPs) shall be written to address the maintenance of the ISO 7 classification.

(c) Compounding volatile HDs:

(1) HEPA filters shall not be the only means of containment used.

(2) for sterile compounding, a biological-safety cabinet (BSC) as defined in USP Chapter 800 Class II Type A1 shall not be used

(b) Where a pass-through is installed in a C-SEC the doors must be gasketed and interlocking. A pass-through is not allowed between the C-SEC into an unclassified space.

(c) Effective January 1, 2026, all pass-through doors shall be a HEPA purge type.

(d) Facility room pressure monitoring equipment shall be placed consistent with CETA Guidelines CAG-003:2022. SOPs shall address corrective and remedial actions in the event of pressure differentials and air changes per hour excursions.

(e) Containment Supplemental Engineering Controls (CSTDs) shall not be used to extend the in-use time, BUD, or expiration of any manufactured product or HD CSP.

1737.6 Environmental Quality and Control

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) An entity's SOPs shall address environmental wipe sampling for HD surface residue, its frequency, areas of testing, levels of measurable contamination, and actions when those levels are exceeded.

(b) When actionable levels of contamination is found, at minimum the following shall occur:

- (1) Reevaluate work practices
- (2) Reevaluate the appropriateness of deactivation, decontamination and cleaning agents
- (3) Re-train personnel on deactivation, decontamination and cleaning
- (4) Re-train personnel on donning and doffing appropriate PPEs

1737.7 Personal Protective Equipment (PPE)

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) Two pairs of gloves that meet the ASTM D-6978 standard shall be worn for handling HD waste, cleaning HD spills, and performing routine cleaning in HD areas.

(b) The outer pair of gloves that meets the ASTM D-6978 standard chemotherapy gloves shall be changed every 30 minutes during compounding unless otherwise recommended by the manufacturer's documentation. Documentation from the manufacturer shall be readily retrievable. For sterile compounding both pairs of gloves labeled to meet the ASTM D-6978 standard chemotherapy gloves shall be sterile.

(c) Outer gloves used for compounding must be changed between each different HD drug and the standards established in Chapter 800 if continuously compounding a single HD preparation. The facilities SOPs shall define the

circumstances under which the gowning and gloves must be changed between HD handling/preparations.

(d) PPE shall be removed to avoid transferring contamination to skin, the environment, and other surfaces. PPE worn during compounding shall be disposed of in the proper waste container before leaving the C-SEC. SOPs must be in place which describe in detail the donning and doffing of PPE and where it takes place in the C-SEC.

(e) An appropriate full-facepiece, chemical cartridge-type respirator, or powered air-purifying respirator (PAPR) shall be worn when there is a risk of respiratory exposure to HDs, including when:

- (1) Attending to HD spills larger than what can be contained with a spill kit
- (2) Deactivating, decontaminating, and cleaning underneath the work surface of a C-PEC
- (3) There is a known or suspected airborne exposure to powders or vapors.

1737.8 Hazard Communication Program

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

The designated person is responsible for participating in the development of the entity's hazardous communication program. The program shall be documented in SOPs and training documents.

1737.9 Personnel Training

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) Any person assigned to provide the training specified in this section shall have demonstrated competency in the skills in which the person will provide training or observe and measure competency described in the facilities SOPs as referenced in section 1737.17. Documentation must be maintained demonstrating compliance.

(b) Personnel of any facility responsible for handling HD who fail any aspect of training in handling HDs, shall not be involved in handling HDs until after successfully passing reevaluations in the deficient area(s), as detailed in the facility's SOPs. A person with only direct oversight over personnel who fails any aspect of handling HD and ongoing training and competency evaluation, may

continue to provide only direct oversight for no more than 14 days while applicable handling HD ongoing training and competency evaluation results are pending.

1737.10 Receiving

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

All HD API and antineoplastic HDs shall be shipped and received from the supplier in segregated impervious plastic and labeled as HD on the outside of the delivery container.

1737.11 Labeling, Packaging, Transport and Disposal

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) Any compounded HD preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5.

(b) All HD API and antineoplastic HDs shall be transported in an impervious plastic container and labeled as HD on the outside of the container.

1737.12 Dispensing Final Dosage Form

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

Equipment used in nonsterile compounding shall be dedicated for use with HDs and shall be decontaminated after each use.

1737.13 Compounding

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) A disposable preparation mat shall be placed on the work surface of the C-PEC when compounding HD preparations. Where the compounding is a sterile preparation, the preparation mat shall be sterile. The preparation mat shall be changed immediately if a spill occurs, after each HD drug, and at the end of daily compounding activity.

