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

ENFORCEMENT AND COMPOUNDING COMMITTEE MEETING MINUTES

DATE: March 23, 2023

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

Participation was also through WebEx.

COMMITTEE MEMBERS PRESENT: Maria Serpa, Licensee Member, Chair
Jig Patel, Licensee Member, Vice Chair
Renee Barker, Licensee Member
Seung Oh, Licensee Member

COMMITTEE MEMBERS NOT PRESENT: Indira Cameron-Banks, Public Member
Ricardo Sanchez, Public Member

STAFF MEMBERS PRESENT: Anne Sodergren, Executive Officer
Debbie Damoth, Executive Manager Specialist

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

Chairperson Maria Serpa called the meeting to order at 9:01 a.m. Dr. Serpa reminded all present that the Board is a consumer protection agency. Dr. Serpa advised the meeting was being conducted with participation through WebEx and being webcast. The meeting moderator provided updated WebEx instructions.

Chairperson Serpa took roll call. Members present included: Jig Patel, Licensee Member; Renee Barker, Licensee Member; Seung Oh, Licensee Member; and Maria Serpa; Licensing Member. A quorum was established.

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

Members of the public were provided the opportunity to provide comments for items not on the agenda.

The Committee heard a comment from a pharmacist representing a compounding pharmacy in Stockton, CA. The compounding pharmacist requested the Committee add to a future agenda to discuss pharmacy technicians being employed at oncologists' offices to prepare chemotherapy infusions for administration without the supervision of a pharmacist. The compounding pharmacist requested this be discussed to prevent and avoid patient harm.

An anonymous commenter reported hearing of Board of Pharmacy inspectors who may have asked other sites to perform a repeater pump media fill test to serve as the media fill competency for employees. The anonymous commenter requested the Board consider commenting on why performing a repeater pump media fill test was considered a more complex aseptic manipulation for employees versus performing 20 manual aseptic transfers from a TSB vial into a TSB bag. The anonymous commenter thought each facility could determine the media fill test based on their most complicated preparation.

Chairperson Serpa advised the first item requested to be added to a future agenda was scheduled to be on a future Licensing Committee Meeting agenda. Executive Officer Anne Sodergren concurred. Members were provided the opportunity to add items to the future agenda. Member Patel stated as long as the pharmacy technician issue was on the Licensing Committee agenda, there was no need to add it to the Enforcement and Compounding Committee agenda.

III. Approval of February 15, 2023, Enforcement and Compounding Committee Meeting Minutes

Chairperson Serpa referenced the draft minutes for the February 15, 2023, Enforcement and Compounding Committee Meeting.

Members were provided an opportunity to provide comments on the draft minutes; however, no comments were made.

Motion: Approve the February 15, 2022, Committee Meeting Minutes as

presented in the meeting materials

M/S: Oh/Patel

Members of the public were provided with an opportunity to provide public comment; however, no comment was provided in Sacramento or via WebEx.

Support: 4 Oppose: 0 Abstain: 0 Not Present: 2

Committee Member	**Vote**
Barker	Support
Cameron-Banks	Not Present
Oh	Support
Patel	Support
Sanchez	Not Present
Serpa	Support

IV. Presentation on USP General Chapter 797, Regarding Pharmaceutical Compounding – Sterile Preparations

Chairperson Serpa introduced Supervising Inspector Christine Acosta who provide a presentation on the revised USP Chapter 797 related to Pharmaceutical Compounding – Sterile Preparations which become effective November 1, 2023.

Supervising Inspector Christine Acosta provided a presentation on USP General Chapter 797, Regarding Pharmaceutical Compounding – Sterile Preparations. Dr. Acosta provided a disclaimer regarding the opinions expressed in the presentation. Dr. Acosta provided an overview including Introduction and Scope; Personnel Training and Evaluation; Personal Hygiene and Garbing; Facility and Engineering Controls; Certification and Recertification; Microbiological Air and Surface Monitoring; Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA; Introducing Items into the SEC and PEC; Equipment, Supplies, and Components; Sterilization and Depyrogenation; Master Formulation and Compounding Records; Release Inspections and Testing; Labeling; Establishing Beyond-Use Dates; Use of Conventionally Manufactured Products as Components;

Use of CSPs as Components; Quality Assurance and Quality Control; CSP Handling, Storage, Packaging, Shipping and Transport; and Documentation.

Members were provided the opportunity to comment. Members thanked Dr. Acosta for the presentation.

Members of the public were provided the opportunity to comment in Sacramento and via WebEx. Comments were received via WebEx.

A commenter pointed out that as part of the new USP regarding demonstration of competency for garbing and hand hygiene, it stated that microbial identification of the colony performing unit (CFU) was not required for fingertip and thumb sampling in the new USP.

A representative of CPhA advised a letter was submitted with comments and wanted to see a focus on clarity and communication particularly the difference between guidelines and regulations. The representative cautioned pulling guidelines into regulations.

The Committee took a break from 10:17 a.m. to 10:30 a.m. Chairperson Serpa took roll call after the break. Members present included: Jig Patel, Licensee Member; Renee Barker, Licensee Member; Seung Oh, Licensee Member; and Maria Serpa; Licensing Member. A quorum was established.

V. Discussion and Consideration of Proposed Addition to Title 16, California Code of Regulations Section 1736 related to Sterile Preparation.

[Note: For the purposes of the minutes, the draft regulation text included for each section includes the draft language that was provided at the meeting with changes made during the meeting.]

Chairperson Serpa advised as the Committee continues the work reviewing the various USP chapters as well as current and proposed regulations that may be necessary to implement, clarify, or make more specific requirements related to those respective chapters, Dr. Serpa believed it was appropriate that any such regulations mirror the structure of the respective chapters. Dr. Serpa provided this meant the numbering format and section titles for proposed regulations would mirror the USP chapter. Dr. Serpa clarified the Committee's goal was not to re-iterate provisions of federal law or USP language but to clarify or make more specific the requirements. Dr. Serpa added if no clarification was needed or no additional requirements were necessary for public safety, there would be no additional language being proposed.

Chairperson Serpa reminded participants the Board is a consumer protection agency and as the Committee considered development of regulations, it would be through the lens of the Board's consumer protection mandate as the law makes clear whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. Dr. Serpa reminded participants this was a dynamic process and individuals will have opportunities to participate throughout the development and rulemaking process.

Chairperson Serpa provided licensees of the Board generally must comply with a myriad of state and federal laws and at times, a licensee may be so focused on a specific section of the law, that they may forget the larger picture and other provisions of law that may be relevant. Dr. Serpa noted this was seen in several areas of pharmacy practice, but it was quite pronounced in compounding.

Chairperson Serpa reminded participants of the excellent overview DCA Counsel Eileen Smiley provided during the January 2023 Committee meeting covering the requirements for authorized individuals to qualify for some exemptions to federal law under provisions of section 503A. Dr. Serpa advised the livestream of the meeting and the presentation slides were available on the Board's website and encouraged individuals interested in this area to watch the livestream recording available from the Board's website. Dr. Serpa added it was important to emphasize again. The Committee would not be looking to add to regulations requirements already laid out in the USP chapters or federal law. The Committee would generally be focused on detailing additional California state requirements related to the changes to the USP chapters. The Committee discussions would be dealing with the standard for compounding pharmacies and compounding pharmacists operating in compliance with the exemption in Section 503A of the federal Food Drug and Cosmetic Act and not with 503B or outsourcing facilities.

Chairperson Serpa advised Section 503A was quite extensive but highlighted that one of the specific conditions a licensee must meet to be eligible for the exemptions provided under 503A is that the drug product is compounded in compliance with USP chapters on pharmacy compounding. Dr. Serpa noted it was important that members and stakeholders understand for the discussion. Business and Professions Code (BPC) section 4126.8 explicitly states the Board has the authority to enforce any USP Chapters where incorporated by reference in Pharmacy Law and its regulations. Dr. Serpa added while the Board has the authority to also add additional requirements to USP language, it can't promulgate a lesser standard in its regulation. Dr. Serpa advised this was further emphasized in BPC section 4126.8. Dr. Serpa noted based on the written comments received in advance of the meeting, Dr. Serpa believed there may be some misunderstanding and thought it appropriate to do some level setting at the front end of the discussion.

Chairperson Serpa ensured Members received all of the written comments received in advance of the meeting. Dr. Serpa thanked all of the individuals that submitted comments in advance of the meeting. Dr. Serpa provided as a result of the comments submitted and as various sections are considered, Dr. Serpa would be recommending changes be made in part to address the issues addressed in the submitted comments. Dr. Serpa advised these were complex issues and having input from all stakeholders was extremely valuable in this process.

Chairperson Serpa advised the language can be refined as a result of the discussion with the understanding that any language amended would be reviewed by counsel. Dr. Serpa believed there were areas where a development of an FAQ may be appropriate to assist licensees and those areas would be identified. Dr. Serpa reminded participants there would be additional opportunities for the Board and the public to consider language and provide comments. Dr. Serpa noted new concepts may be discussed. Dr. Serpa provided Supervising Inspectors Acosta and Panella-Spangler were available to assist where technical input was required.

Members were provided the opportunity to ask questions; however, no questions were asked.

Chairperson Serpa advised the proposed change was to repeal current Article 7 and Sections 1751 – 1751.10 and to add new sections 1736 – 1736.21 to Article 4.5.

