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

DRAFT

COMPOUNDING COMMITTEE MEETING MINUTES

DATE: September 24, 2019

LOCATION: Department of Consumer Affairs
1625 N. Market Blvd.,1st Floor Hearing Room
Sacramento, CA 95834

COMMITTEE MEMBERS PRESENT: Maria Serpa, Licensee Member, Chairperson
Allen Schaad, Licensee Member, Vice Chairperson
Greg Lippe, Public Member, Acting President

STAFF MEMBERS PRESENT: Anne Sodergren, Interim Executive Officer
Christine Acosta, Supervising Inspector
Anna Kalantar, Supervising Inspector
Laura Freedman, DCA Staff Counsel
Norine Marks, DCA Staff Counsel
Debbie Damoth, Administration Manager

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

Chairperson Serpa called the meeting to order at 9:12 a.m. Dr. Serpa provided an update to the USP statement made September 23, 2019. Dr. Serpa read the public statement that the board would be sending out via subscriber alerts.

> The California State Board of Pharmacy acknowledges the recent USP announcement regarding postponement of the official dates of revised USP Chapters 795 and 797 and new USP Chapter 825. While the timing of USP Chapters is unknown at this time, it is the Compounding Committee's intention to continue its efforts to evaluate regulations necessary to ensure safe compounding practices consistent with the board's consumer protection mandate. The timing of board regulations will be determined after additional information is provided by USP.
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> We will be assessing the implications for USP 800 and conferring with other state regulators. We will provide updates regarding this issue as they become available.
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> The board will continue to assess the issue as information is provided by USP. Changes will be posted on the board's website under "What's New" and sent to facilities via subscriber alerts.

Dr. Serpa provided background on the committee's actions during the past meetings. The committee determined and the full board agreed that regulations mirror the structure of the USP chapters, including separate requirements for the various types of compounding preparations. The board would initiate the formal rulemaking process as regulations for each respective chapter are finalized allowing for more immediate transition to the new Chapters and regulations.

Dr. Serpa advised at the July 2019 meeting, the committee discussed proposed regulations relating to nonsterile preparations, that may be necessary to implement, clarify or make more specific requirements related to USP Chapter 795 as well as to ensure safe compounding processes consistent with the board's consumer protection mandate. The committee's recommendation was considered by the board during the July 2019 board meeting. The board voted to initiate the rulemaking process, which is the first step in the rulemaking process. The rulemaking package was submitted to DCA counsel to complete review. Upon completion of the pre-notice review by various control agencies, the board will release a notice and advise all interested parties about the proposed changes and provide a 45-day comment period. Dr. Serpa strongly suggested that anyone interested engage in the regulatory process during the comment period.

Dr. Serpa provided the committee will continue the discussion on proposed regulations for the compounding of Sterile Preparations. The committee will consider regulations that may be necessary to implement, clarify or make more specific requirements related to USP 797 consistent with the board's consumer protection mandate. After completing this review on sterile compounding, the committee will move on to subsequent USP chapters 800 and 825 to consider additional regulations.

Dr. Serpa took roll call and the committee members present at the meeting were: Allen Schaad, Greg Lippe and Maria Serpa. 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. Discussion and Consideration of Proposed Regulations Related to Pharmaceutical Compounding of Sterile Preparations

Dr. Serpa suggested the committee first consider the two sections of regulations where the committee solicited input, specifically on sections 1751 (e) and 1751.9 (e). Following that discussion, the committee will use a similar process used during the September 5, 2019, committee meeting. As the committee moves forward with the discussion, Dr. Serpa provided each section will be discussed one at a time with time for member discussion and public comment on each section. Dr. Serpa added to ensure all members of the public are given an opportunity to comment should they so choose, public comment for each individual were limited to three minutes for each section. Dr. Serpa advised if a delayed implementation is necessary for enhanced language in proposed California regulations to please include this in your comments.

