45-Day Comments

STATE OF CALIFORNIA GAVIN NEWSOM, *Governor*

DEPARTMENT OF INDUSTRIAL RELATIONS
Occupational Safety and Health Standards Board
2520 Venture Oaks Way, Suite 350
Sacramento, CA 95833
Tel: (916) 274-5721
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Via Electronic Submission May 30, 2024

Lori Martinez
Department of Consumer Affairs, Board of Pharmacy
2720 Gateway Oaks Dr., Ste 100
Sacramento, CA 95833

Re: NOTICE OF PROPOSED REGULATORY ACTION CONCERNING: Compounded Drug Products

Dear Ms. Martinez,

The Occupational Safety and Health Standards Board (OSHSB) appreciates the opportunity to comment on the proposed amendments to division 17 of title 16 of the California Code of Regulations (CCR) regarding Compounded Drug Products. The OSHSB is a seven-member body appointed by the Governor, vested with the authority to adopt, amend and repeal occupational safety and health standards for the state of California. The mission of the OSHSB is to promote, adopt, and maintain reasonable and enforceable standards that ensure a safe and healthful workplace for California workers. More information can be found here: https://www.dir.ca.gov/oshsb.

Because compounded drugs can pose a safety risk to workers, it is necessary that pharmacists and health care workers associated with hazardous drug handling be alerted to the safety and health risks associated with exposure to hazardous drugs. OSHSB hopes to raise awareness of the potential for Cal/OSHA regulations found in title 8 of the CCR to simultaneously apply to businesses regulated by the Board of Pharmacy. In an effort to avoid conflicts or inconsistencies, OSHSB suggests adding a note or reference to the proposed regulations, where applicable, making businesses aware of title 8 regulations that could apply to their workplace. Something similar to the following would suffice:

> Note: To ensure proper worker protections, additional safety and health requirements are included in title 8 of the California Code of Regulations.

Feel free to contact OSHSB if you have further questions.

Regards,

Amalia Neidhardt, MPH, CIH, CSP
Principal Safety Engineer

Occupational Safety and Health Standards Board
2520 Venture Oaks Way, Ste 350
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Department of Pharmacy Services

6/3/2024

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Attn: Lori Martinez

On behalf Cedars-Sinai Medical Center, we would like to provide comments and recommendations for consideration to the Board of Pharmacy (Board) for proposed amendments to Article 4.5, and additions of Articles 4.6, 4.7, and 4.8. on compounding regulations and hazardous medications. Attached is a summary for the committees review and consideration. We appreciate the opportunity provided by the Board.

Please contact me should you have any questions.
Sincerely,

Rita Shane, PharmD, FASHP, FCSHP
Vice President & Chief Pharmacy Officer
Rita.shane@cshs.org

Vipul Patel, Pharm.D,
Executive Director of Pharmacy
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Institution/Contact Name	**Cedars-Sinai Medical Center** Department of Pharmacy Services 310-423-5611 Rita Shane, PharmD, FASHP, FCSHP, Vice President & Chief Pharmacy Officer; rita.shane@cshs.org Vipul Patel, PharmD, Executive Director, Pharmacy & Oncology Services; Vipul.patel@cshs.org	
Section, Subdivision	**Proposed Language**	**Recommendation / Comment**
Non-Sterile Compounding		
CCR 1735.1 Introduction and Scope. Subsection (f) (1) (A):	(f) In addition to prohibitions and requirements for compounding established in federal law, no CNSP shall be prepared that: (1) Is essentially a copy of one or more commercially available drug products, unless: (A) the drug product appears in an American Society of Health-System Pharmacists (ASHP) or FDA Drug Shortages Database that are in short supply at the time of compounding and at the time of dispensing, or	**Rationale:** • The ASHP and FDA drug shortage lists do not always reflect real-time real time drug shortages. As an example, the 2023 Akorn recall was posted after the State Board notification of the company shut down which resulted in multiple drug shortages. (see attached) [1] Health systems have monitoring strategies in place to track these drug shortages real-time from drug manufacturers or wholesalers before these get added to the ASHP and FDA drug shortage lists. • Additionally, wholesalers themselves often run out of supply of critical medications (pre-shortage situations). Inability to procure medications or restrictions to compound in these events would have contribute to heightened risk and safety concerns for patients. With the growing number of medications going on shortage[2] and recent manufacturer bankruptcies (i.e. Akorn, Apotex) it is becoming more challenging for Health-Systems to obtain commercially available products. References:  FDA Akorn recall.pdf 1. 2. Drug Shortages Statistics - ASHP **Recommendation:** Recommend the board add language regarding recent drug shortages that may not be reflected on the ASHP and FDA lists or are unavailable from wholesalers. ***1735.1 Introduction and Scope. Subsection (f) (1) (A):*** ***(f) In addition to prohibitions and requirements for compounding established in federal law, no CNSP shall be prepared that:*** ***(1) Is essentially a copy of one or more commercially available drug products,***

		unless: *(A) that drug product is not available by the manufacturer or wholesaler, appears on an ASHP (American Society of Health- System Pharmacists), or FDA list of drugs at the time of compounding and at the time of dispense, or*
CCR 1735.7 Master Formulation and Compounding Records subsection (c):	(c) A compounding record (CR) shall be a single document developed in compliance with USP Chapter 795, and includes the following additional elements:	**Rationale:** Electronic record keeping systems/software that enable documentation compliance to the compounding record requirements do not always have reporting capabilities to list all the elements in a single document. To allow pharmacies to continue to use these systems/software to ensure compliance, recommend the board consider amending this section to make the allow pharmacies to make compounding records readily retrievable. **Recommendation:** Recommend the Board consider modify the language to: *(c) Compounding record requirements shall be readily retrievable to comply with USP Chapter 795 and includes the following additional elements:*
CCR 1735.7 Master Formulation and Compounding Records. subsection (c)(2):	(c)(3) The manufacturer, lot number, and expiration date for each component for the CSP.	**Rationale:** Current language in CCR 1735.3 below has a provision for CSPs compounded in health facilities to prevent delays in care to acutely ill patient, i.e. infections, cancer, critical care, etc. The current language 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:**

		To prevent delays in care to acutely ill patients, recommend the board consider including the same exemption language to the 1735.7 Master Formulation and Compounding Records, subsection (c)(2): *The manufacturer, lot number, and expiration date for each component.* *(i) Exempt from the requirements in this paragraph are non-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 1735.9 Labeling subsection (b):	(c) Any CNSP dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5.	**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 1735.9 Labeling subsection (c):*** *(c) Any CNSP dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5.* *(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.*
1735.12. Quality Assurance and Quality Control. Subsection (b)	(b) The Board shall be notified in writing within 72 hours of the facility's receipt of a complaint of a potential quality problem or the occurrence of an adverse drug event involving a CNSP.	**Rationale:** A requirement of 72 hours may not provide sufficient time for health-systems to investigate and notify the necessary regulatory bodies in cases where the problem occurs over the holiday weekend. **Recommendation** *(b) The Board shall be notified in writing within 3 business days ~~72 hours~~ of the facility's receipt of a complaint of a potential quality problem or the occurrence of an adverse drug event involving a CNSP.*
1735.12. Quality Assurance and Quality Control. Subsection (c)	(c) All complaints related to a potential quality problem with a CNSP and all adverse events shall be reviewed by the	**Rationale:** A requirement of 72 hours may not provide sufficient time for the pharmacist-in-charge to review the quality problem and adverse events if these occur over a holiday weekend

	pharmacist-in-charge within 72 hours of receipt of the complaint or occurrence of the adverse event. Such review shall be documented and dated as defined in the SOPs.	**Recommendation** *(c)All complaints related to a potential quality problem with a CNSP and all adverse events shall be reviewed by the pharmacist-in-charge within 3 business days ~~72 hours~~ of receipt of the complaint or occurrence of the adverse event. Such review shall be documented and dated as defined in the SOPs.*
Sterile Compounding		
CCR 1736.1 Introduction and Scope. Subsection (b):	(b) CSPs for direct and immediate administration as provided in the Chapter shall only be done in those limited situations where the failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need. Documentation for each such CSP shall include identification of the CSP, compounded date and time, number of units, the patient's name and patient's unique identifier and the circumstance causing the immediate need. Such documentation may be available in the patient's medical record and need not be redocumented by the compounding staff if already available.	**Rationale:** • In the instance of a patient emergency such as a code blue or a rapid resuscitation event in a hospital, the requirement for additional documentation will result in a delay in providing immediately needed medication to prevent loss of life. • Existing language could lead to significant unintended consequences such as organizational decisions to have nursing staff compound medications due to risk of delays in drug administration which could be life-threatening. **Recommendation:** We recommend the board consider removal of language requiring documentation due to patient safety concerns. ***1736.1 Sterile Compounding Scope. Subsection (b)*** *(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 patient harm ~~loss of life or intense suffering~~. Any such compounding shall be only in such quantity as is necessary to meet ~~the~~ immediate needs of patients ~~need.~~ ~~Documentation for each such CSP shall include identification of the CSP, compounded date and time, number of units, the patient's name and patient's unique identifier and the circumstance causing the immediate need. Such documentation may be available in the patient's medical record and need not be redocumented by the compounding staff if already available~~*
CCR 1736.1 Introduction and Scope. Subsection (e) (1) (A):	(e) In addition to prohibitions and requirements for compounding established in federal law, no CSP may be compounded that: (1) Is essentially a copy of one or more commercially available drug products, unless: (A) that drug product appears in an	**Rationale:** • The ASHP and FDA drug shortage lists do not always reflect real-time real time drug shortages. As an example, the 2023 Akorn recall was posted after the State Board notification of the company shut down which resulted in multiple drug shortages. (see attached) [1] 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.

	American Society of Health-System Pharmacists (ASHP) or FDA Drug Shortages Database that are in short supply at the time of compounding and at the time of dispensing, or	• Additionally, wholesalers themselves often run out of supply of critical medications (pre-shortage situations). Inability to procure medications or restrictions to compound in these events would have contribute to heightened risk and safety concerns for patients. With the growing number of medications going on shortage[2] and recent manufacturer bankruptcies (i.e. Akorn, Apotex) it is becoming more challenging for Health-Systems to obtain commercially available products. References:  FDA Akorn recall.pdf 1. 2. Drug Shortages Statistics - ASHP **Recommendation:** Recommend the board to add language regarding recent drug shortages that may not be reflected on the ASHP and FDA lists as well as unavailability from wholesalers to ensure that health systems are compliant with requirements. ***1736.1 Sterile Compounding Scope. Subsection (e) (1) (A):*** *(e) 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 is not available (cannot be purchased) by the manufacturer or wholesaler, appears on an ASHP (American Society of Health- System Pharmacists), or FDA list of drugs at the time of compounding ~~and at the time of dispense~~, or*
CCR 1736.2 Personnel Training and Evaluation. Subsection (d)	(d) Compounding personnel or persons with direct oversight over compounding personnel who fail any aspect of the aseptic manipulation ongoing training and competency evaluation shall not be involved in compounding or oversight of the preparation of a CSP until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs. A person	**Rationale:** Multiple factors can contribute to failure of staff in aseptic technique training and competency evaluation including environmental testing failure and engineering control failure. Prohibiting compounding personnel from compounding without an evaluation of contributing factors and timeframe would significantly disrupt patient treatment and jeopardize the ability of health-systems to provide CSPs for critically ill patients. **Recommendation:** Recommend adoption of facility's SOP for an action plan that specifies compounding personnel failing any aspect of aseptic manipulation ongoing

	with only direct oversight over personnel who fails any aspect of the aseptic manipulation ongoing training and competency evaluation may continue to provide only direct oversight for no more than 14 days after a failure of any aspect while applicable aseptic manipulation ongoing training and competency evaluation results are pending	training and competency evaluation. **Proposed Regulation Revision:** *(d) ~~Compounding personnel or persons with direct oversight over compounding personnel who fail any aspect of the aseptic manipulation ongoing training and competency evaluation shall not be involved in compounding or oversight of the preparation of a CSP until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs. A person with only direct oversight over personnel who fails any aspect of the aseptic manipulation ongoing training and competency evaluation may continue to provide only direct oversight for no more than 14 days after a failure of any aspect while applicable aseptic manipulation ongoing training and competency evaluation results are pending~~ Facility's SOP shall include an action plan addressing evaluation follow up and timeframe to mitigate risk when compounding personnel or persons with direct oversight over compounding fail any aspect of the aseptic manipulation ongoing training and competency evaluation.*
CCR. 1736.4 Facilities and Engineering Controls Subsection (c)	(c) Designated compounding area(s) shall typically be maintained at a temperature of 20° Celsius or cooler.	**Rationale:** The USP chapter 797 recommends rather than requires maintaining a temperature of 20° Celsius or cooler for staff comfort within the classified compounding areas where multiple layers of PPE are worn and states that classified compounding rooms and segregated compounding areas maintain room temperature medication which must be stored in temperatures defined in USP Chapter 659 as 20°–25° (68°–77° F). Requiring the temperature to be 20 degrees Celsius of lower is highly dependent on the health-systems' Heating, Ventilation, and Air Conditioning (HVAC) systems and may not always be feasible, especially in older buildings. In these situations, if the temperature is required, health-systems would not be able to compound CSPs for patients. **Recommendation:** Recommend this requirement be removed and pharmacies follow USP 797 standards for temperature requirement. Recommend the Board of Pharmacy to consider removing the requirement of CCR. 1736.4 subsection (c).
CCR 1736.6 Microbiological Air and Surface monitoring. Subsection (a)	(a) At a minimum of every 6 months, air and surface sampling results shall be identified to at least the genus level, regardless of the CFU count to trend for	**Rationale:** USP 797 recommends identifying sampling results on a genus level for actionable CFUs (CFUs exceeding action levels). Infection Control and current evidence does not support that trending genus level below actionable levels will

	growth of microorganisms. Investigation must be consistent with the deviation and must include evaluation of trends.	yield data that will reduce patient risks; however, this will result in increase in costs and workload. **Recommendation:** *(a) At a minimum every 6 months, air and surface sampling results shall be identified to at least the genus level, ~~regardless of~~ when the CFU count exceeds action level to trend for growth of microorganisms. Investigation must be consistent with the deviation and must include evaluation of trends.*
CCR 1736.11 Master Formulation and Compounding Records subsection (c):	(c) A compounding record (CR) shall be a single document. The document shall satisfy the requirements of USP Chapter 797, and also contain the following:	**Rationale:** Electronic record keeping systems/software that enable documentation compliance to the compounding record requirements do not always have reporting capabilities to list all the elements in a single document. To allow pharmacies to continue to use this systems/software to ensure compliance, recommend the board consider amending this section to make the allow pharmacies to make compounding records readily retrievable. **Recommendation:** Recommend the Board consider modify the language to: **Recommendation:** Recommend the Board consider modify the language to: *(c) Compounding record requirements shall be readily retrievable to comply with USP Chapter 797 and includes the following additional elements:*
CCR 1736.11 Master Formulation and Compounding Records. subsection (c)(3):	(c)(3) The manufacturer, lot number, and expiration date for each component for the CSP.	**Rationale:** Current language in CCR 1735.3 below has a provision for CSPs compounded in health facilities to prevent delays in care to acutely ill patient, i.e. infections, cancer, critical care, etc. The current language 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): *(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 1736.13 Labeling subsection (a):	(a) A CSP label shall include all of the following: (1) Route of intended administration; (2) The solution utilized, if applicable; (3) Instructions for administration; (A) For an admixed CSP, the rate of infusion, or range of rates of infusion as prescribed, or the duration for the entire CSP to be administered.	**Rationale:** Most health-systems utilize electronic health record (EHR) system which accurately provides the patient specific order rate, duration of infusion. Requiring a range of rates on the label could cause confusion and result in medication errors if nurses misinterpret the ranges. Rates are updated on an ongoing basis in response to changes in the patient's condition and the EHR is the source of truth for the current rate. The duration may not be specified at the time the CSP is initiated since duration will be based on the patient's response to therapy, e.g. blood pressure changes, determination of infection source, blood glucose, etc. Therefore, instructions for administration may reference the EHR when rate changes are anticipated. Additionally, due to changes in the patient's condition, the rate documented on the label may change by the time the CSP is hung on the pt **Recommendations:** Recommend updating the regulation to: *(a) A CSP label shall include all of the following and these can also be readily retrievable from the EHR:* *(1) Route of intended administration;* *(2) The solution utilized, if applicable;* *(3) Instructions for administration will include the rate and/or reference the EHR which serves as the source of truth for the rate of drug to be infused based on the patient's condition.* *(~~A) For an admixed CSP, the rate of infusion, or range of rates of infusion as prescribed, or the duration for the entire CSP to be administered.~~*
CCR. 1736.14 Establishing Beyond-Use Dates subsection (c)	(c) Prior to furnishing a CSP, the pharmacist performing or supervising sterile compounding is responsible for	**Rationale:** Per USP 797, endotoxin testing, and sterility testing are required to be completed in certain cases for category 2 or 3 CSPs.

	ensuring that sterility and endotoxin testing for BUD determination is performed and has received and reviewed the results. Results must be within acceptable USP limits. Test results must be retained as part of the compounding record.	**Recommendations:** To be consistent with the USP 797 recommendations, we recommend the following revision to this section: *(c) Prior to furnishing a CSP, the pharmacist performing or supervising sterile compounding is responsible for ensuring that sterility and endotoxin testing (when applicable) for BUD determination is performed and has received and reviewed the results.*
CCR. 1736.17 Standard Operating Procedures (SOPS) subsection (d)	(d) The SOPs shall specify the process and products to be used on any equipment and other items entering from an unclassified area into the clean side of the anteroom, entering a PEC and entering the SCA. These SOPs must define at a minimum what product is to be used, the dwell time required, and how dwell time will be monitored and documented.	**Rationale:** Pharmacist/Health-systems have SOPs that define the product used, dwell time (based on manufacturer data), and how staff are monitoring and observations to determine compliance. Requiring documentation for the frequency and quantity of items entering a sterile compounding area in hospital settings or PEC, will adds a significant burden to the workload of sterile compounding staff which could increase the risk of causing an error in compounding. **Recommendation:** *d) The SOPs shall specify the process and products to be used on any equipment and other items entering from an unclassified area into the clean side of the anteroom, entering a PEC and entering the SCA. These SOPs must define at a minimum what product is to be used, the dwell time required, and how dwell time will be monitored. ~~and documented.~~*
CCR. 1736.18 Quality Assurance and Quality Control subsection (c)	(c) In addition to subsection (b), all complaints made to the facility related to a potential quality problem with a CSP and all adverse events shall be reviewed by the pharmacist-in-charge within 72 hours of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs.	**Rationale:** A requirement of 72 hours may not provide sufficient time for health-systems to investigate and notify the necessary regulatory bodies in cases where it occurs over the holiday weekend. **Recommendation:** *(c) In addition to subsection (b), all complaints made to the facility related to a potential quality problem with a CSP and all adverse events shall be reviewed by the pharmacist-in-charge within 3 business days ~~72 hours~~ of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs.*
CCR 1736.21 Compounding Allergenic Extracts subsection (a)	(a) Any allergenic extract compounding shall take place in a dedicated PEC. No other CSP may be made in this PEC.	**Rationale:** USP 797 requires that allergenic extracts be compounded in either a 1) ISO Class 5 Primary Engineering Control chamber (PEC), or (2) in a dedicated Allergenic Extracts Compounding Area (AECA). To require a dedicated PEC for allergenic extracts may not be feasible for many organizations due to existing facility space constraints

		Recommendations: To be consistent with the new USP 797 guidance, recommend revising the language to allow the PEC to be used for other CSPs and not just allergenic extracts. ***CCR 1736.21 Compounding Allergenic Extracts subsection (a):*** *(a) Any allergenic extract compounding shall take place in either a dedicated Allergenic Extracts Compounding Area or a PEC. No other CSP may be made in this PEC at the same time allergenic extract compounding is occurring. Work surface of the PEC must be disinfected immediately after compounding.*
CCR 1736.21 Compounding Allergenic Extracts subsection (b)	(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 Chapter 797.	**Rationale:** USP 797 requires that allergenic extracts be compounded in either a 1) ISO Class 5 Primary Engineering Control chamber (PEC), or (2) in a dedicated Allergenic Extracts Compounding Area (AECA). Limiting allergen extract compounding conditions to category I or 2 will have a significant financial impact on health-systems to design and construct an SCA or a classified area for allergenic extract compounding. In addition, this proposed law creates an ambiguity if allergen extract compounding will have to follow the BUD of category 1 or 2 which would significantly reduce the BUD that is allowed by USP 797. **Recommendations:** Recommend the Board of Pharmacy clarify the intent of this requirement or to remove the requirement and to align with USP 797.
Hazardous drugs		
CCR 1737.2 List of Hazardous Drugs subsection (a) and (b) :	(a) The facility's list of HDs as required by USP Chapter 800 must be reviewed and approved by the designated person and the pharmacist-in-charge (PIC), professional director of a clinic, or designated representative-in-charge, as applicable. The designated person must be a single individual approved by the pharmacist-in-charge to be responsible and accountable for the performance and operation of the facility and personnel as related to the handling of hazardous drugs. The designated person shall not exceed	**Rationale:** Often times, the designated person may be the pharmacist-in-charge **Recommendation:** Recommend revising the language to allow the Pharmacist-in-charge or designated person to review and approve the facility's list of HDs annually. ***CCR 1737.2 List of Hazardous Drugs subsections:*** ***(a) The facility's list of HDs as required by USP Chapter 800 must be reviewed and approved by the designated person ~~and~~ or the pharmacist-in-charge (PIC), or professional director of a clinic, or designated representative-in-charge, as applicable. The designated person must be a single individual approved by the pharmacist-in-charge to be responsible and accountable for the performance***

	the scope of their issued license. When the designated person is not a pharmacist, the PIC must review all practices related to the operations of the facility that require the judgment of a pharmacist. Approval shall be documented at least every 12 months. (b) If an assessment of risk approach is taken as authorized in USP Chapter 800, it shall be approved by the designated person and the pharmacist-in-charge, professional director of a clinic, or designated representative-in-charge, as applicable.	***and operation of the facility and personnel as related to the handling of hazardous drugs. The designated person shall not exceed the scope of their issued license. When the designated person is not a pharmacist, the PIC must review all practices related to the operations of the facility that require the judgment of a pharmacist. Approval shall be documented at least every 12 months.*** *(b) If an assessment of risk approach is taken as authorized in USP Chapter 800, it shall be approved by the designated person ~~and~~ or the pharmacist-in-charge, or professional director of a clinic, or designated representative-in-charge, as applicable.*
CCR 1737.6 Environmental Quality and Control. Subsection (a)	(a) The SOPs of a premises where HDs are handled shall address environmental wipe sampling for HD surface residue, its frequency, areas of testing, levels of measurable contamination, and actions when those levels are exceeded.	**Rationale:** • USP 800 only recommends performing environmental wipe sampling for HD surface residue routinely. • Currently, there are currently no standards for acceptable limits for HD surface contamination.[1] • Requiring additional sampling would result in increased costs for testing without any concrete actionable limits. **Reference** 1. Connor et al. Surface wipe sampling for antineoplastic (chemotherapy) and other hazardous drug residue in healthcare settings: Methodology and recommendations. Journal of Occupational and Environmental Hygiene. **Recommendations**: Request the board to consider removing the section or revise language to “should” to be consistent with USP 800 Chapter based on the absence of published information on actionable limits of HD surface contamination ***CCR 1737.6 Environmental Quality and Control*** *a) The SOPs of a premises where HDs are handled ~~shall~~ should address environmental wipe sampling for HD surface residue, its frequency, areas of testing, levels of measurable contamination, and actions when those levels are exceeded.*
CCR 1737.7. Personal Protective Equipment (PPE), subsection (c).	(c) Outer gloves used for HD compounding shall be changed between each different HD preparation.	**Rationale:** USP 800 recommends chemotherapy gloves should be changed every 30minutes unless otherwise recommended by the manufacturer's documentation and must be changed

		when torn, punctured, or contaminated. 1737.7 (b) states: *The outer pair of gloves that meets the ASTM D-6978 standard chemotherapy gloves shall be changed every 30 minutes during HD compounding.* Requiring additional glove changes between each HD preparation adds significant burden to the workload of sterile compounding staff which could increase the risk of causing an error in compounding. **Recommendations**: Consider removing 1737.7 (c) requirement
CCR 1737.10. Receiving.	All HD APIs and antineoplastic HDs shall be shipped and received from the supplier in segregated impervious plastic and labeled "Hazardous Drugs" on the outside of the delivery container.	**Rationale:** Pharmacies/health-systems cannot control how HD APIs and antineoplastic HDs are shipped and is directly controlled by the distributing companies. Pharmacies/health-system have SOP's for receiving, handling and storage of HD medications including PPE requirements and assessment of damage or breakage. **Recommendations**: Consider removing this section.
CCR 1737.13 Compounding subsection (a):	(a) A disposable preparation mat shall be placed on the work surface of the C-PEC when compounding HD preparations. Where the compounding is a sterile preparation, the preparation mat shall be sterile. The preparation mat shall be changed immediately if a spill occurs, after each HD drug, and at the end of daily compounding activity.	**Rationale:** USP 800 language states that a plastic-backed preparation mat should be placed on the work surfaces of the C-PEC. The mat should be changed immediately if a spill occurs and regularly during use and should be discarded at the end of the daily compounding activity. This will result in additional process steps that could increase risk of errors and organizations will incur additional costs for replace mat after each HD prep. Additionally, CSTDs are used during compounding HD drugs to prevent spills and enhance worker protection. Revise language to be consistent with USP 800 requirements. **Recommendations**: Revise language to be consistent with USP 800 requirements: *(a) A disposable preparation mat ~~shall~~ should be placed on the work surface of the CPEC when compounding HD preparations. Where the compounding is a sterile preparation, the preparation mat shall be sterile. The preparation mat shall be changed immediately if a spill occurs, ~~after each HD drug~~, during decontamination between different HD, and at the end of daily compounding activity.*

