Title 16 Board of Pharmacy Proposed Regulations – Sterile Compounding

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Proposed Language	**Recommendations/Comments**
CCR 1736.2 Personnel Training and Evaluation. subsection (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 compounding drug preparations. 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 identical 3. The PECs are of the same type and sufficiently similar to accommodate the use of the same SOPs describing use and cleaning	**Rationale:** • The new USP 797-chapter requires a significant increase in the frequency of observation, garbing, glove finger testing, media fill and surface sampling. This coupled with the growth in census volumes, complexity of patient diseases requiring IV therapy[1] and the workforce challenges[2,3,] creates significant constraints for hospital pharmacies to complete competency training for each compounding site for all compounding personal. The inability to have staff perform compounding in another licensed site with identical SOPs and PECs would delay patient care and result in potential patient harm • Statement #2 indicating "Facility designs are identical" would further increase the requirements above and associated costs. It is rare and not common that the physical layout of clean rooms or segregated compounding areas are identical. If the intent of the Board is to differentiate the type of room (i.e classified vs non-classified) recommend removing #2 and update #3 to include Secondary Engineering Controls (SEC) are the same type to meet the intent of #2. **Recommendation:** *1. The SOPs are identical.* ~~*2. The facility designs are identical*~~ *3. The PECs and SECs are of the same type and sufficiently similar to accommodate the use of the same SOPs describing use and cleaning* References: 1. Drug Shortages List. American Society of Health-System Pharmacy. https://www.ashp.org/drug-shortages/current-shortages/drug-shortages-list?page=CurrentShortages. Accessed March 20, 2023. 2. Pharmacy technician shortage survey findings executive summary. American Society of Health-System Pharmacy. March 2020. Accessed March 20, 2023. 3. Hospitals Scramble as Pharmacy Technician Shortage Persists (ashp.org) https://www.ashp.org/News/2022/05/02/hospitals-scramble-as-pharmacy-technician-shortage-persists. Accessed March 20, 2023.

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CCR 1736.11 Master Formulation and Compounding Records. subsection (c)(3): The manufacturer, lot number, and expiration date shall be recorded for each component for CSPs.	**Rationale:** Current language in CCR 1735.3 states: (F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply. (i) Exempt from the requirements in this paragraph (1735.3(a)(2)(F)) are sterile preparations compounded in a single lot for administration within seventy-two (72) hours to a patient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for "Redispensed CSPs" found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference. **Recommendation:** Add back the language above: 1736.11 Master Formulation and Compounding Records, subsection (c)(3): ***The manufacturer, lot number, and expiration date shall be recorded for each component for CSPs.*** *(i) Exempt from the requirements in this paragraph are sterile preparations compounded in a single lot for administration within seventy-two (72) hours to a patient in a health care facility licensed under section 1250 of the Health and Safety Code.*
CCR 1736.1 Sterile Compounding Scope. Subsection (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.	**Rationale:** In the instance of a code blue in a hospital, the requirement for additional documentation goes against the very purpose of making a drip to prevent a loss of life. The burden of completing additional documentation while attempting to save a life, could work to the detriment of a patient in an emergent situation. We recommend the board to remove language requiring documentation due to patient safety concerns. **Recommendation:** ***1736.1 Sterile Compounding Scope. Subsection (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.*~~

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CCR 1736.1 Sterile Compounding Scope. Subsection (d) (1) (A): (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	**Rationale:** • The ASHP and FDA drug shortage lists do not always reflect real-time real time drug shortages. Health systems have monitoring strategies in place to track these drug shortages real-time from drug manufacturers or wholesalers before these shortage drugs get added to the ASHP and FDA drug shortage lists. **Recommendation:** Recommend the board to add language regarding recent drug shortages that may not be reflected on the ASHP and FDA lists to ensure that health systems are compliant with requirements. ***1736.1 Sterile Compounding Scope. Subsection (d) (1) (A):*** *(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, or recent drug shortage that has not been added to the aforementioned lists that are in short supply at the time of compounding and at the time of dispense, or*
CCR 1736.11 Master Formulation and Compounding Records subsection (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.	**Rationale:** • Current documentation practices in Health-System pharmacies include utilizing electronic record keeping systems/software. However, it is not always feasible for the required elements of the electronic records to be pulled from computer software on a single document. **Recommendation:** Recommend the Board of Pharmacy to consider removing the requirement of "single document" to readily retrievable document to satisfy the requirements of USP Chapter 797 ***CCR 1736.11 Master Formulation and Compounding Records subsection (c):*** *A compounding record shall be a readily-available ~~single~~ document. The document shall satisfy the requirements of USP Chapter 797, as well as the following:*

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CCR 1736.13 Labeling subsection (b): (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.	**Rationale:** Currently, a health facility, as defined in Section 1250 of the Health and Safety Codes, are exempt from patient centered label requirements. **Recommendations:** To be consistent with current regulations, recommend adding exemption language to the current proposed language for HSC 1250 (a) licensed facilities as the administration of compounded medications to patients are done by health care personnel authorized to administer medications and not dispensed for outpatient use. ***CCR 1736.13 Labeling subsection (b):*** *(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.* *(i) Exempt from this requirement are health facilities, as defined in Section 1250 of the Health and Safety Code, if the prescriptions are administered by a licensed health care professional. Prescriptions dispensed to a patient in a health facility that will not be administered by a licensed health care professional or that are provided to the patient upon discharge from the facility shall be subject to the requirements of this section and the regulations promulgated pursuant to subdivision (b).*