Chairperson Serpa advised proposed section 1736 includes definitions beyond those established in the USP Chapter. Dr. Serpa noted as the language had been publicly available for some time, Dr. Serpa would highlight a few items. Dr. Serpa advised similar to the proposed language in section 1735, the Board's definition of "essentially a copy of a commercially available drug product" incorporated a requirement for the deviation to produce a clinically significant difference in the patient. Dr. Serpa noted the proposed definition of designated person does not limit the types of individuals that may serve in such a capacity; however, it did make specific that where clinical judgement was necessary and the designated person was not a pharmacist, the PIC would review the practices that require professional judgement. Dr. Serpa noted some of the comments received specific to the definition of "essentially a copy" did not appear relevant to the regulation language under consideration as they were related to nonsterile compounded preparations. However, other comments offered appeared appropriate in lieu of the term "comparable." Dr. Serpa advised the language displayed included some updates to the language.

Chairperson Serpa advised there were a few comments regarding the proposed definition of the Certificate of Analysis (COA). Dr. Serpa added having considered all the comments received specific to the proposed definition, Dr. Serpa was the most comfortable with the language offered by Rick Rhoads and noted at her

request, the language being displayed incorporates some of the language change offered by Dr. Rhoads. Dr. Serpa provided the displayed language was offering updated definition of quality in response to the written comments received.

Chairperson Serpa noted that compounding was not defined in this section. Dr. Serpa provided this was an example where, it was recommended additional regulation was not necessary and the Board would rely solely on the definitions in federal law and USP. Dr. Serpa reminded federal law states that the definition of "compounding does not include mixing, reconstituting, or other such actions that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturers directions consistent with that labeling." Dr. Serpa referred to meeting materials where USP defines sterile compounding as combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance to create a sterile preparation.

Chairperson Serpa noted she was recommending that the definition of preparation be removed and was another change that was appropriate based on the review of the written comments received.

Chairperson Serpa believed that the proposed language in section 1736 as displayed provided was appropriate both legally and for consumer protection.

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

1736 Sterile Compounding Definitions
The definitions in in this section shall be applicable to this Article and supplement the definitions provided in USP Chapter 797.

(a) "Certificate of Analysis" (COA) means a document produced by the manufacturer or supplier that certifies the quality of the component and demonstrates that the component conforms to the defined specifications, ~~has been manufactured under recognized principles of current good manufacturing practices~~ and is suitable for use in pharmaceuticals and, if applicable, meets the requirements in USP. Where the COA is from the supplier, it must include the name of the manufacturer.

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

(c) "Designated person(s)" means one or more individuals assigned by the

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

(d) "Essentially a copy" of a commercially available drug product means all preparations that include the same API(s) , as the commercially available drug products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a clinically significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.

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

(f) "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.

(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.

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

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

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

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

Members were provided the opportunity to comment.

Member Barker added a commented about the COA and recommended adding a sentence, "The COA means a document produced by the manufacturer that certifies the quality of the component and demonstrates that the component conforms to the defined specifications. For API, the COA also certifies the components…." Dr. Serpa noted staff would work with the attorneys to make sure it meets the intent of where the gap was identified.

Member Barker suggested updating to the designated person definition from "the" to "a."

Members of the public were provided the opportunity to comment at the Sacramento meeting location and WebEx. Comments were received from participants in Sacramento and via WebEx.

A compounding pharmacist noted his understanding of the regulation codifies a disallowance of compounding drugs that are on the FDA's category one bulk substance list. The compounding pharmacist was concerned about causing a lack of access and patient harm. The compounding pharmacist continued the FDA had allowed compounding of drugs on the list, evaluated drugs on the list and removed drugs that didn't have safety or clinical utility. The compounding pharmacist reported the FDA was currently deliberating on the list and would make final decisions in the coming years to add them to the "can compound" list or on category two which means compounding couldn't be done with that drug. The compounding pharmacist added that some may have heard that chemicals on this list are not USP monographed and are therefore putrid or contaminated but there hasn't been any evidence presented to the public to that fact. The compounding pharmacist noted most of these drugs have been included in the European and Japanese pharmacopoeia. The compounding pharmacist was only aware of contaminated glutathione that was compounded by a pharmacy and caused patient harm but noted the contaminant would have been caught if the pharmacy did endotoxin testing on the finished product which was currently required by pharmacy law. The compounding pharmacist cautioned if access would be removed, potential harm would have to be weighed and some of the drugs on the list were significant to patient health (e.g., Lupus patients, heavy metal toxicity for acute poisoning, etc.). The compounding pharmacist cautioned about removing bulk substances from ability to compound and care for patients. The compounding pharmacist stated people may hear that some medications are best

compounded by 503B pharmacies that have higher standards and noted with the new USP regulations those standards were becoming closer.

Chairperson Serpa reminded participants that the sections will be reviewed one at a time and comments should be limited to the section reviewed at the time.

A compounding pharmacist thanked the Committee for considering comments. The compounding pharmacist commented it was confusing when it stated the COA from the supplier must include the name of the manufacturer when included in BPC 4033, manufacturer already includes someone who repackages any drug or device. The compounding pharmacist added if an API was purchased from PCCA, they would not provide what company it was purchased from or the origin but based on BPC 4033, PCCA should be able to be the manufacturer. The compounding pharmacist noted it was more confusing to put supplier and manufacturer being required for a COA. The compounding pharmacist noted USP 797 makes a clear distinction between supplies and components. The compounding pharmacist asked if there was a reason it was different than the FDA's guideline already of what was essentially a copy. The compounding pharmacist stated as a licensee it was hard to go to two different sources to figure out what it was when it was clearly defined in the FDA guidelines. If the Board intended to go above the FDA guidelines, the compounding pharmacist recommended including only the information above the FDA guidelines.

Chairperson Serpa advised if something was included in the regulation, it was because it was different than USP and a higher standard. If it wasn't included in the Board's regulation, then the Board was using USP.

Chairperson Serpa asked Dr. Acosta to explain why the Board wanted the repackager or the manufacturer. Dr. Acosta clarified there was a different between "a manufacturer" and "the manufacturer" in that the FDA will register people as "a manufacturer" but that doesn't mean they are "the manufacturer" of the product. Dr. Acosta added the Board's draft language requires "the manufacturer" as the one that manufactured the product. Dr. Acosta continued a supplier may be registered with the FDA as a manufacturer but isn't the actual manufacturer of the product.

A representative of CSHP commented in keeping the amendment in there for the COA similar to CPhA. The representative stated the information should be able to be obtained from the wholesaler.

A pharmacist representative of Kaiser Permanente commented on item (c) regarding the definition of designated persons that the phrase "when the designated person isn't a pharmacist, the pharmacist-in-charge (PIC) must review all practices related to the operation of the facility that require professional

judgement" didn't provide the level of clarity needed for the regulated public. The representative recommended clarifying the requirement the specific practices that must be reviewed by the PIC if the designated person was not a pharmacist. The represented suggested a possible approach would be to reference BPC 4051 for practices that must be reviewed by a pharmacist or to have the licensee specify standard operating procedures (SOPs) the elements the professional judgement of a pharmacist was needed. The representative recommended the Board specify the nature of the record that was required to document the PIC's review of practices that require the professional judgment of a pharmacist.

A representative of the Alliance for Pharmacy Compounding (APC) commented in agreement that adding the supplier for the definition of COA made sense. The representative commented about "essentially a copy" including the word "comparable" noting the vague and subjective nature and agreed that it included the same API was an improvement and supported. The representative added with reference to "essentially a copy" definition referencing a commercially available drug, there was concern that it would include drugs compounded by outsourcing facilities under 503B and suggested "FDA approved" might be appropriate.

A representative of Baker Hostetler thanked the Committee for the clarification in the introduction noting this applied to 503A compounding and not 503B compounding or outsourcing facilities. The representative continued it was their understanding that Section 503A did not apply to compounding for animal patients and 503A compounding only applied to human drugs. The representative added for animal/veterinary compounding the FDA relies on GFI 256 which the FDA will begin to inspect for compliance in March 2023. The representative requested the Committee clarify the intent that animal or veterinary compounding was not subject to the proposed regulations as it conflicts with GFI 256.

Chairperson Serpa advised the Board of Pharmacy was looking at practices within pharmacies and if those pharmacies were doing veterinary compounding that was within the Board of Pharmacy's purview. Dr. Acosta added these regulations apply to human and veterinary products as there is no differentiating by patient population. Dr. Acosta noted the Board of Pharmacy was aware of GFI.

Chairperson Serpa summarized the tasks for the section to make additional changes to 1736 (a) COA to deal with the COA for media and supplies
1736 (c) change "the" to "a."

Chairperson Serpa referred to Section 1736.1 Sterile Compounding Scope. Dr. Serpa was comfortable with the language and appreciated the clarity being provided specifically on the immediate administration requirements that specified it shall only be done where failure to administer the preparation could result in loss of life or

intense suffering. Dr. Serpa believed this was an area where an FAQ was appropriate. Dr. Serpa provided as Board Members, they have reviewed enforcement cases where licensees were using the immediate use authorization as a standard of practice rather than for its intended purpose. Dr. Serpa continued the FAQ could include examples of the documentation required such as inclusion of the requirement for required information in the patient's chart. Dr. Serpa offered a slight modification to the language to make this concept clearer in response to comments received.

Chairperson Serpa highlighted that where appropriate the language proposed was consistent with the language included in the Board's proposed non-sterile compounding regulations. Dr. Serpa provided an example was section 1736.1(c) noting that an edit was necessary to update the language from a non-sterile preparation to reflect a sterile preparation. Dr. Serpa recommended a slight change to the language based on the written comments received.

Chairperson Serpa believed an FAQ was also appropriate for section 1736.1(d) as this was an area that arose in enforcement matters. Dr. Serpa agreed with the response to the written comments received which was included in (d)(2) and (d)(3).

1736.1 Sterile Compounding Scope.

This article applies to compounded sterile preparations (CSP)s as defined in United States Pharmacopeia (USP) General Chapter 797 (Chapter 797), titled *Pharmaceutical Compounding – Sterile Preparations*.