(b) Only one HD drug may be handled in a C-PEC at one time if making multiple preparations.

1737.14 Administering

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) When dispensing an HD to a patient or caregiver for administration, the pharmacy shall

1. Place the HD in a decontaminated impervious plastic container with an HD label on the outside of the container and

2. For an antineoplastic HDs, attach and prime all tubing and attach a CSTD when appropriate.

(b) There shall be a sufficient supply of gloves that meet the ASTM D-6978 standard, to allow for appropriate administration, handling, and disposal of HD drugs by the patient or the patient's agent when dispensing an antineoplastic HD.

1737.15 Deactivation, Decontamination, Cleaning, and Disinfecting

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) Deactivating, decontaminating, cleaning, disinfecting and sporicidal agents shall be used in accordance with manufacturers' specifications and shall be surface compatible.

(b) Agents used for deactivation, decontamination, cleaning and disinfecting all areas and equipment involved in HD handling shall be applied through the use of wipes wetted with appropriate solution and shall not delivered by a spray bottle to avoid spreading HD residue.

(c) SOPs for decontamination and deactivation procedures for the final HD preparation shall be created by the entity in accordance with the entity's SOPs and approved by the pharmacist-in-charge, professional director of a clinic, designated representative-in-charge, as applicable.

1737.16 Spill Control

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) The entity shall have an SOP addressing the use of appropriate full-facepiece, chemical cartridge-type respirator, or powered air-purifying respirator (PAPR) if the capacity of the spill kit is exceeded or if there is known or suspected airborne exposure to vapors or gases.

(b) The entity shall maintain a list of properly trained and qualified personnel able to clean up an HD spill. An SOP shall outline how a qualified personal will be available at all times while HDs are handled.

1737.17 Documentation and Standard Operating Procedures

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) Any entity engaged in the compounding or handling of HDs shall maintain and follow written SOPs.

(b) The SOPs for compounding or handling HDs shall include at least the following:

- (1) Hazard communication program
- (2) Occupational safety program
- (3) Designation of HD areas
- (4) Receipt
- (5) Storage
- (6) Compounding, if applicable
- (7) Use and maintenance of proper engineering controls (e.g., C-PECs, C-SECs, and CSTDs), if applicable
- (8) Hand hygiene and use of PPE based on activity (e.g., receipt, transport, compounding, administration, spill, and disposal), if applicable
- (9) Deactivation, decontamination, cleaning, and disinfection
- (10) Dispensing, if applicable
- (11) Transport
- (12) Administering, if applicable
- (13) Environmental monitoring (e.g., wipe sampling)
- (14) Disposal
- (15) Spill control
- (16) Medical surveillance

(c) The pharmacist-in-charge, professional director of a clinic, designated representative-in-charge, as applicable, shall work with the entity's designated person to ensure HD handling SOPs are reviewed at least every 12 months and this review is documented.

(d) SOPs shall be updated whenever changes are implemented. Such changes shall be disseminated in a written format to the staff responsible for handling HDs prior to implementation. All notifications of such changes and the changes shall be documented in SOPs and training documents.

(e) Failure to follow written SOPs shall constitute a basis for enforcement action.

1737.18 Medical Surveillance

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

Elements of a medical surveillance program shall be consistent with the entity's Human Resource policies and employees handling HDs must be aware of the program.

**Article 4.8 draft regulation text
related to radiopharmaceuticals**

Repeal:

1708.3. Radioactive Drugs.

A radioactive drug is any substance defined as a drug in Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act or a radioactive biological product as defined in 21 CFR 600.3(ee) which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any such drug or biological product which is intended to be made radioactive. This definition includes non-radioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds, potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4025, Business and Professions Code.

1708.4. Pharmacist Handling Radioactive Drugs.

A pharmacist handling radioactive drugs must be competent in the preparation, handling, storage, receiving, dispensing, disposition and pharmacology of radioactive drugs. He must have completed a nuclear pharmacy course and/or acquired experience in programs approved by the Board. Education and experience in non-approved programs may be granted partial or equivalent credit, if, in the opinion of the Board, such programs provide the level of competence as approved programs or the Nuclear Pharmacy Competency Statement adopted by the Board.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4021, 4022, 4025, 4036 and 4037, Business and Professions Code.