Section 1751 Sterile Compounding in Licensed Pharmacies

Section 1751 (e)

Dr. Serpa provided the committee would consider the comments received related to Section 1751 (e). At the September 5, 2019, meeting, the committee requested interested parties provide any products that require sterilization to be performed outside of the licensed pharmacy. The committee also asked for an explanation why the sterilization cannot be performed within the pharmacy. The committee requested the information should address why the sterilization process is the only process that works for the product, the names of the companies currently performing the sterilization, and any licensure for those companies, if known.

Dr. Serpa referred the committee to the legal analysis provided by DCA Counsel Freedman. Ms. Freedman provided regarding the legality of using a third party to perform sterilization, the concern is if any part of the compounding process occurs outside the licensed compounding pharmacy. Ms. Freedman provided based on her research of 503A subdivision (a) (1), the federal exemption applies to a state licensed pharmacy that exempts the pharmacy for the manufacturer requirements when compounding. Business and Professions Code sections 4127 and 4127.1 specifically reference the compounding has to occur in a sterile compounding pharmacy – a singular pharmacy – and the license is not transferable thereby emphasizing all compounding exempted under the federal law that occur can in a compounding pharmacy has to occur in a single licensed facility. Ms. Freedman added at this time there are no statutory exemptions and would expect all aspects of compounding to occur in the single regulated unit.

Dr. Serpa provided at the September 2019 meeting, the discussion focused on radiation sterilization occurring outside of the licensed sterile compounding pharmacy. Dr. Serpa added based on this analysis, all forms of sterilization would have to be done in the licensed pharmacy and couldn't be sent to a third party for sterilization. Ms. Freedman stated the compounding pharmacy may purchase sterilized product to use but confirmed anything done as part of the compounding process has to be done by the compounding pharmacy.

Dr. Serpa noted that the committee received two comments related to this topic and confirmed the committee reviewed the comments. However, neither of the comments can overcome the legal prohibition on the practice. Ms. Freedman confirmed Dr. Serpa's understanding was correct as neither the board nor committee can change the limits of the statutes by regulation.

Dr. Serpa commented the E-Beam or gamma radiation outsourcing sterilization are currently being used for hormone pellets. She noted since the last meeting the board has determined the hormone pellets can be lawfully made by licensed outsourcers under current good manufacturering practice (cGMP). Given that patients will have access to the medications should their prescriber deem appropriate, the board is not within its purview to allow the outsourcing sterilization at this point.

The committee received a comment inquiring if an outsourcer could dispense to a patient pursuant to a prescription. Supervising Inspector Christine Acosta provided an outsourcer can sell directly to the provider for insertion. The commenter expressed concern about the market for making pellets according to cGMP standards. Dr. Acosta provided there are at least four outsourcers licensed with the board. The committee also heard concern that California was the only state interpreting 503A in a manner that would not allow for third-party sterilization. The committee heard public comment about

other states having shared services agreements with vendors, but the board does not have the authority to do this at this time. Dr. Serpa explained the board was bound by the statutes and regulations of the board and encouraged the public to work with associations to enact legislation.

Section 1751.9 Equipment, Supplies, and Components

Section 1751.9 (e)
Dr. Serpa provided at the September 5, 2019, meeting, the committee requested comments from interested parties relates to Section 1751.9. (e). The committee specifically requested examples of preparations that would be impacted. At the September 5, 2019, meeting, the committee received public comment specifically about methylcobalamin and the resulting impact to patients as well as the potential impact on the veterinary community.

Dr. Serpa reported the committee received one comment that provided a list of components used in veterinary sterile compounds. As several of the components on the list do have a USP monograph, it would be able to be used under the board's proposed regulations. Dr. Serpa noted as the focus is on patient safety and that may result in changes in how we currently do things and considering the findings of staff, it didn't appear to be able to be determined how this comment would impact patient access.

Dr. Serpa provided although the committee did not receive written comments, board staff researched the potential impact on patients that require methylcobalamin. Staff advised Chairperson Serpa that at least four outsourcers, currently licensed in California, prepare methylcobalamin under cGMP standards. Based on this information, Dr. Serpa didn't believe the board's proposed regulation would impact patient access. Committee member Schaad confirmed there are suppliers of methylcobalamin. Dr. Serpa noted pharmacies would need to change their practice and purchase the preparation from an outsourcer rather than making it.