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

(b) CSPs for direct and immediate administration as provided in the Chapter shall only be done in those limited situations where the failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need. Documentation for each such CSP shall include identification of the CSP, compounded date and time, number of units, the patient's name and patient's unique identifier and the circumstance causing the immediate need and such documentation may be available in the patient's medical record.

(c) A limited quantity of CSP may be prepared and stored in advance of receipt of a patient specific prescription document where, and solely in such quantity, as is necessary to ensure continuity of care for individual patients of the pharmacy based on a documented history of prescriptions for those patient populations. This includes authority to prepare and furnish a limited quantity of

CSPs to veterinarians for office dispensing of not more than a 120-hour supply, solely to the prescriber's owner veterinary patients seen as part of regular treatment in the prescriber's office-, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing

(d) In addition to prohibitions established in federal law, no licensed pharmacy personnel shall compound a CSP that:

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

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

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

(1) by the prescribing practitioner,

(2) the compounding pharmacist, and

(3) the dispensing pharmacist(s).

(C) Documentation of (A) & (B) shall be maintained in a readily retrievable format.

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

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

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

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

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

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

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

Members were provided the opportunity to comment.

Member Barker commented on (c) that it was better but wondered if "types of patients" included a diagnosis. Dr. Serpa clarified it was to address the people receiving the drug. Dr. Acosta suggested adding "patient population."

Member Oh commented on (d) (1)(a) wanting to make sure people can compound that's not only on that list as things are so dynamic. Dr. Oh wanted to ensure people can compound if needed. Dr. Acosta advised there was not a drug shortage if a supplier or wholesaler didn't have the drug. Dr. Acosta added a drug shortage can be reported to ASHP and it can be added quickly to the ASHP list and the FDA list will have drugs added when the FDA deems necessary. Dr. Serpa noted because one supplier didn't have the drug it shouldn't an opportunity to compound. Dr. Oh noted it was not easy for pharmacies to find a new supplier. Dr. Acosta noted the pharmacy could send the patient to another pharmacy who could get the product. Dr. Serpa noted the balance was that the ASHP list was updated very quickly but by opening this up, it creates potential abuse that would be hard to control. Dr. Oh added a note of concern in causing delayed care and the Board was cautious in enforcing. Dr. Barker added in her experience the ASHP list was not very responsive and sometimes even reaching out beyond the contracted wholesaler, the product cannot be purchased. Dr. Barker added sometimes a product was removed from the list and still difficult to obtain and being able to pivot was a challenge. Dr. Acosta noted it takes time to prepare to compound. Dr. Serpa recommended having an FAQ with examples noting flexibility was important but needed to prevent abuse when there wasn't a true shortage.

Members of the public were provided the opportunity to comment at the Sacramento meeting location and WebEx. Comments were received from participants in Sacramento and via WebEx.

A compounding pharmacist appreciated the acceptance of many suggestions. The compounding pharmacist commented about (d)(3) a change was made to change to "non-sterile" component for which a conventionally manufactured sterile product is available and appropriate for the intended CSP. The compounding pharmacist noted there were situations where using sterile to sterile components was not preferred adding there were some stability issues that cannot be validated when you combine two sterile products and there may be stability indicating information or data already using a non-sterile ingredient to make a final product for a patient. The compounding pharmacist was concerned the determination of what was appropriate may not be in the hands of the compounding pharmacist but from someone looking in after the decision was made. The compounding pharmacist noted it was very broad stating if there was a commercially available sterile product that you can't use a non-sterile component

to make something similar. The compounding pharmacist added the intent may need to be drilled down to make it something that doesn't eliminate a lot of the sterile compounding done.

A representative of Sutter Health thanked the Committee for making changes as the items have been discussed in the health system and with compounding pharmacists. The representative commented on (b) agreeing an FAQ would benefit users and also pointed out that the situational requirement so restrictive to the verbiage provided did pose a challenge. The representative added in the past with this situational requirement of emergent need, it was not in the best interest of the public to be providing immediate UCSPs for routine care but the challenge identified was limiting it to only the scenario of loss in life and intense suffering rather than providing a little more clarification to the professional guidance or the pharmacist professional judgement to make a clear determination regarding risk versus benefit. The representative added this restricts the compounding pharmacist to document what a surgeon or nurse would be able to do without any other requirement. The representative stated pharmacy personnel maintain a higher level of ownership and competence in compounding and this shouldn't prohibit if a true need arises or a great risk or benefit is identified. The representative requested the FAQ be developed to be very clear noting pharmacists have decentralized and provided compounding in operating rooms, emergency departments and intensive care units when an immediate use CSP was necessary. The representative added it created ambiguity and confusion resulting in the loss of life or intense suffering.

A director of pharmacy of a rural hospital with Sutter Health commented on (b) regarding immediate use wondering what would be done in a rural hospital without resources nearby when the PEC stops working as equipment sometimes fail. The director of pharmacy added there needed to be a way to continue to care for patients who were acutely ill. Immediate use as currently defined will not allow for taking care of patients. The only option would be to close the hospital which wasn't an option or transferring to the nurses on the units who aren't required to follow the same regulations the pharmacists must follow. The director of pharmacy recommended striking the section as USP gives clear guidance and felt it was safe within USP parameters.

Chairperson Serpa advised equipment failure was discussed in another section. Dr. Acosta reminded (b) was already in the current pharmacy law as 1751.8(e).

A representative of Outsourcing Facility association (OFA), the 503B trade association, commented on (d)(1)(a) noting a contradiction with federal law and other California pharmacy policy aspects and current regulations. The representative stated federal law allows an outsourcing facility which California recognizes and permits specifically to compound drugs on the FDA drug shortage

list and the proposed (d)(1)(a) would allow compounding under a less robust quality standard that California and FDA have recognized USP standards are a lower standard than those utilized 503Bs which is CGMP. The representative added this would allow for 503As to compound an essential copy specifically at a lower standard for those on the ASHP list or the FDA list is actually more lenient and at a lower standard that what was currently allowed for 503Bs facilities. The representative noted it would allow for compounding of FDA drug shortages but also ASHP drug shortages which were also not recognized under federal law. The representative stated outsourcing facilities can't do it under current regulations. The representative had concern if added through regulation for the safety of California patients. If a pharmacy were to follow the proposed regulations, they would be in direct violation of federal law specifically section 503A of the federal Food, Drug and Cosmetic Act as well as final guidance put in place by FDA which don't recognize ability to compound an essential copy for the FDA and ASHP lists except for COVID limitations that will be ending with the public health emergency.

A representative of APC appreciated clarification that USP was a floor not ceiling and noted concerns with inconsistencies with USP, California regulations, federal laws/guidance that makes compliance difficult, limits patient access and jeopardizes patient safety in some cases. The representative commented on 1726.1 (c) regarding the system for compounding sterile preparations for veterinarians to dispense to animal patients doesn't align with now final GFI 256 on animal drug compounding of bulk substances. The representative stated the FDA's expressed intent to start enforcing on April 1, 2023, where GFI sets up the framework where substances can be nominated to the CBM for consideration on a positive list for office stock of bulk substances and once added to the list there was no 120-hour supply limitation or no distinction between sterile and non-sterile. The representative recommended aligning the regulations to GFI 256 where possible to increase compliance on veterinary compounding of bulk substances. The representative pointed out the inconsistency with current federal law but disagreed that the ASHP list would somehow be inappropriate as a carve out for essentially a copy. The representative added the current federal guidance on essentially a copy and shortages only references the FDA shortage list but believed the ASHP list was appropriate noting federal legislation pending to add it.

A pharmacist representative of Cedar Sinai commented on the section for immediate use that the concern the documentation could take away from patient care where no other health care professional was required to provide such documentation. The representative commented there were over 235 drugs recalled last year that impacted over 700 NCDs and agreed that the ASHP list wasn't always up to date. The representative appreciated an FAQ on the ASHP list as the hospital environment was dynamic. The representative stated based on the experience of the representative that most of the harm that occurred with 503B and added it wasn't accurate to say 503As perform at a lower standard. The

representative noted there was very little evidence of contamination coming out of health system pharmacies that provide high level of care but that contaminations are coming from larger 503B facilities based on the evidence and number of recalls as the hospitals have to react when they occur.

A commenter requested 1736.1 (c) should be "office" instead of "officer."

A representative of a smaller hospitals in California commented on the immediate use regulation and wanted to clarify it was part of the current USP 797 but the language "emergent or emergency requirements" was removed as USP felt it wasn't required. The representative agreed with previous commenters that at times PECs fail and the pharmacist has to figure out what to do but are afraid the Board will cite and fine them so they hand it to a nurse who doesn't have the training. The representative noted there needed to be provisions for allowance of immediate use to get outsourcing set up.

A compounding pharmacist thanked the Committee for harmonizing with USP and commented on (d)(b)(3) thinking it clarified the intent to say "non-sterile" but thought there could be unintentional consequences (e.g., more testing for stability studies, USP 51 testing for any multi-use product, etc.) so if there were commercially available products that were on the market that would be problematic for the products when the studies already exist. The compounding pharmacist noted there may not be compatibilities if there are different preservatives that are used. If one of the products was a commercially available sterile product but the other ones are not and they are non-sterile, the representative wasn't sure if it would really mitigate the risk. The representative's preference was to strike the whole item. The representative suggested saying "is made where all of the components are available commercially available in sterile products."