1708.5. Pharmacy Furnishing Radioactive Drugs.

A pharmacy furnishing radioactive drugs is any area, place or premises described in a permit issued by the board where radioactive drugs are stored, processed, compounded, repackaged, or dispensed. A pharmacy exclusively furnishing radioactive drugs shall be exempt from the patient consultation area requirements of Title 16 Cal. Code of Regulations Section 1714(a) unless the Board finds that the public health and safety require their application.

A pharmacist qualified under Section 1708.4 to furnish radioactive drugs shall be in the pharmacy whenever the furnishing of radioactive drugs occurs. All personnel involved in the furnishing of radioactive drugs shall be under the immediate and direct supervision of such a qualified pharmacist.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4008 and 4008.2, Business and Professions Code.

Proposal to Add Article 4.8 as proposed with the following:

Article 4.8 Radiopharmaceutical- Preparation, Compounding, Dispensing, and Repackaging

1738. Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging

This article applies to radiopharmaceuticals as defined in USP Chapter 825. In addition to the requirements provided in this Article, the processing of radiopharmaceuticals shall comply with the standards established by United States Pharmacopeia General Chapter 825, titled *Radiopharmaceuticals* –

Preparation, Compounding, Dispensing, and Repackaging ("USP Chapter 825" for the purposes of this Article).

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code.
Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.1 INTRODUCTION

In addition to the definitions contained in USP Chapter 825, the following definitions apply to this Article and supplement the standards established in USP Chapter 825 when not otherwise provided in USP Chapter 825.

(a) "Added substances" means ingredients that are necessary to compound a preparation but are not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with the terms inactive ingredients, excipients, and pharmaceutical ingredients.

(b) "Designated person" means a pharmacist identified as assigned, responsible, and accountable for the performance and operation of the radiopharmaceutical processing facility and for personnel who prepare, compound, dispense, and repackage radiopharmaceuticals.

(c) "Component" means any ingredient used in the compounding of a preparation, including any active ingredient, added substance, or conventionally manufactured product.

(d) "Diluent" means a liquid with no pharmacological activity used in reconstitution, such as sterile water for injection.

(e) "Processing," "processed" or "processing activity" means the preparation, compounding, repackaging, or dispensing of a radiopharmaceutical.

(f) The use of technologies, techniques, material, and procedures not described in USP 825 shall be based upon published peer-reviewed literature or documents meeting FDA approved labeling requirements in accordance with sections 201.56 and 201.57 of title 21, Code of Federal Regulations, showing the technologies, techniques, material, and procedures to be equivalent or superior to those described in USP Chapter 825.

(g) Processing with human whole blood or human whole blood derivatives shall be done in compliance with Health and Safety Code section 1602.5.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code.
Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.2 RADIATION SAFETY CONSIDERATIONS

In addition to the standards in the USP Chapter 825, the processing of radiopharmaceuticals shall meet the following radiation safety requirements of this section.

(a) Radiation detectors and measuring devices, and other necessary equipment may be placed inside an ISO Class 5 PEC but must be placed in a manner that minimizes disruptions of airflow.

(b) Disposable absorbent pads shall be changed after each type of radiopharmaceutical processing.

(c) Any deviation made to lower radiation exposure to workers shall be evaluated and documented in an SOP by the designated person prior to the deviation occurring. Exceptions to the environmental controls requirements must be documented in the specific radioactive materials license conditions issued by the California Department of Public Health pursuant to section 30190 of Title 17 of the California Code of Regulations, or a specific radioactive materials license issued by another state or the United States Nuclear Regulatory Commission pursuant to pursuant to section 32.72 of title 10 of the Code of Federal Regulations.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code.
Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.3. IMMEDIATE USE OF STERILE RADIOPHARMACEUTICALS

The processing of radiopharmaceuticals for immediate use may only be done in a patient care setting meeting the applicable requirements in this Article. The patient care facility shall maintain all records required in Section 9 of USP Chapter 825 in accordance with Business and Professions Code section 4081.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code.
Reference: Sections 4005, 4081, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.4 PERSONNEL QUALIFICATIONS, TRAINING, AND HYGIENE

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) Processing personnel experiencing any of the following: rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection or and other conditions which could contaminate a sterile radiopharmaceutical, or the environment shall not be allowed to enter the compounding area unless approved by the designated person. Any approvals provided by the designated person shall be documented and the record shall include the name of the individual granted approval, the approval date and time, the reason for granting approval, and the identification of the designated person making the decision.