The committee heard testimony that the commenter considered only having four vendors would create a patient access issue. The committee also heard comments indicating other APIs would not be available. The commenter was advised outsourcers have a way to deal with APIs that do not have monographs that renders the product safe for human use. Dr. Acosta provided under cGMP the facility is required to do vendor qualifications and pretest on anything used so they can qualify something. Outsourcers are required to do vendor qualifications. Outsources can test outside of the product labeling. Pharmacies are only allowed to use a raw material that is for the intended population. Dr. Serpa provided the challenge for the board is that federal regulations allow use of the products differently than the board can allow in the state level. The goal is not to punish pharmacies. The goal is to provide safeguards for patients. Because of the inability for all pharmacies to provide the higher level of testing of every API lot that is required by manufacturering, it is not within the board's purview provided there is patient access.

The committee heard testimony concerned with the section 1751.9 (e) that prohibits a component being used to compound a CSP that meets only the European Pharmacopeia (EP) or Japanese Pharmacopeia standards (JP). Dr. Acosta provided EP and JP are not the same as USP. The process of harmonization of EP, JP and USP started but is not complete. The committee concurred with Dr. Acosta's comments.

Dr. Serpa thanked those who submitted comments in response to the committee's request as it is helpful to fully consider concerns.

Dr. Serpa continued the discussion on the remainder of the regulations and comments received on the proposed regulations.

Section 1751.12 Release Testing

Dr. Serpa noted for Section 1751.12. Release Testing, the language incorrectly reflected Section 1735.12 and was updated.

The committee heard a comment in opposition of adopting USP as law and in support of California writing its own language.

The committee entertained a question if alternative methods of sterility testing would continue to be allowed. Dr. Serpa added the alternative method of sterility testing would be allowed if validated.

Section 1751.13 Labeling

Dr. Serpa noted for Section 1751.13 (a) (3), there was concern raised regarding admixed solutions. She suggested the language be amended in (a)(3) to insert "Prior to dispensing" prior to "Instructions for administration" and add to the end of the sentence "must be included." to read as follows:
"(3) Instructions for administration. Prior to dispensing for admixed CSP solutions, the rate of infusion, or range of rates in infusion, or the duration when the entire CSP is administered must also be included."

The committee heard comments in support of using the medical record and medication administration record as the source of truth. Dr. Serpa noted the intent was to address all patient populations and include a range to assist all settings. Mr. Schaad noted that unintended consequences needed to be considered. Ms. Sodergren commented if the committee was agreeable, staff could work with the Chairperson to develop language that addresses the conflict between regulators. The committee agreed.

The committee agreed with the recommended changes.

The committee took a break at 10:29 a.m. and returned from break at 10:50 a.m.

Section 1751.14 Establishing Beyond-Use Dates

The committee heard a comment about section 1751.14 (c) that "pyrogen testing" should be "endotoxin testing." The committee agreed and changed the language.

Dr. Serpa added "for BUD determination" should be added to (c) to read, "(c) Prior to the dispensing a CSP that requires sterility and endotoxin testing for BUD determination , 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." DCA Counsel Freedman expressed concern on how it could be interpreted. Dr. Serpa and Ms. Freedman agreed to work offline on the nonsubstantive change.

A commenter requested clarification if BUD will be allowed to extend longer than USP. The commenter was provided that USP allowed for BUDs in USP Table 11.

The committee heard concerns on the current USP draft language on BUDs and how USP determined the appropriate BUDs. Commenters inquired how USP will be enforced. Dr. Serpa noted the changing environment with USP and that the board's current regulation will continue to be enforced until USP is changed. As AB 973 was signed into law and effective January 1, 2020, the current USP will remain in effect until USP 795, 797 and 825 are finalized.

The committee heard concerns that many compounding pharmacies have made substantial and financial changes in anticipation of USP being updated that may not be needed after the delay of USP implementation.