A pharmacist representative of Kaiser commented on the immediate use requirements appreciating the clarification of the required documentation associated with immediate use preparations may be present in the medical record; however, Kaiser continues to believe documentation for immediate use will almost certainly interfere with hospital pharmacist ability to provide timely patient care (e.g., code blue) and agreed more with the representative from Cedars Sinai that a pharmacist assisting with a code blue shouldn't be required to provide documentation as required by the proposed requirements. The representative noted USP 797 provides robust guidance on the preparation of immediate use CSPS. The representative understood current regulation in 1736.1 (b) had similar language and disagreed with the current regulation. The representative was not aware of any empirical evidence where immediate use compounding CSPS were used improperly and requested the Board share evidence with the regulated public. If not, the Board should follow its stated approach of only imposing additional requirements that are necessary for public safety and remove the

requirements for immediate use compounding from proposed regulations. The representative commented on (d)(3) regarding prohibitions on compounding and believed the changes made prior to the meeting removed the concern. The representative commented on (d)(4) regarding assuming the intent was for the requirement to apply to CSPS for which sterilization was required before use and suggested adding "when sterilization is required."

A representative of Baker Hostetler commented on (d)(2) because the Board expressed an intent to include animal compounding within the proposal, there was now additional text "unless allowable under AMDUCA" and proposed adding after that statement "or applicable FDA guidance on animal drug compounding" so that GFI 256 was incorporated.

A pharmacist at UCSF commented about (b) regarding the expanded language on documentation noting compounding was frequently needed in the emergency department in code situations agreeing with previous commenters that could cause a delay in patient care.

Chairperson Serpa summarized changes: in (c) change to "patient populations"; for the FAQs address some of the concerns in (d)(1)(a); and recommended for (d)(4) to add "when sterilization is required and cannot be done."

Members were provided the opportunity to comment.

Member Patel commented on (b) stakeholders talked about the time it would take, loss of productivity and could be detrimental to patient health and recommended removing the last sentence, modify the last sentence or reduce required documentation. Dr. Serpa stated this was current law and the number of units was added to the current language. Dr. Serpa explained this information was included in the code sheet that the pharmacist signs at the code. Dr. Acosta advised the information was already available and they attempted to use the documentation already available. Dr. Barker noted what was being discussed was what was required to be put on the label when handing to the code leader versus the final code documentation. The Committee decided to add this to an FAQ.

Chairperson Serpa referred to Section 1736.2 Personnel Training and Evaluation. Dr. Serpa believed the language as presented in the meeting materials was appropriate and consistent with the Board's consumer protection mandate. Ensuring appropriate training was vital to patient safety and the cross reference to the facilities Standard Operating Procedures (SOPs) ensures the issue was fully considered in the compounding operations.

Chairperson Serpa highlighted that as proposed, 1735.2(b) the language would allow for the aseptic qualifications from one premises could be used for another

premises under specified conditions. Dr. Serpa believed this was a big change from the Board's current regulation requirements. Dr. Serpa recommended some changes in response to the public comment received in subsections (b), (c) and (e).

Chairperson Serpa stated comments were received regarding the facility design. Dr. Serpa advised the goal of the language was to allow for competency from one site to transfer to a second site; however, the language may need further refinement to clarify. Dr. Serpa noted facility design was intended to refer to a design proposal or template not an exact architectural drawing to replicate and looked forward to stakeholder comment on how to make the language clearer.

1736.2 PERSONNEL TRAINING AND EVALUATION

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

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

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

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

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

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

CSPs due to poor practices. Aseptic manipulation ongoing training and competency procedures shall be defined in the facilities SOPs.

(d) Compounding personnel or persons with direct oversight over personnel performing compounding, verifying and/or handling CSPs who fail any aspect of aseptic manipulation evaluation shall not be involved in compounding or oversight of the preparation of a CSP until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs. A person with direct oversight over personnel who fails the evaluation, may continue to provide direct oversight for no more than two weeks until successfully passing.

(e) Any person assigned to provide the training specified in this section shall have demonstrated competency in the skills in which the person will provide training or observe and measure competency described in the facilities SOPs as referenced in section 1736.17. Documentation must be maintained demonstrating compliance.
Note: Authority cited: Sections 4001.1, 4005, 4126.8, 4127 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4114, 4115, 4127, 4301 and 4332 of the Business and Profession Code.

Members were provided an opportunity to comment. Dr. Oh commented the "identical" in (b)(2) would be a problem. Dr. Barker suggested changing to "sufficiently similar." The Committee further discussed and updated (b)(2) to read "The facility designs are sufficiently similar to accommodate the use of the same SOPs." Executive Officer Sodergren recommended staff work with the chair and counsel to wordsmith so that the Committee could focus on the policy.

Member Oh left the meeting at 12:08 p.m.

Members of the public were provided the opportunity to comment at the Sacramento meeting location and WebEx. Comments were received from participants in Sacramento and via WebEx.

A compounding pharmacist commented on (b) in favor of the concept.

A representative of Sutter Health commented in support of changes and the ability to utilize competency across facilities with similar options. The representative suggested for (b) adding an FAQ that the "PEC type and unique identifier" all relate to the PEC. The representative recommended using the same verbiage as USP for the facility design that are "of the same type of PEC and design and sufficiently similar." The representative commented on (c) that specific to the QA ongoing training and competency specific to identified gaps in procedures and SOPs shall occur each time a QA program yields an unacceptable. The representative commented on (d) the definition of "compounding personnel"

indicates all persons who have any part of the compounding process which could include all of the roles (e.g., compounding oversight, stocking and cleaning staff, etc.) which would apply aseptic manipulation and recommended changing to "all persons who compound" or remove and say prior to resuming.

Member Oh returned to the meeting at 12:11 p.m.

A commenter spoke in support of (b) permitting compounding to be performed from one license site to another based on criteria. The commenter recommended removing (2) if the intent is to differentiate the type of room as classified vs. non-classified and update (3) to include secondary engineering controls.

A commenter noted (b)(2) if the intent is the secondary engineering control unit should be similar and to specify it as well as saying SOPs are similar in nature surrounding personnel training and evaluation.

A pharmacist representative from Kaiser commented in support of the Board's portability of aseptic competency training and evaluation and requested the Board clarify two elements: 1)It was unclear why the unique identifier of a PEC or PECs used to perform validation must be recorded. The representative recommended removing the requirement or helping the regulated public understand justification. 2) While the term premises was ubiquitous in pharmacy law, the term is not defined in pharmacy law and requested the Board be clearer on the intent of the portability provision (e.g., aseptic qualifications from one licensed pharmacy may used for another licensed pharmacy if all required conditions were met.) and could be an FAQ. The representative echoed concerns on using "identical SOPs."

A compounding pharmacist commented on (d) regarding when a pharmacist fails aseptic manipulation evaluation on the media fill test. The compounding pharmacist noted a concern for pharmacies with 1-2 pharmacists, if a fingertip media test was failed, it would take two weeks to get the results. The compounding pharmacist recommended leeway if the pharmacist fails to have time to or have a pending results.

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

Member Barker commented on (d) regarding compounding personnel that USP requires media fill testing for compounder, designated person(s), personnel with direct oversight of compounding personnel where the proposed language defines it as all persons involved. If naming people, the designated person(s) needs to be added. Dr. Barker recommended removing handling CSPs. Dr. Barker agreed a pharmacist who was not a compounder if they fail the medial fill test, it seemed

stringent that they couldn't provide oversight as it can take up to 14 days to get the results and it is difficult to replace. Dr. Barker didn't see a patient safety issue if the pharmacist isn't compounding. If a pharmacist who was compounding failed the media fill test, the pharmacist shouldn't compound until they pass.

Chairperson Serpa agreed with the handling and noted it didn't specify media fill testing but competencies. Dr. Serpa agreed the definition of compounding personnel could be revised offline. Dr. Serpa felt strongly that oversight personnel should have competency. Dr. Acosta suggested allowing the oversight personnel to have pending results.

The Committee took a break from 12:28 p.m. to 1:15 p.m. Chairperson Serpa took roll call after the break. Members present included: Jig Patel, Licensee Member; Renee Barker, Licensee Member; Seung Oh, Licensee Member; and Maria Serpa; Licensing Member. A quorum was established.

Chairperson Serpa referred to section 1736.3 Personnel Hygiene and Garbing. Dr. Serpa believed the language included modification related to piercings consistent with written comments received. Dr. Serpa believed the language was appropriate and consistent with the Board's consumer protection mandate as personnel hygiene and garbing are core components to avoid contamination of a compounded preparation.

1736.3 PERSONNEL HYGIENE AND GARBING

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

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

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

(c) Personal protective equipment shall be donned 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 facility's SOP define specific processes that must be followed to prevent contamination.

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

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

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

Members were provided with the opportunity to comment.

Member Barker was concerned about the lack of direction for entering the compounding area. Dr. Acosta noted USP contained the minimum requirements. Dr. Serpa recommended adding an FAQ but not less than USP.

Member Patel inquired about religious accommodations for nose rings. Dr. Acosta noted the USP and pharmacy law have accommodations that need to be documented and records kept.

Members of the public were provided the opportunity to comment at the Sacramento meeting location and WebEx. Comments were received from participants in Sacramento and via WebEx.

A representative of Sutter Health commented on proposed (c) dividing the section into two sentences to prevent re-entry of garb that should have been doffed that has been exposed to unclassified spaces unless specified in SOPs.

A director of pharmacy of a rural Sutter Health hospital agreed with the previous commenter and suggested clarification that garb can't be removed outside of the ante area. Dr. Acosta added if it doesn't state where gowns should be doffed, they can be doffed anywhere and risk contamination.

A compounding pharmacist commented about (c) that doffing was more appropriate for HD. The risk of donning and doffing at the same time.

A pharmacist representative from Kaiser commented about no empirical evidence that donning and doffing shouldn't occur at the same place and requested

evidence from the Board prior to imposing additional requirements necessary for public safety.