(b) The pharmacist with direct oversight over personnel performing radiopharmaceutical processing shall demonstrate proficiency in skills necessary to ensure the integrity, potency, quality, and labeled strength of radiopharmaceuticals as defined in the facilities SOPs.

(c) Aseptic manipulation competency initial training and competency and ongoing training and competency documentation shall include the Primary Engineering Control (PEC's) type and PEC unique identifier used during the evaluation. Aseptic manipulation competency evaluation and requalification shall be performed using the same procedures, type of equipment, and materials used in aseptic compounding. Aseptic qualifications from one premises may be used for another premises if all of the following conditions are met:

1. The SOPs related to compounding are identical.
2. The SEC facility designs are sufficiently similar to accommodate the use of the same SOPs.
3. The PECs are of the same type and sufficiently similar to accommodate the use of the same SOPs describing use and cleaning.

(d) SOPs must clearly define the acceptable use and cleaning for reusable gowns that prevent possible contamination of the CSP and designated compounding area. However, laundered garb must not be reused beyond one day unless garb is laundered with a validated cycle. The facility's SOPs must describe the process that must be followed should the facility allow for the reuse of garb.

(e) Eyeglasses shall be cleaned as part of hand hygiene and garbing, consistent with the standards specified in the SOPs.

(f) Garb shall be donned and removed in an ante-area or immediately outside the SPRA. Donning and doffing garb shall not occur in the anteroom at the

same time unless the SOPs define specific processes which must be followed to prevent contamination.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code.
Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.5. FACILITIES AND ENGINEERING CONTROLS

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) A sink used for compounding or hand hygiene shall not be part of a restroom or water closet.

(b) The temperature shall be monitored in SRPAs segregated radiopharmaceutical processing area and classified areas each day that processing is performed, either manually or by a continuous recording device.

(c) Storage and elution of non-direct infusion radionuclide generators shall take place in an ISO Class 8 or better area.

(d) If an SRPA is used:

(1) Except for walls, the SRPA's visible perimeter shall be at least 1 meter from all sides of the PEC or in a separate room.

(2) Surfaces within the SRPA shall be smooth, impervious, free from cracks and crevices, and non-shedding so they can be easily cleaned and disinfected and to minimize spaces in which microorganisms and other contaminants can accumulate.

(3) Compounding shall not take place in the SRPA.

(e)(1) Testing and certification of all classified areas shall be completed by a competent individual. A competent individual is a technician who possesses a current accreditation issued by The Controlled Environment Testing Association (CETA), or under the direct supervision of an individual who possesses a current accreditation issued by CETA Certification shall be completed consistent with the provisions established in the USP Chapter 797, titled "Pharmaceutical Compounding—Sterile Preparations" (USP Chapter 797). The facility shall review and maintain a copy of the accreditation documentation in accordance with requirements in section 1738.9.

(2) CETA standard(s) used to perform certification testing in all classified areas shall be recorded on the certification report as required and specified in USP Chapter 797.

(f) SOPs shall specify steps to be taken if a classified area(s) fails to meet the specified ISO classification including the investigative and corrective actions, allowable activities, and retesting procedures.

(g) All classified spaces and equipment must be recertified when there is any change in the Primary Engineering Control (PEC), or the compounding environment. For purposes of this subsection, a change includes when the PEC is moved, repaired or replaced, when the facility is modified in a manner that affects airflow or traffic patterns, or when improper aseptic techniques are observed. Further, SOPs must address the conditions under which recertification must also be completed when relocating a PEC.

(h) Activities and tasks carried out within the SRPA and classified areas shall be limited to only those necessary for processing a radiopharmaceutical.

(i) Food, drinks, and materials exposed in patient care and treatment areas must not enter SRPA or classified areas.

(j) A dynamic airflow smoke pattern test must be performed initially and at least every 6 months for all classified spaces and equipment. All dynamic airflow smoke pattern tests shall be immediately retrievable during inspection. A copy of the test shall be provided to the Board's inspector if requested in accordance with the timeframes set forth in Section 4105 of the Business and Professions Code.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code.

Reference: Sections 4005, 4081, 4105 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.6. MICROBIOLOGICAL AIR AND SURFACE MONITORING

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) SOPs shall specify steps to be taken for processing radiopharmaceuticals when the microbiological air and surface monitoring action levels are exceeded, including the investigative and corrective actions, allowable activities, and resampling procedures.