The committee had consensus on the changes made to the proposed language.

Section 1751.15. Use of Conventionally Manufactured Products as Components.

The committee heard no comments on Section 1751.15.

Section 1751.16. Use of CSPs as Components

The committee received a request for clarification on how this section is going above USP. Dr. Acosta clarified the intention of this section is to address that nonsterile products are to be treated as sterile products for this section of the regulation. Dr. Serpa added that this section has been marked for the board to add FAQs. A commenter suggested possibly changing the title to add clarity.

Section 1751.17. Standard Operating Procedures (SOPS)

Dr. Serpa noted a change regarding 1751.17 (a)(2)(A) that the word assess is missing and recommended a change to read, "Methods by which the supervising pharmacist shall assess the quality of the compounded drug preparation." Dr. Serpa also noted board staff will remove the duplicate SOP references in section 1751.17 (a) (2).

The committee received a comment to remove section 1751.17 (a) (1) as USP Chapters over 1000 are meant to be informational and not enforceable. The commenter requested removal of section 1751.17 (a) (2) (c) as the requirement is over burdensome.

Dr. Serpa noted the committee understands the intent of USP Chapters over 1000 but the committee determined this was important to be enforceable. Dr. Serpa clarified (A) (2) (c) needs to be included in SOPs but is not needed to be done for each shipment/lot number. Dr. Acosta added it is current law.

The committee heard comments that water for injection is appropriate for use. Dr. Acosta added that the water should meet the requirement of USP <1231>. It is not a requirement for the chapter. Dr.

Acosta clarified that reference to a “shall” and “must” means it needs to be followed and “should” is not required. DCA Counsel Freedman also added context must be factored.

The committee heard concerns that the sterile compounding procedures are being built so complicated that no one will want to work in sterile compounding.

Section 1751.18. Quality Assurance and Quality Control

The committee heard a comment that USP does not have a range for humidity and requested if the committee will develop a range. The commenter was advised it is addressed in USP.

The committee heard comments regarding additional requirements that would be added by incorporating section USP <1163>. An example of testing required in 1163 was provided. Dr. Acosta clarified that the word “should” means highly suggested and the words “shall” and “must” are required. Dr. Serpa noted concern that “should” becomes “shall.”

Ms. Sodergren added this can be included in FAQs. The commenter expressed concern that people will get lost in USP <1163>.. Dr. Serpa added a strong FAQ on this section will assist the regulated public. Dr. Serpa noted adding to the language in section 1751.8 (a) to add “the required elements in” before “section 1711 and USP Chapter 1163” so that section 1751.8 (a) reads, “The quality assurance program shall comply with the required elements in section 1711 and USP Chapter 1161, Quality Assurance in Pharmaceutical Compounding. In addition, the program shall….”

Mr. Lippe expressed concern for the purpose. The board’s mandate is consumer protection but that is not accomplished by causing businesses to close. The committee must consider consumer protection which includes consumer access. Mr. Schaad added that includes the cost to the consumer. Dr. Serpa added the committee must consider impact to patients including consumer access.

The committee heard a comment that referenced USP are more guides and references but are not designed to be enforceable. The concern was made if the guidelines aren’t clear to committee members it may be unclear to the licensees.

Dr. Serpa noted the committee must consider the value in considering reference a detailed section and promulgating regulations that are more detailed.

Section 1751.19. CSP Handling, Packaging, Storage, and Transport

The committee heard no comments on Section 1751.19.

Section 1751.20. Documentation

The committee heard comments requesting keeping the first sentence of section 1751.20 (b) and concern for extensive records. The committee noted the recommendation doesn’t keep track of the person, date, or time. Additionally, this doesn’t address version control issues as not all software companies allow for this

Section 1751.21. Compounding Allergenic Extracts

The committee heard a question inquiring about the USP monograph for allergenic extracts. Dr. Serpa referred to the section in USP on allergenic extracts. The committee confirmed it should be in a dedicated PEC. Dr. Serpa indicated the committee may be interested in striking section 1751.21 (a) but will need more public comment and discussion at a future agenda item.