Chairperson Serpa recommended removing "and removed" in (c). Members discussed language related to area. Executive Officer recommended focusing on policy as staff will need to work with counsel on wording.

Chairperson Serpa referenced section 1735.4 Facilities and Engineering Controls. Dr. Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. Dr. Serpa highlighted that the language was not mandating a use of interlocking doors that were currently used in facilities; however, where a pass-through was installed in a secondary engineering control after the effective date of the regulation, the doors must be interlocking. Dr. Serpa noted the language also explicitly stated that sterile preparations shall not be compounded if the compounding environment fails to meet legal requirements or the facilities SOPs. Dr. Serpa thanked the commenter that highlighted the typo in this section.

Chairperson Serpa clarified the written comment suggesting a pharmacy may be required to cease compounding if environmental issues arise. Dr. Serpa highlighted the language references the facilities SOPs to detail out the appropriate action that must be taken in each variable situation and when/if the compounding should cease.

1736.4 FACILITIES AND ENGINEERING CONTROLS

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

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

(b) If an SCA is used:

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

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

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

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

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

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

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

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

Members were provided with the opportunity to comment.

Member Oh clarified that the section was intending to state the pharmacy must cease compounding operations so it was clear as a policy. Dr. Serpa didn't think it was stating that as policy. Dr. Oh requested this be clarified with counsel.

Member Barker commented on (c)(1) changing "shall" to "to." Dr. Acosta suggested changing "shall" to "also."

Members of the public were provided the opportunity to comment at the Sacramento meeting location and WebEx. Comments were received from participants in Sacramento and via WebEx.

A representative of Sutter Health commented on (e) and believe there was an exception in (b) to see if it qualifies as an exception as there are some wall penetrations with passive controlled through HVAC and wanted to clarify. The representative mentioned in (f) it says "no CSP" was too restrictive and maybe needs to be a category. Dr. Serpa asked the representative to explain what would be a passive ceiling or wall penetration as she believed the intent would be not to allow it. The representative added there are ante room to buffer room to ante room non-HD passive walls that allow airflow but it was not something that the room is controlled with its pressures by that penetration. It was a fixed wall with a small vent. Dr. Acosta added (f) has been current law since 2017 and was not part of (d)

and meant to be its own subsection. Dr. Serpa understood some of the passive penetrations were to assist with some of the limitations found with their HVAC as a band-aid to fix the problem with the room.

A compounding pharmacist asked for clarification with the passive walls as the pharmacy was having a new clean room installed next week that was designed with a standard design; however, under the proposed regulations, it wouldn't be allowed.

A pharmacist representative of Nutrishare cautioned the Board about adding language as the duplicate to USP as USP changes verbiage and recommended referencing USP 797 with additional requirements. The pharmacist said the pass-throughs are designed with open aired pass-through chambers that was tested with USP and recommended the Board look at the systems to determine how those testings were done by those manufacturers of those types of clean rooms with open pass-throughs. The pharmacist said regarding (f) that was also in in 1751.4 and recommended referencing that section.

A pharmacist representative from Kaiser commented on (c)(1) related to the temperature requirements clarification was requested. USP 797 required compounding facilities be designed and controlled to provide a comfortable work environment and then recommend that the clean room suite should generally be maintained at a temperature of 20 degrees or cooler. Based on the text of the chapter compounding personnel comfort was the critical element and a temperature of 20 degrees or less was recommended but not required. The representative requested the Board clarify why it believes the 20 degree temperature must be maintained when that is not always consistent with employee comfort and is not a requirement of USP 797. The representative stated the phrase "shall typically be maintained at a temperature of 20 degrees Celsius or cooler" was ambiguous and requested what it meant for an area to be "typically maintained at 20 degrees Celsius?" The representative stated Kaiser's compounding subject matter experts believed clarity was needed on what areas this requirement applies. The representative suggested modifying one way to approach this might be to modify the definition of designated compounding area to use terms already defined in USP chapter that resolved potential confusion about which locations the temperature requirement applies. Related to (f), the representative asked if the intent was for the facility SOPs to drive when a facility would stop compounding based on a deviation in the compounding environment, then Kaiser respectfully requested the Board modify this section because that was not what (f) clearly stated.

Chairperson Serpa noted historically "typically" was used because temperatures vary and fluctuate. Dr. Acosta stated CCR 1751.4 (k) uses the verbiage "which typically includes a room temperature of 20 degrees or cooler."

A representative from CPS Solutions noted inspectors use enforcement discretion regarding temperature. The representative commented about (c)(1) revision uses the language "the clean room suite" instead of the proposed language of "designated compounding area" and asked if the "compounding area" presumably mean also a "segregated compounding area" or an "SCA" when in a lot of the smaller hospitals the SCA is part of the main pharmacy. To require 68 degrees or below, the whole pharmacy would be cold and it would lower the room temperature that will impact medications that must be stored at room temperature. The representative recommended changing "designated compounding area" to "clean room suite" to match 797 revision and leave the SCAs out of it. With regard to (f), the representative stated seeing smaller hospitals that needed to have the grate or the passive penetration and recommended having passive penetration between ISO controlled areas.

A pharmacist commented about (e) and asked for clarification or at least indication of penetrations or vents that allow the room to be air balanced but not to extend that venting or penetration to the outside air.

Chairperson Serpa reminded participants while it may seem like the words of USP 797 are repeated, it wasn't always a true repetition as one word changed may make the requirements higher in California. Dr. Serpa noted it was purposeful because one word could make a difference.

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

Chairperson Serpa referenced section 1736.5 Certification and Recertification. Dr. Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. Dr. Serpa noted as proposed, the language would incorporate the appropriate CETA standards similar to the Board's current requirement and was necessary as staff have identified as times that an unqualified individual performed the certification.

1736.5 CERTIFICATION AND RECERTIFICATION

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

(a) Testing and certification of all classified areas shall be completed by a qualified technician knowledgeable with certification methods and procedures outlined within the Controlled Environment Testing Association (CETA)'s Certification Guide for Sterile Compounding Facilities as specified in this section. Testing shall be performed in accordance with CETA Certification Guide for

Sterile Compounding Facilities (CAG-003-2006-13, Revised 2022), which is hereby incorporated by reference.

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

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

Members were provided an opportunity to comment.

Member Barker inquired if the citation in (b) should match the citation in 1736.6 (c). Dr. Acosta thought both citations would need to be changed to match the edition being used at the time.

Members of the public were provided the opportunity to comment at the Sacramento meeting location and WebEx; however, no comments were received from participants in Sacramento or via WebEx.

Chairperson Serpa referenced section 1736.6 Microbiological Air and Surface Monitoring. Dr. Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. The language included a cross reference to Controlled Environment Testing Association Certification Application Guide USP Chapter 797 Viable Environmental Sampling and Gowning which would again incorporate the CETA guideline by reference in the regulation. The language would also establish a minimum requirement to trend for growth microorganisms. Dr. Serpa believed this was so important noting while growth can occur, if the root cause was not identified, growth will continue until the issue is remediated. Dr. Serpa added this was an area she believed an FAQ may be helpful to licensees. Dr. Serpa appreciated the written comments received noting the updated language includes some recommended language provided in the written comments.

1736.6 MICROBIOLOGICAL AIR AND SURFACE MONITORING

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

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

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

(c) Environmental sampling shall be done in compliance with the most recent edition of the Controlled Environment Testing Association (CETA)'s Certification Application Guide USP <797> Viable Environmental Sampling & Gowning Evaluation (CAG-009, current version-20XX-XX, Revised October 2022), which is hereby incorporated by reference.

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

Members were provided an opportunity to comment.

Member Barker commented on (b) that it should state "genus level" rather than "genus species" and "regardless of action level" rather than "regardless on action level."

Members of the public were provided the opportunity to comment at the Sacramento meeting location and WebEx. Comments were received from participants in Sacramento and via WebEx.

A compounding pharmacist recommended the last sentence of (b) be reworded to state "if the deviation is identified." to help the licensee better understand the intent.

A representative of Nutrishare commented regarding this section and 1736.2, according to USP microbial identification of the colony forming units (CFUs) was not required for a large fingertip and thumb sampling. The representative wanted to confirm with the Board that the language was correct and the Board didn't want to include that as part of either section.

A pharmacist representative of Kaiser commented on (b) regarding to speciating microorganism recovered, USP does not require identification of microorganisms when less than the action level but it does require trending over time regardless of action level. The representative stated the compounding subject matter experts do not believe identification regardless of the CFU count will enhance patient safety

and was an unnecessary requirement. The representative recommended removal and referral to USP 797.

A pharmacist from UCSD Health agreed in following USP 797 ISO 7 and 8 areas were allowed to have some viable particles and was too burdensome to require identification of all microorganisms.

A pharmacist requested a point of clarification would help if understanding correctly that both air and surface sampling must occur every six months and any microorganism recovered shall be identified. The pharmacist thought what was intended was every six months regardless of whether you have an action level or meaning at least once every six months you have to identify the microorganisms but not every time you sample.

Chairperson Serpa confirmed that was the intent.

A pharmacist from UCSF agreed with other commenters' feedback about identifying to a single CFU but thought the language added it was clear the intent was every six months and during that every six months then adaptation CFUs require was reasonable. The commenter was concerned with overwhelming the lab.

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

Chairperson Serpa referenced section 1736.7 Cleaning, Disinfecting and Applying Sporicidal Agents in Compounding Areas and Sterile 70% IPA. Dr. Serpa noted as proposed the current section would be repealed and a new section added. Dr. Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. Dr. Serpa noted that as proposed the language would explicitly state that cleaning, disinfecting and sporicidal agents must be used in accordance with manufacturer's specifications. It was Dr. Serpa's understanding that regrettably this was not always the case based on inspection findings. Dr. Serpa added in response to one of the written comments about reusable cleaning supplies, a change was offered that was believed to strike a balance.