CCR 1737.16. Spill Control	The premises shall maintain a list of properly trained and qualified personnel able to clean up an HD spill. An SOP shall outline how such a qualified person will be always available while HDs are handled.	**Rationale:** As required by USP 800, personnel are trained to handle HD, which includes cleaning up an HD spill, prior to handling HD. In large and multi-hospital health-systems, maintaining a list of all qualified personnel to attend an HD spill would be difficult. **Recommendations**: Recommend the following revision to the proposed regulation: *~~The premises shall maintain a list of properly trained and qualified personnel able to clean up an HD spill.~~ An SOP shall outline how such a qualified person to clean up an HD spill will be always available while HDs are handled.*
Radiopharmaceutical- Preparation, Compounding, Dispensing, and Repackaging		
CCR 1738.5. Facilities and Engineering Controls subsection (d) (3)	(3) Compounding shall not take place in the SRPA.	**Rationale:** Per USP 825, for compounding sterile radiopharmaceuticals, the ISO 5 PEC must be placed in a classified area. However, non-radiopharmaceutical sterile compounds were not applicable for this restriction in USP 825. Prohibiting all compounding at SRPA would have a significant impact in the workload on health-systems that does not have a dedicated classified room for radiopharmaceuticals as they would not be able to prepare any supportive meds that has an SRPA. **Recommendation** *(d) Radiopharmaceutical compounding shall not take place in the SRPA.*
CCR 1738.5. Facilities and Engineering Controls subsection (j)	(j) A dynamic airflow smoke pattern test must be performed initially and at least every 6 months for all classified spaces and equipment. All dynamic airflow smoke pattern tests shall be immediately retrievable during inspection. A copy of the test shall be provided to the Board's inspector if requested in accordance with the timeframes set forth in Section 4105 of the Business and Professions Code.	**Rationale:** USP 825 requires a visual smoke study for classified spaces if there are no low air returns. The proposed regulation is inconsistent with USP. Pharmacies shall conduct PEC dynamic airflow smoke pattern tests every 6 months, however to include classified space with low air returns results in unnecessary testing and cost burden for institutions. **Recommendation** Request clarification on the purpose of dynamic airflow smoke pattern test for all classified spaces. Recommend the BOP be consistent with USP 825 recommendations and remove this proposed subsection.
CCR 1738.6. Microbiological Air and Surface Monitoring subsection (b)	(b) In addition to the SOPs at a minimum every 6 months, air and surface sampling results shall be identified to at least the genus level, regardless of the colony	**Rationale:** USP 825 recommends identifying sampling results on a genus level for actionable CFUs (CFUs exceeding action levels). Infection Control and current evidence does not support that trending genus level below actionable levels will

	forming units (CFU) count, to trend for growth of microorganisms. Trends of microorganism growth must be identified and evaluated.	yield data that will reduce patient risks; however, this will result in increase in costs and workload. **Recommendation:** *(b) In addition to the SOPs at a minimum every 6 months, air and surface sampling results shall be identified to at least the genus level, ~~regardless of~~ when the colony forming units (CFU) count exceeds action level to trend for growth of microorganisms. Trends of microorganism growth must be identified and evaluated.*
CCR 1738.10. Preparation subsection (c)	(c) When preparing radiopharmaceuticals with minor deviations ("preparation with minor deviations" as defined in USP Chapter 825) an SOP shall at least define the circumstances that necessitated the deviation and all quality control testing requirements and limits. Such circumstances shall, at a minimum, include patient need or facts that support the deviation that maintains the appropriate quality and purity (radiochemical purity and radionuclidic purity) as specified in individual monographs, and other applicable parameters as clinically appropriate in the professional judgment of the pharmacist.	**Rationale:** The proposed language is inconsistent with USP 825 recommendations, will require health-systems to incorporate patient need which may not be pertinent information. **Recommendation:** *(c) When preparing radiopharmaceuticals with minor deviations ("preparation with minor deviations" as defined in USP Chapter 825) an SOP shall at least define the circumstances that necessitated the deviation and all quality control testing requirements and limits. Such circumstances shall, at a minimum, ~~include patient need or~~ facts that support the deviation that maintains the appropriate quality and purity (radiochemical purity and radionuclidic purity) as specified in individual monographs, and other applicable parameters as clinically appropriate in the professional judgment of the pharmacist.*
CCR 1738.14. Quality Assurance and Quality Control subsection (b)	(b) The board shall be notified in writing within 72 hours of a complaint involving a radiopharmaceutical. Recalls and adverse events must be reported to the Board and other agencies in compliance with relevant provisions of law.	**Rationale:** A requirement of 72 hours may not provide sufficient time for health-systems to investigate and notify the necessary regulatory bodies in cases where it occurs over the holiday weekend. **Recommendation:** *(b) The board shall be notified in writing within ~~72 hours~~ 3 business days of a complaint involving a radiopharmaceutical. Recalls and adverse events must be reported to the Board and other agencies in compliance with relevant provisions of law.*
CCR 1738.14. Quality Assurance and Quality	(c) In addition to subsection (b), all complaints related to a potential quality	**Rationale:** A requirement of 72 hours may not provide sufficient time for health-systems to

Control subsection (c)	problem with a radiopharmaceutical and all reported adverse events shall be reviewed by the pharmacist-in-charge within 72 hours of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs.	investigate and notify the necessary regulatory bodies in cases where it occurs over the holiday weekend. **Recommendation:** *(c) In addition to subsection (b), all complaints related to a potential quality problem with a radiopharmaceutical and all reported adverse events shall be reviewed by the pharmacist-in-charge within 3 business days ~~72 hours~~ of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs.*

June 3, 2024

Lori Martinez
Board of Pharmacy
2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833

Submitted via electronic mail to, Lori.Martinez@dca.ca.gov

SUBJECT: Board of Pharmacy Proposed Regulations: Amend title of Article 4.5 and Repeal sections 1735 through 1735.8 of Article 4.5, adopt new titles and sections 1735 through 1735.14 of Division 17 of Title 16 of the California Code of Regulations

Dear Ms. Martinez,

On behalf of more than 400 hospitals and health systems, the California Hospital Association (CHA) appreciates the opportunity to comment on the Board of Pharmacy's (BoP) proposed regulations for nonsterile compounding, sterile compounding, and hazardous drugs.

The BoP plays a key role in partnering with hospitals and their pharmacies to promote quality and safety for patients. Ensuring the safe distribution of medication to patients is a core function of pharmacy practice, and pharmacists are integral in preventing medication errors, ensuring safe drug interactions, and helping avert other adverse medication events for patients. By following laws and regulations, hospital pharmacies and their pharmacists contribute to building trust and confidence with patients, health care professionals, and regulatory bodies. Hospitals are deeply committed to patient safety and regulatory compliance and offer the following feedback for your consideration and action:

Lack of Necessity

Generally, these regulations will not meaningfully enhance protection of, or promote the health and safety of, Californians. Federal law already requires compounding of drug preparations to be consistent with standards in the current version of the United States Pharmacopeia (USP)-National Formulary.

The USP is an independent, scientific nonprofit organization focused on helping ensure a supply of safe, quality medicines. When developing compliance standards, the USP follows a deliberative and evidence-based process to determine when regulations are necessary before becoming legally recognized as the standard of practice. Each step undergoes rigorous scientific review, including input from experts, stakeholders, the public, industry, academia, and regulatory agencies. Input from these diverse perspectives informs regulation development and details legal recognition, conformance, testing practices, and terminology. USP scientists and experts have developed countless effective and evidence-

based regulatory standards, including those governing nonsterile compounding (USP 795), sterile compounding (USP 797), and hazardous drugs (USP 800).

USP standards are referenced in federal regulations enforced by the Food and Drug Administration (FDA), ensuring compliance with the Food, Drug, and Cosmetic Act. Violations of these federal rules could subject licensees to enforcement by the FDA or the U.S. Department of Justice. Hospitals and their pharmacies prioritize compliance with these rigorous requirements.

In addition to conforming with USP standards, hospitals are required to comply with a variety of other federal and state laws and regulations and undergo regular enforcement reviews to maintain their federal certification and state license to operate as hospitals.

Given the existing and extensive federal set of USP compliance standards — developed with scientific rigor, stakeholder input, legal recognition, and a commitment to public health and safety — the necessity and value of these proposed regulatory additions and amendments should be evaluated.

Additionally, the BoP has not provided substantial evidence that hospital pharmacies are failing to follow either the BoP's current regulations or the detailed federal USP standards. No evidence has been presented by the BoP suggesting systemic challenges or indicating patients have been placed in harm's way, or that hospital pharmacies are not meeting safety standards that might necessitate additional BoP regulations.

Duplicative and Resource-Intensive

A lack of high-quality empirical evidence supporting the need for additional regulations is likely to generate confusion and redundancy, and not accomplish, as stated in the Initial Statement of Reason, an "effective and less burdensome" process.

These duplicative regulations will divert patient care dollars from hospitals' finite resources, increase compliance confusion and uncertainty, reduce efficiency, and increase the risk of legal penalties. Striking a balance between necessary oversight and minimizing confusing and inefficient compliance standards is critical to foster a sustainable health care system for the needs of patients today and in the future.

Benefit and Cost Impact Is Unclear

While regulations are necessary for quality and safety, finding a balance between regulations and cost effectiveness remains a critical challenge in health care. In the past decade hospitals have expended millions of dollars to comply with the evidence-based USP standards. These proposed regulations will unnecessarily increase the costs and slow down the compounding process without evidence of the need to do so — at a time when hospitals are at once trying to hold health care cost growth in check and when nearly 50% are losing money every day in caring for patients.

The substantial cost of these proposed regulations on hospital pharmacies has not been articulated or recognized, and there has not been a comprehensive benefit-cost analysis to assess whether these regulations will achieve their intended goals without an undue impact on resources for patient care. For example, one hospital system in California has estimated, conservatively, the annual cost of compliance with these proposals would exceed $7 million annually in supply and labor costs alone.

The California Legislature and the California Department of Health Care Access and Information are working diligently to lower health care costs. Every additional requirement a hospital must fulfill raises costs, which runs counter to this shared goal. These considerations must be balanced when creating new regulations.

There is abundant and effective regulatory guidance provided by the USP and the BoP's proposed regulations would have too many unintended consequences to advance at this time and without a deeper analysis.

CHA appreciates the opportunity to discuss these perspectives. If you have questions, please contact me at slowe@calhospital.org or 916-240-8277.

Sincerely,

Sheree Lowe
Vice President, State Policy

california pharmacists association

Dear California State Board of Pharmacy,

06/03/24

I am writing to express CPhA's concerns regarding the proposed changes to the compounding regulations currently under consideration by the State Board. It is crucial to acknowledge the significant number of organizations and stakeholders providing input on this matter, reflecting the broad impact these changes will have across the healthcare sector.

While CPhA understands the intention behind increasing the number of steps and requirements involved in compounding, CPhA is concerned about the unintended consequences these changes may have, particularly in the context of current healthcare challenges.

1. **High Census with Increased Acuity of Hospital Patients**: Hospitals are experiencing high patient volumes and increased acuity levels, necessitating timely access to compounded medications. The proposed changes could lead to delays in compounding, adversely affecting patient care and outcomes.
2. **Technician Staffing Shortages**: The healthcare industry is currently grappling with a shortage of pharmacy technicians. Adding more steps and requirements to the compounding process will exacerbate this issue, potentially leading to further delays and increased workload on already overburdened staff.
3. **Record Drug Shortages**: Many essential medications are in short supply, and compounding is often a critical solution to address these shortages. Additional regulatory requirements could hinder the ability of pharmacies to quickly and efficiently compound needed medications, prolonging shortages and impacting patient care.
4. **Significant Increase in Sterile Compounding Requirements to Comply with USP 797**: Compliance with the updated USP 797 standards already imposes substantial demands on pharmacies. The proposed changes will add further complexity, increasing the risk of medication errors and harm due to the heightened procedural burden.

Considering these concerns, CPhA urges the State Board to carefully consider the input from the CHART group. It is vital to balance the need for stringent regulations with the practical realities of healthcare delivery. Streamlined and efficient compounding processes are essential to ensure patient safety and access to necessary medications.

CPhA appreciates your attention to these matters and look forward to your thoughtful consideration of the potential impacts on patient care.

Sincerely,

Sean Kim, PharmD

Senior Manager, Practice & Professional Development

California Pharmacists Association

June 3, 2024

Lori Martinez
2720 Gateway Oaks Drive Ste. 100
Sacramento, CA 95833
Email: PharmacyRulemaking@dca.ca.gov

RE: Compounding Regulations

Ms. Martinez:

On behalf of the California Society of Health-System Pharmacists (CSHP) and CSHP Health-System Leaders Council we are submitting comments to the draft Compounding Regulations making comments and recommendations to amend the proposed/drafted Compounding Regulations.

The comments and recommendations for the Draft Compounding Regulations are attached as a separate document to this cover letter titled “CSHP comments to Draft Compounding Regulations_06.03.2024”.

Sincerely,

Loriann De Martini, PharmD, MPH, BCGP
Chief Executive Officer
California Society of Health System Pharmacists

CSHP Public Comments on Proposed Compounding Regulations: June 3, 2024

Section, Subdivision	Proposed Language	Recommendation / Comment
Non-Sterile Compounding		
CCR 1735.1 Introduction and Scope. Subsection (f) (1) (A):	(f) In addition to prohibitions and requirements for compounding established in federal law, no CNSP shall be prepared that: (1) Is essentially a copy of one or more commercially available drug products, unless: (A) the drug product appears in an American Society of Health-System Pharmacists (ASHP) or FDA Drug Shortages Database that are in short supply at the time of compounding and at the time of dispensing, or	**Rationale:** • The ASHP and FDA drug shortage lists do not always reflect real-time real time drug shortages. As an example, the 2023 Akorn recall was posted after the State Board notification of the company shut down which resulted in multiple drug shortages. (see attached). [1] 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. • Additionally, wholesalers themselves often run out of supplies of critical medications (pre-shortage situations). Inability to procure medications or restrictions to compound in these events will contribute to heightened risk and safety concerns for patients. With the growing number of medications going on shortage[2] and recent manufacturer bankruptcies (i.e. Akorn, Apotex) it is becoming more challenging for Health-Systems to obtain commercially available products. • By prohibiting the practice, the Board would impose a burden on licensees and negatively affect patient outcomes in instances when a drug is not available within the institution yet there is an urgent clinical need. For example, a hospitalized patient may need to continue their home therapy of an anti-epileptic drug clobazam. The patient has neurologic deficits and has impaired swallowing and unable to swallow tables whole. The prescriber orders to give the medication as a suspension by mouth. The suspension of clobazam, which is commercially available, is out of stock. Under this statute, the pharmacy would be prohibited from compounding the suspension, which could lead to interruption in care and negative outcomes (e.g., patient having a seizure). Please note this is not a case where the provider and pharmacist determine that the compounding produces a clinically significant difference for the medical need of a patient – it is a case when the commercially available drug product is not readily available for reasons other than a shortage. • This proposed regulation has the potential dramatically impact public heath by disabling health system pharmacies in their efforts to provide life-saving medications to acutely ill patients during the scenarios above. We ask that the Board provide avenues for hospital and health system pharmacies to

		continue to provide adequate care during the scenarios pointed out above the via regulation change proposed below. References:  FDA Akorn recall.pdf 1. 2. Drug Shortages Statistics - ASHP **Recommendation:** Recommend the board to add language regarding recent drug shortages that may not be reflected on the ASHP and FDA lists as well as unavailability from wholesalers to ensure that health systems are compliant with requirements, and make changes as noted below: ***1735.1 Introduction and Scope. Subsection (f) (1) (A):*** *(f) In addition to prohibitions and requirements for compounding established in federal law, no CNSP ~~shall~~ should be prepared that:* *(1) Is essentially a copy of one or more commercially available drug products, unless:* *(A) that drug product is not available by the manufacturer or wholesaler, appears on an ASHP (American Society of Health- System Pharmacists), or FDA list of drugs at the time of compounding and at the time of dispense, or*
CCR 1735.1 Introduction and Scope. Subsection (h):	(h) In addition to the provisions provided in section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning proper use, storage, handling, and disposal of the CNSP and related supplies furnished.	**Rationale:** Section 1707.2 (b)(2) does not require consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, however there are outpatient ambulatory infusions centers where CNSP is being administered by a healthcare professional. **Recommendation:** Would recommend the BOP to provide clarification for CCR 1735.1 in alignment with 1707.2(b)(2), and state that the regulation does not apply to CNSPs administered and dispensed to patients by a healthcare professional. **Proposed Exemption Language**: *A pharmacist is not required by this subsection to provide consultation to a patient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code or where the compounded product will be administered by a licensed healthcare*

		professional, except upon the patient's discharge with the compounded product.
CCR 1735.7 Master Formulation and Compounding Records subsection (c):	(c) A compounding record (CR) shall be a single document developed in compliance with USP Chapter 795, and includes the following additional elements:	**Rationale:** Current documentation practices in Health-System pharmacies include utilizing electronic record keeping systems/software. While all the required record keeping information is stored electronically, the ability to re-produce a single document can be challenging. It must be noted though that the information can be produced reliably which can be used in the instance should a recall be required. It is presumed that this requirement is designed for patient safety and we note that the patient safety requirement is adequately met if records containing the required elements of the record keeping can be utilized for recalls and related investigations. **Recommendation:** We 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. *(c) Compounding record requirements shall be readily retrievable to comply with USP Chapter 795 and includes the following additional elements:*
CCR 1735.7 Master Formulation and Compounding Records. subsection (c)(2):	(c)(3) The manufacturer, lot number, and expiration date for each component for the CSP.	**Rationale:** Current language in CCR 1735.3 below has a provision for CSPs compounded in health facilities to prevent delays in care to acutely ill patient, i.e. infections, cancer, critical care, etc. The current language 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:**

		To prevent delays in care to acutely ill patients, we recommend the board consider including the same exemption language to the 1735.7 Master Formulation and Compounding Records, subsection (c)(2): *The manufacturer, lot number, and expiration date for each component.* *(i) Exempt from the requirements in this paragraph are non-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 1735.9 Labeling subsection (b):	(c) Any CNSP dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5.	**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 1735.9 Labeling subsection (c):*** *(c) Any CNSP dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5.* *(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.*
1735.12. Quality Assurance and Quality Control. Subsection (b)	(b) The Board shall be notified in writing within 72 hours of the facility's receipt of a complaint of a potential quality problem or the occurrence of an adverse drug event involving a CNSP.	**Rationale:** A requirement of 72 hours may not provide sufficient time for health-systems to investigate and notify the necessary regulatory bodies in cases where it occurs over the holiday weekend. **Recommendation** *(b) The Board shall be notified in writing within 3 business days ~~72 hours~~ ~~of the facility's receipt of a complaint of a potential quality problem~~ after a potential quality problem is identified or the occurrence of an adverse drug event involving a CNSP.*
1735.12. Quality Assurance and Quality Control. Subsection (c)	(c) All complaints related to a potential quality problem with a CNSP and all adverse events shall be reviewed by the	**Rationale:**

	pharmacist-in-charge within 72 hours of receipt of the complaint or occurrence of the adverse event. Such review shall be documented and dated as defined in the SOPs.	A requirement of 72 hours may not provide sufficient time for health-systems to investigate and notify the necessary regulatory bodies in cases where it occurs over the holiday weekend. **Recommendation** *(c)All complaints related to a potential quality problem with a CNSP and all adverse events shall be reviewed by the pharmacist-in-charge, or licensed designee, within 3 business days ~~72 hours~~ of receipt of the complaint or occurrence of the adverse event. Such review shall be documented and dated as defined in the SOPs.*
Sterile Compounding		
CCR 1736.1 Introduction and Scope. Subsection (b):	(b) CSPs for direct and immediate administration as provided in the Chapter shall only be done in those limited situations where the failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need. Documentation for each such CSP shall include identification of the CSP, compounded date and time, number of units, the patient's name and patient's unique identifier and the circumstance causing the immediate need. Such documentation may be available in the patient's medical record and need not be redocumented by the compounding staff if already available.	**Rationale:** • It must be noted that the expert panel involved in the creation of the revised USP 797 received feedback nationally and recognized that the previous revision's requirement for emergency situations was inadequate in caring for patients. They acted and removed the emergency requirement for immediate use CSPs based on research evidence that has shown an observed lag phase of bacterial growth once the microorganism is introduced in a suitable growth medium. Allen et al illustrate a batch culture growth experiment where a small number of bacteria are inoculated into a well-shaken container filled with liquid nutrient medium. During the measurement time period, the density of bacteria is measured, and the results are plotted as a function of time. Bacterial growth is characterized by and initial period in which no growth is detected, known as the lag phase. This is followed by a period of exponential growth, known as the exponential phase. This is then followed by a slowing down and eventual cessation of net growth, known as the stationary phase. It is believed that the lag phase occurs because the bacteria need time to adjust to the liquid medium after having been stored under different conditions. Similarly, it is thought that the stationary phase occurs when the population exhausts its nutrient supply or builds up waste products. ***Reference**: Allen RJ Waclaw B. Bacterial Growth As a Statistical Physicist's Guide. Rep Prog Phys. 2019;82(1):016601* **Concern 1:** 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. It must be noted that there are differences in pharmacist practices and code blue

		team expectations across different hospitals and health systems. In one instance the pharmacist may have a supportive role and only hand over medications during a code blue, in another setting pharmacists may have high engagement and assist with chest compressions. It is unreasonable to expect a pharmacist to perform the additional documentations required in this proposed regulation while a life is in peril. While patient safety is always important and we wholeheartedly agree that high standards are needed to assist in keeping patients safe, this proposed rule will be a barrier for pharmacists who are assisting in code blue teams. • We recommend the board to remove language requiring documentation due to patient safety concerns. **Concern 2:** Additionally, this section, seen in the context of 1736.4 (f) which specifies that *'no CSP shall be compounded if the compounding environment fails to meet criteria specified in the law or the facilities SOPs,'* has a significant potential to limit access to life saving medications for patients in hospitals. For example, if the PEC malfunctions in a rural hospital, the pharmacy will not be able to prepare CSP's with an immediate use BUD and the hospital will be unable to care for acutely ill patients. The hospital may be forced to close the hospital and emergently transfer patients out or turn to nursing staff to compounding medications on care units which can lead to a safety risk as well as risk of medication errors. Additionally, consideration must be given that the state of California is prone to natural disasters such as fire storms, earthquakes and flooding which heightens the potential for engineering control failures even in the presence of redundant backup systems. Engineering control failures and malfunctions have been occurring in the state of California and the Board elected to discipline the licenses of pharmacies and licensed professionals for attempting to safely provide continuity of patient care by assigning immediate use beyond use dating to CSP's. • We ask that if the Board of Pharmacy wishes to keep this proposed regulation it must then proactively provide an avenue via regulation for pharmacies to have continuity of CSP compounding service during this scenario potentially dangerous situation.

