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

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

Compounding Committee Report
September 5, 2019

Maria Serpa, Licensee Member, Chair
Allen Schaad, Licensee Member, Vice Chair
Greg Lippe, Public Member

1. Call to Order and Establishment of Quorum

2. Public Comment for Items Not on the Agenda, Matters for Future Meetings*
   **Note: The committee may not discuss or take action on any matter raised during the public comment section that is not included on this agenda, except to decide to place the matter on the agenda of a future meeting. Government Code Sections 11125 and 11125.7(a)*

3. Discussion and Consideration of Proposed Amendments to Regulations Related to Pharmaceutical Compounding of Sterile Preparation

   Attachment 1

   Background
   During its March 13, 2019, meeting, members received a presentation on the proposed revisions to USP General Chapter 797, Pharmaceutical Compounding – Sterile Preparations. As part of that presentation, members were advised of USP's intended publication date of June 1, 2019, for the final chapter. Further, members were advised that December 1, 2019, is the intended official date for the revised chapter.

   USP has since released its final chapter, which is available for download from USP at www.USP.org.

   During this meeting
   During this meeting, members will have the opportunity to review proposed regulations necessary for patient safety. The development of the regulation is predicated on the newly revised USP 797 and other relevant state and federal law.

   The committee will have the opportunity to discuss the proposal and, if appropriate, make recommendations for the board's consideration during its November 2019 meeting. As indicated on the agenda, if the committee is unable to complete its review at this meeting, the committee will convene a subsequent meeting to continue its review.

   Attachment 1 includes two documents:

1. Proposed regulation language to rename Article 7 Sterile Compounding and Repeal Sections 1751-1751.10 and replace with Article 7 Sterile Compounding in Pharmacies including the addition of Sections 1751-1751.10
2. Proposed regulation language that also includes a brief description of the necessity for the regulation provisions.

4. Approval of the June 4, 2019, Meeting Minutes

Attachment 2

Provided in **Attachment 2** for the committee's review and approval are the draft minutes from the June committee meeting.

5. Approval of the July 11, 2019, Meeting Minutes

Attachment 3

Provided in **Attachment 3** for the committee's review and approval are the draft minutes from the July committee meeting.

6. Future Committee Meeting Dates

- September 24, 2019
- October 16, 2019

7. Adjournment

Attachment 1

Proposal to Rename Article 7 Sterile Compounding and Repeal Sections 1751-1751.10 and Replace as Follows:

Article 7 Sterile Compounding in Pharmacies

1751. Sterile Compounding in Licensed Pharmacies.

This article applies to sterile compounding performed in a pharmacy. A pharmacy performing sterile compounding shall comply with the standards established by United States Pharmacopeia (USP) General Chapter 797 (Chapter 797), titled *Pharmaceutical Compounding – Sterile Preparations*, unless additional or different standards are established by this article.

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

(b) Compounded sterile preparation (CSP) for immediate administration shall only be done in those limited situations where there is a need for immediate administration of a CSP and where failure to administer could result in loss of life or intense suffering. Any such CSP shall be labeled "for immediate use only" and with a beyond use date/time of 4 hours or less. The pharmacy shall maintain records of such CSPs shall at least include CSP made, compounded time, and patient name and unique identifier.

(c) Reconstitution in accordance with directions that have not been approved by the FDA, is considered compounding and this article applies.

(d) No CSPs shall be compounded prior to receipt by a pharmacy of a valid patient specific prescription document. Where approval is given orally, that approval shall be noted on the prescription document prior to compounding.

(1) Notwithstanding this subdivision, a pharmacy may prepare and store a limited quantity of a CSP in advance of receipt of a patient specific prescription document.

(2) Notwithstanding this subdivision, a pharmacy may prepare and provide a limited quantity of CSPs to veterinarians for animal patients based on a contract between the pharmacy and veterinarian for office use administration only. The pharmacy and veterinarian are jointly responsible for compliance with this section. The contract shall require the veterinarian to provide the pharmacy with the records documenting the dose administered to each patient or destruction record of CSPs. The pharmacy shall be prohibited from providing additional CSPs to the veterinarian until the pharmacy has received and evaluate the records for compliance with this provision.

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

(1) Is classified by the United States Food and Drug Administration (FDA) as demonstrably difficult to compound;

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

(3) Is a copy or essentially a copy of one or more commercially available drug products,

unless

(A) 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 compounding and at the time of dispense, or (B), the compounding of that CSP is justified by a specific, documented medical need made known to the pharmacist prior to compounding.

The pharmacy shall retain a copy of the documentation of the shortage or the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.

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

(5) Is made with a bulk drugs substance, as defined in Section 503A(b)(1)(A)(i), when there is an FDA approved sterile drug product that is available and appropriate for the intended CSP.

(6) cannot be sterilized within the pharmacy.

(f) Prior to allowing any CSP to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment, as required by Section 1715.

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

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

(i) Storing, weighing, measuring, compounding, and/or performing other manipulation of an active pharmaceutical ingredient (API) or added substance deemed hazardous by Occupational Safety and Health (NIOSH) shall be done in compliance with USP Chapter 800, Hazardous Drugs-Handling in Healthcare Settings and any board regulations.

(j) Storing, weighing, measuring, compounding, and/or performing other manipulation of an antineoplastic under Occupational Safety and Health (NIOSH) shall be done in compliance with USP Chapter 800, Hazardous Drugs- Handling in Healthcare Settings and any board regulations.

1751.1. Compounding Definitions.

The definitions in in this section 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) "Compounded sterile preparation (CSP)" means a preparation intended to be sterile which is created by combining, admixing, diluting, pooling, reconstituting other than as provided in the FDA approved manufacturer package insert, repackaging, or otherwise altering a drug product

or bulk drug substance.
(c) “Copy or essentially a copy” of a commercially available drug product means 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.

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

(e) “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.

(f) “In process material or in process preparation or stock solution” means any material fabricated, compounded, blended, or derived by chemical reaction that is produced for, and used in, the preparation of the CSP. For purposes of this article, “in process material” shall refer to the all terms used in this subdivision.

(g) “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.

(h) “Potency” means an active ingredient’s strength in a preparation which is within a specified range as determined in the facility’s SOP.

(i) “Preparation” means a drug or nutrient compounded in a pharmacy; which may or may not be sterile.

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

(k) “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 formulation document.

(l) “Strength” means amount of active ingredient per unit of a compounded drug preparation.

1751.2 PERSONNEL TRAINING AND, EVALUATION

The requirements of this section apply in addition to the requirements in USP Chapter 797.
(a) Training, evaluation, and requalification procedures for personal preparing, verifying, and/or handling a CSP shall 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) The pharmacist responsible for or directly supervising, aseptic techniques or practices, shall demonstrate proficiency in the skills necessary to ensure the integrity, potency, quality, and labeled strength of a CSP.

(c) Aseptic manipulation evaluation and requalification documentation shall include the PEC's unique identifier used during the evaluation. Aseptic manipulation evaluation and requalification shall be performed using same personnel, procedures, type of equipment, and materials used in compounding drug preparations.

(d) Requalification in hand hygiene, garbing and aseptic manipulation shall occur each time the quality assurance program yields a result that may indicate microbial contamination of CSPs. Requalification procedures shall be defined in the pharmacy's SOPs.

(e) Compounding personnel who fail any aspect of training or demonstrated competency, either initially or during requalification, shall not be involved in compounding a CSP until after successfully passing reevaluations in the deficient area(s).

(f) The pharmacy must document that any person assigned to provide training has obtained training and demonstrated competency in any subject in which the person will provide training or observe and measure competency.

1751.3 PERSONAL HYGIENE AND GARBING

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

(a) Compounding personnel experiencing any of the following: rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection, or other conditions which could contaminate a CSP or the environment shall not be allowed to enter the designated compounding area(s).

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

(c) Personnel protective equipment shall be donned and removed in an ante-area or immediately outside the segregated compounding area (SCA). Donning and doffing garb shall not occur in the ante-room or the SCA at the same time unless the pharmacy's SOP define specific processes that must be followed to prevent contamination.

(d) Eye glasses shall be cleaned as part of hand hygiene and garbing, the standards for which the pharmacy shall specify in its standard operating procedures (SOPs).

(e) RABS and pharmaceutical isolator sleeves and gloves shall be changed according to both the manufacturer's recommendations and the facility's SOP.

(f) Before any hand hygiene or garbing accommodation is granted pursuant to USP 797 Section 3.1, the designated person shall determine that the quality of the environment and any CSPs is not affected. Documentation of the determination shall be done prior to the accommodation being allowed.

1751.4 FACILITIES AND ENGINEERING CONTROLS

The requirements of this section apply 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) Reusable equipment and utensils which have not be sterilized and depyrogenated, and that will come in direct contact with compounding components must be rinsed with sterile, pyrogen free water.

(c) If a segregated compounding area (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.

(d) Any room, regardless of its ISO classification, with a PEC used for sterile compounding shall only be used for Category 1 preparation unless it is entered via an ante-room.

(e) (1) Designated compounding area(s) shall typically be maintained at a temperature of 20° Celsius or cooler and shall 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.

(f) Where a pass-through is installed in a secondary engineering control, SOPs must address how both doors will not be opened at the same time. Effective January 1, 2022, all pass-throughs must be interlocking. A pass-through used to access a negative pressure ISO 7 or better space from a non-classified space, must be a HEPA-filtered purge pass-through.

(g) When a RABS is used, an ingress and egress test shall be performed at each certification. If the main chamber of the RABS is opened, the manufacturer's purge time must be met before cleaning takes place. SOPs shall be developed and implemented to ensure compliance.

(h) No CSP shall be compounded if compounding personnel know, or reasonably should have known, that the compounding environment fails to meet criteria specified in USP Chapter 797, this article, and the pharmacy's written SOPs.

1751.5 CERTIFICATION AND RECERTIFICATION

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

(a)(1) Testing and certification of all classified areas shall be completed by a qualified technician who is familiar with certification methods and procedures outlined within the Controlled Environment Testing Association (CETA)'s Certification Guide for Sterile Compounding Facilities. Testing shall be performed in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised 2015), which is hereby incorporated by reference. Certification shall demonstrate compliance with all standards in USP 797 and established by this article.

(2) CAG standard(s) used to perform certify testing in all classified areas to shall be recorded on certification report.

(b) 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. SOPs shall be followed.

(c) PECs must be recertified whenever the following occurs: 1. Repairs, 2. Alterations to the PEC that could affect airflow or air quality. Further, SOPs must address the conditions under which recertification must also be completed when relocating a PEC.