1736.7 CLEANING, DISINFECTING, AND APPLYING SPORICIDAL AGENTS IN COMPOUNDING AREAS AND STERILE 70% IPA

The requirements of this section apply to performing sterile compounding 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 not for use in the PEC shall not be stored within 1 meter of the PEC.

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

Members were provided the opportunity to comment.

Member Barker requested consistency in the title capitalization.

Members of the public were provided the opportunity to comment at the Sacramento meeting location and WebEx. Comments were received from participants via WebEx.

A representative from Nutrishare requested clarification on storage within one meter of the PEC if that meant when sterile IPA was used in the ante-room but not in the sterile compounding surface that can't be stored within one meter of the PEC. The representative stated typically gloves and hands were cleansed before entering the hood. Dr. Acosta noted the regulations were written for a device you would put a sterile pad on when cleaning the hood and not sterile IPA used for hands or to wipe an item that goes into the hood. Dr. Serpa added the sterile IPA would be considered in use and not stored.

A pharmacist from UCSF was concerned about some cleaning agents in (b).

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

Chairperson Serpa referenced section 1736.8 Introducing Items Into the SEC and PEC. Dr. Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate noting that this section was an example of where it was proposed that the SOPs would need to include at a minimum, products to be used on any equipment. Dr. Serpa noted there was a separate section that provided more specificity on the full requirements for SOPs. Dr. Serpa noted after considering the written response to this section, Dr. Serpa didn't believe any changes were necessary.

1736.8 INTRODUCING ITEMS INTO THE SEC AND PEC

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

SOPs shall specify the process and products to be used on any equipment and other items entering from an unclassified area into the clean side of the 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.

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

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

Members of the public were provided the opportunity to comment at the Sacramento meeting location and WebEx; however, there were no comments.

Chairperson Serpa referenced section 1736.9 Equipment, Supplies and Components. Dr. Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. Similar with prior language considered, the proposed language again specified that equipment and supplies used to compound sterile preparations shall be used in accordance with manufacturers' specifications. Dr. Serpa noted there was a typo in section 1736.9(c). The language should reference any component used to compound a CSP and was corrected.

Dr. Serpa highlighted that the Board was explicitly stating that a certificate of analysis must include as part of the information, the grade of the material and the language regarding where the use of a bulk drug substance was allowed including a provision to allow for exemption from the provisions if authorized by a public health officer in an emergency use situation. Dr. Serpa believed this was an area where an FAQ would be beneficial to provide guidance to licensees in understanding the provisions and the interplay with federal law, USP requirements and the Board's regulations. Dr. Serpa added the language displayed included some changes based on the written comments received.

1736.9 EQUIPMENT, SUPPLIES, AND COMPONENTS

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

(a) All equipment and supplies used to compound CSP shall be used, in accordance with manufacturers' specifications and be of suitable composition such that the surfaces which contact components are not reactive or sorptive.

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

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

(d) All API and excipient components used to compound a CSP shall be manufactured by an FDA-registered facility and suitable for use in sterile pharmaceuticals. A Certificate of Analysis (COA) which includes the compendial name, the grade of the material, and the applicable compendial designations on the COA must be received and evaluated prior to use, unless components are commercially manufactured drug products.

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

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

Members were provided the opportunity to comment.

Member Barker commented in (b) "process cleaning" was missing "of" to read "process of cleaning."

Members of the public were provided the opportunity to comment at the Sacramento meeting location and WebEx. Comments were received from participants in Sacramento and via WebEx.

A representative from Sutter Health commented on (a) "are not reactive or sorptive" and greater specificity was warranted as some components may have reactivity absorption and are accounted for and mitigated. Dr. Serpa asked for an example. The representative provided a PVZC bag that was made of DEHP. Dr. Serpa added the IV bag would be part of the component. Dr. Acosta agreed the language was narrow in the vision and there were known items that need to be addressed.

A compounding pharmacist commented on (e) proposed adding substances that come from 503B facility as being substances being used in a compounded CSP and requested it be added. The compounding pharmacist tried to figure out who a public health official could be and asked who had the authority.

Dr. Acosta noted the 503B comment would be addressed in section 1736.16. Dr. Acosta added the public health official was added because the Board did have a public health official who had a product that was needed to be made that was not within any section. Dr. Acosta added it would be someone with the Department of Public Health that has prescribing authority. Dr. Serpa added the key word was "authorized" and provided an example of making medication for malaria for the CDC.

A compounding pharmacist commented on (e) and brought back the applicability of the FDA category one list which is their list of non-USP substances that were being evaluated for the availability to compound. The understanding of the FDA's guidance on this is they are allowed to compound with those until a final decision has been made by the FDA to establish as accepted to compound or not acceptable to compound. The compounding pharmacist requested the Board's position and asked the Board to consider a very substantial list of important medications some of which are lifesaving.

A pharmacist representative from Kaiser commented on (b) related to incubators using the same calibrated temperature monitoring device used for monitoring room temperature and asked the Board to modify the regulation to clarify that annual calibration may not be required if an alternative calibrated temperature monitoring device was being used to monitor and adjust temperature of the incubator. The representative commented on (c) related to storage and asked the Board how it intends to balance the proposed requirement for the compounding area to be maintained at a temperature of 20 degrees or less while room temperature was 20-25 degrees. The representative commented on (d) related to COA, USP 797 requires compounders to receive COA but only requires receipt and

evaluation of COA for components that cannot be obtained from an FDA registered facility. To receive and evaluate COAs for components that have been obtained from an FDA registered facility was burdensome and didn't enhance patient safety and requested it be deleted and revert to the USP 797 requirement.

A representative for APC commented on (d) related to the requirement that all components used to compound a CSP be manufactured by an FDA registered facility suitable for use in sterile pharmaceuticals fails to recognize that many APIs even those USP grade do not specify suitable for use in sterile pharmaceuticals only that they are suitable for manufacturering. There was concern that all APIs contain some level of impurities incipient that are not manufactured in FDA facility so that compliance with this section would require all components to come from an FDA registered facility becomes difficult and requested clarification. The representative commented on (e) of a concern that the regulation change would result in prohibition on compounding sterile products from bulk substances on the FDA's interim list while the substances are under review by the agency to determine if they should be included in the CFR on the list of bulk substances that can be used to compound. There was a concern that the proposal would eliminate patient access to several compounded drugs in California as FDA reviews those bulk substances including methylcobalamin and glutathione and was inconsistent with the vast majority of other state regulations and federal guidance on the bulk list that specifically authorizes compounding of those substances while they are under review on the category one list. The representative stated the list was created to avoid lapses in patient access to compound drugs prescribed by providers while FDA reviews those substances that can take months or years. By putting the substances on the list, they have been nominated with enough data for the agency to conduct the review and there's not an immediate patient safety risk associated with compounding. APC strongly recommended amending the proposal to allow compounding of sterile products on FDA's interim list to align with federal policy.

Members were provided the opportunity to comment.

Member Oh requested clarification of category one. Dr. Serpa stated the language says listed in CFR 21-1216.

Chairperson Serpa referenced section 1736.10 Sterilization and Depyrogenation. Dr. Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. Dr. Serpa noted references to various USP chapters including chapters related to Dry Heat Depyrogenation, Sterilizing Filtration of Liquids, Steam Sterilization by Direct Contact, and Sterilization of Compendial Articles. Dr. Serpa added this provides clarity to licensees that requirements established in these USP Chapters were applicable to compounding of sterile preparations. Dr. Serpa believed an FAQ would be helpful to highlight

federal 503A requirements related to end-to-end compounding and thanked the written commenter that identified the typo in subsection (f).

1736.10 STERILIZATION AND DEPYROGENATION

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

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

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

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

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

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

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

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

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

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

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

Chairperson Serpa referenced proposed language for section 1736.11 related to Master Formulation and Compounding Records. Chairperson Serpa believed the language as presented was appropriate and consistent with the Board's consumer

protection mandate noting similar to the proposed language for nonsterile compounded preparation, the language provides authority for the prescription document to serve as the master formula under specified conditions.

Chairperson Serpa believed FAQs were appropriate in this section to clarify that a master formula record must be prepared. Dr. Serpa added as proposed, the compounding record must be clear that all staff involved in the compounding must be documented. Dr. Serpa added an FAQ was appropriate to highlight to licensees the types of staff, including for example those involved in staging activities. Dr. Serpa noted in response to some written comment, the language offers some changes to the referenced source material. Dr. Serpa added that a public comment was submitted specifically related to (c)(3) to exempt documentation of compounding of some sterile products and noted that this issue has been raised over the years and has been considered by the Board on several occasions. Dr. Serpa didn't believe this was appropriate.

1736.11 MASTER FORMULATION AND COMPOUNDING RECORDS

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

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

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

(2) Instructions for handling the compounded drug preparation.

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

(c) A compounding record 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 manufacturer, lot number, and expiration date shall be recorded for each component for CSPs.

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

(5) The identity of each person performing the compounding and pharmacist verifying the final drug preparation

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

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

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

Members of the public were provided the opportunity to comment. Comments were received in Sacramento and via WebEx.

A pharmacist representative of Sutter Health commented on (c) in the first sentence that a single document may not be retrievable but is often in the EHR record and requested clarification. For (c)(1), the representative agreed with the time and date of the preparation and requested clarification it being a date only for the BUD might be good. For (c)(2), the representative commented on the assigned internal identification number shall be unique for each compounded drug preparation noting in current processes doing batch or lot type preparations where a unique number is assigned to the batch or lot and not each unique CSP.

Chairperson Serpa clarified each drug preparation would be the lot and not each individual unit.