The committee took a break at 12:41 p.m. and resumed at 1:30 p.m.

The committee reviewed the proposed changes to the proposed language to be forwarded to the board as a recommendation.

> 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 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 patient unique identifier.
>
> (c) Reconstitution in accordance with directions that have not been approved by the FDA, is considered compounding and this article applies.
>
> (d) Except as identified below, 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) A pharmacy may prepare and store a limited quantity of a CSP in advance of receipt of a patient specific prescription document.
> (2) 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 practice 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 the same CSP to the veterinarian until the pharmacy has received and evaluated 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 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 licensed location.

(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 derived or other biological materials 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 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 (Primary Engineering Control) 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 an unacceptable result as defined in the Standard Operating Procedure (SOP)s 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 cannot be sterilized and depyrogenated, and that will come in direct contact with compounding components must be rinsed with either sterile water for injection or sterile water for irrigation, .

(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 [two years from the effective date of the regulation], all pass-throughs must be interlocking.

(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 certification 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 by a qualified microbiologist, at least to the genus level, 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 may, but need not, include gram-negative rods, coagulase positive staphylococcus, and certain molds and yeasts.

(c)Whenever cfu action levels are exceeded or an organism of concern 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. These SOPs will define at a minimum, what product is to be used, the dwell time required, and how dwell time will be monitored and documented.

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 (1) considering issued Guidance Documents and Alerts (2) in accordance with all industry standards including the following:
(A) United States Pharmacopeia (USP) – National Formulary (NF),
(B) Food Drug and Cosmetic Act (FD&CA) and federal regulations adopted to implement that act,
(C) Food Drug Administration (FDA) requirements and, and
(D) 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.

1751.12 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. Prior to dispensing, for admixed CSP solutions, the rate of infusion, or range of rates in infusion, or the duration when the entire CSP is administered must also be included.

Note: Staff to work with committee chair and legal to address range issues in acute care.

(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 endotoxin testing for BUD determination, 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 SOPs listed in USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding, include:
(A) Methods by which the supervising pharmacist will assess 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 the required elements in 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) 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.)

Motion: Approve the language as presented to the committee subject to the change in 1751.13 by the chair, staff and legal counsel and recommend to the board to move forward in promulgating regulations.

M/S: Lippe/Schaad

The committee heard public comment on the motion.

Danny Martinez of the California Pharmacist Association commented that four outsourcing facilities producing methylcobalamin does constitute limited patient access. Outsourcing facilities do not provide medication to the patient. The time the patient would have to wait and added expense for the physician or if a 503A pharmacy could access from a 503B facility would represent patient access problems. Mr. Martinez requested the board reconsider.

Grant Miller, a veterinarian and Regulatory Director at the California Veterinary Medical Association, (CVMA) commented on section 1715 (d) pertaining to veterinary medicine. Dr. Miller discussed the CVMA's concerns with the proposed regulation. He stated the restriction of the use of sterile compounds to office administration use only is an impossible mandate for the veterinary profession. Veterinarians must be able to dispense sterile compounded medications to clients for the health and welfare of their animals. He provided an example of ophthalmology practice as veterinarians do not specialize and can treat all kinds of ailments in the animal. The sterile compounding regulations will impact this area of the veterinary practice. When an animal has a fungal infection or autoimmune disorder of the eye, the patient may receive an initial treatment from a veterinarian in-house but will need to go home with the medication in hand. With most eye conditions, veterinarians treat the animal 4-6 times daily. The animal is picked up in the evening when the practice closes, and the animal needs immediate treatment. Because few pharmacies compound veterinary ophthalmic medications and there is a delay in obtaining sterile compounded products, veterinarians must ensure the animal patient has the medication while the client gets the prescription filled. It is critical that the veterinarian can dispense these medications to ensure continuity of care. Veterinarians that treat eyes rely extensively on compounded sterile preparations because very few FDA approved legend or generic formulations exist for most of the products required to treat conditions that occur in animal eyes. He added there is a litany of drugs that can only be obtained from compounded pharmacies as there are

no FDA approved formulations. Dr. Miller stated consumer protection is at risk. If the regulation is approved as written, the animals will not receive the care they need and that is unacceptable to the profession.