		Recommendation: We recommend the board consider removal of language requiring documentation due to patient safety and public health concerns. ***1736.1 Sterile Compounding Scope. Subsection (b)*** ~~*(b) CSPs for direct and immediate administration as provided in the Chapter shall only be done in those limited situations where the failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need. Documentation for each such CSP shall include identification of the CSP, compounded date and time, number of units, the patient's name and patient's unique identifier and the circumstance causing the immediate need. Such documentation may be available in the patient's medical record and need not be redocumented by the compounding staff if already available.*~~
CCR 1736.1 Introduction and Scope. Subsection (e) (1) (A):	(e) In addition to prohibitions and requirements for compounding established in federal law, no CSP may be compounded that: (1) Is essentially a copy of one or more commercially available drug products, unless: (A) that drug product appears in an American Society of Health-System Pharmacists (ASHP) or FDA Drug Shortages Database that are in short supply at the time of compounding and at the time of dispensing, or	**Rationale:** • The ASHP and FDA drug shortage lists do not always reflect real-time real time drug shortages. As an example, the 2023 Akorn recall was posted after the State Board notification of the company shut down which resulted in multiple drug shortages. (see attached). 1 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. • Additionally, wholesalers themselves often run out of supplies of critical medications (pre-shortage situations). Inability to procure medications or restrictions to compound in these events will contribute to heightened risk and safety concerns for patients. With the growing number of medications going on shortage2 and recent manufacturer bankruptcies (i.e. Akorn, Apotex) it is becoming more challenging for Health-Systems to obtain commercially available products. • This proposed regulation has the potential dramatically impact public heath by disabling health system pharmacies in their efforts to provide life-saving medications to acutely ill patients during the scenarios above. We ask that the Board provide avenues for hospital and health system pharmacies to continue to provide adequate care during the scenarios pointed out above the via regulation change proposed below. References:

		 FDA Akorn recall.pdf 1. 2. Drug Shortages Statistics - ASHP **Recommendation:** Recommend the board to add language regarding recent drug shortages that may not be reflected on the ASHP and FDA lists as well as unavailability from wholesalers to ensure that health systems are compliant with requirements. ***1736.1 Sterile Compounding Scope. Subsection (e) (1) (A):*** *(e) 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 is not available (cannot be purchased) by the manufacturer or wholesaler, appears on an ASHP (American Society of Health- System Pharmacists), or FDA list of drugs at the time of compounding ~~and at the time of dispense~~, or*
CCR 1736.1 Introduction and Scope. Subsection (g):	(g) In addition to the provisions provided in Section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning proper use, storage, handling and disposal of the CSP and related supplies furnished	**Rationale:** Section 1707.2 (b)(2) does not require consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, however there are outpatient ambulatory infusions centers where CNSP is being administered by a healthcare professional. **Recommendation:** Would recommend the BOP to provide clarification for CCR 1736.1 in alignment with 1707.2(b)(2), and state that the regulation does not apply to CNSPs administered and dispensed to patients by a healthcare professional. **Proposed Exemption Language**: *(g) In addition to the provisions provided in Section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning proper use, storage, handling and disposal of the CSP and related supplies furnished* *(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.*
CCR 1736.1 Introduction and Scope. Subsection (h):	(h) CSPs with human whole blood or human whole blood derivatives shall be	**Rationale:** The current health and safety code section 1602.5 states the following:

	produced in compliance with Health and Safety Code section 1602.5.	(a) No person shall engage in the production of human whole blood or human whole blood derivatives unless the person is licensed under this chapter and the human whole blood or human whole blood derivative is collected, prepared, labeled, and stored in accordance with both of the following:" The proposed regulation in its current state would cause confusion as it would enforce a law that is not applicable to any human whole blood or human whole blood derivative that is already manufactured by a pharmaceutical company (e.g. Albumin, Factor products, IVIG etc.) **Recommendation:** Would recommend the board to revise the proposed language to provide clarification to state that the regulation does not apply to CSPs made with human blood/derivative that is manufactured by pharmaceutical companies. *(h) CSPs with patient's own whole blood or human whole blood derivatives from the patient shall be produced in compliance with Health and Safety Code section 1602.5.*
CCR 1736.2 Personnel Training and Evaluation. Subsection (b)	Initial and ongoing aseptic manipulation training and competency documentation shall include the Primary Engineering Control (PEC) type and PEC unique identifier used during the evaluation. Aseptic manipulation competency evaluation and requalification shall be performed using the same procedures, type of equipment, and materials used in aseptic compounding. Aseptic qualifications from one premises may be used for another premises if all of the following conditions are met: (1) The Standard Operating Procedures (SOPs) required by section 1736.17 related to compounding are identical. (2) The Secondary Engineering Control (SEC) facility designs are sufficiently similar to accommodate the use of the same SOPs.	**Rationale:** The current USP 797 chapter does not require the PEC unique identifier to be documented for personnel training. Requiring a PEC unique identifier only adds to the additional documentation burden. **Recommendation:** Recommend the Board of Pharmacy to consider removing the requirement of "PEC unique identifier" **Proposed Regulation Revision:** *Initial and ongoing aseptic manipulation training and competency documentation shall include the Primary Engineering Control (PEC) type ~~and PEC unique identifier~~ used during the evaluation.*

	(3) The PECs are of the same type and sufficiently similar to accommodate the use of the same SOPs describing use and cleaning.	
CCR 1736.2 Personnel Training and Evaluation. Subsection (d)	(d) Compounding personnel or persons with direct oversight over compounding personnel who fail any aspect of the aseptic manipulation ongoing training and competency evaluation shall not be involved in compounding or oversight of the preparation of a CSP until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs. A person with only direct oversight over personnel who fails any aspect of the aseptic manipulation ongoing training and competency evaluation may continue to provide only direct oversight for no more than 14 days after a failure of any aspect while applicable aseptic manipulation ongoing training and competency evaluation results are pending	**Rationale:** Multiple factors can contribute to failure of staff in aseptic technique training and competency evaluation including environmental testing failure, and engineering control failure. Prohibiting compounding personnel from compounding without an evaluation of contributing factors and timeframe would significantly disrupt patient treatment and for jeopardize health-systems ability to operate. **Recommendation:** Recommend adoption of facility's SOP for an action plan that specifies compounding personnel failing any aspect of aseptic manipulation ongoing training and competency evaluation. **Proposed Regulation Revision:** *(d) ~~Compounding personnel or persons with direct oversight over compounding personnel who fail any aspect of the aseptic manipulation ongoing training and competency evaluation shall not be involved in compounding or oversight of the preparation of a CSP until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs. A person with only direct oversight over personnel who fails any aspect of the aseptic manipulation ongoing training and competency evaluation may continue to provide only direct oversight for no more than 14 days after a failure of any aspect while applicable aseptic manipulation ongoing training and competency evaluation results are pending~~ Facility's SOP shall include action plan addressing compounding personnel or persons with direct oversight over compounding that fail any aspect of the aseptic manipulation ongoing training and competency evaluation.*
CCR. 1736.4 Facilities and Engineering Controls Subsection (c)	(1) Designated compounding area(s) shall typically be maintained at a temperature of 20° Celsius or cooler.	**Rationale:** • The USP chapter 797 recommends maintaining a temperature of 20° Celsius or cooler for staff comfort within the classified compounding areas where multiple layers of PPE are worn. • The term "designed compounding area" is defined by CCR. 1736 as a restricted location within a facility that limits access, where only activities and items related to

		compounding are present. This definition would include both classified compounding areas and segregated compounding areas. • If the language remains as is, 'shall typically' this can lead to severe consequences for many health systems, as many would have to make significant changes to their Heating, Ventilation, and Air Conditioning (HVAC) systems to be compliant with this requirement. Additionally, many of these classified compounding rooms and segregated compounding areas maintain room temperature medication which must be stored in temperatures defined in USP Chapter 659 as 20°–25° (68°–77° F). • It is further unclear what the term 'shall typically' mean in the regulatory context since typical regulatory and statutory language generally use the terms 'shall' or 'shall not'. **Recommendation:** We recommend this requirement be removed and pharmacies follow USP 797 standards for temperature requirement. Recommend the Board of Pharmacy to consider removing the requirement of CCR. 1736.4 subsection (c). ~~(1) Designated compounding area(s) shall typically be maintained at a temperature of 20° Celsius or cooler.~~
CCR. 1736.4 Facilities and Engineering Controls Subsection (f)	(f) No CSP shall be compounded if the compounding environment fails to meet criteria specified in law or the facility's SOPs.	**Rationale:** • In smaller rural hospitals, this proposed law in combination with CCR 1736.1 Introduction and Scope. Subsection (b) would lead to severe and devastating public health consequences for patients. For example, if a designated compounding area fails to meet the criteria specified in the law, and hospitals are unable to compound for immediate use, they would have to cease operations as they would not be able to provide appropriate patient care. • **Please see our comments above regarding 1736.1(b)** **Recommendation:** We recommend the Board of Pharmacy to consider removing the requirement of CCR. 1736.4 subsection (f) and defer to USP 797.
CCR 1736.6 Microbiological Air and Surface monitoring. Subsection (a)	(a) At a minimum of every 6 months, air and surface sampling results shall be identified to at least the genus level, regardless of the CFU count to trend for growth of microorganisms. Investigation must be consistent with the deviation and	R**ationale:** USP 797 recommends identifying sampling results on a genus level for actionable CFUs (CFUs exceeding action levels). Infection Control and current evidence does not support that trending genus level below actionable levels will yield data that will reduce patient safety risks; however, this will result in

	must include evaluation of trends.	increase in costs and workload. If there is high quality evidence supporting this requirement, we ask that the board share this with the public. **Recommendation:** *(a) At a minimum every 6 months, air and surface sampling results shall be identified to at least the genus level, ~~regardless of~~ when the CFU count exceeds action level to trend for growth of microorganisms. Investigation must be consistent with the deviation and must include evaluation of trends.*
CCR 1736.11 Master Formulation and Compounding Records subsection (c):	(c) A compounding record (CR) shall be a single document. The document shall satisfy the requirements of USP Chapter 797, and also contain the following:	**Rationale:** Current documentation practices in Health-System pharmacies include utilizing electronic record keeping systems/software. While all the required record keeping information is stored electronically, the ability to re-produce a single document can be challenging. It must be noted though that the information can be produced reliably which can be used in the instance should a recall be required. It is presumed that this requirement is designed for patient safety and we note that the patient safety requirement is adequately met if records containing the required elements of the record keeping can be utilized for recalls and related investigations. **Recommendation:** We 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. We recommend the Board consider modify the language to: *(c) Compounding record requirements shall be readily retrievable to comply with USP Chapter 797 and includes the following additional elements:*
CCR 1736.11 Master Formulation and Compounding Records. subsection (c)(3):	(c)(3) The manufacturer, lot number, and expiration date for each component for the CSP.	**Rationale:** Current language in CCR 1735.3 below has a provision for CSPs compounded in health facilities to prevent delays in care to acutely ill patient, i.e. infections, cancer, critical care, etc. The current language 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): *(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 1736.11 Master Formulation and Compounding Records. subsection (c)(5):	(c) (5) The identity of each person performing the compounding, that has direct oversight of compounding, and pharmacist verifying the final drug preparation.	**Rationale:** Current compounding practices in Health-System pharmacies have the pharmacist that has direct oversight of compounding, also verifying the final drug preparation. Moreover, requirements needing three different individuals within the sterile compounding space will prove to be difficult for smaller hospitals within California with their limited number of staff. **Recommendation:** Recommend the Board of Pharmacy clarify the intent of this requirement or consider adding verbiage allowing one person to suffice the requirements of both direct oversight of compounding and verifying final drug preparations.
CCR 1736.13 Labeling subsection (a):	(a) A CSP label shall include all of the following: (1) Route of intended administration; (2) The solution utilized, if applicable; (3) Instructions for administration; (A) For an admixed CSP, the rate of infusion, or range of rates of infusion as prescribed, or the duration for the entire CSP to be administered.	**Rationale:** • Most health-systems utilize electronic health record (EHR) system that can provide the required label components in readily retrievable format. • We would like to thank the Board for using clarifying language regarding the rate of infusion that now also includes the duration when the entire CSP shall be administered. This clarification is aligned with safe medication administration principles and will benefit patients. However, the proposed language regarding the rate of infusion is potentially confusing since it would imply that ALL admixed CSP's be labelled with a rate of infusion. It must be noted that not all admixed CSP's are infused, for example eye

		drops, intramuscular and subcutaneous injections, baths and soaks. It is recommended that the proposed language be changed to the following: **Recommendations:** Recommend updating the regulation to: *(a) A CSP label shall include all of the following and these can also be readily retrievable from the EHR:* *(1) Route of intended administration;* *(2) The solution utilized, if applicable;* *(3) Instructions for administration;* *(A) For an admixed CSP that are to be infused, the rate of infusion, or range of rates of infusion as prescribed, or the duration for the entire CSP to be administered.*
CCR 1736.13 Labeling subsection (b):	(b) Any CSP dispensed or ready to be dispensed to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5.	**Rationale:** It is requested that hospital pharmacies functioning in HSC Section 1250 (a) acute care hospitals where medications are administered to patients be exempted specifically in this subsection. The language 'dispensing to patients' should be differentiated by language such as 'medication prepared for administration in a facility licensed as HSC section 1250 (a) facility is exempt from this requirement'. For reference: BPC 4076.5 Standardized Patient Centered Labels (d) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) prescriptions dispensed to a patient in a health facility, 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 (a). **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.*
CCR. 1736.14 Establishing Beyond-Use Dates subsection (c)	(c) Prior to furnishing a CSP, the pharmacist performing or supervising sterile compounding is responsible for ensuring that sterility and endotoxin testing for BUD determination is performed and has received and reviewed the results. Results must be within acceptable USP limits. Test results must be retained as part of the compounding record.	**Rationale:** Per USP 797, endotoxin testing, and sterility testing are required to be completed in certain cases for category 2 or 3 CSPs. **Recommendations:** To be consistent with the USP 797 recommendations, we recommend the following revision to this section: *(c) Prior to furnishing a CSP, the pharmacist performing or supervising sterile compounding is responsible for ensuring that sterility and endotoxin testing (when applicable) for BUD determination is performed and has received and reviewed the results.*
CCR. 1736.17 Standard Operating Procedures (SOPS) subsection (a)(2)(c)	(a)(2)(c) The methods a pharmacist will use to determine and approve the ingredients and the compounding process for each preparation before compounding begins;	**Rationale:** Many health-systems currently utilize IV room workflow system that utilizes barcode scanning to check for correct components before allowing technicians to proceed with compounding. Moreover, with pharmacy recruitment issues, it would become challenging for health-systems to provide manual individual checks for a large number of CSPs. **Recommendations:** The methods a pharmacist will use to determine and approve the ingredients and the compounding process for each preparation before compounding begins; *(i) A sterile compounding workflow system may be utilized for verification of correct components used for preparing a CSP.*
CCR. 1736.17 Standard Operating Procedures (SOPS) subsection (d)	(d) The SOPs shall specify the process and products to be used on any equipment and other items entering from an unclassified area into the clean side of the anteroom, entering a PEC and entering the SCA. These SOPs must define at a minimum what product is to be used, the dwell time	**Rationale:** In many health-system pharmacies there are many items entering the sterile compounding spaces including into the SEC and PEC. Requiring monitoring and documentation of the monitoring of the dwell time for each individual item adds a significant burden to the workload of sterile compounding staff. It will take them away from performing the work of compounding medications for acutely ill patients and will further contribute to the potential for increased compounding while providing no demonstratable benefits. In practice, this requirement could be interpreted that the

	required, and how dwell time will be monitored and documented.	wiping and dwell time of medication and related sterile compounding items such as syringes, needles etc. sterile isopropyl alcohol be individually timed and documented when introduced to the PEC for sterile compounding. We suspect that the intent of this regulation is for SOPs to sufficiently address documentation and following manufacturer recommended dwell times as part of sterile compounding practice and wish to point out the potential for misinterpretation during enforcement inspections. **Recommendation:** *d) The SOPs shall specify the process and products to be used on any equipment and other items entering from an unclassified area into the clean side of the anteroom, entering a PEC and entering the SCA. These SOPs must define at a minimum what product is to be used~~, the dwell time required, and how dwell time will be monitored. and documented.~~*
CCR. 1736.18 Quality Assurance and Quality Control subsection (c)	(c) In addition to subsection (b), all complaints made to the facility related to a potential quality problem with a CSP and all adverse events shall be reviewed by the pharmacist-in-charge within 72 hours of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs.	**Rationale:** A requirement of 72 hours may not provide sufficient time for health-systems to investigate and notify the necessary regulatory bodies in cases where it occurs over the holiday weekend. **Recommendation:** *(c) In addition to subsection (b), all complaints made to the facility related to a potential quality problem with a CSP and all adverse events shall be reviewed by the pharmacist-in-charge, or licensed designee, within 3 business days ~~72 hours~~ of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs.*
CCR 1736.21 Compounding Allergenic Extracts subsection (a)	(a) Any allergenic extract compounding shall take place in a dedicated PEC. No other CSP may be made in this PEC.	**Rationale:** The new USP 797 chapter requires that allergenic extracts be compounded in either a 1) ISO Class 5 Primary Engineering Control chamber (PEC), or (2) in a dedicated Allergenic Extracts Compounding Area (AECA). To require a dedicated PEC for allergenic extracts would lead to operational and financial burden which will reduce patient access to care for their allergy treatments while there is no evidence-based benefit for requiring these stringent standards. It must be noted that allergenic extracts, unlike pharmaceutical manufactured products, are highly preserved and therefore has little potential for microorganism growth. To be consistent with the new USP 797 guidance, we recommend revising the language to allow the PEC to be used for other CSPs and not just allergenic extracts. In addition, for the purpose of enhancing availability of this treatment to the public while also

		containing the cost of care and capital investments in expensive facilities and equipment, we recommend allowing pharmacies and pharmacy licensees to be able to compound allergenic extracts in Allergenic Extracts Compounding Areas. During the committee meeting in 2023 on this topic, a board staff member acknowledged that there was no evidence based reason for including the PEC requirement in this regulation other than a wish to have pharmacy practice at a perceived higher level than other healthcare practice settings. In fact, this regulation may actually achieve just the opposite effect by healthcare settings electing to forego the expertise of pharmacists since installing PEC's and additional engineering controls comes at a very high cost. Additionally, during committee meeting, board staff acknowledged that they had very little knowledge regarding the practice and compounding of allergenic extracts, and they were not able to provide evidence for the requirement that allergenic extracts to be compounded in a dedicated PEC. **Recommendations:** To be consistent with the new USP 797 guidance, recommend revising the language to allow the PEC to be used for other CSPs and not just allergenic extracts. ***CCR 1736.21 Compounding Allergenic Extracts subsection (a):*** *(a) Any allergenic extract compounding shall take place in either a dedicated Allergenic Extracts Compounding Area or a PEC. No other CSP may be made in this PEC at the same time allergenic extract compounding is occurring. Work surface of the PEC must be disinfected immediately after compounding.*
CCR 1736.21 Compounding Allergenic Extracts subsection (b)	(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 Chapter 797.	**Rationale:** The new USP 797 chapter requires that allergenic extracts be compounded in either a 1) ISO Class 5 Primary Engineering Control chamber (PEC), or (2) in a dedicated Allergenic Extracts Compounding Area (AECA). Limiting allergen extract compounding conditions to category I or 2 will have a significant financial impact on health-systems to design and construct an SCA or a classified area for allergenic extract compounding. In addition, this proposed law creates an ambiguity if allergen extract compounding will have to follow the BUD of category 1 or 2 which would significantly reduce the BUD that is allowed by USP 797. **Recommendations:** Recommend the Board of Pharmacy to remove the requirement and to align with USP 797.

Hazardous drugs		
CCR 1737.1 Introduction and Scope	In addition to providing consultation in compliance with section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning handling and disposal of an HD or related supplies furnished.	**Rationale:** Section 1707.2 (b)(2) does not require consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, however there are outpatient ambulatory infusions centers where CNSP is being administered by a healthcare professional. **Recommendation:** Would recommend the BOP to provide clarification for CCR 1737.1 in alignment with 1707.2(b)(2), and state that the regulation does not apply to CNSPs administered and dispensed to patients by a healthcare professional. **Proposed Exemption Language**: *A pharmacist is not required by this subsection to provide consultation to a patient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code or where the compounded product will be administered by a licensed healthcare professional, except upon the patient's discharge with the compounded product.*
CCR 1737.2 List of Hazardous Drugs subsection (a) and (b) :	(a) The facility's list of HDs as required by USP Chapter 800 must be reviewed and approved by the designated person and the pharmacist-in-charge (PIC), professional director of a clinic, or designated representative-in-charge, as applicable. The designated person must be a single individual approved by the pharmacist-in-charge to be responsible and accountable for the performance and operation of the facility and personnel as related to the handling of hazardous drugs. The designated person shall not exceed the scope of their issued license. When the designated person is not a pharmacist, the PIC must review all practices related to the operations of the facility that require the judgment of a pharmacist. Approval shall be documented at least every 12 months. (b) If an assessment of risk approach is	**Rationale:** Often times, the designated person may be the pharmacist-in-charge **Recommendation:** Recommend revising the language to allow the Pharmacist-in-charge or designated person to review and approve the facility's list of HDs annually. ***CCR 1737.2 List of Hazardous Drugs subsections:*** *(a) The facility's list of HDs as required by USP Chapter 800 must be reviewed and approved by the designated person ~~and~~ or the pharmacist-in-charge (PIC), or professional director of a clinic, or designated representative-in-charge, as applicable. The designated person must be a single individual approved by the pharmacist-in-charge to be responsible and accountable for the performance and operation of the facility and personnel as related to the handling of hazardous drugs. The designated person shall not exceed the scope of their issued license. When the designated person is not a pharmacist, the PIC must review all practices related to the operations of the facility that require the judgment of a pharmacist. Approval shall be documented at least every 12 months.* *(b) If an assessment of risk approach is taken as authorized in USP Chapter 800,*

	taken as authorized in USP Chapter 800, it shall be approved by the designated person and the pharmacist-in-charge, professional director of a clinic, or designated representative-in-charge, as applicable.	*it shall be approved by the designated person ~~and~~ or the pharmacist-in-charge, or professional director of a clinic, or designated representative-in-charge, as applicable.*
1737.5 Facilities and Engineering Controls. Subsection (c)	(c) Where a pass-through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking. A pass-through is not allowed between the C-SEC into an unclassified space.	**Rationale:** USP 800 does not prohibit using a pass-through between a classified space and an unclassified space. In addition, this requirement without an exemption for previously built classified areas will put a significant burden financially and operationally on institutions that utilize a passthrough to be compliant with the new regulations. **Recommendation:** Revise language to remove the requirement and to align with USP 800 to read as follows: ***CCR 1737.5 Facilities and Engineering Controls:*** *(c) Where a pass-through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking. A pass-through is not allowed between the C-SEC into an unclassified space.* • *A passthrough may be allowed if installed before [OAL insert effective date].* • *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.*
CCR 1737.6 Environmental Quality and Control. Subsection (a)	(a) The SOPs of a premises where HDs are handled shall address environmental wipe sampling for HD surface residue, its frequency, areas of testing, levels of measurable contamination, and actions when those levels are exceeded.	**Rationale:** • USP 800 only recommends performing environmental wipe sampling for HD surface residue routinely. • Currently, there is currently no standard for acceptable limits for HD surface contamination.[1] • Additionally, requiring additional sampling will add an undue burden to test without any concrete actionable limits. **Reference** 1. Connor et al. Surface wipe sampling for antineoplastic (chemotherapy) and other hazardous drug residue in healthcare settings: Methodology and recommendations. Journal of Occupational and Environmental Hygiene. **Recommendations**:

		Request the board to consider removing the section or revise language to "should" to be consistent with USP 800 Chapter and to provide guidance on the specific requirement such as action level, frequency what to do when actionable levels have been reached as there is no standards provided. ***CCR 1737.6 Environmental Quality and Control*** *a) The SOPs of a premises where HDs are handled ~~shall~~ should address environmental wipe sampling for HD surface residue, its frequency, areas of testing, levels of measurable contamination, and actions when those levels are exceeded.*
CCR 1737.7. Personal Protective Equipment (PPE), subsection (c).	In addition to the standards in USP Chapter 800, Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article. (a) Two pairs of gloves that meet the ASTM D-6978 standard shall be worn for handling HD waste, cleaning HD spills, and performing routine cleaning in HD areas. (b) The outer pair of gloves that meets the ASTM D-6978 standard chemotherapy gloves shall be changed every 30 minutes during HD compounding unless otherwise recommended by the manufacturer's documentation. Documentation from the manufacturer shall be readily retrievable. For sterile HD compounding, both pairs of gloves labeled to meet the ASTM D-6978 standard shall be sterile. (c) Outer gloves used for HD compounding shall be changed between each different HD preparation.	**Rationale:** • The proposed rule requiring outer glove changes every 30 minutes during HD compounding appears arbitrary and not based on scientific evidence. While it is intended to protect staff and patients, it is unclear how this will be achieved since chemical permeation tests shows that some drugs permeate the glove in less than 30 minutes while most drugs takes longer. The rule will be closer aligned with its author's intents if it allows compounding staff and facilities to determine via SOP's the frequency of glove exchanges based on the drugs compounded. • Additionally, many health-system pharmacies use closed system transfer device (CSTD) when compounding antineoplastic HDs. The use of CSTD has shown to significantly reduce overall chemical contamination (12.24% vs. 26.39%).[1] ***Reference*** 1. *Simon N, Vasseur M, Pinturaud M, et al. Effectiveness of a Closed-System Transfer Device in Reducing Surface Contamination in a New Antineoplastic Drug-Compounding Unit: A Prospective, Controlled, Parallel Study. Ahmad A, ed. PLoS One 2016;11:e0159052. Available at: https://dx.plos.org/10.1371/journal.pone.0159052.* **Recommendations**: Revise the proposed language to: *b) The outer pair of gloves that meets the ASTM D-6978 standard chemotherapy gloves shall be changed ~~every 30 minutes~~ on a frequency determined by SOPs during HD compounding unless otherwise recommended by the manufacturer's documentation. Documentation from the manufacturer shall be readily retrievable. For sterile HD compounding, both pairs of gloves labeled to meet the ASTM D-6978 standard shall be sterile.* *(c) Outer gloves used for HD compounding shall be changed between each different HD preparation if a closed system transfer device (CSTD) is not used.*

CCR 1737.10. Receiving.	All HD APIs and antineoplastic HDs shall be shipped and received from the supplier in segregated impervious plastic and labeled "Hazardous Drugs" on the outside of the delivery container.	**Rationale:** How HD APIs and antineoplastic HDs are shipped is something pharmacies cannot control and is directly controlled by the distributing companies and entities. **Recommendations**: To consider removing the entire section.
CCR 1737.11. Labeling, Packaging, Transport and Disposal (a):	(a) Any compounded HD preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5.	**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 1737.9 Labeling subsection (a):*** *(a) Any compounded HD preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5* *(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.*
CCR 1737.13 Compounding subsection (a):	(a) A disposable preparation mat shall be placed on the work surface of the C-PEC when compounding HD preparations. Where the compounding is a sterile preparation, the preparation mat shall be sterile. The preparation mat shall be changed immediately if a spill occurs, after each HD drug, and at the end of daily compounding activity.	**Rationale:** USP 800 language states that a plastic-backed preparation mat should be placed on the work surfaces of the C-PEC. The mat should be changed immediately if a spill occurs and regularly during use and should be discarded at the end of the daily compounding activity. Additionally, CSTDs are used when compounding HD drugs to prevent spills and enhance worker protection. If the regulation required for preparation mats be used when compounding HD drugs, this can be a patient safety concern in the event of a shortage as institutions will no longer be able to do HD compounding for patients.