(b) At a minimum every 6 months, air and surface sampling results shall be identified to at least the genus level, regardless of the CFU count to trend for growth of microorganisms. Professional judgement and SOPs shall be used to determine the appropriate action necessary to remedy identified trends. Investigation must be consistent with the deviation and must include evaluation of trends.

(c) Environmental sampling shall be done in compliance with the most recent edition of the Controlled Environment Testing Association (CETA)'s Certification Application Guide USP <797> Viable Environmental Sampling & Gowning Evaluation (CAG-009, Revised October 2022), which is hereby incorporated by reference.

(d) The designated person shall review the sampling results and identify data trends at least every time sample results are received. The designated person shall evaluate trends to determine if corrective action is needed. The results of the review shall be documented in the facility's SOPs and readily retrievable during inspection in accordance with the requirements in section 1738.9.

(e) Incubators must be calibrated and operated in accordance with the manufacturer's specifications and temperatures must be monitored during incubation, either manually or by a continuous recording device, and the results must be reviewed and documented as described in the facility's SOPs.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code.
Reference: Sections 4005, 4081, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.7. CLEANING AND DISINFECTING

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) Cleaning, disinfection, and sporicidal agents shall be used in accordance with manufacturers' specifications and shall occur at the minimum frequencies listed in Table 5 of USP Chapter 825. Incubators must be cleaned at least monthly.

(b) Reusable cleaning supplies, not for use in the PEC, shall not be stored within 1 meter of the PEC.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code.
Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.8. ASSIGNING BUD

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) A radiopharmaceutical CSP's beyond-use date (BUD) shall not exceed the shortest BUD of any of its components.

(b) No radiopharmaceutical CSP shall be administered after the labeled BUD. A dose shall not be sent for a scheduled administration that would occur after the labeled BUD.

(c) Extension of a conventionally manufactured kit with a suggested use-by time shall not exceed the BUDs in Table 7 of USP Chapter 825, for the sterility of the preparation or product.

Prior to the extension of a suggested use-by time for a conventionally manufactured kit, the SOPs must document at a minimum the following:

(1) Factors which necessitate its extension, which shall include a full assessment of patient needs for the extension.

(2) Evidence which supports that the extension maintains the appropriate quality and purity (radiochemical purity and radionuclidic purity) as specified in individual monographs, and other applicable parameters as clinically appropriate.

For the purposes of this section, the facility shall have SOPs that cover and are specific to each facility's location and kit.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code.
Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.9. DOCUMENTATION

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) A record of a preparation must include a compounding record compliant with section 9.2 of USP Chapter 825.

(b) Records of preparation with minor deviations or compounding shall be a single document. The document shall satisfy the requirements of USP Chapter 825, as well as the following:

(1) The assigned internal identification number shall be unique for each preparation.

(2) The manufacturer, lot number, and expiration date shall be recorded for each component for CSPs. Documenting solely the National Drug Code (NDC) does not meet this requirement.

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

(4) The identity of each person performing the compounding and pharmacist verifying the final drug preparation

(5) When applicable, endotoxin level calculations and readings.

(c) Records required by USP Chapter 825 or this Article, shall be maintained in a readily retrievable form, for at least three years from the date the record was created or relied upon. 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.

(d) Records created shall be created and maintained in a manner to provide an audit trail for revisions and updates of each record document. Prior versions of each record must be maintained in a readily retrievable format and include the changes to the document, identification of individual who made the change, and the date of each change.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code.
Reference: Sections 4005, 4081, 4105, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.10. PREPARATION

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) Processing nonsterile radiopharmaceutical shall:

(1) Follow manufacturer preparation instructions, unless minor deviations are made pursuant to subsection (c).

(2) Only use an area which is suitably cleaned and is uncluttered.

(3) Have documented processes in its SOPs for activities (e.g., cleaning) between the preparation cycles of different nonsterile products.

(b) Processing sterile radiopharmaceutical (including intravascular devices) shall:

- (1) Follow manufacturer preparation instructions, unless minor deviations are made pursuant to subsection (c).
- (2) Use at least the minimum environmental standards from section 7 of USP Chapter 825.

(c) When preparing radiopharmaceuticals with minor deviations ("preparation with minor deviations" as defined in the USP Chapter 825) an SOP shall at least define the circumstances which necessitated the deviation and all quality control testing requirements and limits. Such circumstances shall, at a minimum, include patient need or facts that support the deviation that maintains the appropriate quality and purity (radiochemical purity and radionuclidic purity) as specified in individual monographs, and other applicable parameters as clinically appropriate in the professional judgment of the pharmacist.