A compounding pharmacist comment on (c)(2) agreeing with the Sutter Health representative requesting it be changed to "shall be unique for each compounding record" to help clarify for the licensees.

A pharmacist representative of Cedar Sinai commented on (c) requesting changing "single document" to "readily accessible document" as current health systems utilize electronic record keeping systems and software but it was not always feasible for the required elements of the electronic records to be pulled into a

single document. Regarding (c)(3), the current language in CCR 1735.3 does exempt healthcare facilities licensed under Health and Safety Code (HSC) section 1250 from the requirement of including the manufacture, lot number and expiration date of each component of a sterile compound. If the sterile compound is using a single log for administration for a patient in a health facility within 72 hours of administration. The representative requested the Board reconsider adding that exemption to the current proposed language to allow healthcare facilities licensed under HSC 1250 to be exempt from including these elements. Various technology and software were used to track the NDC that can be traced back to the lot and manufacturer of the medication.

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

Chairperson Serpa referenced section 1735.12 Release Inspections and Testing. Dr. Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. Dr. Serpa noted the proposed language includes cross reference to applicable USP Chapters. Dr. Serpa reported receiving comments regarding the need for endotoxin testing for limited BUD products prior to release. Dr. Serpa noted this was an interesting concept that balanced patient access with patient safety and would be interested in hearing additional comments in this area.

1736.12 RELEASE INSPECTIONS AND TESTING

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

(a) A pharmacist performing, or supervising compounding is responsible for the integrity, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, so long as the label instructions for storage and handling are followed after the preparation is received by the patient or patient's agent.

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

(c) Injectable CSP's made from nonsterile components regardless of Category, must be tested to ensure that they do not contain excessive bacterial endotoxins, as established in Chapter 85. Results must be reviewed and documented in the compounding record prior to release.

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

Members were provided the opportunity to comment.

Member Barker requested the title be added to USP Chapter 85.

Members of the public were provided the opportunity to comment. Comments were received in Sacramento and via WebEx.

A compounding pharmacist commented on (b) related to validation of alternative method and inquired who can do the validation and what makes it acceptable.

Supervising Inspector Panella-Spangler stated labs have a standard set of bacteria used for every single validation of the sterility test called method suitability and all that needs to be done is to get a method suitability for the exact formula.

A pharmacy director of a rural Sutter Health hospital commented on (a) related to the reference to patient or patient's agent is appropriate in many instances but pharmacists don't always deal with the patient or patient's agent and requested it be consistently applied and also evaluated for its applicability to all care settings.

A compounding pharmacist representing Hartley Medical commented on (c) requiring bacteria endotoxin testing for all CSPs regardless of the category. The compounding pharmacist felt that produces an unrealized burden for the health care provider but would also impact patient care. The compounding pharmacist stated the proposal was not consistent with the new USP which doesn't require endotoxin testing for category one. The compounding pharmacist provided a summary of his background and endotoxin testing noting in all of his career he hasn't observed endotoxins from non-sterile ingredients that were associated with sterile preparations and requested the Board reconsider regarding testing of category one when utilizing non-sterile ingredients.

A pharmacist from UCSF commented on (c) that the change would result in patient care delay and could take up to a week.

Chairperson Serpa requested the Dr. Acosta explain the two concepts mentioned in the written and verbal testimony. Dr. Acosta noted for the first concept, she was wondering what hospital was doing non-sterile to sterile compounding that the endotoxin testing would apply. Dr. Acosta questioned what product was being made in acute care setting that was non-sterile. Dr. Acosta noted for the second concept, it was being made in a category one facility where the chapter wouldn't

be required. Dr. Acosta noted in general when doing non-sterile to sterile compounding endotoxin testing was done in-house. The chapter does require for category two to extend BUD and sterility testing. Dr. Acosta noted the concern was for products made in a category one that may be inadvertently used on multiple patients without any sterility or endotoxin testing. Once the CSPs leave the pharmacy, there is no control of when they will be used or for how long they will be used. Dr. Acosta recalled endotoxins cause harm in one vial on eight patients in California.

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

The Committee took a break from 2:55 p.m. to 3:05 p.m. Chairperson Serpa took roll call after the break. Members present included: Jig Patel, Licensee Member; Renee Barker, Licensee Member; Seung Oh, Licensee Member; and Maria Serpa; Licensing Member. A quorum was established.

Chairperson Serpa referenced section 1736.13 Labeling. Dr. Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. Dr. Serpa noted the change being proposed in 1736.13(a) that provided greater flexibility on the label for an admix CSP solution. Dr. Serpa didn't believe written comments specific to this section was received.

1736.13 LABELING

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

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

(1) Route of intended administration, and

(2) For admixed CSP, the solution utilized, and

(3) Instructions for administration. For admixed CSP solutions, the rate of infusion, or range of rates of infusion, or the duration when the entire CSP shall be administered unless included in the patient chart record for an inpatient of a facility licensed pursuant to HSC 1250.

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

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

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

Members were provided the opportunity to comment.

Member Barker had concerns about (a)(3) regarding the instructions for administration about the rate of infusion, range of infusion, and rates of infusion duration because in Dr. Barker's experience the source of truth for the rate was the EHR and not on the label. Dr. Acosta explained it was changed based on feedback received on current law required the rate of infusion and was trying to allow for a range of rates (e.g., drip that tapers up/down based on BP). Dr. Serpa added the language was designed to cover the dynamic situation of an acute care patient. Member Patel inquired if the label could refer to the EHR. Dr. Serpa stated it only covered narrow portion of patients as not everyone was receiving sterile product was at an acute care or has an EHR. Mr. Patel suggested adding a safety range or max. Dr. Barker noted the "or" allows for different options.

Members of the public were provided the opportunity to comment. Comments were received in Sacramento and via WebEx.

A director of pharmacy at a rural Sutter Health hospital commented (a)(3) assumes all CSPs are administered at a certain rate where some are compounded at volume with different rate. The pharmacist stated it didn't allow for CSPs where administrative rate is not relative (e.g., IV push, irrigations, or filmic dosage forms, etc.). The pharmacist requested defining rate. The pharmacist suggested changing (a)(3) to "for admix IV infusions the rate will apply to that but nothing else." The pharmacist commented on (a)(4) and (b) requesting an exemption for HSC 1250 acute care hospitals.

A pharmacist representative of Sutter Health added if there was not an exemption regarding display of both the compounding and dispensing facility in USP it mentioned the requirement must be displayed in labeling if outside the health care system and so referencing the labeling requirement of USP could be a balance for the current language.

A representative of CPS Solutions commented in support of written comment from Cedars Sanai requesting an exemption to (b) for health facilities licensing under H&S section 1250.

A pharmacist representative of Kaiser commented in support of a change for (a)(3) to allow for the label to point to the EHR range of infusion.

A pharmacist representative of Cedar Sinai commented in support of adding to (a)(3) to reference the EHR and preferably revising "CSP solutions" to "CSP infusions." The representative reiterated written comment regarding (b) to be consistent with current regulations for hospitals licensed under H&S section 1250 when administered by a health care professional and not dispensed.

Chairperson Serpa had a question about (b). Dr. Acosta noted the difference was dispense versus administered. Dr. Serpa suggested adding to FAQ or rewording. Dr. Oh was in support of making it clearer. Dr. Serpa agreed to work offline to clarify the wording.

Chairperson Serpa referenced the comment regarding (a)(3) and proposed adding "or seeing patient chart record." Dr. Acosta noted the law applies to everyone and would have to have safeguards and may possibly used exemption for acute care hospitals licensed under H&S section 1250. Dr. Serpa suggested working on this and the word "admix CSP solutions."

Chairperson Serpa referenced to section 1736.14 Establishing Beyond-Use Dates. Dr. Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. Dr. Serpa noted the section emphasized some items that Dr. Serpa believed were common sense, but regrettably enforcement actions arise where a beyond-use date was established that was beyond that of one of the components used in the preparation.

Chairperson Serpa recommend FAQs for this section to clarify some of the USP Chapter requirements using a CSP as a component related to in-use time versus a BUD. An FAQ should also be developed to highlight to licensees the need to comply with sterility provisions as part of the considerations when establishing a BUD. Dr. Serpa noted that while USP provides a table for BUD establishment, for a specific CSP that table information may not be applicable. Dr. Serpa noted that written comment for this section was received regarding the meaning of the term data as in stability data; however, noted this was a common term and made no changes.

1736.14 ESTABLISHING BEYOND-USE DATES

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

(a) A CSP's beyond-use date (BUD) shall not exceed:
(1) The chemical and physical stability data of the active pharmaceutical ingredient and any added substances in the preparation,

(2) The compatibility of the container–closure system with the finished preparation (e.g., possible leaching, interactions, and storage conditions),

(3) The shortest remaining expiration date or BUD of any of the starting components except for pH-altering solutions.

(b) A CSP labeled with a BUD with only a date shall expire at midnight at that date.
(c) Prior to dispensing a CSP that requires sterility and endotoxin testing for BUD determination, test results shall be received. Results must be within acceptable limits. Test results must be retained as part of the compounding record.

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

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

Members of the public were provided the opportunity to comment. Comments were made via WebEx.

A representative from Nutrishare suggested adding date and time when shipping outside of California.

Chairperson Serpa referenced section 1736.15 Use of Conventionally Manufactured Products and Components. Dr. Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate.

1736.15. USE OF CONVENTIONALLY MANUFACTURED PRODUCTS AS COMPONENTS
The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) A single-dose container entered or punctured outside of an ISO Class 5 area, must be discarded immediately.

(b) A single-dose container entered or punctured inside of an ISO class 5 area must be discarded within 12 hours.

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

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

Members of the public were provided the opportunity to comment. Comments were made in Sacramento and via WebEx.