1751.6 MICROBIOLOGICAL AIR AND SURFACE MONITORING

The requirements of this section apply 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) During biannual recertification, all microorganism recovered (growth) shall be identified at least to the genus species, regardless of the cfu count. When identification of an organism of concern, action shall be taken. Organisms of concern shall be identified by the PIC or designated person and shall be documented in a SOP. Some possible organisms of concern would be gram-negative rods, coagulase positive staphylococcus, molds and yeasts.

(c)Whenever growth is identified as specified in (a) or (b), required action shall include at a minimum, an investigation of (1) cleaning and compounding operations, (2) sampling, (3) personnel training, (4) incubator functionality, (5) facility management, and (6) resampling.

Consultation with a competent microbiologist, infection control professional, or industrial hygienist is required when resampling results in growth of an organism of concern or when action levels are exceeded, regardless of count. All actions taken shall be documented.

(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.

(e) Environmental sampling shall be done in compliance with CETA Certification Application Guide USP <797> Viable Environmental Sampling & Gowning Evaluation (CAG-009, current version-20XX-XX, Revised XX), which is hereby incorporated by reference.

1751.7 CLEANING, DISINFECTING, AND APPLYING SPORICIDAL AGENTS IN COMPOUNDING AREAS

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

(a) Cleaning, disinfection, and sporicidal agents shall be used in accordance with manufacturers' specifications.

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

1751.8 INTRODUCING ITEMS INTO THE SEC AND PEC

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

(a) SOPs shall define the process and products to be used on any equipment and other items entering from an unclassified area into the clean side of the ante-room, entering a PEC, and entering the SCA. This 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.

1751.9 EQUIPMENT, SUPPLIES, AND COMPONENTS

The requirements of this section apply 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 be of suitable composition such that the surfaces which contact components are not reactive or sorptive.

(b) Incubators used by the pharmacy shall be cleaned, maintained, calibrated, and operated in accordance with manufacturers' specifications. For incubators without specific manufacturers' specifications, cleaning shall take place at least monthly and calibration shall take place at least every 12 months. SOPs shall specify the frequency and process 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.

(c) Any component used to compound a CSP shall be used and stored in accordance with all industry standards including the following:

(1) United States Pharmacopeia (USP) – National Formulary (NF),

(2) Food Drug and Cosmetic Act (FD&CA) and federal regulations adopted to implement that act,

(3) Food Drug Administration (FDA) requirements and considering issued Guidance Documents and Alerts, and

(4) Manufacturers' specifications and requirements.

(d) Any active pharmaceutical ingredient (API) or added substance used to compound a CSP shall be obtained from an FDA-registered facility and shall be accompanied by a valid certificate of analysis (COA). This COA shall be, at minimum, in English and shall at least meet the requirements of USP Chapter 1080, - - Bulk Pharmaceutical Excipient-Certificate of Analysis. All COAs shall be readily retrievable for at least 3 years from last use in CSP.

(e) No component shall be used to compound a CSP that meets only the European Pharmacopoeia standards, Japanese Pharmacopoeia standards, dietary supplement standards (such as USP-NF dietary monographs), food ingredient standards (such as Food-Chemical Codex (FCC)), food additive standards (such as General Standard for Food Additive (GSFA)), reagent standard (such as American Chemical Society (ASC)) or is of unspecified quality.

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

1751.10 STERILIZATION AND DEPYROGENATION

The requirements of this section apply 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.

(c) Sterilizing filters used must be labeled for pharmaceutical use and reflect a sterilizing grade.

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

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

(f) A pharmacy shall not compound a CSP from nonsterile components when the pharmacy cannot sterilize the CSP appropriately with steam sterilization, dry heat sterilization or sterilization by filtration.

1751.11 MASTER FORMULATION AND COMPOUNDING RECORDS

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

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

(1) Active pharmaceutical ingredient (API) or added substance(s) and their amounts, which shall include, at a minimum, salt form and purity grade, when available,
(2) Container–closure systems to be used, which shall include, container and closure types and volume(s).
(3) The source referenced to assign the 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.
(4) Instructions for storage and handling of the compounded drug preparation.

(b) Where a pharmacy does not routinely compound a particular drug preparation, the master formulation record for that preparation may be recorded on the prescription document itself. This record shall comply with USP Chapter 797 and this section.

(c) A compounding record 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 compounded drug preparation.
(3) The vendor (manufacturer/repackager), 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.
(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 and pharmacist verifying the final drug preparation
(6) When applicable, endotoxin level calculations and readings.

1735.12 RELEASE TESTING

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

(a) A pharmacist performing, or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, when label instructions for storage and handling are followed after the preparation is dispensed.

(b) Validation of an alternative method for sterility testing shall be done in compliance with USP Chapter 1223, Validation of Alternative Microbiological Methods showing it to be non-inferior to USP Chapter 71, Sterility Tests, and shall demonstrate the method to be suitable for each CSP formulation for which the alternate method is used.

(c) Except for CSPs made for inhalation or ophthalmic administration, prior to releasing a CSP made from one or more nonsterile component(s) the pharmacy shall review and document the results of bacterial endotoxin testing. Results shall be documented in the compounding record.

1751.13 LABELING

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

(a) A CSP label shall also include the following:
(1) For admixed CSP, the solution utilized; and
(2) Name and contact information of the compounding pharmacy and, if different, the dispensing pharmacy;
(3) Instructions for administration. For admixed CSP solutions, the rate of infusion, or range of rates in infusion, or the duration when the entire CSP is administered.

(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 by Business and Professions Code section 4076 and section 1707.5.

1751.14 ESTABLISHING BEYOND-USE DATES

The requirements of this section apply 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 API 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) 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 midnight at that date.

(c) Prior to the dispensing a CSP that requires sterility and pyrogen testing, the pharmacy shall receive test results and ensure that the results are within acceptable limits. The pharmacy shall retain the results as part of the compounding record.

(d) A CSP shall not be assigned a longer BUD based on an unvalidated alternative microbiological method.

1751.15. USE OF CONVENTIONALLY MANUFACTURED PRODUCTS AS COMPONENTS
The requirements of this section apply in addition to the requirements in USP Chapter 797.

If a single-dose container is entered or punctured outside of an ISO Class 5 area, the product must be discarded immediately.

1751.16. USE OF CSPS AS COMPONENTS

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

(a) Where an in process material is nonsterile, it shall be treated as a sterile product for purposes of this article.

1751.17 Standard Operating Procedures (SOPS)

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

(a) Standard operating procedures (SOPs) shall:
(1) Comply with USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding,
(2) In addition to the SOP SOPs listed in USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding, include:
(A) Methods by which the supervising pharmacist will the quality of compounded drug preparations.
(B) Procedures for handling, compounding and disposal of infectious materials. The written SOPs shall describe the pharmacy 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
(b) Any pharmacy engaged in compounding CSPs shall maintain and follow written SOPs for compounding.

(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. The SOPs shall be updated whenever changes are implemented. Such changes shall be disseminated to the affected staff prior to implementation.

1751.18 QUALITY ASSURANCE AND QUALITY CONTROL

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

(a) The quality assurance program shall comply with section 1711 and USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. In addition, the program shall include:

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

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

(3) A written procedure addressing each of the USP Chapter 1163's integrated components and standard operating procedures.

(4) Quality assurance program shall be compliant with section 1711.

(b) The pharmacy shall process recalls and adverse event reporting in compliance with Business and Professions Code section 4127.8.

(c) All complaints related to a potential quality problem with a compounded drug preparation and all adverse events shall be reviewed by the pharmacist-in-charge. Such review shall be documented and dated.

1751.19 CSP HANDLING, PACKAGING, STORAGE, AND TRANSPORT

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

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

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

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

1751.20 DOCUMENTATION

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

(a) Pharmacies shall maintain each record required by USP Chapter 797 or this article in the

pharmacy, in a readily retrievable form, for at least three years from the date the record was last used. 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 maintained in a manner to allow for all versions of the document to be viewed. When a change to a record must be made, the record's original text must be maintained, and the record must reflect each change, the person who made the change, and the date and time the change was made.

1751.21 COMPOUNDING ALLERGENIC EXTRACTS

The requirements of this section apply 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) All required documentation for a Category 1 or Category 2 CSPs are required for allergenic extract compounding. (i.e. Compounding records, labeling, cleaning, temperatures logs, patient specific prescriptions etc.)

Proposal to Rename Article 7 Sterile Compounding and Repeal Sections 1751-1751.10 and Replace as Follows:

Article 7 Sterile Compounding in Pharmacies

1751. Sterile Compounding in Licensed Pharmacies.

This article applies to sterile compounding performed in a pharmacy. A pharmacy performing sterile compounding shall comply with the standards established by United States Pharmacopeia (USP) General Chapter 797 (Chapter 797), titled *Pharmaceutical Compounding – Sterile Preparations*, unless additional or different standards are established by this article.

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

Necessity: Defines the locations for USP applicability to the board's regulated public.

(b) Compounded sterile preparation (CSP) for immediate administration shall only be done in those limited situations where there is a need for immediate administration of a CSP and where failure to administer could result in loss of life or intense suffering. Any such CSP shall be labeled "for immediate use only" and with a beyond use date/time of 4 hours or less. The pharmacy shall maintain records of such CSPs shall at least include CSP made, compounded time, and patient name and unique identifier.

Necessity: Providing guidance to the regulated public on the conditions under which immediate use compounding can be done.

(c) Reconstitution in accordance with directions that have not been approved by the FDA, is considered compounding and this article applies.

Necessity: This provides clarity as USP does not provide direction on what type of practice constitutes reconstitution of a preparation.

(d) No CSPs shall be compounded prior to receipt by a pharmacy of a valid patient specific prescription document. Where approval is given orally, that approval shall be noted on the prescription document prior to compounding.

(1) Notwithstanding this subdivision, a pharmacy may prepare and store a limited quantity of a CSP in advance of receipt of a patient specific prescription document.

(2) Notwithstanding this subdivision, a pharmacy may prepare and provide a limited quantity of CSPs to veterinarians for animal patients based on a contract between the pharmacy and veterinarian for office use administration only. The pharmacy and veterinarian are jointly responsible for compliance with this section. The contract shall require the veterinarian to provide the pharmacy with the records documenting the dose administered to each patient or destruction record of CSPs. The pharmacy shall be prohibited from providing additional CSPs to the veterinarian until the pharmacy has received and evaluate the records for compliance with this provision.

Necessity: Ensures consistency with Federal 503A provisions. The language includes a limited exception for veterinary medications.