		Recommendations: Revise language to be consistent with USP 800 requirements: *(a) A disposable preparation mat ~~shall~~ should be placed on the work surface of the CPEC when compounding HD preparations. Where the compounding is a sterile preparation, the preparation mat shall be sterile. The preparation mat shall be changed immediately if a spill occurs, ~~after each HD drug~~, during decontamination between different HD, and at the end of daily compounding activity.*
CCR 1737.14. Administering subsection (b)	(b) When furnishing an antineoplastic HD, a sufficient supply of gloves that meet the ASTM D-6978 standard to allow for appropriate administration, handling, and disposal of HD drugs by the patient or the patient's agent shall be provided.	**Rationale:** In health system facilities where antineoplastic HD are dispensed and administered by licensed health care professionals who are trained to handle HDs. Supplies such as ASTM D-6978 grade gloves, and HD disposal bins are readily available. **Recommendations:** 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 trained and authorized to administer HD medications and not dispensed for outpatient use. *(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.*
CCR 1737.16. Spill Control	The premises shall maintain a list of properly trained and qualified personnel able to clean up an HD spill. An SOP shall outline how such a qualified person will be always available while HDs are handled.	**Rationale:** As required by USP 800, personnel are trained to handle HD, which includes cleaning up an HD spill, prior to handling HD. In large and multi-hospital health-systems, maintaining a list of all qualified personnel to attend an HD spill would be a major challenge. Some hospitals and health care facilities can train only a few individuals or disciplines while others train their full staff which can consist of thousands of staff. It appears that this rule is intended for pharmacy personnel since the wording 'the premises' is used in this undefined context and likely could be interpreted as pertaining to the definition of a pharmacy in Business and Professions Code 4037(a) which states that, "Pharmacy" means an area, place, **or premises** licensed by the board in which the profession of pharmacy is practiced and where prescriptions are compounded. **Recommendations**: Recommend the following revision to the following proposed regulation: *~~The premises shall maintain a list of properly trained and qualified personnel able to clean up an HD spill.~~ An SOP shall outline how such a qualified person to clean up an HD spill will be always available while HDs are handled.*

Radiopharmaceutical- Preparation, Compounding, Dispensing, and Repackaging		
CCR 1738.4 Personnel Qualifications, Training, and Hygiene subsection (c)	(c) Aseptic manipulation competency initial training and competency and ongoing training and competency documentation shall include the Primary Engineering Control (PEC's) type and PEC unique identifier used during the evaluation. Aseptic manipulation competency evaluation and requalification shall be performed using the same procedures, type of equipment, and materials used in aseptic compounding.	**Rationale:** The current USP 825 chapter does not require the PEC unique identifier to be documented for personnel training. Requiring a PEC unique identifier only adds to the additional documentation burden. **Recommendation:** Recommend the Board of Pharmacy to consider removing the requirement of "PEC unique identifier" **Recommendation:** *(c) Aseptic manipulation competency initial training and competency and ongoing training and competency documentation shall include the Primary Engineering Control (PEC's) type ~~and PEC unique identifier~~ used during the evaluation. Aseptic manipulation competency evaluation and requalification shall be performed using the same procedures, type of equipment, and materials used in aseptic compounding.*
CCR 1738.5. Facilities and Engineering Controls subsection (d)	(d) Compounding shall not take place in the SRPA.	**Rationale:** Per USP 825, for compounding sterile radiopharmaceuticals, the ISO 5 PEC must be placed in a classified area. However, non-radiopharmaceutical sterile compounds were not applicable for this restriction in USP 825. Prohibiting all compounding at SRPA would have a significant impact in the workload on health-systems that does not have a dedicated classified room for radiopharmaceuticals as they would not be able to prepare any supportive meds that has an SRPA. **Recommendation** *(d) Radiopharmaceutical compounding shall not take place in the SRPA.*
CCR 1738.5. Facilities and Engineering Controls subsection (j)	(j) A dynamic airflow smoke pattern test must be performed initially and at least every 6 months for all classified spaces and equipment. All dynamic airflow smoke pattern tests shall be immediately retrievable during inspection. A copy of the test shall be provided to the Board's inspector if requested in accordance with the timeframes set forth in Section 4105 of the Business and Professions Code.	**Rationale:** USP 825 requires a visual smoke study for classified spaces if there are low air returns. A dynamic airflow smoke pattern test is conducted initially and every 6 months to ensure proper PEC placement and staff maintaining unidirectional airflow (first air). **Recommendation** Request clarification on the purpose of dynamic airflow smoke pattern test for all classified spaces. In addition, recommend the BOP be consistent with USP 825 recommendations and remove this proposed subsection.

CCR 1738.6. Microbiological Air and Surface Monitoring subsection (b)	(b) In addition to the SOPs at a minimum every 6 months, air and surface sampling results shall be identified to at least the genus level, regardless of the colony forming units (CFU) count, to trend for growth of microorganisms. Trends of microorganism growth must be identified and evaluated.	R**ationale:** USP 825 recommends identifying sampling results on a genus level for actionable CFUs (CFUs exceeding action levels). BOP language is not consistent with USP 825 recommendations, and in contrast will require health-systems to identify every CFU count at least to the genus level regardless of if they exceeded the CFU action levels. **Recommendation:** *(b) In addition to the SOPs at a minimum every 6 months, air and surface sampling results shall be identified to at least the genus level, ~~regardless of~~ when the colony forming units (CFU) count exceeds action level to trend for growth of microorganisms. Trends of microorganism growth must be identified and evaluated.*
CCR 1738.10. Preparation subsection (c)	(c) When preparing radiopharmaceuticals with minor deviations ("preparation with minor deviations" as defined in USP Chapter 825) an SOP shall at least define the circumstances that necessitated the deviation and all quality control testing requirements and limits. Such circumstances shall, at a minimum, include patient need or facts that support the deviation that maintains the appropriate quality and purity (radiochemical purity and radionuclidic purity) as specified in individual monographs, and other applicable parameters as clinically appropriate in the professional judgment of the pharmacist.	**Rationale:** The proposed language is inconsistent with USP 825 recommendations, will require health-systems to incorporate patient need which may not be pertinent information. **Recommendation:** *(c) When preparing radiopharmaceuticals with minor deviations ("preparation with minor deviations" as defined in USP Chapter 825) an SOP shall at least define the circumstances that necessitated the deviation and all quality control testing requirements and limits. Such circumstances shall, at a minimum, ~~include patient need or~~ facts that support the deviation that maintains the appropriate quality and purity (radiochemical purity and radionuclidic purity) as specified in individual monographs, and other applicable parameters as clinically appropriate in the professional judgment of the pharmacist.*
CCR 1738.14. Quality Assurance and Quality Control subsection (b)	(b) The board shall be notified in writing within 72 hours of a complaint involving a radiopharmaceutical. Recalls and adverse events must be reported to the Board and other agencies in compliance with relevant	**Rationale:** A requirement of 72 hours may not provide sufficient time for health-systems to investigate and notify the necessary regulatory bodies in cases where it occurs over the holiday weekend.

	provisions of law.	**Recommendation:** (*b) The board shall be notified in writing within ~~72 hours~~ 3 business days of a complaint involving a radiopharmaceutical. Recalls and adverse events must be reported to the Board and other agencies in compliance with relevant provisions of law.*
CCR 1738.14. Quality Assurance and Quality Control subsection (c)	(c) In addition to subsection (b), all complaints related to a potential quality problem with a radiopharmaceutical and all reported adverse events shall be reviewed by the pharmacist-in-charge within 72 hours of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs.	**Rationale:** A requirement of 72 hours may not provide sufficient time for health-systems to investigate and notify the necessary regulatory bodies in cases where it occurs over the holiday weekend. **Recommendation:** *(c) In addition to subsection (b), all complaints related to a potential quality problem with a radiopharmaceutical and all reported adverse events shall be reviewed by the pharmacist-in-charge within 3 business days ~~72 hours~~ of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs.*

1838 South Coast HWY
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Coast Compounding PHARMACY

Dear Board of Pharmacy

I am writing to request the implementation of new regulations or the amendment of existing ones regarding the pharmacist to technician ratio in retail compounding pharmacies. The current regulations, while addressing several important aspects, do not fully account for the unique requirements of compounding areas, especially in the context of hazardous, non-hazardous, and sterile compounding.

The Board of Pharmacy has enacted regulations 4115, 4127.15, and 4132, recognizing that when distinctly separate areas need to be staffed, the pharmacist to technician ratios need to be addressed accordingly:

- 4115 "(b)(1) In addition to the tasks specified in subdivision (a) a pharmacy technician may, under the direct supervision and control of a pharmacist, prepare and administer influenza and COVID-19 vaccines via injection or intranasally, prepare and administer epinephrine, perform specimen collection for tests that are classified as waived under CLIA, receive prescription transfers, and accept clarification on prescriptions under the following conditions: (A) The pharmacy has scheduled another pharmacy technician to assist the pharmacist by performing the tasks provided in subdivision (a)."

- 4127.15 "(2) Satisfy the ratio of not less than one pharmacist on duty for a total of two pharmacy technicians on duty. (3) Ensure immediate supervision, as defined in Section 70065 of Title 22 of the California Code of Regulations, by a pharmacist of licensed ancillary staff involved in sterile compounding."

- 4132 "(b) Notwithstanding Section 4115, a registered pharmacy technician may perform order entry, packaging, manipulative, repetitive, and other nondiscretionary tasks at a remote dispensing site pharmacy under the supervision of a pharmacist at a supervising pharmacy using a telepharmacy system."

The new Board of Pharmacy compounding regulations require distinctly separate areas for hazardous, non-hazardous, and sterile compounding. It is also necessary to limit the number of times employees enter clean room and hazardous compounding areas to a minimum. It is thus in the interest of public safety to avoid the same compounding technician moving in and out of these areas to compound in the non-hazardous compounding area.

If the Board of Pharmacy would consider adding compounding areas to 4115 or enacting a new regulation to address these issues, it would enhance compounding services and public safety. By establishing specific ratios and guidelines for technicians working in distinct compounding areas, we can ensure that these areas are adequately staffed, thereby reducing the risk of contamination and enhancing the overall safety and efficiency of retail compounding pharmacy operations.

Thank you for considering this request. I look forward to your positive response and the timely implementation of these crucial regulations.

Sincerely,
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dieter@ccprx.com
760-433-6233

Due to the length of the proposed regulation, the Board requests that comments be submitted to the Board in a word document (.doc or .docx) in the following format:

Section, Subdivision	Proposed Language	Recommendation / Comment
Non-Sterile Compounding		
CCR 1735 Compounding Definitions. Subsection (d)	(d) "Essentially a copy" of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (API(s)) as the commercially available drug product, except that it does not include any preparation in which there has been a change made for an identified individual patient that produces for that patient a clinically significant difference, as determined by the prescribing practitioner, between that compounded preparation and the comparable commercially available drug product	**Rationale:** • The proposed language does not distinguish commercially available drug products with the same active pharmaceutical ingredient(s) (API(s)) with drug dosage form(s). • To make it clear that drug dosage forms not available commercially can be compounded for patient specific clinical needs. **Recommendation:** Recommend the board to add language to the definition of "essentially a copy" to include "the same dosage form" in addition to the same active ingredient(s) (API(s)).
CCR 1735.1 Introduction and Scope. Subsection (f) (1) (A):	(f) In addition to prohibitions and requirements for compounding established in federal law, no CNSP shall be prepared that: (1) Is essentially a copy of one or more commercially available drug products, unless: (A) the drug product appears in an American Society of Health-System Pharmacists (ASHP) or FDA Drug Shortages Database that are in short supply at the time of compounding and at the time of dispensing, or	**Rationale:** • The ASHP and FDA drug shortage lists do not always reflect real-time real time drug shortages. As an example, the 2023 Akorn recall was posted after the State Board notification of the company shut down which resulted in multiple drug shortages. (see attached) [1] 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. • Additionally, wholesalers themselves often run out of supply of critical medications (pre-shortage situations). Inability to procure medications or restrictions to compound in these events would have contribute to heightened risk and safety concerns for patients. With the growing number of medications going on shortage[2] and recent manufacturer bankruptcies (i.e. Akorn, Apotex) it is becoming more challenging for Health-Systems to obtain commercially available products. References:

		1. 2. Drug Shortages Statistics - ASHP **Recommendation:** Recommend the board to add language regarding recent drug shortages that may not be reflected on the ASHP and FDA lists as well as unavailability from wholesalers to ensure that health systems are compliant with requirements. ***1735.1 Introduction and Scope. Subsection (f) (1) (A):*** *(f) In addition to prohibitions and requirements for compounding established in federal law, no CNSP shall be prepared that:* *(1) Is essentially a copy of one or more commercially available drug products, unless:* *(A) that drug product is not available by the manufacturer or wholesaler, appears on an ASHP (American Society of Health- System Pharmacists), or FDA list of drugs at the time of compounding and at the time of dispense, or*
CCR 1735.1 Introduction and Scope. Subsection (h):	(h) In addition to the provisions provided in section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning proper use, storage, handling, and disposal of the CNSP and related supplies furnished.	**Rationale:** Section 1707.2 (b)(2) does not require consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, however there are outpatient ambulatory infusions centers where CNSP is being administered by a healthcare professional. **Recommendation:** Would recommend the BOP to provide clarification for CCR 1736.1 subsection (h), and state that the regulation does not apply to CNSPs administered and dispensed to patients by a healthcare professional. **Proposed Exemption Language**: *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.*
CCR 1735.7 Master Formulation and	(c) A compounding record (CR) shall be a single document developed in compliance with USP Chapter 795, and includes the	**Rationale:**

Compounding Records subsection (c):	following additional elements:	Current documentation practices in Health-System pharmacies utilize electronic record keeping systems/software to meet compounding record requirements which limits the ability to provide the information in a single document. **Recommendation:** Recommend the Board consider modify the language to: *(c) Compounding record requirements shall be readily retrievable to comply with USP Chapter 795 and includes the following additional elements:*
CCR 1735.7 Master Formulation and Compounding Records. subsection (c)(2):	(c)(3) The manufacturer, lot number, and expiration date for each component for the CSP.	**Rationale:** Current language in CCR 1735.3 below has a provision for CSPs compounded in health facilities to prevent delays in care to acutely ill patient, i.e. infections, cancer, critical care, etc. The current language 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:** To prevent delays in care to acutely ill patients, recommend the board consider including the same exemption language to the 1735.7 Master Formulation and Compounding Records, subsection (c)(2): *The manufacturer, lot number, and expiration date for each component.* *(i) Exempt from the requirements in this paragraph are non-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 1735.9 Labeling subsection (b):	(c) Any CNSP dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5.	**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 1735.9 Labeling subsection (c):*** *(c) Any CNSP dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5.* *(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.*
1735.12. Quality Assurance and Quality Control. Subsection (b)	(b) The Board shall be notified in writing within 72 hours of the facility's receipt of a complaint of a potential quality problem or the occurrence of an adverse drug event involving a CNSP.	**Rationale:** A requirement of 72 hours may not provide sufficient time for health-systems to investigate and notify the necessary regulatory bodies in cases where it occurs over the holiday weekend. **Recommendation** *(b) The Board shall be notified in writing within 3 business days ~~72 hours~~ of the facility's receipt of a complaint of a potential quality problem or the occurrence of an adverse drug event involving a CNSP.*
1735.12. Quality Assurance and Quality Control. Subsection (c)	(c) All complaints related to a potential quality problem with a CNSP and all adverse events shall be reviewed by the pharmacist-in-charge within 72 hours of receipt of the complaint or occurrence of the adverse event. Such review shall be documented and dated as defined in the SOPs.	**Rationale:** A requirement of 72 hours may not provide sufficient time for health-systems to investigate and notify the necessary regulatory bodies in cases where it occurs over the holiday weekend. **Recommendation** *(c)All complaints related to a potential quality problem with a CNSP and all adverse events shall be reviewed by the pharmacist-in-charge within 3 business days ~~72 hours~~ of receipt of the complaint or occurrence of the adverse event. Such review shall be documented and dated as defined in the SOPs.*
Sterile Compounding		

CCR 1736.1 Introduction and Scope. Subsection (b):	(b) CSPs for direct and immediate administration as provided in the Chapter shall only be done in those limited situations where the failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need. Documentation for each such CSP shall include identification of the CSP, compounded date and time, number of units, the patient's name and patient's unique identifier and the circumstance causing the immediate need. Such documentation may be available in the patient's medical record and need not be redocumented by the compounding staff if already available.	**Rationale:** • In the instance of a patient emergency such as a code blue or a rapid resuscitation event in a hospital, the requirement for additional documentation will result in a delay in providing immediately needed medication to prevent loss of life. • Existing language could lead to significant unintended consequences such as organizational decisions to have nursing staff compound medications due to risk delays in drug administration which could be life-threatening. **Recommendation:** We recommend the board consider removal of language requiring documentation due to patient safety concerns. ***1736.1 Sterile Compounding Scope. Subsection (b)*** *(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 patient harm ~~loss of life or intense suffering~~. Any such compounding shall be only in such quantity as is necessary to meet the immediate need. ~~Documentation for each such CSP shall include identification of the CSP, compounded date and time, number of units, the patient's name and patient's unique identifier and the circumstance causing the immediate need. Such documentation may be available in the patient's medical record and need not be redocumented by the compounding staff if already available~~*
CCR 1736.1 Introduction and Scope. Subsection (e) (1) (A):	(e) In addition to prohibitions and requirements for compounding established in federal law, no CSP may be compounded that: (1) Is essentially a copy of one or more commercially available drug products, unless: (A) that drug product appears in an American Society of Health-System Pharmacists (ASHP) or FDA Drug Shortages Database that are in short supply at the time of compounding and at the time of dispensing, or	**Rationale:** • The ASHP and FDA drug shortage lists do not always reflect real-time real time drug shortages. As an example, the 2023 Akorn recall was posted after the State Board notification of the company shut down which resulted in multiple drug shortages. (see attached) [1] 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. • Additionally, wholesalers themselves often run out of supply of critical medications (pre-shortage situations). Inability to procure medications or restrictions to compound in these events would have contribute to heightened risk and safety concerns for patients. With the growing number of medications going on shortage[2] and recent manufacturer bankruptcies (i.e. Akorn, Apotex) it is becoming more challenging for Health-Systems to obtain commercially available products. References:

		 FDA Akorn recall.pdf 1. 2. Drug Shortages Statistics - ASHP **Recommendation:** Recommend the board to add language regarding recent drug shortages that may not be reflected on the ASHP and FDA lists as well as unavailability from wholesalers to ensure that health systems are compliant with requirements. ***1736.1 Sterile Compounding Scope. Subsection (e) (1) (A):*** *(e) 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 is not available (cannot be purchased) by the manufacturer or wholesaler, appears on an ASHP (American Society of Health- System Pharmacists), or FDA list of drugs at the time of compounding ~~and at the time of dispense~~, or*
CCR 1736.1 Introduction and Scope. Subsection (g):	(g) In addition to the provisions provided in Section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning proper use, storage, handling and disposal of the CSP and related supplies furnished	**Rationale:** Section 1707.2 (b)(2) does not require consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, however there are outpatient ambulatory infusions centers where CSP is being administered by a healthcare professional. **Recommendation:** Would recommend the BOP to provide clarification for CCR 1736.1 subsection (g), in an FAQ to state that the regulation does not apply to CSPs administered and dispensed to patients by a healthcare professional. **Proposed Exemption Language**: *(g) In addition to the provisions provided in Section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning proper use, storage, handling and disposal of the CSP and related supplies furnished* *(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.*
CCR 1736.1 Introduction and Scope. Subsection (h):	(h) CSPs with human whole blood or human whole blood derivatives shall be	**Rationale:** The current health and safety code section 1602.5 states the following:

	produced in compliance with Health and Safety Code section 1602.5.	(a) No person shall engage in the production of human whole blood or human whole blood derivatives unless the person is licensed under this chapter and the human whole blood or human whole blood derivative is collected, prepared, labeled, and stored in accordance with both of the following:" The proposed regulation in its current state would cause confusion as it would enforce a law that is not applicable to any human whole blood or human whole blood derivative that is already manufactured by a pharmaceutical company (e.g. Albumin, Factor products, IVIG etc.) **Recommendation:** Would recommend the board to revise the proposed language to provide clarification to state that the regulation does not apply to CSPs made with human blood/derivative that is manufactured by pharmaceutical companies. *(h) CSPs with patient's own whole blood or human whole blood derivatives from the patient shall be produced in compliance with Health and Safety Code section 1602.5.*
CCR 1736.2 Personnel Training and Evaluation. Subsection (b)	Initial and ongoing aseptic manipulation training and competency documentation shall include the Primary Engineering Control (PEC) type and PEC unique identifier used during the evaluation. Aseptic manipulation competency evaluation and requalification shall be performed using the same procedures, type of equipment, and materials used in aseptic compounding. Aseptic qualifications from one premises may be used for another premises if all of the following conditions are met: (1) The Standard Operating Procedures (SOPs) required by section 1736.17 related to compounding are identical. (2) The Secondary Engineering Control (SEC) facility designs are sufficiently similar to accommodate the use of the same SOPs.	**Rationale:** The current USP 797 chapter does not require the PEC unique identifier to be documented for personnel training. Requiring a PEC unique identifier only adds to the additional documentation burden. **Recommendation:** Recommend the Board of Pharmacy to consider removing the requirement of "PEC unique identifier" **Proposed Regulation Revision:** *Initial and ongoing aseptic manipulation training and competency documentation shall include the Primary Engineering Control (PEC) type ~~and PEC unique identifier~~ used during the evaluation.*