Dr. Miller noted he has never seen a regulation that would require veterinarians to enter into a contract with another private business and seemed unprecedented in the context of the area of practice. Dr. Miller indicated they are jointly responsible for compliance with the regulation and this regulation adds a new regulatory requirement to veterinary practice that would have to be added to the veterinary practice act. Dr. Miller stated it seems the Board should be working with the Veterinary Medical Board as there are huge differences between human and animal practices. Dr. Miller continued he appreciated that including this provision in the law to show the Board at least preliminarily understands the differences in veterinarian practice. Dr. Miller continued CVMA believes there are critical conversations that need to take place between the Board and in consultation with the Veterinary Medical Board if the Board were to move forward in this regard.

Dr. Miller stated jurisdictional authority over the veterinary profession should also be discussed. Contracts that require veterinarians to provide records to the pharmacy creates a new record keeping and reporting requirement. Dr. Miller advised the committee such requirements need to involve the oversight of the Veterinary Medical Board. Dr. Miller indicated the CVMA is unclear as to how enforcement would be completed as one licensee over another since the pharmacist will withhold medication from the veterinarian if the veterinarian does not comply with the contract agreement. Dr. Miller stated it was very confusing to CVMA.

Dick Sullivan, a veterinarian, past member of the Veterinary Medical Board, and current member of the multidisciplinary advisory committee to the Veterinary Medical Board, stated compounding is essential for veterinarians to treat their patients ranging in size from a few ounces to the size of elephants. He continued guidelines 795 and 797 are on hold because of appeals from stakeholders including the Veterinary Medical Board, CVMA, and the American Veterinary Medical Association. This is due to the concern for the ability to treat the more serious cases. Dr. Sullivan suggested the Board follow suit, slow down the process and work with the Veterinary Medical Board to identify the specific problems and resolve the problems together without impeding the ability of the veterinarians to take care of their patients.

Dr. Sullivan reported to the committee a few weeks prior he along with the Veterinary Medical Board Executive Officer and Counsel met with Board staff to discuss compounding issues that affects the veterinary profession. Dr. Sullivan stated today's subject was never brought up. Dr. Sullivan reported he was very surprised to receive a text from the Veterinary Medical Board's Executive Officer requesting he attend this meeting to speak about the proposed changes. Dr. Sullivan thanked the Committee for allowing him to address the Committee and looks forward to working with Board and staff to resolve these issues for the betterment of the Veterinary Medical Board's patients.

Dr. Cheryl Waterhouse representing the Veterinary Medical Board as Vice President expressed curiousness that representatives of the Veterinary Medical Board met with Board of Pharmacy staff last month and reported nothing was mentioned of this. She continued this would institute a lot of new reporting and regulatory requirements for veterinarians. She stated she would like to work with Board of Pharmacy, but the Board of Pharmacy needs to know that veterinary medicine is hugely different than human medicine in some regards. Dr. Waterhouse stated she is a practicing veterinarian,

and these are unworkable. She stated patients will suffer and costs will go up tremendously. She provided an example of a dog that needs to have eye meds put in 6-8 times a day. If it is a compounded medication, it will take 72 hours to 14 days to get the compounded medication from a compounding pharmacy. She stated the patient would have to go to an emergency clinic that would charge $200-$300 per a day to treat the dog. Dr. Waterhouse asked the committee to multiply that out and know there were will be a lot of complaints from consumers who cannot afford it and the animal cannot be treated. Dr. Waterhouse stated this is a huge problem and our boards need to talk together.