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

(1) Is classified by the United States Food and Drug Administration (FDA) as demonstrably difficult to compound;

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

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

(A) 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 compounding and at the time of dispense, or

(B), the compounding of that CSP is justified by a specific, documented medical need made known to the pharmacist prior to compounding.

The pharmacy shall retain a copy of the documentation of the shortage or the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.

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

(5) Is made with a bulk drugs substance, as defined in Section 503A(b)(1)(A)(i), when there is an FDA approved sterile drug product that is available and appropriate for the intended CSP.

(6) cannot be sterilized within the pharmacy.

Necessity: To ensure consistency with general provisions of federal law including 503A provisions SEC 503a (353a (b)(3)(A), SEC 503a (353a (b)(1) (C), CFR 216.24 and SEC 503a (353a (b)(1) (D), as well ast o allow use of the specified ASHP list as necessary for patient care. Duplication with federal law provides for ease of use with the board's regulated public. Further proposed sections (e)(1) – (3) are consistent with current regulations. Further, (e)(4)-(5) ensures only appropriately graded bulk drug substance (based on intended use, patient, etc.). Would prohibit inappropriate graded bulk drug substance from use in compounded products, and (e)(6) ensures that preparations are compounded and sterilized by the pharmacy.

(f) Prior to allowing any CSP to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment, as required by Section 1715.

Necessity: This is consistent with current regulation and provides for consumer protection through self-education and assessment by licensee.

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

Necessity: This is consistent with current requirements.

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

Necessity: Provides clarity to the regulated public about the supplemental requirements established the HSC.

(i) Storing, weighing, measuring, compounding, and/or performing other manipulation of an active pharmaceutical ingredient (API) or added substance deemed hazardous by Occupational Safety and Health (NIOSH) shall be done in compliance with USP Chapter 800, Hazardous Drugs-Handling in Healthcare Settings and any board regulations.

Necessity: Provides clarity to the regulated public about the supplemental requirements that must be followed in USP 800.

(j) Storing, weighing, measuring, compounding, and/or performing other manipulation of an antineoplastic under Occupational Safety and Health (NIOSH) shall be done in compliance with USP Chapter 800, Hazardous Drugs- Handling in Healthcare Settings and any board regulations.

Necessity: Provides clarity to the regulated public about the supplemental requirements that must be followed in USP 800.

1751.1. Compounding Definitions.

The definitions in in this section 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.

Necessity: Provides guidance to the regulated public about the board's expectation. Further, the term is used throughout the Chapter but does not include a definition.

(b) "Compounded sterile preparation (CSP)" means a preparation intended to be sterile which is created by combining, admixing, diluting, pooling, reconstituting other than as provided in the FDA approved manufacturer package insert, repackaging, or otherwise altering a drug product or bulk drug substance.

Necessity: Provides clarity to the board's regulated public regarding reconstitution and where such action is included in the definition of CSP.

(c) "Copy or essentially a copy" of a commercially available drug product means 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.

Necessity: Ensures consistency with the provisions of 503A with the increase of the word "clinically' to eliminate abuse. Reference: SEC 503a (353a (b)(1) (D)(2)).

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

Necessity: Provides clarity to the board's regulated public about what a diluent is for purposes of compounding and its implications for FDA labeling. USP does not provide a definition.

(e) "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.

Necessity: Provides clarity to the board's regulated public as the term is broadly used throughout the Chapter but is not defined.

(f) "In process material or in process preparation or stock solution" means any material fabricated, compounded, blended, or derived by chemical reaction that is produced for, and used in, the preparation of the CSP. For purposes of this article, "in process material" shall refer to the all terms used in this subdivision.

Necessity: Provides clarity to the board's regulated public about what is considered an "in process material". Further the definition is consistent with 21 CFR 210.3(b)(9).

(g) "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.

Necessity: Term is broadly used throughout the Chapter but is not defined. Further, the definition is consistent with current legal definition.

(h) "Potency" means an active ingredient's strength in a preparation which is within a specified range as determined in the facility's SOP.

Necessity: Provides clarify to the board's regulated public and ensures consistency with other proposed regulations. Note: when developing the regulations for Nonsterile Compounding, members of the pubic requested inclusion of a definition.

(i) "Preparation" means a drug or nutrient compounded in a pharmacy; which may or may not be sterile.

Necessity: This provision is consistent with the board's current regulation. Further, the definition is necessary to ensure that the regulated public understands that a preparation refers to an item that is compounded versus a commercially available product. The term is broadly used throughout the Chapter but is not defined.

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

Necessity: The term is broadly used throughout the Chapter but is not defined.

(k) “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 formulation document.

Necessity: The term is broadly used throughout the Chapter but is not defined.

(l) “Strength” means amount of active ingredient per unit of a compounded drug preparation.

Necessity: The term is broadly used throughout the Chapter but is not defined.

1751.2 PERSONNEL TRAINING AND, EVALUATION

The requirements of this section apply in addition to the requirements in USP Chapter 797.
(a) Training, evaluation, and requalification procedures for personal preparing, verifying, and/or handling a CSP shall 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

Necessity: Comprehensive training is essential to ensure the safety of California consumers dispensed or administered a CSP.

(b) The pharmacist responsible for or directly supervising, aseptic techniques or practices, shall demonstrate proficiency in the skills necessary to ensure the integrity, potency, quality, and labeled strength of a CSP.

Necessity: Because USP requires a facility to designate one or more individuals, a designated person, this needs to be clarified to ensure that the requirement applies to a pharmacist, who under pharmacy law, must be supervising or performing the compounding.

(c) Aseptic manipulation evaluation and requalification documentation shall include the PEC’s unique identifier used during the evaluation. Aseptic manipulation evaluation and requalification shall be performed using same personnel, procedures, type of equipment, and materials used in compounding drug preparations.

Necessity: This is consistent with current regulation. Further, provides clarity to the board’s regulated public about its expectations.

(d) Requalification in hand hygiene, garbing and aseptic manipulation shall occur each time the quality assurance program yields a result that may indicate microbial contamination of CSPs. Requalification procedures shall be defined in the pharmacy's SOPs.

Necessity: This is consistent with current regulations. Further, the requirement provides essential consumer protection safeguards.

(e) Compounding personnel who fail any aspect of training or demonstrated competency, either initially or during requalification, shall not be involved in compounding a CSP until after successfully passing reevaluations in the deficient area(s).

Necessity: Allowing an individual to compound inappropriately will compromise consumer protection, as such immediate remediation is necessary.

(f) The pharmacy must document that any person assigned to provide training has obtained training and demonstrated competency in any subject in which the person will provide training or observe and measure competency.

Necessity: Provides clarity to the regulated public that any person who has proper training may provide training to others, as long as the person can demonstrate appropriate competency to do so. Also, provides clarity that other staff besides the PIC, if properly trained, may provide training or observational review.

1751.3 PERSONAL HYGIENE AND GARBING

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

(a) Compounding personnel experiencing any of the following: rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection, or other conditions which could contaminate a CSP or the environment shall not be allowed to enter the designated compounding area(s).

Necessity: To eliminate the potential contamination of CSPs, such protections are mandatory, not discretionary.

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

Necessity: Provides clarity to the regulated public that such items must be removed for patient care. Further, proper fit of garb should not be subjective.

(c) Personnel protective equipment shall be donned and removed in an ante-area or immediately outside the segregated compounding area (SCA). Donning and doffing garb shall not occur in the ante-room or the SCA at the same time unless the pharmacy's SOP define specific processes that must be followed to prevent contamination.

Necessity: Provides clarity to the board's regulated public as the Chapter does not explicitly specify where such activities must occur.

(d) Eye glasses shall be cleaned as part of hand hygiene and garbing, the standards for which the pharmacy shall specify in its standard operating procedures (SOPs).

Necessity: To prevent product contamination, some level of cleaning must be performed.

(e) RABS and pharmaceutical isolator sleeves and gloves shall be changed according to both the manufacturer's recommendations and the facility's SOP.

Necessity: To ensure that RABS and isolators are maintained appropriately to ensure safe CSPs and to prevent product contamination.

(f) Before any hand hygiene or garbing accommodation is granted pursuant to USP 797 Section 3.1, the designated person shall determine that the quality of the environment and any CSPs is not affected. Documentation of the determination shall be done prior to the accommodation being allowed.

Necessity: To provide accommodation and flexibility to staff after full assessment of the risk has been considered and determination has been made that any CSP preparation will not be compromised.

1751.4 FACILITIES AND ENGINEERING CONTROLS

The requirements of this section apply 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.

Necessity: USP is silent on the location of a sink. Restroom sinks are a significant source of contamination and as such are not an appropriate location for such function to occur. This is also consistent with current board regulation.

(b) Reusable equipment and utensils which have not be sterilized and depyrogenated, and that will come in direct contact with compounding components must be rinsed with sterile, pyrogen free water.

Necessity: To ensure no product contamination results from the use of poor quality (tap water) water being used to wash the equipment used in compounding.

(c) If a segregated compounding area (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.

Necessity: Provisions are current law. Provides clarity to the board's regulated public on its expectations regarding cleaning.

(d) Any room, regardless of its ISO classification, with a PEC used for sterile compounding shall only be used for Category 1 preparation unless it is entered via an ante-room.

Necessity: Provides clarity to the board's regulated public as the Chapter does not explicitly state the requirements.

(e) (1) Designated compounding area(s) shall typically be maintained at a temperature of 20° Celsius or cooler and shall 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.

Necessity: Provides clarity to the board's regulated public about the board's expectation regarding the comfort of compounding staff and the risk of contamination.

(f) Where a pass-through is installed in a secondary engineering control, SOPs must address how both doors will not be opened at the same time. Effective January 1, 2022, all pass-throughs must be interlocking. A pass-through used to access a negative pressure ISO 7 or better space from a non-classified space, must be a HEPA-filtered purge pass-through.

Necessity: Provides clarity to the board's regulated public and notification of a new standard. As drafted, the provision would become mandatory in January 2022. Note: the provision is consistent with the Chapter, however the Chapter does not mandate the use of interlocking doors.

(g) When a RABS is used, an ingress and egress test shall be performed at each certification. If the main chamber of the RABS is opened, the manufacturer's purge time must be met before cleaning takes place. SOPs shall be developed and implemented to ensure compliance.

Necessity: Provides clarity to the board's regulated public and ensure proper use of the device. Note: this is not adding a testing requirement, just ensuring that the regulated public is aware of the requirement.