	(3) The PECs are of the same type and sufficiently similar to accommodate the use of the same SOPs describing use and cleaning.	
CCR 1736.2 Personnel Training and Evaluation. Subsection (d)	(d) Compounding personnel or persons with direct oversight over compounding personnel who fail any aspect of the aseptic manipulation ongoing training and competency evaluation shall not be involved in compounding or oversight of the preparation of a CSP until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs. A person with only direct oversight over personnel who fails any aspect of the aseptic manipulation ongoing training and competency evaluation may continue to provide only direct oversight for no more than 14 days after a failure of any aspect while applicable aseptic manipulation ongoing training and competency evaluation results are pending	**Rationale:** Multiple factors can contribute to failure of staff in aseptic technique training and competency evaluation including environmental testing failure, and engineering control failure. Prohibiting compounding personnel from compounding without an evaluation of contributing factors and timeframe would significantly disrupt patient treatment and for jeopardize health-systems ability to operate. **Recommendation:** Recommend adoption of facility's SOP for an action plan that specifies compounding personnel failing any aspect of aseptic manipulation ongoing training and competency evaluation. **Proposed Regulation Revision:** *(d) ~~Compounding personnel or persons with direct oversight over compounding personnel who fail any aspect of the aseptic manipulation ongoing training and competency evaluation shall not be involved in compounding or oversight of the preparation of a CSP until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs. A person with only direct oversight over personnel who fails any aspect of the aseptic manipulation ongoing training and competency evaluation may continue to provide only direct oversight for no more than 14 days after a failure of any aspect while applicable aseptic manipulation ongoing training and competency evaluation results are pending~~ Facility's SOP shall include action plan addressing compounding personnel or persons with direct oversight over compounding that fail any aspect of the aseptic manipulation ongoing training and competency evaluation.*
CCR. 1736.4 Facilities and Engineering Controls Subsection (c)	(1) Designated compounding area(s) shall typically be maintained at a temperature of 20° Celsius or cooler.	**Rationale:** • The USP chapter 797 recommends maintaining a temperature of 20° Celsius or cooler for staff comfort within the classified compounding areas where multiple layers of PPE are worn. • The term "designed compounding area" is defined by CCR. 1736 as a restricted location within a facility that limits access, where only activities and items related to

		compounding are present. This definition would include both classified compounding areas and segregated compounding areas. • If the language remains as is, 'shall typically' this can lead to severe consequences for many health systems, as many would have to make significant changes to their Heating, Ventilation, and Air Conditioning (HVAC) systems to be compliant with this requirement. Additionally, many of these classified compounding rooms and segregated compounding areas maintain room temperature medication which must be stored in temperatures defined in USP Chapter 659 as 20°–25° (68°–77° F). **Recommendation:** Recommend this requirement be removed and pharmacies follow USP 797 standards for temperature requirement. Recommend the Board of Pharmacy to consider removing the requirement of CCR. 1736.4 subsection (c).
CCR. 1736.4 Facilities and Engineering Controls Subsection (f)	(f) No CSP shall be compounded if the compounding environment fails to meet criteria specified in law or the facility's SOPs.	**Rationale:** In smaller rural hospitals, this proposed law in combination with CCR 1736.1 Introduction and Scope. Subsection (b) would lead to severe consequences for patients. For example, if a designated compounding area fails to meet the criteria specified in the law, and hospitals are unable to compound for immediate use, they would have to cease operations as they would not be able to provide appropriate patient care. **Recommendation:** Recommend the Board of Pharmacy to consider removing the requirement of CCR. 1736.4 subsection (f) and defer to USP 797.
CCR 1736.6 Microbiological Air and Surface monitoring. Subsection (a)	(a) At a minimum of every 6 months, air and surface sampling results shall be identified to at least the genus level, regardless of the CFU count to trend for growth of microorganisms. Investigation must be consistent with the deviation and must include evaluation of trends.	**Rationale:** USP 797 recommends identifying sampling results on a genus level for actionable CFUs (CFUs exceeding action levels). Infection Control and current evidence does not support that trending genus level below actionable levels will yield data that will reduce patient risks; however, this will result in increase in costs and workload. **Recommendation:** *(a) At a minimum every 6 months, air and surface sampling results shall be identified to at least the genus level, ~~regardless of~~ when the CFU count exceeds action level to trend for growth of microorganisms. Investigation must be consistent with the deviation and must include evaluation of trends.*

CCR 1736.11 Master Formulation and Compounding Records subsection (c):	(c) A compounding record (CR) shall be a single document. The document shall satisfy the requirements of USP Chapter 797, and also contain the following:	**Rationale:** Current documentation practices in Health-System pharmacies utilize electronic record keeping systems/software to meet compounding record requirements which limits the ability to provide the information in a single document. **Recommendation:** Recommend the Board consider modify the language to: *(c) Compounding record requirements shall be readily retrievable to comply with USP Chapter 797 and includes the following additional elements:*
CCR 1736.11 Master Formulation and Compounding Records. subsection (c)(3):	(c)(3) The manufacturer, lot number, and expiration date for each component for the CSP.	**Rationale:** Current language in CCR 1735.3 below has a provision for CSPs compounded in health facilities to prevent delays in care to acutely ill patient, i.e. infections, cancer, critical care, etc. The current language 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): *(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 1736.11 Master Formulation and Compounding Records. subsection (c)(5):	(c) (5) The identity of each person performing the compounding, that has direct oversight of compounding, and pharmacist verifying the final drug preparation.	**Rationale:** Current compounding practices in Health-System pharmacies have the pharmacist that has direct oversight of compounding, also verifying the final drug preparation. Moreover, requirements needing three different individuals within the sterile compounding space will prove to be difficult for smaller hospitals within California with their limited number of staff. **Recommendation:** Recommend the Board of Pharmacy clarify the intent of this requirement or consider adding verbiage allowing one person to suffice the requirements of both direct oversight of compounding and verifying final drug preparations.
CCR 1736.13 Labeling subsection (a):	(a) A CSP label shall include all of the following: (1) Route of intended administration; (2) The solution utilized, if applicable; (3) Instructions for administration; (A) For an admixed CSP, the rate of infusion, or range of rates of infusion as prescribed, or the duration for the entire CSP to be administered.	**Rationale:** Most health-systems utilize electronic health record (EHR) system that can provide the required label components in readily retrievable format. **Recommendations:** Recommend updating the regulation to: *(a) A CSP label shall include all of the following and these can also be readily retrievable from the EHR:* *(1) Route of intended administration;* *(2) The solution utilized, if applicable;* *(3) Instructions for administration;* *(A) For an admixed CSP that are to be infused, the rate of infusion, or range of rates of infusion as prescribed, or the duration for the entire CSP to be administered.*
CCR 1736.13 Labeling subsection (b):	(b) Any CSP dispensed or ready to be dispensed 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.*
CCR. 1736.14 Establishing Beyond-Use Dates subsection (c)	(c) Prior to furnishing a CSP, the pharmacist performing or supervising sterile compounding is responsible for ensuring that sterility and endotoxin testing for BUD determination is performed and has received and reviewed the results. Results must be within acceptable USP limits. Test results must be retained as part of the compounding record.	**Rationale:** Per USP 797, endotoxin testing, and sterility testing are required to be completed in certain cases for category 2 or 3 CSPs. **Recommendations:** To be consistent with the USP 797 recommendations, we recommend the following revision to this section: *(c) Prior to furnishing a CSP, the pharmacist performing or supervising sterile compounding is responsible for ensuring that sterility and endotoxin testing (when applicable) for BUD determination is performed and has received and reviewed the results.*
CCR. 1736.17 Standard Operating Procedures (SOPS) subsection (a)(2)(c)	(a)(2)(c) The methods a pharmacist will use to determine and approve the ingredients and the compounding process for each preparation before compounding begins;	**Rationale:** Many health-systems currently utilize IV room workflow system that utilizes barcode scanning to check for correct components before allowing technicians to proceed with compounding. Moreover, with pharmacy recruitment issues, it would become challenging for health-systems to provide manual individual checks for a large number of CSPs. **Recommendations:** The methods a pharmacist will use to determine and approve the ingredients and the compounding process for each preparation before compounding begins; *(i) A sterile compounding workflow system may be utilized for verification of correct components used for preparing a CSP.*
CCR. 1736.17 Standard Operating Procedures (SOPS) subsection (d)	(d) The SOPs shall specify the process and products to be used on any equipment and other items entering from an unclassified area into the clean side of the anteroom, entering a PEC and entering the SCA. These SOPs must define at a minimum what product is to be used, the dwell time	**Rationale:** In many health-systems there are many items entering the sterile compounding spaces including into the PEC. Requiring documentation of monitoring dwell time adds a significant burden to the workload of sterile compounding staff which could increase the risk of causing an error in compounding. **Recommendation:**

	required, and how dwell time will be monitored and documented.	*d) The SOPs shall specify the process and products to be used on any equipment and other items entering from an unclassified area into the clean side of the anteroom, entering a PEC and entering the SCA. These SOPs must define at a minimum what product is to be used, the dwell time required, and how dwell time will be monitored. ~~and documented.~~*
CCR. 1736.18 Quality Assurance and Quality Control subsection (c)	(c) In addition to subsection (b), all complaints made to the facility related to a potential quality problem with a CSP and all adverse events shall be reviewed by the pharmacist-in-charge within 72 hours of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs.	**Rationale:** A requirement of 72 hours may not provide sufficient time for health-systems to investigate and notify the necessary regulatory bodies in cases where it occurs over the holiday weekend. **Recommendation:** *(c) In addition to subsection (b), all complaints made to the facility related to a potential quality problem with a CSP and all adverse events shall be reviewed by the pharmacist-in-charge within 3 business days ~~72 hours~~ of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs.*
CCR 1736.21 Compounding Allergenic Extracts subsection (a)	(a) Any allergenic extract compounding shall take place in a dedicated PEC. No other CSP may be made in this PEC.	**Rationale:** The new USP 797 chapter requires that allergenic extracts be compounded in either a 1) ISO Class 5 Primary Engineering Control chamber (PEC), or (2) in a dedicated Allergenic Extracts Compounding Area (AECA). To require a dedicated PEC for allergenic extracts would lead to operational and financial burden. **Recommendations:** To be consistent with the new USP 797 guidance, recommend revising the language to allow the PEC to be used for other CSPs and not just allergenic extracts. ***CCR 1736.21 Compounding Allergenic Extracts subsection (a):*** *(a) Any allergenic extract compounding shall take place in either a dedicated Allergenic Extracts Compounding Area or a PEC. No other CSP may be made in this PEC at the same time allergenic extract compounding is occurring. Work surface of the PEC must be disinfected immediately after compounding.*
CCR 1736.21 Compounding Allergenic Extracts subsection (b)	(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 Chapter 797.	**Rationale:** The new USP 797 chapter requires that allergenic extracts be compounded in either a 1) ISO Class 5 Primary Engineering Control chamber (PEC), or (2) in a dedicated Allergenic Extracts Compounding Area (AECA). Limiting allergen extract compounding conditions to category I or 2 will have a significant financial impact on health-systems to design and construct an SCA or a classified area for allergenic extract compounding. In addition, this proposed law creates an ambiguity if allergen extract compounding will have to follow the BUD of category 1 or 2 which would significantly reduce the BUD that is allowed by USP 797.

		Recommendations: Recommend the Board of Pharmacy clarify the intent of this requirement or to remove the requirement and to align with USP 797.
Hazardous drugs		
CCR 1737.1 Introduction and Scope	In addition to providing consultation in compliance with section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning handling and disposal of an HD or related supplies furnished.	**Rationale:** • Section 1707.2 (b)(2) does not require consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, however there are outpatient ambulatory infusions centers where CSP is being administered by a healthcare professional. • If the proposed regulation requires consultation for all hazardous medication being dispensed and administered in an outpatient infusion center, this will put a significant workload impact on health-systems to comply with this requirement. **Recommendation:** Would recommend to provide clarification for CCR 1737 to state that the regulation does not apply to CSPs administered and dispensed to patients by a healthcare professional. **Proposed Exemption Language**: *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.*
CCR 1737.2 List of Hazardous Drugs subsection (a) and (b) :	(a) The facility's list of HDs as required by USP Chapter 800 must be reviewed and approved by the designated person and the pharmacist-in-charge (PIC), professional director of a clinic, or designated representative-in-charge, as applicable. The designated person must be a single individual approved by the pharmacist-in-charge to be responsible and accountable for the performance and operation of the facility and personnel as related to the handling of hazardous drugs.	**Rationale:** Often times, the designated person may be the pharmacist-in-charge **Recommendation:** Recommend revising the language to allow the Pharmacist-in-charge or designated person to review and approve the facility's list of HDs annually. ***CCR 1737.2 List of Hazardous Drugs subsections:*** *(a) The facility's list of HDs as required by USP Chapter 800 must be reviewed and approved by the designated person ~~and~~ or the pharmacist-in-charge (PIC), or professional director of a clinic, or designated representative-in-charge, as applicable. The designated person must be a single individual approved by the*

	The designated person shall not exceed the scope of their issued license. When the designated person is not a pharmacist, the PIC must review all practices related to the operations of the facility that require the judgment of a pharmacist. Approval shall be documented at least every 12 months. (b) If an assessment of risk approach is taken as authorized in USP Chapter 800, it shall be approved by the designated person and the pharmacist-in-charge, professional director of a clinic, or designated representative-in-charge, as applicable.	*pharmacist-in-charge to be responsible and accountable for the performance and operation of the facility and personnel as related to the handling of hazardous drugs. The designated person shall not exceed the scope of their issued license. When the designated person is not a pharmacist, the PIC must review all practices related to the operations of the facility that require the judgment of a pharmacist. Approval shall be documented at least every 12 months.* *(b) If an assessment of risk approach is taken as authorized in USP Chapter 800, it shall be approved by the designated person ~~and~~ or the pharmacist-in-charge, or professional director of a clinic, or designated representative-in-charge, as applicable.*
1737.5 Facilities and Engineering Controls. Subsection (c)	(c) Where a pass-through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking. A pass-through is not allowed between the C-SEC into an unclassified space.	**Rationale:** USP 800 does not prohibit using a pass-through between a classified space and an unclassified space. In addition, this requirement without an exemption for previously built classified areas will put a significant burden financially and operationally on institutions that utilize a passthrough to be compliant with the new regulations. **Recommendation:** Revise language to remove the requirement and to align with USP 800 to read as follows: ***CCR 1737.5 Facilities and Engineering Controls:*** *(c) Where a pass-through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking. A pass-through is not allowed between the C-SEC into an unclassified space.* • *A passthrough may be allowed if installed before [OAL insert effective date].* • *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.*
CCR 1737.6 Environmental Quality and Control. Subsection (a)	(a) The SOPs of a premises where HDs are handled shall address environmental wipe sampling for HD surface residue, its frequency, areas of testing, levels of measurable contamination, and actions when those levels are exceeded.	**Rationale:** • USP 800 only recommends performing environmental wipe sampling for HD surface residue routinely. • Currently, there is currently no standard for acceptable limits for HD surface contamination.[1]

		• Additionally, requiring additional sampling will add an undue burden to test without any concrete actionable limits. **Reference** 1. Connor et al. Surface wipe sampling for antineoplastic (chemotherapy) and other hazardous drug residue in healthcare settings: Methodology and recommendations. Journal of Occupational and Environmental Hygiene. **Recommendations**: Request the board to consider removing the section or revise language to "should" to be consistent with USP 800 Chapter and to provide guidance on the specific requirement such as action level, frequency what to do when actionable levels have been reached as there is no standards provided. ***CCR 1737.6 Environmental Quality and Control*** *a) The SOPs of a premises where HDs are handled ~~shall~~ should address environmental wipe sampling for HD surface residue, its frequency, areas of testing, levels of measurable contamination, and actions when those levels are exceeded.*
CCR 1737.7. Personal Protective Equipment (PPE), subsection (c).	(c) Outer gloves used for HD compounding shall be changed between each different HD preparation.	**Rationale:** Many health-systems use closed system transfer device (CSTD) when compounding antineoplastic HDs. The use of CSTD has shown to significantly reduce overall chemical contamination (12.24% vs. 26.39%).[1] **Reference** 1. Simon N, Vasseur M, Pinturaud M, et al. Effectiveness of a Closed-System Transfer Device in Reducing Surface Contamination in a New Antineoplastic Drug-Compounding Unit: A Prospective, Controlled, Parallel Study. Ahmad A, ed. PLoS One 2016;11:e0159052. Available at: https://dx.plos.org/10.1371/journal.pone.0159052. **Recommendations**: Revise the proposed language to: *(c) Outer gloves used for HD compounding shall be changed between each different HD preparation if a closed system transfer device (CSTD) is not used.*

CCR 1737.10. Receiving.	All HD APIs and antineoplastic HDs shall be shipped and received from the supplier in segregated impervious plastic and labeled "Hazardous Drugs" on the outside of the delivery container.	**Rationale:** How HD APIs and antineoplastic HDs are shipped is something health-systems cannot control and is directly controlled by the distributing companies. **Recommendations**: To consider removing the entire section.
CCR 1737.11. Labeling, Packaging, Transport and Disposal (a):	(a) Any compounded HD preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5.	**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 1737.9 Labeling subsection (a):*** *(a) Any compounded HD preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5* *(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.*
CCR 1737.13 Compounding subsection (a):	(a) A disposable preparation mat shall be placed on the work surface of the C-PEC when compounding HD preparations. Where the compounding is a sterile preparation, the preparation mat shall be sterile. The preparation mat shall be changed immediately if a spill occurs, after each HD drug, and at the end of daily compounding activity.	**Rationale:** USP 800 language states that a plastic-backed preparation mat should be placed on the work surfaces of the C-PEC. The mat should be changed immediately if a spill occurs and regularly during use and should be discarded at the end of the daily compounding activity. Additionally, CSTDs are used when compounding HD drugs to prevent spills and enhance worker protection. If the regulation required for preparation mats be used when compounding HD drugs, this can be a patient safety concern in the event of a shortage as institutions will no longer be able to do HD compounding for patients. **Recommendations**: Revise language to be consistent with USP 800 requirements: *(a) A disposable preparation mat ~~shall~~ should be placed on the work surface of the CPEC when compounding HD preparations. Where the compounding is a*

		sterile preparation, the preparation mat shall be sterile. The preparation mat shall be changed immediately if a spill occurs, ~~after each HD drug~~, during decontamination between different HD, and at the end of daily compounding activity.
CCR 1737.14. Administering subsection (b)	(b) When furnishing an antineoplastic HD, a sufficient supply of gloves that meet the ASTM D-6978 standard to allow for appropriate administration, handling, and disposal of HD drugs by the patient or the patient's agent shall be provided.	**Rationale:** In health facilities where antineoplastic HD are dispensed and administered by licensed health care professionals who are trained to handle HDs. Supplies such as ASTM D-6978 grade gloves, and HD disposal bins are readily available. **Recommendations:** 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 trained and authorized to administer HD medications and not dispensed for outpatient use. *(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.*
CCR 1737.16. Spill Control	The premises shall maintain a list of properly trained and qualified personnel able to clean up an HD spill. An SOP shall outline how such a qualified person will be always available while HDs are handled.	**Rationale:** As required by USP 800, personnel are trained to handle HD, which includes cleaning up an HD spill, prior to handling HD. In large and multi-hospital health-systems, maintaining a list of all qualified personnel to attend an HD spill would be difficult. **Recommendations**: Recommend the following revision to the following proposed regulation: *~~The premises shall maintain a list of properly trained and qualified personnel able to clean up an HD spill.~~ An SOP shall outline how such a qualified person to clean up an HD spill will be always available while HDs are handled.*
Radiopharmaceutical- Preparation, Compounding, Dispensing, and Repackaging		
CCR 1738.4 Personnel Qualifications, Training, and Hygiene subsection (c)	(c) Aseptic manipulation competency initial training and competency and ongoing training and competency documentation shall include the Primary Engineering Control (PEC's) type and PEC unique identifier used during the evaluation. Aseptic manipulation competency evaluation and requalification	**Rationale:** The current USP 825 chapter does not require the PEC unique identifier to be documented for personnel training. Requiring a PEC unique identifier only adds to the additional documentation burden. **Recommendation:** Recommend the Board of Pharmacy to consider removing the requirement of "PEC unique identifier"

	shall be performed using the same procedures, type of equipment, and materials used in aseptic compounding.	**Recommendation:** *(c) Aseptic manipulation competency initial training and competency and ongoing training and competency documentation shall include the Primary Engineering Control (PEC's) type ~~and PEC unique identifier~~ used during the evaluation. Aseptic manipulation competency evaluation and requalification shall be performed using the same procedures, type of equipment, and materials used in aseptic compounding.*
CCR 1738.5. Facilities and Engineering Controls subsection (d)	(d) Compounding shall not take place in the SRPA.	**Rationale:** Per USP 825, for compounding sterile radiopharmaceuticals, the ISO 5 PEC must be placed in a classified area. However, non-radiopharmaceutical sterile compounds were not applicable for this restriction in USP 825. Prohibiting all compounding at SRPA would have a significant impact in the workload on health-systems that does not have a dedicated classified room for radiopharmaceuticals as they would not be able to prepare any supportive meds that has an SRPA. **Recommendation** *(d) Radiopharmaceutical compounding shall not take place in the SRPA.*
CCR 1738.5. Facilities and Engineering Controls subsection (j)	(j) A dynamic airflow smoke pattern test must be performed initially and at least every 6 months for all classified spaces and equipment. All dynamic airflow smoke pattern tests shall be immediately retrievable during inspection. A copy of the test shall be provided to the Board's inspector if requested in accordance with the timeframes set forth in Section 4105 of the Business and Professions Code.	**Rationale:** USP 825 requires a visual smoke study for classified spaces if there are low air returns. A dynamic airflow smoke pattern test is conducted initially and every 6 months to ensure proper PEC placement and staff maintaining unidirectional airflow (first air). **Recommendation** Request clarification on the purpose of dynamic airflow smoke pattern test for all classified spaces. In addition, recommend the BOP be consistent with USP 825 recommendations and remove this proposed subsection.
CCR 1738.6. Microbiological Air and Surface Monitoring subsection (b)	(b) In addition to the SOPs at a minimum every 6 months, air and surface sampling results shall be identified to at least the genus level, regardless of the colony forming units (CFU) count, to trend for growth of microorganisms. Trends of microorganism growth must be identified and evaluated.	**Rationale:** USP 825 recommends identifying sampling results on a genus level for actionable CFUs (CFUs exceeding action levels). BOP language is not consistent with USP 825 recommendations, and in contrast will require health-systems to identify every CFU count at least to the genus level regardless of if they exceeded the CFU action levels. **Recommendation:** *(b) In addition to the SOPs at a minimum every 6 months, air and surface*

		sampling results shall be identified to at least the genus level, ~~regardless of~~ when the colony forming units (CFU) count exceeds action level to trend for growth of microorganisms. Trends of microorganism growth must be identified and evaluated.
CCR 1738.10. Preparation subsection (c)	(c) When preparing radiopharmaceuticals with minor deviations ("preparation with minor deviations" as defined in USP Chapter 825) an SOP shall at least define the circumstances that necessitated the deviation and all quality control testing requirements and limits. Such circumstances shall, at a minimum, include patient need or facts that support the deviation that maintains the appropriate quality and purity (radiochemical purity and radionuclidic purity) as specified in individual monographs, and other applicable parameters as clinically appropriate in the professional judgment of the pharmacist.	**Rationale:** The proposed language is inconsistent with USP 825 recommendations, will require health-systems to incorporate patient need which may not be pertinent information. **Recommendation:** *(c) When preparing radiopharmaceuticals with minor deviations ("preparation with minor deviations" as defined in USP Chapter 825) an SOP shall at least define the circumstances that necessitated the deviation and all quality control testing requirements and limits. Such circumstances shall, at a minimum, ~~include patient need or~~ facts that support the deviation that maintains the appropriate quality and purity (radiochemical purity and radionuclidic purity) as specified in individual monographs, and other applicable parameters as clinically appropriate in the professional judgment of the pharmacist.*
CCR 1738.14. Quality Assurance and Quality Control subsection (b)	(b) The board shall be notified in writing within 72 hours of a complaint involving a radiopharmaceutical. Recalls and adverse events must be reported to the Board and other agencies in compliance with relevant provisions of law.	**Rationale:** A requirement of 72 hours may not provide sufficient time for health-systems to investigate and notify the necessary regulatory bodies in cases where it occurs over the holiday weekend. **Recommendation:** *(b) The board shall be notified in writing within ~~72 hours~~ 3 business days of a complaint involving a radiopharmaceutical. Recalls and adverse events must be reported to the Board and other agencies in compliance with relevant provisions of law.*
CCR 1738.14. Quality Assurance and Quality Control subsection (c)	(c) In addition to subsection (b), all complaints related to a potential quality problem with a radiopharmaceutical and all reported adverse events shall be reviewed by the pharmacist-in-charge within 72 hours of receipt of the complaint or occurrence. Such review shall be	**Rationale:** A requirement of 72 hours may not provide sufficient time for health-systems to investigate and notify the necessary regulatory bodies in cases where it occurs over the holiday weekend. **Recommendation:**

	documented and dated as defined in the SOPs.	*(c) In addition to subsection (b), all complaints related to a potential quality problem with a radiopharmaceutical and all reported adverse events shall be reviewed by the pharmacist-in-charge within 3 business days ~~72 hours~~ of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs.*

KAISER PERMANENTE®

May 31, 2024

Lori Martinez
California State Board of Pharmacy
2720 Gateway Oaks Dr., Ste 100
Sacramento, CA 95833

Submitted via electronic mail to: Lori Martinez, California State Board of Pharmacy

RE: ***Compounded Drug Products Regulations***

Dear Ms. Martinez:

Kaiser Permanente appreciates the opportunity to respond to the California Board of Pharmacy's request for comments on the proposed regulations addressing nonsterile compounding, sterile compounding, and hazardous drugs. Kaiser Permanente comprises the non-profit Kaiser Foundation Health Plan, the non-profit Kaiser Foundation Hospitals; and the Permanente Medical Groups, self-governed physician group practices that exclusively contract with Kaiser Foundation Health Plan. These entities work together seamlessly to meet the health needs of Kaiser Permanente's nine million members in California. Kaiser Permanente's pharmacy enterprise in California is comprised of hundreds of licensed pharmacies that are staffed by thousands of individual pharmacy licentiates. The frontmatter of this letter comprises our general comments on the entirety of the proposed regulations; our comments on specific elements of the regulations are in the table that follows.