For the purposes of this section, the facility shall have SOPs that cover and are specific to each location and manufacturer. Preparations with minor deviations shall maintain the same ingredients but may differ in their proportions. A deviation from the ingredients or proportions thereof exceeds the provisions allowed under a minor deviation and is not allowed under this Article.

(d) Equipment and supplies initially used for processing of blood components (included Red Blood Cells) shall be solely dedicated for processing of blood components. Equipment and supplies shall be thoroughly cleaned and disinfected, in accordance with section 1738.7, prior to initiation of the next patient's prescription.

(e) When processing blood components all garb must be removed and replaced for each patient.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code.
Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.11. COMPOUNDING

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) All compounding of radiopharmaceuticals shall comply with all radioactive materials licensing requirements for appropriate radiation safety considerations issued by the California Department of Public Health pursuant to section 30190 of Title 17 of the California Code of Regulations, another state licensing agency that issues specific radioactive materials licenses, or the United States Nuclear

Regulatory Commission pursuant to pursuant to section 32.72 of title 10 of the Code of Federal Regulations, and utilize applicable environmental controls.

b) All API and excipient components used to compound a CSP shall be manufactured by an FDA-registered facility, be accompanied by a Certificate of Analysis (COA) and suitable for use in sterile pharmaceuticals. A COA which includes the compendial name, the grade of the material, and the applicable compendial designations on the COA must be received and evaluated prior to use, unless components are commercially available drug products. API and excipient components provided without this data shall not be used in a CSP

(1) When the COA is received from a supplier, it must provide the name and address of the manufacturer.

(c) Except for sterile radiopharmaceuticals made for inhalation or ophthalmic administration, prior to releasing a sterile radiopharmaceutical made from one or more nonsterile component(s) results of bacterial endotoxin testing shall be reviewed and recorded. Results shall be documented in the compounding record specified in Section 9.2 of the USP Chapter 825.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code.
Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.12. DISPENSING

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) All dispensed radiopharmaceutical doses shall be labeled with the information required by Business and Professions Code section 4076 and section 1707.5. Outer shielding labels shall contain the name and contact information of the dispensing pharmacy.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code.
Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.13. REPACKAGING

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) The inner container of a repackaged radiopharmaceutical shall be labeled with the following:

- (1) Standard radiation symbol
- (2) The words "Caution—Radioactive Material"
- (3) The radionuclide and chemical form (generic name)
- (4) Radioactivity with units at time of calibration and the calibration time

(b) The outer shielding of a repackaged radiopharmaceutical shall be labeled with the following:

- (1) Standard radiation symbol
- (2) The words "Caution—Radioactive Material"
- (3) The radionuclide and chemical form (generic name)
- (4) Radioactivity with units at time of calibration and the calibration time
- (5) Volume, or number of units (e.g., capsules), as applicable
- (6) Product expiration or BUD (consistent with Table 7 of USP Chapter 825), as applicable
- (7) Special storage and handling instructions

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code.
Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.14. QUALITY ASSURANCE AND QUALITY CONTROL

The requirements of this section apply to the processing of radiopharmaceuticals in addition to the standards established in USP Chapter 825.

(a) The quality assurance program shall comply with section 1711 and the standards contained in USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. In addition, the program shall include the following:

- (1) A written procedure for scheduled action, such as a recall, in the event any radiopharmaceutical processing is discovered to be outside the expected standards for integrity, quality, and purity.
- (2) A written procedure for responding to out-of-range temperature variations within the medication storage areas where a furnished drug may be returned for furnishing to another patient.

(b) The Board shall be notified in writing within 72 hours of a complaint. Recalls and adverse reporting must be completed in compliance with relevant provisions of law.

(c) In addition to subsection (b), all complaints related to a potential quality problem with a radiopharmaceutical and all adverse events shall be reviewed by the pharmacist-in-charge within 72 hours of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs.

(d) The SOPs shall specify the steps to be taken if a classified area(s) fails to meet the specified ISO classification including the investigative and corrective actions, allowable activities, and retesting procedures.

(e) The SOPs shall be reviewed on an annual basis by the pharmacist-in-charge. Such review shall be documented by the pharmacist-in-charge consistent with the SOPs. The SOPs shall be updated to reflect changes to compounding processes, facility changes or other changes that impact the CSP. Such SOP changes shall be disseminated to the affected staff prior to implementation.

(f) Failure to follow written SOPs shall constitute a basis for enforcement action.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code.

Reference: Sections 125.9, 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.