(h) No CSP shall be compounded if compounding personnel know, or reasonably should have known, that the compounding environment fails to meet criteria specified in USP Chapter 797, this article, and the pharmacy's written SOPs.

Necessity: Requires the cessation of compounding in an environment found to be noncompliant

to prevent the risk of contamination.

1751.5 CERTIFICATION AND RECERTIFICATION

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

(a)(1) Testing and certification of all classified areas shall be completed by a qualified technician who is familiar with certification methods and procedures outlined within the Controlled Environment Testing Association (CETA)'s Certification Guide for Sterile Compounding Facilities. Testing shall be performed in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised 2015), which is hereby incorporated by reference. Certification shall demonstrate compliance with all standards in USP 797 and established by this article.

(2) CAG standard(s) used to perform certify testing in all classified areas to shall be recorded on certification report.

Necessity: This is consistent with current law and USP requirements however the board is limiting the applicability to a single recognized standard.

(b) 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. SOPs shall be followed.

Necessity: This is a consumer safety issue and is consistent with current law.

(c) PECs must be recertified whenever the following occurs: 1. Repairs, 2. Alterations to the PEC that could affect airflow or air quality. Further, SOPs must address the conditions under which recertification must also be completed when relocating a PEC.

Necessity: Provides clarity to the regulated public as the Chapter could be interpreted differently. This is also a consumer safety issue.

1751.6 MICROBIOLOGICAL AIR AND SURFACE MONITORING

The requirements of this section apply 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.

Necessity: The provision is consistent with currently law and provides clarity to the board's regulated public about its expectations regarding microbiological monitoring activities.

(b) During biannual recertification, all microorganism recovered (growth) shall be identified at least to the genus species, regardless of the cfu count. When identification of an organism of

concern, action shall be taken. Organisms of concern shall be identified by the PIC or designated person and shall be documented in a SOP. Some possible organisms of concern would be gram-negative rods, coagulase positive staphylococcus, molds and yeasts.

Necessity: The provision is consistent with current practice. Further, it provides clarity to the board's regulation public about its expectations regarding the activities that must be initiated when the cfu count is exceeded.

(c) Whenever growth is identified as specified in (a) or (b), required action shall include at a minimum, an investigation of (1) cleaning and compounding operations, (2) sampling, (3) personnel training, (4) incubator functionality, (5) facility management, and (6) resampling. Consultation with a competent microbiologist, infection control professional, or industrial hygienist is required when resampling results in growth of an organism of concern or when action levels are exceeded, regardless of count. All actions taken shall be documented.

Necessity: Provides clarity to the regulated public on all the steps that must be taken as the Chapter does not explicitly state the actions required when unacceptable microbiological growth is identified.

(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.

Necessity: Provides clarity to the board's regulated public as the Chapter does not explicitly state who is responsible what action need to occur.

(e) Environmental sampling shall be done in compliance with CETA Certification Application Guide USP <797> Viable Environmental Sampling & Gowning Evaluation (CAG-009, current version-20XX-XX, Revised XX), which is hereby incorporated by reference.

Necessity: Provides clarity to the board's regulated public regarding the standards that must be complied with when environmental sampling is performed.

1751.7 CLEANING, DISINFECTING, AND APPLYING SPORICIDAL AGENTS IN COMPOUNDING AREAS

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

(a) Cleaning, disinfection, and sporicidal agents shall be used in accordance with manufacturers' specifications.

Necessity: To ensure proper cleaning occurs and appropriate information documented to confirm compliance.

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

Necessity: To provide clarity to the board's regulation public about the board's expectations regarding storage of supplies to reduce inadvertent contamination.

1751.8 INTRODUCING ITEMS INTO THE SEC AND PEC

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

(a) SOPs shall define the process and products to be used on any equipment and other items entering from an unclassified area into the clean side of the ante-room, entering a PEC, and entering the SCA. This 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.

Necessity: To provide clarity to the board's regulation public about the board's expectations minimum practices for products brought into compounding area(s) as the Chapter does not explicitly state necessary requirements.

1751.9 EQUIPMENT, SUPPLIES, AND COMPONENTS

The requirements of this section apply 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 be of suitable composition such that the surfaces which contact components are not reactive or sorptive.

Necessity: Failure to use equipment according to manufacturer's specification or of suitable composition can impact the safety and efficacy of the preparation.

(b) Incubators used by the pharmacy shall be cleaned, maintained, calibrated, and operated in accordance with manufacturers' specifications. For incubators without specific manufacturers' specifications, cleaning shall take place at least monthly and calibration shall take place at least every 12 months. SOPs shall specify the frequency and process 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.

Necessity: To ensure proper cleaning, maintenance and calibration of incubators to validate personnel processes as well as SEC and PEC microbiological monitoring to ensure safe compounding.

(c) Any component used to compound a CSP shall be used and stored in accordance with all industry standards including the following:

(1) United States Pharmacopeia (USP) – National Formulary (NF),

(2) Food Drug and Cosmetic Act (FD&CA) and federal regulations adopted to implement that act,

(3) Food Drug Administration (FDA) requirements and considering issued Guidance Documents and Alerts, and

(4) Manufacturers' specifications and requirements.

Necessity: To ensure safe and appropriate component selection in CSPs to avoid patient harm.

(d) Any active pharmaceutical ingredient (API) or added substance used to compound a CSP shall be obtained from an FDA-registered facility and shall be accompanied by a valid certificate of analysis (COA). This COA shall be, at minimum, in English and shall at least meet the requirements of USP Chapter 1080, - - Bulk Pharmaceutical Excipient-Certificate of Analysis. All COAs shall be readily retrievable for at least 3 years from last use in CSP.

Necessity: The FD&C establishes that only APIs from a registered facility can be used. To ensure only proper added substances are used, the same threshold as required for APIs must be applied related to purchasing and COA requirements to avoid patient harm.

(e) No component shall be used to compound a CSP that meets only the European Pharmacopoeia standards, Japanese Pharmacopoeia standards, dietary supplement standards (such as USP-NF dietary monographs), food ingredient standards (such as Food-Chemical Codex (FCC)), food additive standards (such as General Standard for Food Additive (GSFA)), reagent standard (such as American Chemical Society (ASC)) or is of unspecified quality.

Necessity: To ensure only proper components are used to make a CSP to avoid patient harm.

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

Necessity: To provide clarity to the board's regulated public about the board's expectation to ensure compliance with the stated Chapter.

1751.10 STERILIZATION AND DEPYROGENATION

The requirements of this section apply 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.

Necessity: To provide clarity to the board's regulated public about the board's expectation

to ensure compliance with the stated Chapter.

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

Necessity: To provide clarity to the board's regulated public about the board's expectation to ensure compliance with the stated Chapter.

(c) Sterilizing filters used must be labeled for pharmaceutical use and reflect a sterilizing grade.

Necessity: To provide clarity to the board's regulated public about the board's expectation to ensure compliance with the appropriate use of such devices and the standard of practice.

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

Necessity: To provide clarity to the board's regulated public about the board's expectation to ensure compliance with the stated Chapter.

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

Necessity: To provide clarity to the board's regulated public about the board's expectation to ensure compliance with the stated Chapter.

(f) A pharmacy shall not compound a CSP from nonsterile components when the pharmacy cannot sterilize the CSP appropriately with steam sterilization, dry heat sterilization or sterilization by filtration.

Necessity: To provide clarity to the board's regulated public about the board's expectation to ensure ensures that preparations are compounded and appropriately sterilized by the pharmacy.

1751.11 MASTER FORMULATION AND COMPOUNDING RECORDS

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

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

(1) Active pharmaceutical ingredient (API) or added substance(s) and their amounts, which shall include, at a minimum, salt form and purity grade, when available,
(2) Container–closure systems to be used, which shall include, container and closure types and volume(s).

(3) The source referenced to assign the 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.
(4) Instructions for storage and handling of the compounded drug preparation.

Necessity: Provides clarification regarding the expectation for documentation to ensure complete records. Note: this does not expand upon USP requirements regarding master formulations but does require additional detail regarding the specific information that must be documented.

(b) Where a pharmacy does not routinely compound a particular drug preparation, the master formulation record for that preparation may be recorded on the prescription document itself. This record shall comply with USP Chapter 797 and this section.

Necessity: This will allow the current practice for such documentation to continue for those CSPs not routinely compounded.

(c) A compounding record 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 compounded drug preparation.
(3) The vendor (manufacturer/repackager), 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.
(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 and pharmacist verifying the final drug preparation
(6) When applicable, endotoxin level calculations and readings.

Necessity: Provides clarification as what is expected in the documentation to ensure complete records and establishes a requirement to document the staff involved in the compounding on the log, including the pharmacist performing verification of the final drug preparation. Such documentation ensures a complete record and allows for identification and remediation of staff if necessary.

1735.12 RELEASE TESTING

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

(a) A pharmacist performing, or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, when label instructions for storage and handling are followed after the preparation is dispensed.

Necessity: This is current law. USP does not establish the responsibility of the pharmacist involvement in compounding as the USP Chapter applies to all settings where compounding occurs. Clarification is necessary to ensure the board's regulated public has a clear understanding of his or her responsibility.

(b) Validation of an alternative method for sterility testing shall be done in compliance with USP Chapter 1223, Validation of Alternative Microbiological Methods showing it to be non-inferior to USP Chapter 71, Sterility Tests, and shall demonstrate the method to be suitable for each CSP formulation for which the alternate method is used.

Necessity: To provide clarity to the board's regulated public as the Chapter does not explicitly state the process to be used to validate an alternative microbiological method to be determined appropriate.

(c) Except for CSPs made for inhalation or ophthalmic administration, prior to releasing a CSP made from one or more nonsterile component(s) the pharmacy shall review and document the results of bacterial endotoxin testing. Results shall be documented in the compounding record.

Necessity: To provide clarity to the board's regulated public about the board's expectations regarding the use of non-sterile components and the resulting endotoxin testing that must occur when using such components.

1751.13 LABELING

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

(a) A CSP label shall also include the following:
(1) For admixed CSP, the solution utilized; and
(2) Name and contact information of the compounding pharmacy and, if different, the dispensing pharmacy;
(3) Instructions for administration. For admixed CSP solutions, the rate of infusion, or range of rates in infusion, or the duration when the entire CSP is administered.

Necessity: It is imperative that any CSP leaving a facility shall be properly labeled for patient safety and to avoid patient harm. USP provisions make these items recommendations only. Patients must have a clear understanding of how to take their medications as well as how to contact the compounding pharmacy.

(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 by Business and Professions Code section 4076 and section 1707.5.