Kaiser Permanente supports commonsense compounding standards that promote the preparation of safe and effective compounded drug products, which is the reason that we support the adoption of the United States Pharmacopeial Standard's (USP) compounding standards for non-sterile and sterile drug products. Just as the USP expert committee created the USP compounding standards using deliberative and evidence-based process, we believe that any state compounding regulations that exceed the requirements in the USP compounding chapters should be supported by high-quality empirical evidence. The process of developing the new USP compounding chapters spanned more than 10 years with rigorous review of current scientific evidence and more than 10,000 public comments.[1] In this rulemaking package, the Board has proposed expansive compounding regulations, some of which would make recommendations in the USP chapters compulsory and some of which were not included in USP's compounding standards. The Board claims that its "USP plus" approach to regulating compounding is necessary to protect California consumers. However, throughout the rulemaking process (including the publication of this rulemaking package), the Board has failed to provide any empirical evidence (e.g. peer-reviewed journal articles, meta-analyses, etc.) to support any of its proposed compounding regulations.

In the Initial Statement of Reasons for this rulemaking, the Board claims that it considered two alternative options, which it determined would not be "more effective in carrying out the purpose for which the action is proposed," nor would it "be as effective and less burdensome to affected private persons and equally

[1] Alana Hippensteele, *USP Expert Discusses Revisions to Compounding Chapters <795>, <797>*, Pharmacy Times (Nov. 18, 2022), https://www.pharmacytimes.com/view/usp-expert-discusses-revisions-to-compounding-chapters-795-797-.

effective in achieving the purposes of the regulation."[2] The two alternatives that the Board allegedly considered were: (1) not implementing the proposed regulation and (2) "not establishing additional regulatory standards beyond the minimum national standards set by USP." Kaiser Permanente agrees with the Board's determination that taking no action and leaving the Board's current compounding regulations in place would cause confusion among the regulated public. The Board's stated justification for declining to adopt any compounding regulations and simply requiring the regulated public to meet the applicable USP standards is that the Pharmacy Law gives the Board the authority to adopt regulations that exceed USP standards and that doing so "provides clarification to the board's regulated public and benefits the health and welfare of California residents."

Kaiser Permanente disagrees with the Board's conclusion that establishing additional regulatory requirements is more effective and less burdensome than choosing to enforce the USP compounding chapters. During the Board's February 2023 Enforcement Committee meeting, the Board presented photographs showing dirty and disorganized pharmacies, ostensibly as "evidence" that the "USP plus" approach to regulating compounding is necessary to protect the health and welfare of California residents.[3] While we acknowledge the unacceptable state of the pharmacies in the photographs presented by the Board, we strongly disagree that the photographs presented by the Board provide substantial evidence, as defined in California Government Code section 11349(a), of the need for the proposed regulation.[4] First, the pharmacies in the photographs presented by the Board were almost certainly in violation of existing Board of Pharmacy regulations (e.g. 16 CCR 1714(c) and 16 CCR 1735.6(b)) as well as USP standards (e.g. USP 795, 4.1). If the problems that Board inspectors have encountered in pharmacies that compound medications are violations of the laws and regulations that the Board already enforces, these photographs provide no evidence that additional regulations that exceed the USP standards are necessary. Second, the photographs presented by the Board are, at best, hearsay evidence as defined in California Evidence Code section 1200(a) and, as such, we believe that if the evidence supporting the regulation is challenged (e.g. in a petition for declaratory relief), it is possible that the trier of fact could determine that the supporting evidence is composed solely of hearsay and declare the regulation invalid.[5]

We have focused our discussion of the evidence presented by the Board on the photographs presented at the February 2023 Enforcement and Compounding Committee meeting because the Board has not presented any other evidence to justify this rulemaking in any public forum. Given the Board's failure to present substantial evidence that the proposed regulation is necessary, we recommend that the Board withdraws this regulation and either (1) presents bona fide evidence that the proposed regulation is necessary or (2) enforce the standards provided in the USP compounding chapters as required by California Business and Professions Code section 4126.8.

In the Notice of Proposed Action for this regulation, the Board claims "the Board is not aware of any negative cost impacts that a representative private person or business would necessarily incur in reasonable compliance with proposed action."[6] It is possible that the Board is not aware of any negative

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[2] California Board of Pharmacy, *Initial Statement of Reasons Compounded Drug Products*, https://www.pharmacy.ca.gov/laws_regs/1735_isr_24.pdf (last visited May 23, 2024).
[3] California Board of Pharmacy, *February 2022 Enforcement and Compounding Committee Report*, https://www.pharmacy.ca.gov/meetings/agendas/2023/23_feb_enf_mat.pdf (last visited May 23, 2024).
[4] Cal. Gov't Code § 11349(a).
[5] Cal. Evid. Code § 1200(a).
[6] California Board of Pharmacy, *Notice of Proposed Regulatory Action Concerning: Compounded Drug Products*, https://www.pharmacy.ca.gov/laws_regs/1735_npa_24.pdf (last visited May 23, 2024).

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cost impacts that business will suffer in complying with this regulation; however, we find that claim dubious. It ought to have been obvious to the Board that the proposed requirements to change outer chemotherapy gloves (16 CCR 1737.7(c)) and disposable preparation mats (16 CCR 1737.13(a)) after each Hazardous Drug (HD) preparation would be likely to have a material impact on supply costs for every pharmacy that engages in a substantial amount of HD compounding. Kaiser Permanente conservatively estimates that these two requirements alone will increase our organization's supply costs by $4.5 million per year. We further estimate that the additional time it takes to change gloves and preparation mats is likely to require hiring additional compounding personnel resulting in an estimated $2.8 million increase in annual labor costs. We expect other organizations are likely to experience similar cost impacts. As such, we encourage the Board to reassess the potential economic impacts of this regulation and, if required, provide the analysis required by California Government Code section 11346.5(a)(7).[7]

Finally, the rulemaking package did not include information about when the Board intends for the proposed regulation to take effect. Over the past decade, Kaiser Permanente has expended significant time and money to ensure that our pharmacies meet the requirements of the USP compounding chapters and the Board's compounding regulations. It will similarly take a great deal of time and money for us to meet the requirements of the proposed regulations. Therefore, we implore the Board to set an effective date for the regulations that will provide the regulated public with ample time to come into compliance with these new requirements. We suggest that at least one year from the date that the regulation is filed with the Secretary of State would be a reasonable effective date.

Kaiser Permanente appreciates the opportunity to provide feedback in response to the proposed regulations addressing nonsterile compounding, sterile compounding, and hazardous drugs. If you have questions, please contact John Gray (562.417.6417; john.p.gray@kp.org) or Rebecca Cupp (562.302.3217; rebecca.l.cupp@kp.org).

Respectfully,

John P. Gray, PharmD, MSL
Director, National Pharmacy Legislative and Regulatory Affairs
Kaiser Permanente

[7] Cal. Gov't Code § 11346.5(a)(7).

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Section, Subdivision	Proposed Language	Recommendation/Comment
Article 4.5 Nonsterile Compounding		
1735.1(a)	Nonsterile compounding is performed by or under the direct supervision and control of a licensed pharmacist pursuant to a patient specific prescription, unless otherwise specified in this article.	"Direct supervision and control," is a defined term in the Pharmacy Law, while "supervision" is not. To provide clarity to the regulated public on the nature of pharmacist supervision that is required for pharmacy technicians compounding CNSPs, we recommend using the defined term.
1735.1(h)	When a CNSP is furnished to a patient or patient's agent, ~~I~~in addition to the provisions provided in section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning proper use, storage, handling, and disposal of the CNSP and related supplies furnished.	To avoid confusion about the situations in which consultation is required, the regulation should specify that consultation is only required when the CNSP is furnished to the patient or patient's agent.
1735.3(a)	~~Prior to admitting any personnel into a compounding area, the supervising pharmacist shall evaluate whether compounding personnel is experiencing any of the following: rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection, or any other medical condition, to determine if such condition could contaminate a CNSP or the environment ("contaminating condition"). After such evaluation and determination, the supervising pharmacist shall not allow personnel with potentially contaminating conditions to enter the compounding area.~~	The USP 795 chapter adequately addresses the requirement for the designated person to evaluate individuals with "potentially contaminating conditions," and determine whether they should be excluded from working in the compounding area until their condition is resolved. In the Initial Statement of Reasons, the Board claims that this regulation is necessary "to prevent contamination of the CNSP."[8] However, the Board has failed to provide any concrete evidence that establishing this more prescriptive requirement will be more effective in preventing contamination of CNSPs than the requirement in Section 3 of USP 795.
1735.4(b)	~~Purified water, distilled water, or reverse osmosis water shall be used for rinsing equipment and utensils.~~	The USP 795 chapter adequately addresses the recommended use of purified, distilled, or reverse osmosis water for rinsing equipment and utensils. In the Initial Statement of Reasons, the Board claims that the use of purified water, distilled water, or reverse osmosis water is necessary to "ensure cross contamination does not occur from chemical elements within tap water."[9] However, the Board has failed to provide any concrete evidence regarding the frequency with which 'cross contamination' from 'chemical elements' in tap water occurs or that such cross contamination presents a bona fide risk to consumers.
1735.7(c)(1)	The date ~~and time~~ of compounding, which is the time when compounding of the CNSP started, and which determines when the assigned BUD starts.	The Initial Statement of Reason erroneously states that the requirement to document the date and time of compounding is "included within the USP Chapter."[10] In fact, the USP 795 chapter

[8] Initial Statement of Reasons, supra.
[9] Initial Statement of Reasons, supra.
[10] Initial Statement of Reasons, supra.

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		provides the flexibility to record either the date or the date and time. Since it appears that the Board's intent is to align with the USP chapter, we recommend deleting "and time" from the regulation.
1735.7(c)(5)	The identity of each person performing the compounding, the person ~~who has~~ exercising direct supervision and control over ~~oversight of~~ compounding, and the pharmacist verifying the final drug preparation.	The term "direct oversight" is vague. Conversely, "Direct supervision and control," is a defined term in the Pharmacy Law. In some facilities, there might be several pharmacists who are engaged in the compounding workflow. We recommend amending the regulation to use the term "direct supervision and control" to make it clear to the regulated public which individuals' identities should be recorded in the compounding record.
1735.10(c)	If antimicrobial effectiveness testing results provided by a current FDA-registered drug establishment or outsourcing facility or published in current peer-reviewed literature sources are used, the reference in its entirety (including the raw data and testing method suitability) shall be readily retrievable in the compounding pharmacy in accordance with Business and Professions Code section 4081 for three years from the last date the CNSP was dispensed.	To ensure that this information is available to Board of Pharmacy inspectors as the regulation intends, we believe the regulation should be amended to indicate that the required reference must be readily retrievable in the pharmacy that performed the compounding of the CNSP in question.
1735.11(a)(2)	(a) The facility's standard operating procedures (SOPs) for nonsterile compounding shall be followed and shall: ~~(1) Comply with USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding.~~ (2) Also describe the following: ~~(A) Methods by which the supervising pharmacist will ensure the quality of CNSPs.~~ (~~B~~A) If applicable, the ~~P~~procedures for handling, compounding, and disposal of infectious materials. The SOPs shall also describe the facility's protocols for cleanups and spills in conformity with local health jurisdictional standards, if applicable.	In the Initial Statement of Reasons, the Board contends that pharmacies are required to meet the requirements of USP Chapter 1163 "per BPC 4126.8."[11] Business and Professions Code section 4126.8 requires pharmacies to compound drug preparations in a manner consistent with "the pharmacy compounding chapters of USP including relevant testing and quality assurance [requirements]."[12] The USP 795 chapter already provides relevant quality assurance requirements, including referencing USP chapter 1163; therefore, including a requirement for facilities' Standard Operating Procedures (SOP) to comply with all elements of USP chapter 1163 is unnecessary. A justification for 1735.11(a)(2)(A), the requirement that the facility's SOPs address how "the supervising pharmacist will ensure the quality of CNSPs," is conspicuously absent from the Initial Statement of Reasons. As such, we are unsure why this requirement was included

[11] Initial Statement of Reasons, supra.
[12] Cal. Bus. & Prof. Code § 4126.8.

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		in the proposed regulation. We recommend that this SOP requirement be deleted because it is duplicative with the rest of the article and USP Chapter 795. Specifically, the methods by which the supervising pharmacist will ensure the quality of CNSPs will be to comply with the requirements of the regulation and USP 795. Not all facilities that compound CNSPs handle infectious materials. The facility's SOPs should only be required to address the handling, compounding, and disposal of infectious materials if the facility handles infectious materials.
1735.12(a)	(a) The facility's quality assurance program shall comply with section 1711 ~~and the standards contained in USP Chapter 1163, entitled Quality Assurance in Pharmaceutical Compounding.~~ In addition, the facility's quality assurance program shall include ~~the following:~~ ~~(1) A~~a written procedure for scheduled action, such as a recall, in the event any CNSP 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.~~	In the Initial Statement of Reasons, the Board contends that pharmacies are required to meet the requirements of USP Chapter 1163 "per BPC 4126.8."[13] Business and Professions Code section 4126.8 requires pharmacies to compound drug preparations in a manner consistent with "the pharmacy compounding chapters of USP including relevant testing and quality assurance [requirements]."[14] The USP 795 chapter already provides relevant quality assurance requirements, including referencing USP chapter 1163; therefore, including a requirement for pharmacies to meet all elements of USP chapter 1163 is unnecessary. The USP 795 chapter addresses temperature monitoring, documentation, and follow-up for areas where CNSPs are stored in sufficient detail that requiring a written standard operating procedure would be duplicative. In the Initial Statement of Reasons, the Board claims that this regulation is necessary to "ensure appropriate action will be taken timely should it be needed to ensure patient safety."[15] The Board fails to recognize that existing regulations (e.g. 16 CCR 1714(b)) require all pharmacies to ensure that medications are "safely and properly maintained and secured" and that existing law (e.g. BPC 4084 and 4086) prohibits pharmacies from trading in adulterated drugs. Because the USP 795 Chapter and existing law and regulation

[13] Initial Statement of Reasons, supra.
[14] Cal. Bus. & Prof. Code § 4126.8.
[15] Initial Statement of Reasons, supra.

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		require pharmacies to store drugs at the appropriate temperature, the proposed regulation in 1735.12(a)(2) is unnecessary.
1735.12(b)	~~The Board shall be notified in writing within 72 hours of the facility's receipt of a complaint of a potential quality problem or the occurrence of an adverse drug event involving a CNSP.~~	Business and Professions Code section 4126.9 already requires a pharmacy that issues a recall notice for a CNSP to notify the patient, prescriber, and Board within 12 hours of the recall notice if certain conditions are met. The Agency for Healthcare Research and Quality defines an adverse drug event as "harm experienced by a patient as a result of exposure to a medication."[16] The requirement in existing law ensures that the Board is notified of serious quality and safety issues while reducing the likelihood that the Board will be notified of spurious issues (e.g. upset stomach, headache, etc.), which could be construed to meet the definition of an 'adverse drug event.' In contrast, if the regulation is adopted as written, one could argue pharmacies would be required to report to the Board any time a patient complains of any minor problem that they attribute to the use of a CNSP. Therefore, we recommend deleting this requirement from the proposed regulation.
1735.14(b)	Policies and procedures and SOPs required by USP Chapter 795 and this article ~~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~~ policy and procedure and SOP 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.	As the proposed regulation is written, any and all records related to compounding CNSPs would be required to include a complete audit trail showing "all revisions and updates." Complying with this requirement would be administratively burdensome, would increase costs associated with document retention (whether electronic or hard copy records), and in some cases is likely to be impracticable based on the capabilities of the software system(s) used to generate and maintain the records. To more appropriately balance the recordkeeping burden with the Board's needs to understand when and by whom documents were edited, we recommend amending the proposed regulation to require pharmacies to maintain an audit trail of changes to policies and procedures and SOPs.
Article 4.6 Sterile Compounding		
1736(a)	"Compounding personnel" means any person involved in any procedure, activity, or oversight of ~~the~~ compounding ~~process~~.	The term "compounding process" is not defined in the Pharmacy Law or the USP 797 Chapter. The term "compounding" is defined in the USP 797 Chapter. We recommend using the defined term "compounding" rather than the potentially ambiguous term

[16] *Medication Errors and Adverse Drug Events*, Patient Safety Network (Sept. 7, 2019), https://psnet.ahrq.gov/primer/medication-errors-and-adverse-drug-events.

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		"compounding process" in the definition of the term "compounding personnel."
1736.1(a)	For the purposes of this article, sterile compounding occurs, by or under the direct supervision and control of a licensed pharmacist, pursuant to a patient specific prescription, unless otherwise specified in this article.	"Direct supervision and control," is a defined term in the Pharmacy Law, while "supervision" is not. To provide clarity to the regulated public on the nature of pharmacist supervision that is required for pharmacy technicians compounding CSPs, we recommend using the defined term.
1736.1(b)	~~CSPs for direct and immediate administration as provided in the Chapter shall only be compounded in those limited situations where the failure to administer such CSP could result in loss of life or intense suffering of an identifiable patient. Any such compounding shall be only in such quantity as is necessary to meet the immediate need of the patient. Documentation for each such CSP shall include identification of the CSP, compounded date and time, number of units compounded, the patient's name and patient's unique identifier and the circumstance causing the immediate need of the patient. Such documentation may be available in the patient's medical record and need not be redocumented by the compounding staff if already available.~~	The USP 797 Chapter provides sufficient guidance on the preparation of immediate use CSPs. We are very concerned that this proposed regulation will lead to delays in the preparation and administration of potentially lifesaving medications during urgent and emergent situations (e.g. Code Blues in the hospital setting). The additional requirements in the proposed regulation—some of which are in the Board's current compounding regulations—are likely to have a chilling effect on the preparation of immediate use CSPs out of fear that the Board will take disciplinary or administrative action against licensees. Furthermore, we believe that very few Board inspectors have completed the specialized training (e.g. a post-graduate hospital pharmacy residency) related to the treatment of critically ill hospital patients that would be required to make a well-reasoned assessment of whether the failure to administer a CSP could result in the loss of life or intense suffering. Finally, by including medical record documentation requirements for immediate use CSPs in the regulation, we believe that a pharmacist whose attention should be fully devoted to preparing an urgently needed CSP will likely be distracted by the comparably mundane task of ensuring that the documentation in the medical record meets the Board's requirements.
1736.1(g)	When a CSP is furnished to a patient or patient's agent, ~~i~~in addition to the provisions 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.	To avoid confusion about the situations in which consultation is required, the regulation should specify that consultation is only required when the CSP is furnished to the patient or patient's agent.
1736.2(d)	Compounding personnel ~~or persons with direct oversight over compounding personnel~~ who fail any aspect of the aseptic manipulation ongoing training and competency evaluation shall not be involved in the compounding ~~or oversight of the~~	To more clearly delineate the difference in approach to a failed evaluation between compounding personnel and persons with only direct oversight of compounding personnel, we recommend deleting the reference to "persons with direct oversight over compounding

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	~~preparation~~ of a CSP using the procedures and type of equipment associated with the failed evaluation until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs. A person with only direct oversight over compounding personnel who fails any aspect of the aseptic manipulation ongoing training and competency evaluation may continue to provide only direct oversight for no more than ~~14~~ 21 days after a failure of any aspect while applicable aseptic manipulation ongoing training and competency evaluation results are pending.	personnel" from the first sentence. There might be situations in which a compounding personnel fails their competency evaluation for preparing CSPs in the hazardous drug compounding suite but passes their evaluation for compounding non-hazardous drugs. The regulation should clearly indicate that, in such a case, the individual could continue to compound in the non-hazardous drug compounding suite. Finally, to accommodate for shortages and shipping delays (e.g. due to inclement weather) of compounding testing supplies, we suggest increasing the time period that a person with only direct oversight over compounding personnel can continue to provide direct oversight to 21 days.
1736.4(c)	~~(c)(1) Designated compounding area(s) shall typically be maintained at a temperature of 20° Celsius or cooler.~~	The proposed regulation, which says, "compounding areas ***shall typically*** be maintained at a temperature of 20° Celsius or cooler," and the USP 797 Chapter, which says "the cleanroom suite ***should be*** maintained at a temperature of 20° or cooler," have the same meaning. The phrase "shall typically" in the Board's proposed regulation allows for situations in which the compounding area is not at a temperature of 20° Celsius or cooler just as the phrase "should be" in the USP 797 Chapter does. Given the fact that USP and the proposed regulation are functionally the same, we recommend deleting the proposed regulation.
1736.4(f)	No CSP shall be compounded if the compounding environment fails to meet criteria specified in law or the facility's SOPs. This paragraph does not prohibit a pharmacy from treating a compounding environment that is typically USP classified space as a segregated compounding area if all applicable criteria specified in law and the facility's SOPs are met.	There can be cases in which deviations in the performance of the compounding environment would not support the assignment of a Category 2 BUD but would support a Category 1 BUD. For example, there might be fluctuations in the pressures of the containment secondary engineering control with no impact on the functioning of the primary engineering control(s). The regulation should be clear that if all requirements in the law and the facility's SOPs are met, it would not be prohibited to continue to use the compounding environment and assign shorter (i.e. Category 1) BUDs.
1736.5(a)	Testing and certification of all ISO classified areas shall be completed by a qualified technician knowledgeable with certification methods and procedures outlined in 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 the most recent version of the CETA	To promote the durability of the regulation and reduce the need for future rulemaking to reference revised CETA standards, we recommend amending the regulation such that it references the most recent version of the CETA Certification Guide for Sterile Compounding Facilities.

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	Certification Guide for Sterile Compounding Facilities ~~(CAG003, Revised 2022)~~, which is hereby incorporated by reference.	
1736.6(a)	~~At a minimum of every 6 months, air and surface sampling results shall be identified to at least the genus level, regardless of the CFU count to trend for growth of microorganisms.~~ Investigation of air and surface sampling results that exceed action levels must be consistent with the deviation and must include evaluation of trends.	In the Initial Statement of Reasons, the Board attempts to justify the requirement to perform speciation to the genus level of microbes that are identified during viable air and surface sampling at least every six months by raising the hypothetical concern that a microorganism that is not speciated might be a highly pathogenic microorganism.[17] In the Initial Statement of Reasons, the Board also implies that not speciating microbes that do not exceed the USP action levels could lead to patient deaths. This is pure speculation. Kaiser Permanente performed a literature review (see Appendix A for search terms and results) to assess whether there are data to support the practice of speciating isolated microbes to the genus level when the USP action level is not exceeded. Based on our literature review, we found no relevant peer reviewed studies; therefore, we conclude that there is no compelling evidence to support adopting this practice. Additionally, the Board has failed to provide any concrete evidence to support the notion that speciating all microbes found during air and surface sampling that do not exceed action levels will improve safety or prevent untoward events; therefore, this requirement should be removed from the proposed regulation.
1736.9(b)	(b) Incubators used by the facility shall be cleaned, maintained, calibrated, and operated in accordance with manufacturers' specifications. (1) For incubators without specific manufacturers' specifications, cleaning shall take place at least every 30 days and calibration shall take place at least every 12 months. (2) If an external temperature monitoring device is used to monitor the temperature of an incubator, then the temperature monitoring device shall be calibrated in accordance with the manufacturer's specifications.	Some organizations might choose to use a continuous temperature monitoring system to monitor incubator temperatures. The regulation should be amended to clarify that practice is permitted if the temperature monitoring device is calibrated according to the manufacturer's specifications.
1736.11(c)(5)	The identity of each person performing the compounding, the person ~~that has~~ exercising direct supervision and control over	The term "direct oversight" is vague. Conversely, "Direct supervision and control," is a defined term in the Pharmacy Law. In some facilities, there might be several pharmacists who are engaged in the

[17] Initial Statement of Reasons, supra.

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	~~oversight of~~ compounding, and the pharmacist verifying the final drug preparation.	compounding workflow. We recommend amending the regulation to use the term "direct supervision and control" to make it clear to the regulated public which individuals' identities should be recorded in the compounding record.
1736.12(b)	If applicable, ~~A~~a pharmacist performing or supervising sterile compounding is responsible for ensuring validation of an alternative method for sterility testing is done in compliance with USP Chapter 1223, Validation of Alternative Microbiological Methods and shall receive and maintain documentation of the method-suitability for each CSP formulation for which the alternate method is used.	Sterility testing is required for Category 3 and some Category 2, depending on the assigned Beyond Use Date, CSPs. Because the regulation does not apply to Category 1 and some Category 2 CSPs, we suggest that the regulation be modified to indicate that this requirement needs to be met only when applicable to the CSP in question.
1736.14(c)	If applicable, ~~P~~prior to furnishing a CSP, the pharmacist performing or supervising sterile compounding is responsible for ensuring that sterility and endotoxin testing for BUD determination is performed and has received and reviewed the results. Results must be within acceptable USP limits. Test results must be retained as part of the compounding record.	Sterility and/or endotoxin testing are not required for all CSPs. Therefore, the regulation should be modified to indicate that this requirement needs to be met only when applicable to the CSP in question.
1736.17(a)	(a) Standard operating procedures (SOPs) for sterile compounding shall be followed and shall: ~~(1) Comply with USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding; and~~ (2) Define the following: ~~(A) Methods by which the pharmacist compounding or supervising the compounding will ensure the quality of compounded drug preparations;~~ (B) If applicable, the ~~P~~procedures for handling, compounding, and disposal of infectious materials. The SOPs shall describe the facility protocols for cleanups and spills in conformity with local health jurisdictional standards;	The Initial Statement of Reasons does not include a justification for the addition of the requirement to comply with USP Chapter 1163. We assume that the Board's view is that pharmacies are required to meet the requirements of USP Chapter 1163 "per BPC 4126.8," (as with 1735.12(a)).[18] Business and Professions Code section 4126.8 requires pharmacies to compound drug preparations in a manner consistent with "the pharmacy compounding chapters of USP including relevant testing and quality assurance [requirements]."[19] The USP 797 chapter already provides relevant quality assurance requirements, including referencing USP chapter 1163; therefore, including a requirement for facilities' Standard Operating Procedures (SOP) to comply with all elements of USP chapter 1163 is unnecessary. The Board's justification for the inclusion of 1736.17(a)(2)(A), the requirement that the facility's SOPs address how "the supervising pharmacist will ensure the quality of CNSPs," is also not present in the

[18] Initial Statement of Reasons, supra.
[19] Cal. Bus. & Prof. Code § 4126.8.