A pharmacist representative of Sutter Health commented on (b) noting USP states that the single dose entered or punctured may be used for up to 12 hours; this states it must be discarded within 12 hours. However, it doesn't state that it can be stored if stored under appropriate storage conditions.

A representative from CPS Solutions commented (b) was already in USP 797 and recommended discarding.

Chairperson Serpa asked the inspectors about change on storage location or changing "maybe" to "must." Dr. Acosta noted (b) was broadened from a single dose vial to single dose container. Neither the Board nor USP addressed the storage.

Chairperson Serpa referred to section 1736.16 Use of CSPs as Components. Dr. Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. This section provided clarity regarding the use of compounded stock solutions. Dr. Serpa thanked the commenter who caught the error in the language and noted the displayed language included the correction.

1736.16. USE OF CSPS AS COMPONENTS

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

(a) A compounded stock solution intended for use in a CSP must comply with all provisions of this article including Category 1, Category 2, or Category 3.
(b) Nothing in this section shall prohibit the use of a CSP obtained from a California Licensed Outsourcing Facility.

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

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

A compounding pharmacist thanked the Board for the clarification.

Members were provided an opportunity to comment after public comment; no additional comments were made.

Chairperson Serpa referred to section 1736.17 Standard Operating Procedures. Dr. Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. This section cross referenced the related USP Chapter 1163 Quality Assurance in Pharmaceutical Compounding and provides clarity and explicit requirements to licensees to allow for clear understanding of the Board's requirements. The language also explicitly provided that PIC was required to review SOPs on an annual basis and documentation of such review. The language explicitly stated that failure to follow SOPs is a basis for enforcement action.

1736.17 Standard Operating Procedures (SOPS)

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

(a) Standard operating procedures (SOPs) shall be followed and shall:
(1) Comply with USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding.
(2) In addition to the SOPs required in USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding, SOPs must also be developed to describe the following:
(A) Methods by which the supervising pharmacist will ensure the quality of compounded drug preparations.
(B) Procedures for handling, compounding, and disposal of infectious materials. The written policies and procedures shall describe the facility protocols for cleanups and spills in conformity with local health jurisdictional standards.
(C) The methods a pharmacist will use to determine and approve the ingredients and the compounding process for each preparation before compounding begins.
(b) The SOPs shall specify the steps to be taken if a classified area(s) fails to meet the specified ISO classification including the investigative and corrective actions, allowable activities, and retesting procedures.

(c) The SOPs shall be reviewed on an annual basis by the pharmacist-in-charge. Such review shall be documented by the pharmacist-in-charge consistent with the SOPs. The policies and procedures shall be updated to reflect changes to compounding processes, facility changes or other changes that impact the CSP. Such SOP changes shall be disseminated to the affected staff prior to implementation.

(d) Failure to follow written SOPs shall constitute a basis for enforcement action. Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

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

Members of the public were provided the opportunity to comment. Comments were made via WebEx.

A pharmacist representative of Kaiser raised a general concern in these sections and other sections regarding compliance with entirety of all USP chapters as incorporated by reference. The representative noted if elements of a chapter are needed for a licensed sterile compounding facility, the required elements should be incorporated rather than the entire chapter.

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

Member Oh left the meeting at 3:34 p.m.

Chairperson Serpa referenced 1736.18 Quality Assurance and Quality Control. Dr. Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. The proposed language included an explicit requirement for the PIC to review all complaints related to potential quality problems within 72 hours. This action would be in addition to other required actions established in state and federal law and detailed in USP. Dr. Serpa believed an FAQ was appropriate to highlight all of the different legal requirements surrounding product quality issues, for example, when a recall and adverse drug events must be conducted, notification timeframes, etc.

1736.18 QUALITY ASSURANCE AND QUALITY CONTROL

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

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

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

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

(b) Recalls and adverse reporting must be completed in compliance with relevant provisions of pharmacy law.

(c) In addition to subsection (b), all complaints related to a potential quality problem with a CSP and all adverse events shall be reviewed by the pharmacist-in-charge within 72 hours. Such review shall be documented and dated as defined in the SOPs.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8, 4127, 4127.2, and 4127.11, Business and Professions Code.

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

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

Chairperson Serpa referenced section 1736.19 CSP Handling, Storage, Packaging, Shipping and Transport. Dr. Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. This section emphasized some items that Dr. Serpa believed were common sense, such as a requirement that the packaging materials need to protect CSPs from damage, leakage, contamination, degradation, and absorption while preventing inadvertent exposure to transportation personnel. Dr. Serpa noted there was a typo in (b) that would be corrected.

1736.19 CSP HANDLING, STORAGE, PACKAGING, SHIPPING, AND TRANSPORT

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

(a) There shall be written procedures for qualification of storage, shipping containers and transportation of temperature sensitive CSPs to preserve quality standards for integrity, quality and labeled strength.

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

(c) A pharmacist compounding or supervising compounding, is responsible for the integrity, quality, and labeled strength of a CSP until the beyond-use date

indicated on the label so long as label instructions for storage and handling are followed after the preparation is received by the patient or patient's agent.

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

Members were provided the opportunity to comment

Member Oh returned to the meeting at 3:37 p.m.

Member Barker commented (c) required additional clarification. Dr. Acosta recommended changing to "a pharmacist compounding or overseeing compounding is responsible." Dr. Barker noted the second part at the end of (c) the "received" was not clear. Dr. Acosta clarified the intent was to be as long as the patient was following what it was labeled as, then it was good to use the BUD. Dr. Acosta continued the pharmacist should be responsible for the labeled BUD as long as the patient handled it according to the label. Dr. Serpa noted this could be fixed to be less complicated.

Members of the public were provided the opportunity to comment. Comments were received in Sacramento or via WebEx.

A pharmacist representative for Sutter Health commented on (c) regarding the reference use of patient/agent if applicable when dispensed to other health care workers/facilities and defining if those applications are applicable in those settings.

A pharmacist representative for Kaiser commented on (c) noting it was identical to 1736.12(a) and was curious if it needed to be present in both places. Dr. Acosta noted it was not needed in both places and it could be fixed.

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

Chairperson Serpa referenced section 1736.20 Documentation. Dr. Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. Dr. Serpa noted documentation was essential and appreciated the clarity being provided in the proposed language including a requirement for an audit trail of the revisions made.

1736.20 DOCUMENTATION

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

(a) Records shall be maintained as required by USP Chapter 797 or this article, in a readily retrievable form, for at least three years from the date the record was created or relied upon. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070.
(b) Records created shall be created and maintained in a manner to provide an audit trail for revisions and updates of each record document. Prior versions of each record must be maintained in a readily retrievable format and include the changes to the document, identification of individual who made the change, and the date of each change.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4081, 4105, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

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

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

Chairperson Serpa referenced section 1736.21 Compounding Allergenic Extracts. Dr. Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. Dr. Serpa noted that USP requirements related to compounding allergenic were far more specific in the new chapter.

1736.21 COMPOUNDING ALLERGENIC EXTRACTS

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

(a) Any allergenic extract compounding shall take place in a dedicated PEC. No other CSP may be made in this PEC.

(b) Compounding of allergenic extracts are limited to patient-specific prescriptions and the conditions limited to Category I and Category 2 CSPs as specified in USP 797.

(c) Any stock solution made shall comply with the requirements established in USP 51 and container closure integrity tests consistent with Chapter 1207. Compounding records are required for stock solutions.

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

Members were provided the opportunity to comment.

Member Barker requested the chapter name be added and the second "closure" could be removed.

Members of the public were provided the opportunity to comment. Comments were made in Sacramento and via WebEx.

A pharmacist representative of Sutter Health commented on (a) wanting to point out the allowance sounds to restrict the allowable ACA and suggested changing to a dedicated PEC or a dedicated allergenic extract compounding area. The pharmacist noted allergenic extracts are from FDA and sterilized and asked if there was a reason they had to have a dedicated area. Dr. Acosta added the intent was not to remove the allowance for it but the question would be do we want to allow it to be compounded not in a PEC. Dr. Serpa and Dr. Acosta agreed there were concerns about cross contamination. Members decided to think about it further.

A director of pharmacy at a rural Sutter Health hospital explained based on previous experience, it was well preserved and a PEC was not needed. As it gets diluted, the BUD gets shortened. The pharmacist agreed the Board may choose to leave it out but if kept, it should be changed to say that it must occur in ISO class 5 PEC or as USP requires in a dedicated allergenic extract compounding area (AECA).

A pharmacist from UCSF commented about (a) requesting to use the USP verbiage.

The Committee heard a comment from someone who couldn't speak for the comment and typed into the comment box read by the moderator "Being in agreement with sticking to what USP states AECA also allows for compounding of/for off-label use of sublingual immunotherapy slit in compounding pharmacies. The AECA is not to allow for other compounded preparations in the same space."

Chairperson Serpa thanked all for their participation in the discussions today. Dr. Serpa noted in addition to changes that were discussed today and given the significant changes today, with the Committee's agreement, Dr. Serpa would work with staff and counsel to finalize language. Dr. Serpa ensured she would be working with staff to ensure consistency between these proposed requirements and those in the proposed requirements for the compounding of nonsterile preparations,

radiopharmaceuticals, and hazardous drugs where appropriate. Dr. Serpa advised these changes would be completed prior to the Board's consideration of all of proposed regulations during the April 2023 Board Meeting. The Committee agreed.

VII. Future Committee Meeting Dates

Chairperson Serpa reminded the next meeting was scheduled April 13, 2023, at which time the Committee will review proposed changes to hazardous preparations. Dr. Serpa advised the meeting will be via WebEx.

VIII. Adjournment

The meeting adjourned at 3:58 p.m.