Necessity: This is current law and requires patient specific labeling on a compounded product.

1751.14 ESTABLISHING BEYOND-USE DATES

The requirements of this section apply 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 API 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) shortest remaining expiration date or BUD of any of the starting components.

Necessity: To avoid patient harm the above parameters shall be used to assign the BUD. Under USP section 14, the above items may be optional in establishment of a BUD. To ensure the integrity, potency, quality and labeled strength of a preparation the above parameters shall be used to limit the BUD.

(b) A CSP labeled with a BUD with only a date shall expire at midnight at that date.

Necessity: This is current law and requires patient specific labeling on a compounded product.

(c) Prior to the dispensing a CSP that requires sterility and pyrogen testing, the pharmacy shall receive test results and ensure that the results are within acceptable limits. The pharmacy shall retain the results as part of the compounding record.

Necessity: To provide clarity to the board's regulated public regarding the board's expectations to ensure sterility and pyrogen testing are not only performed, but results evaluated prior to releasing the CSP. This is a patient safety issue.

(d) A CSP shall not be assigned a longer BUD based on an unvalidated alternative microbiological method.

Necessity: To provide clarity to the board's regulated public as the Chapter does not explicitly state the requirement.

1751.15. USE OF CONVENTIONALLY MANUFACTURED PRODUCTS AS COMPONENTS
The requirements of this section apply in addition to the requirements in USP Chapter 797.

If a single-dose container is entered or punctured outside of an ISO Class 5 area, the product must be discarded immediately.

Necessity: To provide clarity to the board's regulated public as the Chapter does not explicitly state the process that must be followed if the container is punctured outside of the specified classified area.

1751.16. USE OF CSPS AS COMPONENTS

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

(a) Where an in process material is nonsterile, it shall be treated as a sterile product for purposes of this article.

Necessity: To provide clarity to the board's regulated public as the Chapter does not explicitly state that in process materials must be treated as.

1751.17 Standard Operating Procedures (SOPS)

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

(a) Standard operating procedures (SOPs) shall:

(1) Comply with USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding,

(2) In addition to the SOP SOPs listed in USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding, include:

(A) Methods by which the supervising pharmacist will the quality of compounded drug preparations.

(B) Procedures for handling, compounding and disposal of infectious materials. The written SOPs shall describe the pharmacy 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.

Necessity: Ensures compliance with relevant USP Chapters and provides clarity to the board's regulated public on the board's expectation.

(b) Any pharmacy engaged in compounding CSPs shall maintain and follow written SOPs for compounding.

Necessity: The above language is in current law in the under CCR 1735.3(a) and 1735.5(a) and provides clarity to the regulated public on the board's expectations.

(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. The SOPs shall be updated whenever changes are implemented. Such changes shall be disseminated to the affected staff prior to implementation.

Necessity: The above language is in current law and clarifies the need to document any changes in the policy prior to implementation.

1751.18 QUALITY ASSURANCE AND QUALITY CONTROL

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

(a) The quality assurance program shall comply with section 1711 and USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. In addition, the program shall include:

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

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

(3) A written procedure addressing each of the USP Chapter 1163's integrated components and standard operating procedures.

(4) Quality assurance program shall be compliant with section 1711.

Necessity: A robust QA program is essential for consumer protection. The proposed language is consistent with current legal requirements in board regulation. USP established separate sections for Quality Assurance and Quality Control (Section 18) and Complaint Handling and Adverse Event Reporting (Section 18.2.) Further, a comprehensive QA program must include the process to follow in the event of a recall and procedures to follow in the event of a temperature excursion. This section also provides cross reference to relevant USP chapters to assist with full compliance with USP and to ensure consistency within the practice.

(b) The pharmacy shall process recalls and adverse event reporting in compliance with Business and Professions Code section 4127.8.

Necessity: Establishes a cross-reference to the underlying statute regarding recall provisions for compounded drug products.

(c) All complaints related to a potential quality problem with a compounded drug preparation and all adverse events shall be reviewed by the pharmacist-in-charge. Such review shall be documented and dated.

Necessity: As USP requirements apply to all settings where compounding can occur, clarification on the board's expectation regarding the responsibility of the PIC is necessary to ensure a common understanding of the applicability of the requirement for board licensees.

1751.19 CSP HANDLING, PACKAGING, STORAGE, AND TRANSPORT

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

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

Necessity: A process and procedure is necessary to ensure the product arrives with the same integrity, potency, quality and labeled strength as labeled. USP provides general requirements but lacks sufficient specificity on the minimum requirements.

(b) Packaging materials shall protect CSPs from damage, leakage, contamination, degradation, and adsorption while preventing inadvertent exposure to transportation personnel.
Necessity: USP provides this as a recommendation only, however to ensure proper packaging of a CSP to ensure patient safety it must be a requirement.

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

Necessity: This provision is consistent with current board regulation. Further, because USP is applicable in all settings where compounding can occur, clarification to board licensees on the board's requirements and board jurisdiction is necessary.

1751.20 DOCUMENTATION

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

(a) Pharmacies shall maintain each record required by USP Chapter 797 or this article in the pharmacy, in a readily retrievable form, for at least three years from the date the record was last used. 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.

Necessity: The above language is in current law (CCR 1735.3(b)) and clarifies the board's expectation for compliance.

(b) Records created shall be maintained in a manner to allow for all versions of the document to be viewed. When a change to a record must be made, the record's original text must be maintained, and the record must reflect each change, the person who made the change, and the date and time the change was made.

Necessity: Records should not editable to ensure proper tracking and compliance. This is needed to ensure the original document is correct and appropriate audit of changes is maintained.

1751.21 COMPOUNDING ALLERGENIC EXTRACTS

The requirements of this section apply 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.

Necessity: To provide clarity to the board's regulated public on the board's expectations regarding the use of an allergenic extract in compounding to avoid cross-contamination.

(b) All required documentation for a Category 1 or Category 2 CSPs are required for allergenic extract compounding. (i.e. Compounding records, labeling, cleaning, temperatures logs, patient specific prescriptions etc.)

Necessity: To provide clarity to the board's regulated public on the board's expectations of the documentation when compounding of an allergenic extract.

Attachment 2

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 515-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

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

DRAFT

COMPOUNDING COMMITTEE MEETING MINUTES

DATE:	June 4, 2019
LOCATION:	Department of Consumer Affairs First Floor Hearing Room 1625 N. Market Blvd. Sacramento, CA 95834
COMMITTEE MEMBERS PRESENT:	Maria Serpa, Licensee Member, Chairperson Victor Law, Licensee Member Allen Schaad, Licensee Member
COMMITTEE MEMBERS NOT PRESENT:	Shirley Kim, Public Member Stan Weisser, Licensee Member, Vice Chairperson
STAFF MEMBERS PRESENT:	Anne Sodergren, Interim Executive Officer Julia Ansel, Chief of Enforcement Christine Acosta, Supervising Inspector Debbie Damoth, Administration Manager Laura Freedman, DCA Staff Counsel Kelsey Pruden, DCA Staff Counsel

1. **Call to Order and Establishment of Quorum and General Announcements**

   Chairperson Serpa called the meeting to order at 10:04 am. Board members present at the meeting were: Allen Schaad, Maria Serpa, and Victor Law. A quorum was established.

2. **Public Comment on Items not on the Agenda/Agenda Items for Future Meetings**

   There were no comments from the committee or the public.

3. **Presentation on the Proposed USP Chapter 825 – Radiopharmaceutical – Preparation, Compounding, Dispensing, and Repackaging**

   The committee heard a presentation on the current proposed revisions to USP General Chapter 825 regarding radio pharmaceutical preparation, compounding, dispensing, and repackaging by Paul B. Mahan, RPh., BCNP, Senior Regulatory Affairs Specialist with PETNET Solutions/Siemens Corporation. A copy of the presentation is attached to the minutes.

Mr. Mahan provided the committee that he is a member of the Regulatory Affairs department at PETNET Solutions/Siemens Corporation and a member of the USP <825> Expert Panel. Mr. Mahan stated he is not representing the USP Organization during the presentation.

- USP Chapter <825> - Mr. Mahan provided an overview of the history of USP <825> as well as the official effective date of official effective date of Dec. 1, 2019. He explained USP <825> is not enforceable at the state level unless all USP standards have been incorporated by reference into regulations. USP Chapters under 1000 are enforceable by the 1938 Food, Drug and Cosmetic Act. USP Chapters over 1000 are informational Chapters.
- Representation within <825> - Mr. Mahan explained the representation of the committee as a diverse group including engagements with FDA agents and USP <797> Committee.
- Types of Nuclear Pharmacies – Mr. Mahan explained the two types of nuclear pharmacies as non-PET or SPET (single-photon emission computed tomography) and PET (positron emission tomography). In SPET, all activities conducted are included in the practice of pharmacy (e.g., diagnostic imaging, therapeutic and blood component agents). In PET, most of the activities conducted as an FDA-registered manufacturer where multi-dose vials of radiopharmaceuticals are made. For PET, pharmacy processes are limited to dispensing and repackaging after the product release.
- Table of Contents and Glossary – Mr. Mahan provided the USP <825> table of contents and industry terms.
- Introduction – Mr. Mahan informed the committee that USP <825> intends to provide uniform minimum standards for the preparation, compounding, dispensing, and repackaging of sterile and nonsterile radiopharmaceuticals for humans and animals that occur as part of state-licensed activities (e.g., the practice of pharmacy and the practice of medicine). He stated the standards apply to all radiopharmaceutical processing activities. Mr. Mahan provided for the activities the chapter does not apply.
- Nonsterile and Sterile Radiopharmaceuticals – Mr. Mahan explained the application of USP <825> to nonsterile and sterile radiopharmaceuticals.
- Radiation Safety Concerns – Mr. Mahan provided intent of worker safety and keeping exposure levels for workers involved as low as reasonably achievable (ALARA) practices as well as balancing aseptic handling practices with radiation safety concerns.
- Radiation Contamination Control – Mr. Mahan explained how USP <825> addresses radiation contamination control and the important concern for protection.
- Personnel Qualifications, Training and Hygiene – Mr. Mahan informed the committee personnel must be trained to work with radiopharmaceuticals according to policies and standard operating procedures.
- Aseptic Qualifications – Mr. Mahan reviewed for the committee gloved fingertip and thumb sampling and media-fill testing requirements.
- Re-Evaluation, Retraining and Requalification – Mr. Mahan provided the timing of re-evaluation and requalification. If personnel have not been working performing radiopharmaceutical processing in more than 6 months, the personnel must be requalified in all core competencies before resuming duties. Additionally, personnel who perform sterile compounding using nonsterile drug substance or components must be requalified in all core competencies every 6 months.
- Ancillary Personnel – Mr. Mahan explained only personnel who handle sterile preparations are required to complete training on media-fill testing. Visitors must adhere to garbing SOPs but not competencies.