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		Initial Statement of Reasons. As such, we are unsure why this requirement was included in the proposed regulation. We recommend that this SOP requirement be deleted because it is duplicative with the rest of the article and USP Chapter 797. Specifically, the methods by which the supervising pharmacist will ensure the quality of CSPs will be to comply with the requirements of the regulation and USP 797. Not all facilities that compound CSPs handle infectious materials. The facility's SOPs should only be required to address the handling, compounding, and disposal of infectious materials if the facility handles infectious materials.
1736.18(a)	(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 facility's quality assurance program shall include ~~the following:~~ ~~(1)~~ ~~A~~a written procedure for scheduled action, such as a recall, in the event any CSP 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.~~	In the Initial Statement of Reasons, the Board contends that pharmacies are required to meet the requirements of USP Chapter 1163 "per BPC 4126.8."[20] Business and Professions Code section 4126.8 requires pharmacies to compound drug preparations in a manner consistent with "the pharmacy compounding chapters of USP including relevant testing and quality assurance [requirements]."[21] The USP 797 chapter already provides relevant quality assurance requirements, including referencing USP chapter 1163; therefore, including a requirement for pharmacies to meet all elements of USP chapter 1163 is unnecessary. The USP 797 chapter addresses temperature monitoring, documentation, and follow-up for areas where CSPs are stored in sufficient detail that requiring a written standard operating procedure would be duplicative. In the Initial Statement of Reasons, the Board claims that this regulation is necessary to "ensure appropriate action will be taken timely should it be needed to ensure patient safety."[22] The Board fails to recognize that existing regulations (e.g. 16 CCR 1714(b)) require all pharmacies to ensure that medications are "safely and properly maintained and secured" and that existing law (e.g. BPC 4084 and 4086) prohibits pharmacies from trading in adulterated

[20] Initial Statement of Reasons, supra.
[21] Cal. Bus. & Prof. Code § 4126.8.
[22] Initial Statement of Reasons, supra.

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		drugs. Because the USP 797 Chapter and existing law and regulation require pharmacies to store drugs at the appropriate temperature, the proposed regulation in 1736.18(a)(2) is unnecessary.
1736.20(b)	Policies and procedures and SOPs required by this article ~~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~~ policy and procedure and SOP 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.	As the proposed regulation is written, any and all records related to compounding CNSPs would be required to include a complete audit trail showing "all revisions and updates." Complying with this requirement would be administratively burdensome, would increase costs associated with document retention (whether electronic or hard copy records), and in some cases is likely to be impracticable based on the capabilities of the software system(s) used to generate and maintain the records. To more appropriately balance the recordkeeping burden with the Board's needs to understand when and by whom documents were edited, we recommend amending the proposed regulation to require pharmacies to maintain an audit trail of changes to policies and procedures and SOPs.
Article 4.7 Hazardous Drugs		
1737.1	When an HD is furnished to a patient or patient's agent, ~~I~~in addition to providing consultation in compliance with section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning handling and disposal of an HD or related supplies furnished.	To avoid confusion about the situations in which consultation is required, the regulation should specify that consultation is only required when the HD is furnished to the patient or patient's agent.
1737.5(c)	Where a pass-through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking. ~~A pass-through is not allowed between the C-SEC into an unclassified space.~~	In the Initial Statement of Reasons, the Board claims that "minor transfers [of gasses or vapors] may still occur and can impact the sterility of the area," in the case of a pass-through into unclassified space.[23] Kaiser Permanente performed a literature review (see Appendix A for search terms and results) to assess whether there are data to support the notion that a properly designed pass-through cannot be used between a C-SEC and unclassified space. Based on our literature review, we found no relevant peer reviewed studies; therefore, we conclude that there is no compelling evidence to support adopting this regulation. Additionally, the Board has failed to provide any concrete evidence to support the notion that a pass through between a C-SEC and unclassified space presents an unacceptable risk of contamination if the pass through is of an appropriate design. Therefore, we conclude that there is no empirical

[23] Initial Statement of Reasons, supra.

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		evidence that demonstrates a risk of contamination when there is a pass-through that connects that C-SEC to unclassified space when the pass-through has sealed, interlocking doors and is HEPA filtered and we recommend that this portion of the regulation be deleted.
1737.6	~~1737.6. Environmental Quality and Control.~~ ~~In addition to the standards in USP Chapter 800, Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article.~~ ~~(a) The SOPs of a premises where HDs are handled shall address environmental wipe sampling for HD surface residue, its frequency, areas of testing, levels of measurable contamination, and actions when those levels are exceeded.~~ ~~(b) When any actionable level of contamination is found, at a minimum the following shall occur as described in the SOPs:~~ ~~(1) Reevaluate work practices;~~ ~~(2) Reevaluate the appropriateness of deactivation, decontamination, and cleaning agents;~~ ~~(3) Re-train personnel on deactivation, decontamination, and cleaning; and~~ ~~(4) Re-train personnel on donning and doffing appropriate personal protective equipment (PPE).~~ ~~Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, and 4126.8, Business and Professions Code.~~	Commercially available HD wipe testing kits only test for a handful of HDs.[24] This severely limits the usefulness of wipe testing because a Designated Person will not know whether a wipe test was negative because compounding personnel are following the facility's SOPs or because the area tested was not exposed to the specific HDs that the selected testing kit tests for. Kaiser Permanente performed a literature review (see Appendix A for search terms and results) to assess whether there are data to support the practice of routine wipe sampling for HD residue. Based on our literature review, we found 13 peer-reviewed studies that utilized wipe sampling in the context of compounded HD preparations. Of those 13 studies, six used wipe sampling to assess the effectiveness of Closed-System Transfer Devices in limiting employee exposure to HDs, five used wipe sampling as a proxy for occupational exposure to HDs, and two used wipe sampling to assess the effectiveness of pharmacy automation in limiting employee exposure to HDs. Only one study assessed healthcare worker exposure to HDs using laboratory testing; in the case of this study, employee urine samples were tested for traces of four HDs. The investigators found that none of the 398 urine samples collected had "detectable or outside-of-the-reference-population concentrations for the four drugs evaluated."[25] Based on our literature review, we conclude that there is no compelling evidence to indicate that routine wipe sampling for hazardous drug residue improves employee or patient safety. Therefore, we recommend that this proposed regulation be deleted.
1737.7(c)	~~Outer gloves used for HD compounding shall be changed between each different HD preparation.~~	In the Initial Statement of Reasons, the Board claims that the requirement to change outer gloves between each different HD preparation is "necessary to prevent inadvertent cross

[24] Blake Shay & Alex Hayes-Porter, *Review HD Wipe Sampling Vendors*, 20 Pharmacy Purchasing and Products 6 (2023).
[25] Stefano Dugheri et al., *Analytical strategies for assessing occupational exposure to antineoplastic drugs in healthcare workplaces*, Medycyna Pracy (2018).

Section, Subdivision	Proposed Language	Recommendation/Comment
		contamination."[26] This justification is vague; however, we assume the Board means cross contamination of other HD preparations with HD residues. Kaiser Permanente performed a literature review (see Appendix A for search terms and results) to assess whether there are data to support the practice of changing the outer glove between each different HD preparation. Based on our literature review, we found one study that mentioned the practice of changing gloves during HD compounding. However, this study only assessed compounding employee perceptions of HD exposure and referenced 30-minute interval between glove changes as the standard.[27] The study did not assess the impact of more frequent glove changes (e.g. between different HD preparations) on cross contamination with HD residue. Therefore, we conclude that there is no compelling evidence to indicate that changing the outer chemotherapy gloves more frequently than the USP 800 Chapter recommends improves employee or patient safety. Additionally, the Board has failed to provide any concrete evidence that changing the outer chemotherapy gloves every 30 minutes or when torn, punctured, or contaminated, as recommended in the USP 800 Chapter, leads to an increased risk of 'cross contamination.' In attempting to establish this requirement, the Board also fails to recognize that many pharmacies routinely use Closed System Drug-Transfer Devices (CSTDs), which have been proven to prevent contamination with HD residues and vapors.[28] This requirement will also significantly increase supply costs for organizations. We conservatively estimate that this requirement will increase Kaiser Permanente's supply cost by $1.5 million per year. Because the proposed regulation will increase costs to organizations with no established benefits, we encourage the Board to remove the requirement to change outer gloves between each different HD preparation.
1737.8	~~1737.8. Hazard Communication Program.~~	In the Initial Statement of Reasons, the Board claims that this requirement is "in addition to the requirements of Title 8, California

[26] Initial Statement of Reasons, supra.

[27] Clémence Delafoy et al., Perception, knowledge, practices and training regarding the risk of exposure to antineoplastic drugs in three French compounding units, 29 Journal of Oncology Pharmacy Practice 1893–1906 (2023).

[28] *Closed System Drug-Transfer Device (CSTD)*, National Institute for Occupational Safety and Health (NIOSH) (Feb. 9, 2024), https://www.cdc.gov/niosh/healthcare/hazardous-drugs/cstd-research.html?CDC_AAref_Val=https://www.cdc.gov/niosh/topics/hazdrug/CSTD.html.

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	~~In addition to the standards in USP Chapter 800, Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article. The designated person shall develop the premise's hazardous communication program and document the program in the SOPs and training documents.~~ ~~Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, and 4126.8, Business and Professions Code.~~	Code of Regulations, Division 1," and the designated person "must develop the [Hazard Communication] program because the designated person "maintains the operations of the facility."[29] The Board's assessment fails to recognize that many facilities are fortunate to employ Environmental Health and Safety (EH&S) professionals who have specialized knowledge, skills, and experience in implementing hazard communication programs. While we believe it is reasonable for the designated person to collaborate with EH&S professionals to ensure that the hazard communication program will meet the needs of the pharmacy, it is not reasonable to expect the designated person to be solely responsible for developing and implementing the program when other expert resources are available. The Board also fails to recognize that the one paragraph proposed in this section of the regulation pales in scope to both state (8 CCR 5194) and federal regulations (29 CFR 1910.1200) and will add nothing to the rigor of the hazard communication programs are already required to be in place healthcare facilities. Additionally, the USP 800 Chapter includes rigorous requirements that all facilities, regardless of whether they employ an EH&S professional, are required to meet. However, unlike the Board's proposed regulation, which would make the designated person solely responsible for the facility's hazard communication program, the USP 800 Chapter is written in such a way that facilities that are fortunate enough to have an EH&S professional can leverage that individual's expertise to design and implement the hazard communication program. Given these factors, we recommend that this proposed regulation be deleted.
1737.10	~~1737.10. Receiving.~~ ~~In addition to the standards in USP Chapter 800, Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article. All HD APIs and antineoplastic HDs shall be shipped and received from the supplier in segregated impervious plastic and labeled "Hazardous Drugs" on the outside of the delivery container.~~	In the Initial Statement of Reasons, the Board claims that this regulation is necessary to "avoid contamination in the event of a spill during the shipping and receiving of an API and that the package also be immediately identifiable as a hazardous product to protect those handling the package."[30] The Board fails to recognize that pharmacies have no control over the manner in which their upstream suppliers ship hazardous drugs. Based on the text of the proposed regulation, if a pharmacist received a tote with unknown contents that contained a

[29] Initial Statement of Reasons, supra.
[30] Initial Statement of Reasons, supra.

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Section, Subdivision	Proposed Language	Recommendation/Comment
	~~Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, and 4126.8, Business and Professions Code.~~	hazardous drug, they would be in violation of the regulation through no fault of their own. This stance is unreasonable. If the Board believes it is necessary to establish a requirement to ship hazardous drugs in the manner described in the proposed regulation, then the Board should initiate a rulemaking to add such a requirement to 16 CCR 1783 (Manufacturer, Wholesaler, or Third-Party Logistics Provider Furnishing Drugs and Devices).
1737.13	~~1737.13. Compounding.~~ ~~In addition to the standards in USP Chapter 800, Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article.~~ ~~(a) A disposable preparation mat shall be placed on the work surface of the C-PEC when compounding HD preparations. Where the compounding is a sterile preparation, the preparation mat shall be sterile. The preparation mat shall be changed immediately if a spill occurs, after each HD drug, and at the end of daily compounding activity.~~ ~~(b) Only one HD preparation may be handled in a C-PEC at one time.~~ ~~Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, and 4126.8, Business and Professions Code.~~	In the Initial Statement of Reasons, the Board explains that it chose to establish the requirement to change the disposable preparation mat after each HD drug [preparation] "to reduce the risk of cross contamination as well as to ensure the sterility of the environment."[31] Kaiser Permanente performed a literature review (see Appendix A for search terms and results) to assess whether there are data to support the practice of changing the disposable preparation mat after each HD is prepared. Based on our literature review, the selected search terms yielded one study; however, it was not related to the use of preparation mats during HD compounding. Therefore, we conclude that there is no compelling evidence to indicate that changing the disposable preparation mat before compounding a different HD preparation reduces the risk or cross contamination or ensures the sterility of the compounding environment. Additionally, the Board has failed to provide any concrete evidence that changing the preparation mat in the event of a spill and regularly during use, as recommended in the USP 800 Chapter, leads to an increased risk of 'cross contamination' or threatens the sterility of the compounding environment. In attempting to establish this requirement, the Board also fails to recognize that many pharmacies routinely use CSTDs, which have been proven to prevent contamination with HD residues and vapors.[32] This requirement will also significantly increase supply costs for organizations. We conservatively estimate that this requirement will increase Kaiser Permanente's supply cost by $3 million per year. Because the proposed regulation will increase costs to organizations with no established benefits, we encourage the

[31] Initial Statement of Reasons, supra.
[32] NIOSH, supra.

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		Board to remove the requirement to change the disposable preparation mat after each HD drug preparation. The word "handled" is ambiguous. At its most conservative, the proposed 1737.13(b) could be applied to prohibit batch compounding of HDs, as defined in the USP 797 Chapter, because multiple HD preparations would be handled in the C-PEC during the same discrete batch compounding process. Additionally, some HDs (e.g. Abraxane) require a long time to go into solution. It would be unreasonable if the proposed regulation were applied such that compounding personnel could not work on compounding another preparation while waiting for the drug to dissolve. Given the ambiguous nature of the proposed regulation and the operational challenges that ambiguity would create, we suggest removing this provision from the regulation.
1737.14(b)	When furnishing an antineoplastic HD to the patient or patient's agent, a sufficient supply of gloves that meet the ASTM D-6978 standard to allow for appropriate administration, handling, and disposal of HD drugs by the patient or the patient's agent shall be provided.	To avoid confusion about the cases in which gloves must be provided to the patient or patient's agent, we recommend clarifying the regulation to indicate that this requirement applies only to situations in which the HD is supplied to the patient or patient's agent.
1737.16	The ~~premises~~ designated person shall maintain a list of properly trained and qualified personnel able to clean up an HD spill. An SOP shall outline how such a qualified person will be available at all times while HDs are handled.	A premises is a building, and a building is not able to maintain a list; therefore, we recommend amending the regulation by changing the term "premises" to "designated person".
1737.17(a)	The designated person for A~~A~~any ~~premises~~ pharmacy engaged in the compounding or handling of HDs shall maintain and follow written SOPs.	A premises is a building, and a building is not able to maintain a list; therefore, we recommend amending the regulation by changing the term "premises" to "designated person".

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Appendix A: Literature Review

The table below shows the results of PubMed literature searches to assess whether there is empirical evidence to support selected elements of the proposed regulations. The table provides the section, subdivision, and topic of the regulation in question as well as the PubMed search terms used, and the total number (relevant and irrelevant) of studies returned using these search terms.

Section, Subdivision	Topic	PubMed Search Terms	Number of Studies
1736.6(a)	Speciating to genus level	Search: (((pharmac*) AND (genus)) AND (microb* OR microorganis*)) AND ("air sampling" OR "surface sampling")	3
1737.5(c)	Pass-through from C-SEC to unclassified space	Search: ((("sterile compounding" OR "pharmacy compounding") AND ("pass through" OR "pass-through")) AND (hazardous)) AND (unclassified) Search: (((compoun*) AND ("pass through" OR "pass-through")) AND (hazardous)) AND (unclassified)	0
1737.6	Wipe sampling	Search: (("wipe sampling" OR "wipe testing" OR "wipe sample" OR "wipe test") AND (hazardous)) AND (compoun*)	20
1737.7(c)	Changing outer gloves	Search: ((((pharmac*) AND (hazardous)) AND (compoun*)) AND (chang*)) AND (glov*)	4
1737.13(c)	Changing preparation mats	Search: ((((pharmac*)) AND ("preparation mat" OR mat)) AND (hazardous)) AND (compoun*)	1

June 3, 2024

Dear CA Board of Pharmacy,

My name is Jasmine Parker, I graduated from University of the Pacific in 2021, and have been working as a staff pharmacist in a small independent compounding pharmacy for the last three years. While still new to the field, I have become increasingly familiarized with the ins and outs of compounding regulation through my experience both as a compounder and a supervisor of compounding activities. Though we are a very small business, we have been able to provide a unique service to hundreds of patients throughout the San Joaquin Valley in providing access to non-commercial and specialty medicines to expand the limits of patient care. As such, it is my duty to give input on laws and regulations that may negatively affect the patients we serve in an effort to prevent limitation or disruption of care. I have had the opportunity to use sections of my colleague Marie Cottman's document on the most recently proposed document on regulatory actions concerning compounded drug products and, from it, have compiled a list of the sections that were of particular interest to me. I have detailed my concerns for certain verbage used or the rationale behind the addition of new requirements. I ask that you take my comments into consideration and continue to stand true to your mission statement of protecting and promoting the health and safety of Californians by pursuing the highest quality of pharmacist's care and the appropriate use of pharmaceuticals through fair and accurate legislation, regulation, and enforcement.

Jasmine Parker, Pharm.D.
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Subdivision	Proposed Language	Comment/Concern/Recommendations
Article 4.5 Section 1735.2 (c)	*(c) Compounding personnel or persons with direct oversight over personnel performing compounding, who fail any aspect of ongoing training and evaluation shall not be involved in compounding or oversight of the preparation of a CNSP until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs.*	**COMMENT:** This statement removes a compounder from any and all compounding tasks, despite having only failed in one area. For example, if a pharmacist fails training in making capsules, can they suddenly no longer oversee the making of solutions? **RECOMMENDATION:** Please reword to: *(c) Compounding personnel or persons with direct oversight over personnel performing compounding, who fail any aspect of ongoing training and evaluation shall not be involved in the compounding or supervision of compounding of that specific dosage form ~~or oversight of the preparation of a CNSP~~ until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs.*
Article 4.5 Section 1735.4 (a)	*(b) Purified water, distilled water, or reverse osmosis water shall be used for rinsing equipment and utensils.*	**COMMENT:** This is overly complicated way to say "Don't use sink/tap water" **RECOMMENDATION:** Re-word to include all grades of water equal to or better than Purified Water. "*(b) Purified water, ~~distilled water, or reverse osmosis~~ or better grade of water shall be used for rinsing equipment and utensils."*
Article 4.5 Section 1735.10 (b)	*(b) A CNSP's BUD shall not exceed any of the following: (1) The chemical and physical stability data of the active pharmaceutical ingredient (API) and any added component in the preparation, (2) The compatibility and degradation of the container–closure system with the finished preparation (e.g., possible leaching, interactions, and storage conditions),*	**COMMENT:** There is often limited to no data regarding compounded formulations because they are novel and created based on individual patient need. As such, there would be no large studies or published data to detail things such as compatibility of ingredients or degradation due to a huge variety of possible inactive ingredients when compounding. **RECOMMENDATION:** Remove**.**
STERILE		
Article 4.6 Section 1736.1(e)(1)(B)	*(B) the preparation produces a clinically significant difference based on the medical need of an identified individual patient, as determined by:* *(i) the prescribing practitioner,* *(ii) the compounding pharmacist, and (iii) the dispensing pharmacist(s).*	**COMMENT:** There is no definition of "clinically significant" that can be applied **RECOMMENDATION:** Allow Federal statute 503A of the FD&C Act to stand on its own
Article 4.6 Section 1736.1(e)(3)	*(3) Is made with a non-sterile component for which a conventionally manufactured sterile component is available and appropriate for the intended CSP.*	**COMMENT:** There is no definition of "appropriate" that can be applied, this is based on pharmacist judgment. **RECOMMENDATION:** Remove.

Article 4.6 Section 1736.9(d)	*(d) All API and excipient components used to compound a CSP shall be manufactured by an FDA-registered facility, be accompanied by a Certificate of Analysis (COA), and suitable for use in sterile pharmaceuticals. A COA that includes the compendial name, the grade of the material, and the applicable compendial designations on the COA, must be received and evaluated prior to use, unless components are commercially available drug products. When the COA is received from a supplier, it must provide the name and address of the manufacturer. API and excipient components provided with a COA without this data shall not be used in a CSP.*	**COMMENT:** There is no definition of what constitutes "suitable for use in sterile pharmaceuticals" **RECOMMENDATION:***(d) All API and excipient components used to compound a CSP shall be manufactured by an FDA-registered facility, be accompanied by a Certificate of Analysis (COA)~~, and suitable for use in sterile pharmaceuticals~~. A COA that includes the compendial name, the grade of the material, and the applicable compendial designations on the COA, must be received and evaluated prior to use, unless components are commercially available drug products. When the COA is received from a supplier, it must provide the name and address of the manufacturer. API and excipient components provided with a COA without this data shall not be used in a CSP.*
Article 4.6 Section 1736.13(a)(4)	*(4) Name of compounding facility and dispensing facility (if different).*	**COMMENT:** Having one pharmacy put another pharmacy's name on its product label can create confusion regarding accuracy and liability**.** **RECOMMENDATION:** *(4) Name of compounding facility ~~and dispensing facility (if different)~~.*
Article 4.6 Section 1736.14(a)(1-3)	*(a) A CSP's beyond-use date (BUD) shall not exceed: (1) The chemical and physical stability data of the active pharmaceutical ingredient(s) 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); and* *(3) The shortest remaining expiration date or BUD of any of the starting components.*	**COMMENT:** This uses USP language for extended BUDs beyond and applies it to any compounded preparation. This will block the ability for any custom compounding, there is no way for there to be data regarding every possible formulation of CSP. **RECOMMENDATION:** Remove regulation.
Article 4.6 Section 1736.21(a)	*(a) Any allergenic extract compounding shall take place in a dedicated PEC. No other CSP may be made in this PEC.*	**COMMENT:** No basis in scientific fact. **RATIONALE:** If you can clean a chemo hood and use it to compound other non-chemo products, why are allergens not handled in the same way? **RECOMMENDATION:** Remove.
HAZARD		

Article 4.7 Section 1737.7(c)	(c) Outer gloves used for HD compounding shall be changed between each different HD preparation.	**COMMENT:** Regarding sterile compounding, this process is costly and wasteful of gloves, and gives more opportunities for possible contamination of the hood during each re-gloving. When compounding using CSTDs, there is expected to be no leakage, exposure, or contamination from the drug products, and as such, is not expected to soil outer gloves. **RECOMMENDATION:** *Outer gloves used for sterile HD compounding shall be changed in compliance with 1737.7 (b).*
Article 4.7 Section 1737.7(d)	*(d) PPE shall be removed to avoid transferring contamination to skin, the environment, and other surfaces. PPE worn during compounding shall be disposed of in the proper waste container before leaving the C-SEC. SOPs shall detail the donning and doffing of PPE and where it takes place in the C-SEC.*	**COMMENT:** Removing garb in the sterile C-SEC (buffer room) will increase the risk of contaminating the C-SEC with particulates from the compounder. **RECOMMENDATION:** Add language to clarify difference between non sterile and sterile area donning and doffing procedures including the specific situation.
Article 4.7 Section 1737.13(b)	*(b) Only one HD preparation may be handled in a C-PEC at one time.*	**COMMENT:** There are products that take significant time to reconstitute (15 to 30 min) and if there is only one available hood to work in, this severely hinder's the ability of a facility to service multiple orders at once. **RECOMMENDATION:** *(b) Only one type of HD preparation may be handled in a C-PEC at one time.*
Article 4.7 Section 1737.14(a)(2)	*and (2) For an antineoplastic HD, attach and prime all tubing and attach a CSTD when appropriate.*	**COMMENT:** Not all antineoplastic HDs are infused. Some are injected IM, others IV push, and some administered as ophthalmic injections or drops. **RECOMMENDATION:** *(2) For an antineoplastic HD infusions, attach and prime tubing if appropriate and attach a CSTD when appropriate.*
Article 4.7 Section 1737.14(b)	*(b) When furnishing an antineoplastic HD, a sufficient supply of gloves that meet the ASTM D-6978 standard to allow for appropriate administration, handling, and disposal of HD drugs by the patient or the patient's agent shall be provided.*	**COMMENT:** If not furnishing the drug directly to the patient (ex. Going to a facility or other provider to adm sinister), they should provide their own gloves. **RECOMMENDATION:** *(b) When furnishing an antineoplastic HD, a sufficient supply of gloves that meet the ASTM D-6978 standard to allow for appropriate administration, handling, and disposal of HD drugs by the patient or the patient's agent ~~shall be provided.~~ should be made available, when needed.*
Article 4.7 Section 1737.15(b)	*(b) Agents used for deactivation, decontamination, cleaning, and disinfecting all areas and equipment involved in HD handling*	**COMMENT:** This working is overly limiting of how a chemical shall be applied. What if i'm pouring from the spray bottle and not spraying it? Several companies sell their products packaged in sprayer bottles, however, we do not use the nozzle and instead

	shall be applied through the use of wipes wetted with the appropriate solution and shall not be applied or delivered to the wipe by use of a spray bottle to avoid spreading HD residue.	wet the wipe by pouring **R** **RECOMMENDATION:** (b) Agents used for deactivation, decontamination, cleaning, and disinfecting all areas and equipment involved in HD handling shall be applied through the use of wipes wetted with the appropriate solution and shall not be applied or delivered to a surface by spraying to avoid spreading HD residue.