Dr. Serpa thanked the representatives for coming and indicated she was glad to hear the veterinary community appealed USP, as USP has previously been silent to the veterinary community. Dr. Serpa added the Board attempted to bridge the gap to address as much as possible in the absence of USP's addressing the veterinary community. Dr. Serpa stated while the service contracts may be new for the veterinary community, they are not new for the pharmacy practice. Dr. Serpa continued the pharmacy practice has had to do this with outsourcing and because of the law, any ordering must be patient specific. In order to get the next shipment of antibiotics from a manufacturer, a list of patients had to be supplied receiving the next order.

Dr. Miller stated he worked with Dr. Acosta in 2017 on the nonsterile regulations regarding 1735. The challenge with providing a list would be a crystal ball is required to look into the future for ordering compounded medications. The pharmacy would ask how many are you ordering them for and that is hard to know. Dr. Serpa provided this is retrospective. Dr. Miller stated they understood the premise, but that the execution is untenable for the veterinary profession.

Ms. Sodergren clarified statements made by prior speakers indicating that the context of the prior discussion with the Veterinary Medical Board representatives. Ms. Sodergren noted that under current law compounding is limited to 120 hours for administration and the current abuse and fraudulent behavior that is happening surrounding current veterinary use limitations in the law. Ms. Sodergren indicate that as originally prepared the proposal would not have allowed compounding for veterinary office use and that the Board is trying to find a balance. Ms. Sodergren noted that this is the beginning of the regulation process and that there will be additional opportunities for comment on the regulation proposal. Ms. Sodergren reiterated that during the meeting with the Veterinary Medical Board representatives, she spoke about the compounding regulations, fraud identified in the marketplace, and how best to manage and navigate that behavior.

Si Pham of McGuff commented on using sterile water for injection to clean reusable equipment and submitted the monograph. Dr. Pham requested UJ and UK be acceptable as failure to include would be detrimental to patient access. Dr. Pham expressed concern of regulations impacting businesses. He stated he failed to see how allergenic extract can meet the requirements in the section as USP does not have a current monograph for allergenic extracts. He stated methylcobalamin has a USP dietary monograph and listed as bulk substance to compound.

Dr. Serpa responded to Dr. Pham and encouraged him to submit comments to USP regarding instances where there are limitations to BUD or different forms of testing. Allergenic is addressed separately in USP.

Rita Shane of Cedars-Sanai commented on section 1751 (b) related to just immediate use. The request is for consideration for situations for urgent or life-threatening situation to not have to record the

compounded time. Dr. Shane commented on section 1751.6 related to air and surface monitoring and requested consistency with USP 797.

Dr. Serpa recalled the September 5, 2019, meeting the discussion was to have a biannual recertification to get a genus level on everything. Dr. Acosta clarified that everything that is grown should be identified at least every six months.

Dr. Shane commented on section 1751.11 requested to retain language for a single lot for administration within 72 hours. Dr. Serpa stated this was purposefully left out as most systems contain all required elements.

Dr. Serpa called for the vote.

Support: 3 Oppose: 0 Abstain: 0

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

Ms. Sodergren stated this will go to the board for vote to start the rulemaking process. If approved by the board, there will be a review process before being noticed for 45 days. Ms. Sodergren recommended having a regulation hearing to allow stakeholders to testify at the hearing and would go back to the board for consideration.

4. Approval of the September 5, 2019, Meeting Minutes

Dr. Serpa provided the meeting minutes for the September 5, 2019, Committee Meeting were provided in the meeting materials.

Motion: Approve the September 5, 2019, committee meeting minutes with the following edits:

- On page 10 of 17 in 1751.4 (f), strike "and won't be allowed in hospital."
- On page 15 of 17 in 1751.11 (c), in the second sentence of the last paragraph to change "which" to "currently" and add a sentence to the end of the paragraph, "This exemption is not maintained in the proposed regulations."

M/S: Lippe/Schaad

Support: 3 Oppose: 0 Abstain:0

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

5. Future Committee Meeting Dates

Chairperson Serpa announced the committee's next meeting is scheduled for October 16, 2019, in Sacramento.

6. Adjournment

Chairperson Serpa adjourned the meeting at 2:29 pm.