- Facility Design and Environmental Controls – Mr. Mahan reviewed the temperature and humidity requirements as well as explained the temperature requirements apply to both processing and storage. Mr. Mahan also reviewed types of secondary engineering control and processing environment requirements specific to radiopharmaceuticals.
- Remote Aseptic Processing Involving a Hot-Cell – Mr. Mahan explained to the committee the unique requirements for the hot-cell device used with radiopharmaceuticals.
- Environmental Controls – Mr. Mahan provided an overview of environmental controls specific for radiopharmaceuticals.
- Microbiological Air and Surface Monitoring – Mr. Mahan reviewed requirements for air and surface monitoring procedures.
- General Monitoring Requirements – Mr. Mahan provided to the committee in addition to specific samplings described in the section, sampling is also required in certain circumstances (e.g., new or modification of facilities/equipment, in response to identified problems/trends, changes that could impact controlled area environments, etc.)
- Monitoring Air Quality for Viable Airborne Particulates: Viable Air Sampling: Timing and Locations – Mr. Mahan explained the frequency of required volumetric active air sampling in all classified areas.
- Monitoring Air Quality for Viable Airborne Particulates – Mr. Mahan explained requirements and required actions for measurements of viable air monitoring programs exceeding action levels. Investigations and corrective action required for measurements exceeding actions are consistent with USP <797>. A change was made requiring if levels exceed the action levels, an attempt must be made to identify any microorganism recovered to the genus level with the assistance of a qualified individual such as a microbiologist or industrial hygienist. This change is more consistent with California sterile compounding regulations.
- Monitoring Surfaces for Viable Particles: Surface Sampling: Timing and Locations – Mr. Mahan described the surface sampling is required at least monthly which is six times more stringent than previous requirements even though current USP <797> states periodically.
- Monitoring Surfaces for Viable Particles – Mr. Mahan noted the only change was for an ISO Class 8 levels dropped from greater than 100 to greater than 50.
- Cleaning and Disinfecting – Mr. Mahan reviewed the cleaning, disinfecting and sporicidal for various sites.
- Assigning BUD: Preparation Conditions – Mr. Mahan provided the different manipulations required for PECs, SECs, and BUD (h). Mr. Mahan noted they spend the most time on this section and brought in experts.
- Documentation – Mr. Mahan noted applicable hard-copy or electronic records including policies and SOPs must be maintained for all activities involved in repackaging, preparing, preparing with minor deviation, compounding, and dispensing radiopharmaceuticals. He reviewed the required documentation records.
- Master Formulation Record (MFR) – Mr. Mahan advised an MFR is required only for a preparation with minor deviations or compounding as described in USP Chapter <825>.
- Preparation Following Manufacturer Instructions: Nonsterile Preparations – Mr. Mahan reviewed the requirements for nonsterile preparations. He stated the area should be suitably clean and uncluttered to ensure the overall integrity and quality of the prepared radiopharmaceutical with a documented process. Mr. Mahan noted it is important between preparation cycles to make sure there is no contamination of other products.
- Preparation Following Manufacturer Instructions: Sterile Preparations – Mr. Mahan provided to follow instructions form the manufacturer while accounting for radiation safety, environmental controls, and aseptic handling to maintain sterility.

- Preparation with Minor Deviations – Mr. Mahan provided examples of minor deviations.
- Preparation of Radiolabeled Blood Components – Mr. Mahan noted the 6 hours after blood sample is obtained from the patient or blood bank. Mr. Mahan provided if the blood samples are taken, there is a high risk that the blood has an infection. Proper precautions must be followed to ensure the safety of the patients and workers.
- Compounding Nonsterile Radiopharmaceuticals – Mr. Mahan reviewed the requirements for the committee.
- Sterile Compounding – Mr. Mahan reviewed the requirements for sterile compounding and indicated the designated person is held accountable for all activities.
- Sterile Compounding Using a Nonsterile Drug Substance or Components – Mr. Mahan reviewed the requirements as well as when testing described in Chapter <85> must be performed .
- Dispensing and Radioassay – Mr. Mahan noted except for an unopened manufactured container, the final dose or ordered amount must be radioassayed.
- Labeling – Mr. Mahan noted the minimum labeling requirements are noted. If a blood product or therapeutic product, the patient name must be added.
- Repackaging – Mr. Mahan reviewed the definition of repackaging.
- Quality Assurance and Quality Control – Mr. Mahan differentiated the differences in definitions for quality assurance and quality control.
- Notification About and Recall of Out-of-Specification Dispensed Radiopharmaceuticals – Mr. Mahan reviewed the steps to take should such an event occur to immediately notify the prescriber and determine if a recall is necessary.
- Complaint Handling – Mr. Mahan provided a system must be in place to receive complaints customers who will be using the radiopharmaceuticals including facilities and patients.

Committee member Schaad inquired about the occasion of therapeutic use of nonsterile radiopharmaceuticals. Mr. Mahan provided there is occasion.

Board President Law inquired about the types of complaints received. Mr. Mahan provided the most common complaint for PETNET is that doses are late based on the contractual agreement. Board President Law thanked Mr. Mahan for the site tour provided to board members and staff the previous day.

Supervising Inspector Acosta asked if kit splitting was considered repackaging. Mr. Mahan responded it is considered compounding.

Chairperson Serpa thanked Mr. Mahan for the tours provided to board members and staff the previous day.

Chairperson Serpa inquired what is the role of the board for regulating the use of radiopharmaceuticals in licensed pharmacies where non-pharmacy personnel are doing activities in the licensed care environment but are not staff by pharmacy personnel. Mr. Mahan provided that is a difficult area as physicians are using it in the practice of medicine. Chairperson Serpa indicated this may be the purview of the board to inspect radiopharmaceuticals outside of the licensed pharmacy. Massachusetts has statutory authority. DCA Counsel Freedman added the board is working with the Medical Board. Interim Executive Officer Sodergren added that both entities have defined jurisdiction. At the staff level, the board will be looking at the Massachusetts model should the committee desire. Chairperson Serpa added even if it is not under the purview or scope of the board, it is still under the purview of

pharmacy leadership and other regulators (e.g., Joint Commission, CDPH) to hold the pharmacy accountable for all compounding including radiopharmaceuticals.

A member of the public inquired if the board will be forwarding the blood labeling process to the agency that accredits laboratories for CLIA certification. Chairperson Serpa provided it has not been discussed at the committee level as there are multiple regulators in the area.

4. Approval of the April 16, 2019, Meeting Minutes

Chairperson Serpa requested delay of the April 16, 2019, meeting minutes until the committee had time to review the minutes.

5. Future Committee Meeting Dates

Chairperson Serpa announced the committee's next meeting is scheduled for July 11, 2019, in Sacramento. Chairperson Serpa noted that the board's website has been updated to reflect the future meeting date.

6. Adjournment

Chairperson Serpa adjourned the meeting at 11:30 am.

Presentation on the Proposed USP Chapter 825 – Radiopharmaceutical – Preparation, Compounding, Dispensing, and Repackaging by Paul B. Mahan, RPh., BCNP, Senior Regulatory Affairs Specialist with PETNET Solutions/Siemens Corporation

A copy of these documents will be made available for public inspection at the meeting and are available upon request. Requests may be emailed to debbie.damoth@dca.ca.gov.

Attachment 3

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

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

DRAFT

COMPOUNDING COMMITTEE MEETING MINUTES

DATE:	July 11, 2019
LOCATION:	Department of Consumer Affairs California State Board of Pharmacy – Building Two 1747 N. Market Blvd., Room 186 Sacramento, CA 95834
COMMITTEE MEMBERS PRESENT:	Maria Serpa, Licensee Member, Chairperson Greg Lippe, Public Member Allen Schaad, Licensee Member
COMMITTEE MEMBERS NOT PRESENT:	Victor Law, Licensee Member
STAFF MEMBERS PRESENT:	Anne Sodergren, Interim Executive Officer Julia Ansel, Chief of Enforcement Christine Acosta, Supervising Inspector Debbie Damoth, Staff Services Manger Laura Freedman, DCA Staff Counsel Kelsey Pruden, DCA Staff Counsel

1. **Call to Order and Establishment of Quorum**

   Chairperson Serpa called the meeting to order at 10:01 am. Board members present: Maria Serpa, Allen Schaad and Greg Lippe. A quorum was established.

2. **Public Comment on Items not on the Agenda/Agenda Items for Future Meetings**
   Chairperson Maria Serpa invited public comment.

   Seth DePaquale of BET Pharm, Lexington, Kentucky suggested the following items be considered:
   - Extension of Beyond Use Dating for sterile preparations
   - Office use for veterinary compounding for sterile preparations

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

   CCR 1735 Compounding in Licensed Pharmacies

Chairperson Serpa began the discussion by recommending to the committee and the full board to promulgate regulations as necessary to mirror structure of United States Pharmacopeia (USP) chapters. She recommended that as regulations for the respective chapters are finalized that the board initiate the rulemaking process one chapter at a time to allow for more immediate transition to the new regulations. Draft regulations as prepared by staff, were presented to the committee to be considered. Chairperson Serpa stated the draft regulations are to repeal Article 4.5 and replace it with an entirely new Article 4.5, nonsterile compounding.

DCA Counsel, Laura Freedman suggested, with board approval, there may be some non-substantive edits that can be addressed outside of the meeting that can be handled organizationally.

Mr. Lippe asked if the public should be afforded the opportunity to comment on non-substantive changes.

Ms. Freedman stated any changes made whether substantive or non-substantive would go to the full board for review.

Dr. Serpa advised everyone present that as the committee moved forward with its discussion, each section would be discussed one at a time. Further, Dr. Serpa would provide opportunity for board member comments followed by public comment. Dr. Serpa noted that the proposed language would be projected and during the discussion live edits would be made and documented through consensus.

The committee initiate its review with Section 1735, entitled, "Compounding in Licensed Pharmacies"

As part of public comment on this section, Danny Martinez, CPhA, asked if CCR 1735(b) and (c) are necessary. Business and Professions Code (BPC) 4052.7 addresses repackaging. Mr. Martinez suggest striking these two sections as he believes they are duplicative and unnecessary, particularly in a hospital setting. Dr. Serpa asked for clarification on why this would be more problematic in a hospital setting. Mr. Martinez stated he would provide further clarification at a later date.

Mr. Martinez referenced CCR 1735 (d), noting that that obtaining further documentation that a prescription from a prescriber has approved use of a compounded drug preparation will be laborious for compounders. He stated patient care will be delayed by this section and asked that it be stricken. He recommended if the board is unwilling to strike this, he is suggested to add the following after the first sentence, "If it is unclear whether a compounded preparation was intended, approval shall be obtained orally or in writing." Mr. Martinez commented if the prescription is written for a compounded product, there should not be a need to call the prescriber back to verify.

Christine Versichele, Dynalabs, under CCR 1735(c) , suggested that the word "repackaging" be corrected to read "reconstitution."

Marie Cottman, Pacific Compounding Pharmacy, suggested an allowance for a delay in the implementation of these regulations as some of the suggested language is an undue burden.

Dr. Cottman commented that under CCR 1735(a) USP describes compounding to include "all places but not limited to pharmacies". Dr. Serpa explained the purview of the board is limited to what occurs in a pharmacy, thus the limitation. Dr. Cottman suggested 1735(d) to replacing "perpetrations" with "preparations" and replace "noncommercial" with "noncommercially". Dr. Cottman referred to the

word disposal under CCR 1735(g) and stated under CCR 1707.2 disposal is not referenced. She suggested the board consider adding the word disposal under Duty to Consult language.

Dr. Serpa responded that any discussion on the delay of implementation needs to be related to language the board drafts in the regulation that goes above USP guidance.

Ranel Larsen, compounding pharmacist, commented that under BPC 4037(a), compounding is defined and is unclear why we are restating the definition under 1735(a). Dr. Larsen noted that she did not see reference to this definition in USP 795 and suggested it should be removed from this regulation entirely. Dr. Larsen mentioned under 1735(e)(3), "documented medical need" is not defined and as such should be defined or removed. She requested that discussion should be had on delay on implementation of of 1735(i) and (j) and suggested they be combined as they are very similar. Dr. Larsen asked for clarification on CCR 1735(b), specifically why it references repackaging for nonsterile compounding when USP 795 is silent on repackaging when it comes to nonsterile drug preparations. She stated repackaging needs to be addressed for sterile preparations but not nonsterile.

Lorri Walmsley, Walgreens, explained that the proposed regulations could prevent community pharmacies from potentially flavoring antibiotics if they are not USP 795 compliant. Inspector Christine Acosta stated the USP 795 committee intended for the inclusion of a flavoring agent to be considered compounding.

Joe Grasela, University Compounding Pharmacy, referred to 1735(d) and stated contacting a doctor every time to confirm a compound is overwhelming and unnecessary. He agreed with Mr. Martinez's statement regarding the conditions under which such documentation would be appropraite if it is unclear whether a compounded product is necessary. Mr. Grasela asked that this section be stricken from the draft regulation. Dr. Acosta responded that the expectation is not to be documented on every prescription. MDr. Serpa added part of the intent is to make the patient aware a product they are receiving is compounded and not manufactured, but it is certainly not intended for each and every compounded product.

Board staff noted their belief that the proposed regulation provision is consistent with federal law governing 503A facilities, but staff would confirm.

Nichole DiLoretta, Dynalabs, commented that with respect to repackaging, many pharmacists are making compounded kits and they would appreciate guidance on these products. She asked if it would be possible for a pharmacist to perform an assessment of risk when making compounding kits. Dr. Acosta stated 1735(c) is attempting to clarify compounding kits. Dr. Acosta clarified that if the kit does not have FDA approved labeling then reconstitution is compounding. Dr. Serpa stated the board and staff is considering drafting FAQs to provide additional education on the regulation.

Dr. Serpa reviewed the proposed edits offered through public comment for section 1735 and asked the committee members if they agree with said changes. The committee reached consensus on proposed changes to the drafted language.

1735.1 Introduction and Scope and Compounding Definitions

The committee continued its review and proceeded to Section 1735.1 including public comment.

Ask part of public comment, Marie Cottman commented there is no definition of potency in the new language and requested it be added. She stated section (f) is missing from the document and quality

and strength are both listed as section (k). Dr. Cottman stated that in 1735.1(g), repackaging sounds like dispensing and asked for clarification on the differences between the two. Dr. Acosta stated that definition is taken from USP 797 and the regulation is attempting to explain what is meant by repackaging. Dr. Serpa asked if adding words at the end of that section to read, "that is not pursuant to a patient prescription", would make the section clearer. Mr. Lippe agreed the section clearer with that edit.

Dr. Acosta suggested under (j) to have it read "potency means an active ingredient strength typically within +/-10% (or range specified in USP) of the labeled amount". Ms. Freedman suggested cross referencing USP to be clear. Ms. Sodergren wanted to make clear that potency will be defined with the language of "+/-10% of the labeled amount".

Dr. Larsen suggested under 1735.1(a) to add "approved mixing directions" for continuity. She recommended under (b) that the word clinically be removed for clarity. Ms. Sodergren stated it was a deliberate deviation. Dr. Acosta said there is a distinct difference between a "clinically significant" and "significant" noting that wanting to decrease the cost of producing a product could fall under the latter. Dr. Acosta stated clinically significant could mean the patient cannot take this drug because he will have an allergic reaction versus cost savings. Dr. Larsen requested to add back the words "sterile product" under section (g) for the definition of repackaging. Dr. Serpa stated that was not the intent of this section and that this regulation is for nonsterile and specifically sterile was removed.

The discussion continued regarding 1735(a) regarding adding "mixing directions". Dr. Acosta requested that Dr. Larsen provide more information on this section.

Public comment suggested that referring to potency with a +/- 10% range is not appropriate. It was suggested that a USP monograph be used instead.

Mr. Grasela suggested using FDA guidelines under section (b) to make the section clearer.

Dr. Cottman, suggested to simplify section (g) add a comma after manipulation so the section reads: "manipulation, not pursuant to a prescription." She suggested to add potency to the definitions or remove it from 1735.8.

Jacqueline Sitack, Dignity Health, suggested that for strength and potency, to revise the term to reference "labeled strength". Dr. Serpa stated concern with limiting this to labeled strength because a compounder could have strength in the master formula and the definition would not apply.

Dr. Serpa reviewed the proposed edits for CCR 1735.1(a) – (j) and asked the committee members if they agree with said changes. The committee reached consensus on proposed changes to the drafted language. A definition of potency will be added and under (g) repackaging – the words "that is not pursuant to a prescription" will be added.

1735.2 Personnel Training and Evaluation

Having reached consensus on section 1735.1, the committee moved to review and consideration of proposed section 1735.1. Mr. Lippe asked that CSNP be changed to CNSP in section (b). The committee then received public comment.

As part of public comment, Mr. Martinez stated that CCR 1735.2 (a),(b), and (e) in that the proposed regulation restates information in USP on training and is duplicative. Dr. Serpa stated it may be appropriate to provide an FAQ for clarity on this section.

Dr. Cottman suggested changing section (b) to read "in all skills as listed in USP 795". Dr. Acosta stated the intent of the requirement is for the pharmacist to have documented skills for anything they oversee. Dr. Serpa noted that everyone involved in the compounding process should have the necessary skills and demonstrate proficiency. The committee decided to keep the language as written.

Dr. Serpa asked if the committee or board staff had any concerns about the changes suggested in CCR 1735.2 and stated these changes will be presented in the motion at the end of the meeting. The committee reached consensus on the section.

CCR 1735.3 Personal Hygiene and Garbing

With no comments being made from members, the committee heard public comments related to Section 1735.3

Dr. Cottman suggested changing the phrasing "shall not be allowed" to "should not allow" in section (a). She stated that she would like to exercise professional judgment to determine if compounding personnel with specified conditions should be prohibited from entering the compounding area because of potential risk of contamination. Dr. Cottman suggested if you be appropriate to allow the supervising pharmacist to make the decision whether to allow personnel into the compounding area. Dr. Serpa suggested the section be more specific and suggested a brief break to allow for drafting of possible revision to the language for consideration.

After the break the following language was drafted by staff 1735.3(a):
"The supervising pharmacist shall evaluate compounding personnel experiencing any of the following: rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection and or any other conditions to determine if such condition could contaminate a CNSP or the environment. The supervising pharmacist shall not allow personnel with potentially contaminating conditions to enter the compounding area."

Dr. Serpa asked the public if this section satisfied the publics concerns. Dr. Cottman stated the language is good and acceptable, but these conditions are already stated in USP 795. She suggested the following alternative language "The designated person or pharmacist supervisor shall document evaluation of individuals posing a possible contamination risk prior to allowing the individuals to enter the compounding area." Dr. Cottman agreed to the statement as drafted by board staff.

Dr. Cottman stated section (b) indicates any exposed piercing must be removed noting she believes including ear piercings in this instance or nose piercings that are covered by a hair or face mask is excessive and unnecessary. She mentioned under section (f), having to wash glasses multiple times a day is excessive. Dr. Acosta clarified that section (f) states the facility can determine through their SOPs how and when they want to wash glasses.

Dr. Larsen noted her concurrence with Dr. Cottman on the jewelry removal issue, indicating that a compounding professional should be able to determine whether jewelry will interfere. Dr. Larsen agreed that hand and wrist jewelry should be removed, as that would be the most problematic in compounding, but that not all jewelry should be included in the removal requirement under section (f).

Mr. Martinez stated CPhA will be submitting a full letter with all the suggested changes they have from its members. He mentioned that if you are a CPhA member and have suggested changes that are not voiced today they will incorporate those suggestions in their letter to the board. Mr. Martinez noted that he will submit the letter in a timely matter, so it is available for review at the full board meeting.

Dr. Serpa asked if the committee has consensus on the language in CCR 1735.3 and stated these changes will be presented in the motion at the end of the meeting.

1735.4 Building and Facilities

Having no committee discussion on section 1735.4, the committee entertained public comment on section 1735.4.

As part of public comment, Mr. Martinez commented that under section (d), the proposed regulation is very vague and open to interpretation regarding the compounding area. He stated many activities other than compounding occur during the compounding operations. Mr. Martinez suggested adding the phrase "when compounding is performed no other activity shall take place in the adjacent area without adequate controls to prevent contamination of the compounding area and preparations". Dr. Serpa requested clarification on what "adjacent area" means, as it is very broad. She stated the board was attempting to provide some flexibility in this instance. Mr. Martinez stated they will work on this issue in the document they will be presenting to the board.

Dr. Cottman, suggested alternative language to section (d): "If compounding is performed daily, activities not related to the preparation of CNSPs shall not take place in the compounding area." Dr. Serpa noted the challenge with the language as there are different compounding environments and the board's goal is to not limit compounding but to assure that compounding occurs in a safe environment. Ms. Sodergren and Dr. Acosta suggested removing this section. Dr. Serpa noted that removing the section doesn't impact patient safety, but it does impact practice environment.

Dr. Serpa asked if the committee has consensus on the language in CCR 1735.4 including removing (d) relating to the compounding area. She stated these changes will be presented in the motion at the end of the meeting.

CCR 1735.5 Cleaning and Sanitizing

The committee did not have comments on section 1735.5 and requested public comments.

As part of public comment, Dr. Cottman commented under 1735.5(a) that cleaning is done all the time as part of the practice. Dr. Cottman noted her belief that compounding staff will just write it down, that cleaning occurred, even when it has not. She questioned the value of such documentation and how it was related to consumer protection. Dr. Serpa explained there has to be minimum amount of documentation. Dr. Cottman encourage documentation at least once a day, but not every time and suggested it may be a training issue, that an SOP needs to be written, it needs to be monitored and a daily documentation of what agents were used is appropriate.

Dr. Acosta stated the intention is to capture documentation of the cleaning and sanitizing of the compounding area to include the personnel who are performing this task and the agents used.

Dr. Serpa asked if the committee has consensus on the language in CCR 1735.5. She stated these changes will be presented in the motion at the end of the meeting.

CCR 1735.6 Equipment and Components

Dr. Serpa stated section 1735.6 discusses new technology, which will require new equipment to be purchased and that the committee and board may want to consider a delay in implementation. She encouraged the public to provide comments specific to delayed implementation and timelines.

As part of public comment, Dr. Walmsley, Walgreens, and Michael Cuellar, Manager of Walgreens compounding center, suggested striking 1735(b) relating to the required use of a closed system processing device for any weighing, measuring, or other manipulations of components in powder form. She stated in the current version of USP 795 it references that an assessment of whether powder should be handled in a BSC or CVE and would like this USP guidance to stand. Dr. Cuellar mentioned the requirement of an assessment being captured in an SOP as to whether or not a hood is required for a nonsterile preparation is appropriate. Dr. Walmsley commented the would have a significant cost component for pharmacies and believes an enforcement delay would be appropriate as powder hood would need to be purchased and there have been significant delays for 800 compliant hoods of up to 8 to 16 weeks.

Public comments under section (b) included adding the word "containment" before "ventilated enclosures" to reflect the CVE as the enclosure.

Tim Frost, CVS Health, suggested removing section (b) as he is concerned on how this would affect access and patient safety (particularly patients who cannot swallow pills). Dr. Frost stated if this is not stricken then he would like the board to consider and amendment to include single use containment glove bags as a third option.

Dr. Cottman agrees with section (d), but in existing law 1735.3(c) or (e) compounders use commercially made FDA approved products and crush them to make smaller strengths. She explained this requires a Certificate of Analysis (CofA) for any API or added substance, but there is no CofA for tablets. In our current language we do have that a CofA is not required for FDA approved products. She would like to see this added to section (d). Dr. Acosta stated API is a bulk substance not a manufactured product and suggested to reference USP 800. Dr. Serpa suggested to address this issue in a FAQ.

Dr. Cottman added she would like to see FAQ information on section (e) regarding when components not used in compounded can be returned to the original container versus when such components must be discarded. She asked for clarification on where to you draw the line on what has been removed from the original container and are you able to add product back into a container if removed by a single use disposable spoon? Dr. Cottman suggested "should be discarded" instead of "shall be discarded". Ms. Freedman suggested changing the language to "shall be discarded if the returning to the original container could result in contamination". Dr. Cottman suggested the following "Once removed form the original container, components that have been contaminated and not used in compounding shall be discarded." Dr. Acosta responded that such an approach could create challenges with enforcement of the requirement. Dr. Cottman noted that the requirement as written would increase cost, decrease access and increase waste. Dr. Acosta stated USP is written as "should" versus "shall" and suggested to eliminate section (e).

Mr. Martinez asked for clarification on (b)(1) in that for CVEs there are no guidelines. Dr. Acosta said currently there are no guidelines for CVEs, but that they are under way in a new revision of CETA. Dr. Acosta noted that vendors know to certify to CETA guidelines and are specific to each unit.

Dr. Larsen stated under (c)(1), relating to requirements for components used, that a National Formula (NF) doesn't exist for everything and suggested adding the phrase "if one exists" as without this phrase there is confusion. Dr. Acosta stated this is much broader than a monograph and doesn't change the context. Dr. Serpa noted that the regulation is referring to the concepts in USP not drug specific information in USP. She noted that Dr. Larsen and Dr. Acosta are both correct. Dr. Acosta stated this is not referencing a specific product, it is a specific component, noting this section is not referring to the end product.

Dr. Serpa noted that section 1735.6 is probably the most significant of regulations as it will change how pharmacy is practiced in facilities where powders are being used. She asked how to implement this section in a manner that does not limit access to patients. Mr. Schaad questioned the value of requiring a CVE for nonsterile compounding, but noted the need for hazardous compounded preparations.

Dr. Acosta noted that one of the challenges with the assessment approach is determining the standard for such an assessment. Dr. Serpa stated safety of patient, personnel and environment should drive the decision.

The committee considered the requirement of the CVE and significant public comment, both in support of and opposed to the mandated requirement. Ultimately the committee reached consensus and removed the requirement but agreed to readdress the issue at a later time.

Dr. Serpa asked if the committee has consensus on the language in CCR 1735.6. She stated these changes will be presented in the motion at the end of the meeting.

1735.7 Master Formula and Compounding Records
The committee did not have comments on section 1735.7 but heard public comment.

As part of public comment, Dr. Cottman stated that in USP 795, already reference to "API or added substance identities and amounts must include at least a salt form and purity grade". Dr. Acosta stated yes, but after that phrase USP states, if applicable and makes this optional. Dr. Cottman agreed with (a)(2) regarding container closure but she believes the "at least volume" is not practical and excessive, particularly in the veterinary world based on the size of an animal. Dr. Acosta noted the difference between making a 10ml vial and a 1ml vial and the master formula should tell you how much and how many you are making.

Dr. Cottman requested that under 1735.7(c) the board can change the word "log" to "record", so it is congruent with USP 795.

Mr. Martinez asked in 1735.7(a)(3) how does a pharmacy make the reference fully available for an inspector and was advised that the pharmacy must have the article fully available and it does not say printed.

Dr. Larsen requested under section (a)(1) to add "if applicable" in congruence with USP, because not every single substance has a salt form and requested that the language be stricken.

Dr. Larsen stated her agreement with Dr. Cottman's comments regarding the container-closure system indicating the proposed language is restrictive and should not include the volume. Public comment noted the difference between CNSPs and CSP and the significance the volume for each.

Dr. Sitack suggested changing, under 1735.7 (a)(b), the wording "master formula document" and "master formula record" to "master formulation record" in congruence with USP.

Dr. Serpa asked if the committee has consensus on the language in CCR 1735.7. She stated these changes will be presented in the motion at the end of the meeting.

CCR 1735.8 Release Inspections
No committee discussion.

No public comment.

CCR 1735.9 Labeling
There were not comments by the committee however the committee heard public comments.

As part of public comment, Dr. Cottman inquired about the provisions under (a)(1)(A) and requiring inclusion of the "route of intended administration" on the prescription label. Dr. Serpa stated that the intent is to have the label requirement in the future to be the same across all prescriptions. Dr. Cottman also asked why (a)(2)(B) (regarding labeling) is necessary to provide "any warning statements that are applicable" and was advised that DMSO, and other things that are specific to your product.

CCR 1735.10 Establishing Beyond-Use Dates
There were not comments by the committee however the committee received public comments.

As part of public comment, Mr. Martinez commented that stability studies are left out of the regulation. Ms. Sodergren commented that it was left out because it is referenced in USP 795. Dr. Serpa stated the regulation is addressing items that go above and beyond USP guidelines and USP has written an informative FAQ on this topic.

CCR 1735.11 SOPs
Having no committee comments, the committee entertained public comments.

As part of public comment, Dr. Cottman asked for clarification of what is meant by "procedures for handling, compounding and disposal of infectious materials" and was advised the language is consistent with current law.

CCR 1735.12 Quality Assurance and Quality Controls
No committee discussion.

No public comment.

CCR 1735.13 Packaging and Transporting
There were not comments by the committee however the committee received public comments.

As part of public comment, Dr. Cottman asked under CCR 1735.13 (c) to consider changing the term "delivery" to dispensing.

The committee reached consensus on the section.

CCR 1735.14 Complaint Handling and Adverse Event Reporting
No committee discussion.

No public comment.

CCR 1735.15 Documentation
There were not comments by the committee however the committee received public comments.

As part of public comment, a member of the public asked about documentation in general regarding master formulas if there is an audit trail in the batch record is that satisfactory. Dr. Acosta responded that several vendors have software that allows for edits in the electronic system and the board cannot tell if edits were made. She stated if the compounder is making an edit in the log or the master formula the board wants to be able to see the original record and the edit itself. Dr. Acosta commented that systems need to provide some type of audit trail and not all software has an audit trail. Dr. Acosta noted that a dispensing record can be deleted but a hard copy prescription cannot be deleted.

Dr. Cottman stated when edits are made to master formulas, they are dated and signed and questioned the value of documenting the time an edit occurs. Dr. Acosta stated time is important to documented.

Having reached consensus, the committee concluded its review of the regulation proposal.

Motion: Recommend to the board the approval of the proposal to repeal and replace Article 4.5 related to compounding and propose a new Article 4.5 related to Nonsterile Preparations, including sections CCR 1735 through 1735.15, as reviewed and edited today.

No public comment on the motion.

M/S: Allen/Greg

Support: 3 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Kim				x
Law				x
Schaad	x			
Serpa	x			
Lippe	x			

4. Approval of the April 16, 2019 Meeting Minutes

Motion: Approve the April 16, 2019, committee meeting minutes.

M/S: Allen/Maria

Support: 2 Oppose: 0 Abstain: 1

Board Member	Support	Oppose	Abstain	Not Present
Kim				x
Law				x
Schaad	x			
Serpa	x			
Lippe			x	

5. Future Committee Meeting Dates

Chairperson Serpa announced the committee's next meeting is scheduled for August 28, 2019, in Irvine, California.

6. Adjournment

Chairperson Serpa adjourned the meeting at 3:23p.m.