END OF DOCUMENT

Every event that increases costs reduces patient access to care.

~~I would like to offer my public comment on the proposed changes to California compounding regulation. For a long time I was a self declared policy nerd. In 2016, I was awarded a Master's degree in Pharmaceutical Outcomes Policy, therefore, my policy nerd status is now acknowledged by the University of Florida School of Pharmacy. I also comment with 20-plus years of compounding experience in non-sterile compounding (hazardous and non-hazardous).~~

I was a policy nerd all the way through pharmacy school and the University of Florida elevated me to Policy Geek with a Master's degree in Pharmaceutical Outcomes and Policy. Now, with 20+ years of hazardous and non-hazardous compounding experience in a retail pharmacy under my belt. I would like to take this opportunity for public comment help the Board refocus their energies in pharmacy compound regulations. Pharmaceutical compounding regulation shares its twin goals with the Board itself: compounded products must be safe and accessible to protect the public health.

A colleague once eloquently stated that 97% of patients can be properly treated with commercial products. The other 3% require some type of special formulation:

- Removal of an allergen (lactose, corn products, peanut oil, just to name a few of my patient needs.
- Cultural/personal considerations (vegetarian, religious, etc)
- Physical considerations such as the ability to swallow tablets
- Age considerations: My most delicate patient population is the pediatric cardiac patient, propranolol, amioderone, amlodipine, captopril, etc are not commercially made in liquid form for pediatric dosing. Rifampin Suspension is also not commercially available in a liquid dosage form suitable for pediatrics. Just a small sample of my patients.

This is compounding!

~~I recognition that the Board's prime directive is to protect the population of California from the poor execution of the practice of pharmacy; however, I question the boards qualifications to expand and establish policy and regulation beyond the standards presented by Unites States Pharmacopeia (referred to as USP from this point forward) especially after reviewing the biographies posted on the Boars's web page, none of the current Board members mention any compounding experience…with the possible~~

~~exception of Ms. Barker. In light of this lack of experience I challenge the Board to produce evidence based-data to support the proposed changes will actually improve patient care, or reduce potential harm.~~

I do not want to insult any of the learned members of the Board; but I do ask what evidence based research or literature the Board used to craft these expanded regulations. When I review the current boards members biographies I do not see anyone sharing any experience with pharmacy compounding, with the possible exception of Ms. Barker.

Much of the Board's new compounding regulation goes beyond or just duplicates the most recent USP chapters. Introducing extraneous, non-standard, non-evidence-based regulation. ~~**it decrease effectiveness and national continuity (the purpose of the standard developed by USP), confusing the public's ability to understand that the Board is watching out for their best interest.**~~ **I suggest that this produces two unintended outcomes. First, additional regulation is confusing to inspectors and practitioners. Additional regulations can be contrary to standard USP procedure. For example, … Any time we 'improve' on USP standards, we decrease consistency on a national level. Patients need to know that a compounded product is reliably the same across the country. Second, the most recent USP chapter changes increased costs significantly.** Keep in mind that none of the compounders I know bill compounded products to third-party payers, and CMS explicitly excluded compounded products from the Medi-Care part D program. Most patients are paying out-of -t cash for compounded prescriptions. **Every additional regulation beyond the USP standards increases patient costs even further. Increased cost to a very vulnerable patient population in contrary to the Board's mission of protecting public health, and maintaining patient access to care through the best pharmacy practices.**

~~The more complex the requirements become, the more infrastructure required, the more time needed to complete superfluous documentation, the more it costs to produce a compounded product. These increased costs must be passed along to the patient.~~ .

Every event that increases costs reduces patient access to care.

Specific examples:

1735.1(a) The documentation of cleaning supplies and materials used **each day** is superfluous, redundant, and un-necessary action that only adds time and costs to compounded product without adding any patient benefit or harm reduction. Which cleaning products to be used, order and frequency are defined in the SOP's required by USP chapters 795, 797, and 800. Again, adding complications and time increases patient costs, resulting in reduced patient access to care.

1735.1(e) What is the purpose of limiting Veterinary office use supplies to 7 days? We are allowed to supply human providers with what they need for office, use with proper orders and documentation with the only restriction that only a 3 day or less supply be give to a patient to take home. Again a complexity that drives cost of care up.

1735.7(a)(1) The requirement of recording the time of compounding for CNSP.

- USP BUD guidance for CNSP is in days, not hours.
- There is no benefit to patient care or safety to record time a CNSP was initiated.
- For the purpose of BUD determination it is sufficient for CNSP's to be considered timed in at 0000 hours (midnight) of the day compounded, with the BUD to be 2359 hrs of the determined BUD date. (As the board codified in 1735.10(a)). If the BUD defaults to 2359, there is no benefit to recording the time a process as started.

Complicating documentation with data that does not improve patient safety adds unnecessary costs that can further drive costs and limit patient access to care.

1735.9 Labeling: Not specifically addressed by this section, I ask the board to considers the size of most pharmacy labels vs. minimum font size vs. limitations of pharmacy software systems (finite number of character spaces that define the drug name field) vs. the use of common abbreviations vs. compliance with patient centered label requirements. Often compounded medications have multiple ingredients that make including all active ingredients in 12 point type in the patient centered area flat out impossible. Abbreviations will be necessary with full names in the required 12 point type on an auxiliary label that will be adjacent to, but not in the patient centered area of the label. Essentially, the Board MUST recognize the limitations of labels, dispensers, and other packaging products (which go through their own approval process) when crafting regulation regarding label requirements.

1735.11 SOP's: there is nothing new in this section that is not already addressed in the USP chapters and therefore redundant and unnecessary. Further the language of 1735.11(c) is unnecessarily aggressive and threatening not suiting a professional regulatory organization. There is always the possibility of some extenuating circumstance that may cause a temporary but necessary departure from adopted SOP's. One recent example is

the COVID pandemic, when gloves were in such shortage that SOP was suspended for a year or more until glove supply chain shortages were resolved.

1735.12 The board may find this 72 hours reporting of ANY complaint or ADR will lead to an unmanageable reporting load similar to what the board experienced with when any shortage of controlled substance discovered during the quarterly CS reconciliation was initiated, then later dialed back. There are many reasons a patient may contact the pharmacy with a quality complaint about a compounded medication:

- Taste
- Texture
- Smell
- Color
- Dispenser malfunction
- Claim of lack if potency (which should not be reported until potency test are completed. I had a patient claim lack of potency, testing results showed the product to be within 3% of the labeled strength).
- Claim of lack of effect.
- Just to list a few.

1735.14(b) Having read this section many times, I can not interpret what the board is trying to say here. The Board needs to clarify what records it is referring to. Historical compounding log records can not be changed as any other completed medical record can not be changed. Revision's of current P&P's, or SOP's would reflect changes in guidance from USP or the Board and not require tracking. Changes in Master Formula Cards (MFC) may need temporary adjustment based on material shortages, bases and diluents, such as a cream base with a different density would require a measurable percentage of quantity change; but should not necessarily require an entirely new compound entity. Major changes such as the discontinuation of a gelling agent and the substitution of a new gelling agent would be cause for creating a new formula(MFC) altogether. Changes in formula due to the results of potency testing is the only change I can think of that the Board may want to track. This section needs more clarity.

1737.15(b) the application of a decontaminating solution to a wipe via spray bottle will not disturb the hazardous residue when the application to the wipe is not in the direction of the residue or done outside of the BSC. I will agree that the solution should NOT be sprayed directly on to the residue area to prevent aerosolization of the residue. This is a section that expands on USP guidance that needs to be supported with evidence before being codified.

Paragraphs a & c are already addressed in USP 800 and a redundancy.

I do not have any expertise or experience with sterile or nuclear compounding and will leave comments on those portions to more qualified individuals.

My final comment is now that the Board has codified multiple chapters of USP, (795, 797, 800,1163, 1178, 1207, 1223, 1228.1). I will remind the Board that you must make those captors available to the public and registrants without either group needing to purchase a subscription to USP or the individual documents from USP As is the case as of the writing of the letter.

Respectfully,

K. Scott Guess, PharmD, MS, RPh, APh

Keck Medicine of USC

June 3, 2024

SENT VIA ELECTRONIC MAIL TO CALIFORNIA BOARD OF PHARMACY (BOP) CONTACT PERSON: LORI MARTINEZ (PharmacyRulemaking@dca.ca.gov)

Re: Compounded Drug Preparations, Notice of Proposed Action, Proposed New Sections 1735-1738 of Title 16, Division 17, Articles 4.5-4.8 of the California Code of Regulations

Dear Ms. Martinez,

On behalf of the Keck Medicine of USC Department of Pharmacy and its seven licensed pharmacies, the following comments on the proposed regulations for compounded drug preparations are respectfully submitted.

Institution/ Contact Name	Keck Medicine of USC Pharmacies	Contact Name: Daniel I. Kudryashov
Section, Subdivision	**Proposed Language**	**Recommendation / Comment**
1735.1(f)	In addition to prohibitions and requirements for compounding established in federal law, **no CNSP shall** be prepared that:	**Comment**: This requirement goes above and beyond current FDA guidance for industry on a similar subject, and in doing so, will impose unjustified burden on health-system pharmacies, create gaps in patient care and negatively affect clinical patient outcomes. The FDA guidance to industry documents use the term "should" when discussing the topic of compounding in 503A facilities. By prohibiting the practice, the BOP would impose a burden on licensees and negatively affect patient outcomes in instances when a drug is not available within the institution yet there is an urgent clinical need. For example, a hospitalized patient may need to continue their home therapy of an anti-epileptic drug clobazam. The patient has neurologic deficits and has impaired swallowing and unable to swallow tables whole. The prescriber orders to give the medication as a suspension by mouth. The suspension of clobazam, which is commercially available, is out of stock. Under this statute, the pharmacy would be prohibited from compounding the suspension, which could lead to interruption in care and negative outcomes (e.g., patient having a seizure). Please note this is not a case where the provider and pharmacist determine that the compounding produces a clinically significant difference for the medical need of a patient – it is a

		case when the commercially available drug product is not readily available for reasons other than a shortage. **Recommendation**: To allow for continuity of care, change the language to "In addition to prohibitions and requirements for compounding established in federal law, **no CNSP should** be prepared that".
1735.12(b)	(b) The Board shall be notified in writing within 72 hours of the facility's receipt of a complaint of a potential quality problem or the occurrence of an adverse drug event involving a CNSP. (c) All complaints related to a potential quality problem with a CNSP and all adverse events shall be reviewed by the pharmacist-in-charge within 72 hours of receipt of the complaint or occurrence of the adverse event. Such review shall be documented and dated as defined in the SOPs.	**Comment**: The underlined language in subsection (b) allows for a variety of interpretations and can potentially result in inefficiencies and false escalations. Not all complaints will meet the definition of a "quality issue" as defined under 1735(f). Additionally, the requirement for PIC review within 72 hours as stated in subsection (c) would not allow the PIC to be away from the pharmacy for more than a 72-hour period. This is not a reasonable standard, both from a patient safety and humanistic perspectives. **Recommendation**: Revise sections (b) and (c) as follows: (b) The Board shall be notified in writing within 3 business days after a potential quality problem is identified or the occurrence of an adverse drug event involving a CNSP. (c) All complaints related to a potential quality problem with a CNSP and all adverse events shall be reviewed by the pharmacist-in-charge or designated pharmacist within 3 business days of receipt of the complaint or occurrence of the adverse event. Such review shall be documented and dated as defined in the SOPs.
1736.1(b)	(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	**Comment:** In most cases, compounding of CSPs for immediate use occurs in instances of bedside compounding by a pharmacist in cases of a "code blue" to meet an urgent patient care need. A "code blue" is a situation where patient who is in cardiac arrest or otherwise in a life-threatening condition is being

	such compounding shall be only in such quantity as is necessary to meet the immediate need. Documentation for each such CSP shall include identification of the CSP, compounded date and time, number of units, the patient's name and patient's unique identifier and the circumstance causing the immediate need. Such documentation may be available in the patient's medical record and need not be redocumented by the compounding staff if already available.	resuscitated by a trained medical team. The requirement to document 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, will go against the very core of the need to have an allowance for immediate use compounding. It would be a threat to patient safety to introduce the requirement for documentation in a situation where every second counts and the pharmacist's full attention and focus is required. Additionally, the proposed documentation requirements pose questionable benefit, if any. Furthermore, the prohibition on immediate use compounding outside of the very narrow exception of "*situations where the failure to administer could result in loss of life or intense suffering*" may adversely impact the ability of hospital pharmacies to adequately meet patient care needs in cases of inadvertent failure of standard engineering controls. For example, in the case of sudden HVAC system failure in a small hospital with only a single cleanroom, the hospital pharmacy will have no alternatives to provide critical medications to the hospitalized patients. Compounding with an immediate use BUD could be a short-term plan while the HVAC issue is addressed or a long-term plan is determined. However, this proposed regulation would prohibit that option, and patients would face delays in care that can cause harm in the long term or adversely impact care outcomes. **Recommendation:** In light of significant safety concerns and barriers for access to care in unexpected downtime situations, the Board is urged to remove this section completely and follow USP 797 recommendations with regards to immediate use compounding.
1736.13(a)(3)(A)	(a) A CSP label shall include all of the following: (3) Instructions for administration; (A) For an admixed CSP, the <u>rate of infusion, or range of</u>	**Comment**: Displaying "rate of infusion, or range of rates of infusion" is not feasible to accomplish in many contemporary electronic medical record (EMR) systems. Specifically, this would not be possible in cases where a CSP infusion intended to be titrated

	rates of infusion as prescribed, or the duration for the entire CSP to be administered.	per institutional nursing protocol per provider order. For example, in Oracle Cerner EMR the required order elements include the initial rate, titratable units, titration frequency, subjective titration goal, and maximum rate of infusion. In these cases, the "rate" that is generated on the label states "As Directed", and the order details are specified in the EMR. This practice meets patient safety recommendations outlined in The Joint Commission elements of performance (MM.04.01.02). It is a safer practice to maintain those elements in the EMR to make the most up-to-date information available to the administering nurse in real time. In acute care settings where provider orders frequently change, the source of truth regarding medication rates must remain as the EMR (not the printed label). This requirement will impose major operational challenges for health-system pharmacies to develop processes for manual modification of labels, and therefore increase risk of errors and adverse impact on patients. **Recommendation**: This new proposal is not aligned with CMS-approved accreditation agency standards for patient care and not feasible to achieve with some, of not all of the current EMR systems. It will likely result in higher risk of medication errors and adversely impact patient care. Recommend to revise as follows: "A) For an admixed CSP, the rate of infusion, or range of rates of infusion as prescribed (unless the infusion rate is specified in a shared electronic medical record system), or the duration for the entire CSP to be administered."
1736.18(c)	(c) In addition to subsection (b), all complaints made to the facility related to a potential quality problem with a CSP and all adverse events shall be reviewed by the pharmacist-in-charge within 72 hours of receipt of the complaint or occurrence. Such review shall	**Comment**: The requirement, as written, would not allow the PIC to be away from the pharmacy for more than a 72-hour period. This is not a reasonable standard, both from a patient safety and humanistic perspectives. **Recommendation**:

	be documented and dated as defined in the SOPs.	There should be an option for a designated pharmacist to perform the duty. For example: "(c) In addition to subsection (b), all complaints made to the facility related to a potential quality problem with a CSP and all adverse events shall be reviewed by the pharmacist-in-charge or designated pharmacist within 3 business days of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs."
1737.5(c)	(c) Where a pass-through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking. A pass-through is not allowed between the C-SEC into an unclassified space.	**Comment**: The prohibition on the presence of a pass-through between a C-SEC and unclassified space has not been a requirement in USP 797 nor USP 800 and would be a new mandatory requirement for pharmacies, if passed. The passage of this requirement will place extreme hardship on existing facilities that may have this design in current BOP-approved licensed sterile compounding pharmacies. Given extremely high cost of cleanroom construction and modifications, this requirement may lead to pharmacy closures, negatively affecting patient access to care. **Recommendation**: The BOP is urged to reconsider requiring this standard, or otherwise providing for a process to allow the presence in existing construction (e.g., grandfathering). For example: "(c) Where a pass-through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking. A pass-through is not allowed between the C-SEC into an unclassified space in cleanrooms constructed after [insert date]."
1737.6 Subsection (a) and (b)	(a) The SOPs of a premises where HDs are handled shall address environmental wipe sampling for HD surface residue, its frequency, areas of testing, levels of measurable contamination, and actions when those levels are exceeded.	**Comment**: Environmental quality and control utilizing wipe sampling for hazardous drug surface residue is not a mandatory requirement in USP 800. While this is a worthwhile effort that pharmacies compounding hazardous drugs *should* follow, there are several significant barriers that arise when this requirement is made mandatory.

	(b) When any actionable level of contamination is found, at a minimum the following shall occur as described in the SOPs: (1) Reevaluate work practices; (2) Reevaluate the appropriateness of deactivation, decontamination, and cleaning agents; (3) Re-train personnel on deactivation, decontamination, and cleaning; and (4) Re-train personnel on donning and doffing appropriate personal protective equipment (PPE).	First, as stated in USP 800, "*there are currently no studies demonstrating the effectiveness of a specific number or size of wipe samples in determining levels of HD contamination."* The proposed regulation would force pharmacies to make their own arbitrary standards, without a way to confirm the effectiveness of their SOP in determining levels of HD contamination. Additionally, the proposed regulation would require pharmacies to set their own actionable contamination limits. However, per USP 800, "*there is currently no standard for acceptable limits for HD surface contamination.*" Given the absence of widely accepted standards for actionable limits, pharmacies will be forced to make a subjective determination without relying on evidence. It is unwarranted for the BOP to put forth this requirement in the absence of clear evidence of negative staff outcomes and associated acceptable HD surface contamination levels. Furthermore, per USP 800, "t*here are currently no certifying agencies for vendors of wipe sample kits.*" Accordingly, there may be a degree of variability with performance of wipe sampling kits. Detection of trace surface contamination levels would require a high degree of test sensitivity and specificity to determine that a test is accurate enough (e.g., accurate 90% of the time with low risk of false positives or negatives). Pharmacies currently do not have a way to evaluate commercial wipe sampling kits against an established certification standard or a badge of assurance. This could pose concerns with the accuracy of the entire wipe sampling program. Lastly, there is a wide variety of chemotherapeutic agents compounded in pharmacies, and there is not a wipe sample kit vendor that, to the best of our knowledge, offers sampling kits for all chemotherapeutic agents currently available for patient care. Therefore, a pharmacy attempting to comply with the new requirement and the apparent intent of the environment quality and control program, will not be successful in doing so at present.

		Recommendation: The Board's proposed requirement to establish an environmental wipe sampling cannot be justified given several significant concerns and barriers listed above. We recommend the Board considers removing the proposed additional requirements and follow the standards outlined in USP 800 as it related to this section.
1737.10	In addition to the standards in USP Chapter 800, Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article. All HD APIs and antineoplastic HDs shall be shipped and received from the supplier in segregated impervious plastic and labeled "Hazardous Drugs" on the outside of the delivery container	**Comment**: It is unclear if this section refers to internal shipments of hazardous drugs which a pharmacy may make, or if this standard applies to the process of receiving hazardous drugs purchased from wholesalers. If the latter, then pharmacies do not have authority over wholesalers beyond a contractual relationship with purchasing medications, and this standard would place the burden of compliance on the pharmacy, rather than the supplier. If the intent is the former, then we would recommend clarifying the statement. **Recommendation**: Make the following clarification, as below: "In addition to the standards in USP Chapter 800, Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article. When the pharmacy ships HD APIs and antineoplastic HDs to another pharmacy or location, the HD APIs and HDs shall be shipped in segregated impervious plastic and labeled "Hazardous Drugs" on the outside of the delivery container."
1737.13(a)	(a) A disposable preparation mat shall be placed on the work surface of the C-PEC when compounding HD preparations. Where the compounding is a sterile preparation, the preparation mat shall be sterile. The preparation mat shall be changed immediately if a spill occurs, after each HD drug,	**Comment**: This requirement would create unnecessary risk for contamination and potentially bacterial growth thereby negatively affecting patient care. The preparation mats have the theoretical benefit of containing possible spills. HD spills are now extremely uncommon given that USP 800 mandates the use of closed-system transfer devices for compounding antineoplastic drugs. On the other hand, the mats are associated with risks that may outweigh this theoretical benefit. The mat,

	and at the end of daily compounding activity.	even if itself sterile, presents an additional unnecessary element in the PEC that may promote bacterial growth by not allowing the surface underneath the mat to dry thoroughly. The process of frequent exchanges of the mat (required to be changed after each HD drug in this section) may promote unwarranted ingress and egress of material and thereby increase contamination – the mats are not completely lint-free, but rather, low-lint. In addition to increasing the risk of contamination while providing minimal, if any, added benefit for protecting compounding personnel, the cost of the sterile mats would place undue burden on compounding pharmacies. For instance, one popular vendor of healthcare products makes such sterile chemotherapy preparation mats available at a cost of $695 for a case of 100. Taking only a single pharmacy within our health-system, the annualized financial impact of this subjective regulation would amount to -**$291,900,** not including tax. To our knowledge, the pharmacy profession has been moving away from using prep mats over the past decade. Our health-system pharmacies have not used HD mats for many years without any spill incidents, positive employee satisfaction, and pristine surface sampling results. In our view, making the use of HD preparation a requirement will be a backwards step for patient safety and healthcare efficiency. **Recommendation**: Make the use of the preparation mats optional, and if used, then facilities shall follow the outlined steps. Recommend re-writing the section as follows: "(a) A disposable preparation mat <u>may</u> be placed on the work surface of the C-PEC when compounding HD preparations. Where the compounding is a sterile preparation <u>and a preparation mat is used, the mat shall be sterile</u>. <u>If used,</u> the preparation mat shall be changed immediately if a spill occurs, after each HD drug, and at the end of daily compounding activity."

Keck Medicine of USC

Respectfully,

Krist Azizian, PharmD, MHA Chief Pharmacy Officer | Keck Medicine of USC Chief Regional Cancer Officer | USC Care
Daniel Kudryashov, PharmD, MSL, MHA Medication Safety Officer Keck Medical Center of USC

Valor Compounding Pharmacy Lauren Honda lhonda@vcprx.com		
Section, Subdivision	**Proposed Language**	**Recommendation / Comment**
1736.1 (e) (3)	(e) In addition to prohibitions and requirements for compounding established in federal law, no CSP may be compounded that: (3) is made with a non-sterile component for which a conventionally manufactured sterile component is available and appropriate for the intended CSP.	As a concerned citizen and compounding pharmacist, I must respectfully express my disagreement with the proposed law mandating compounding with a conventionally manufactured component when it is available. While the intention of the regulation may be to increase safety by using a commercially available sterile product, it fails to account for the nuanced considerations regarding beyond use dates and continuity of care for patients in need of sterile compounds. Currently, with the stability study that our facility has invested in we are able to offer our patients atropine ophthalmic drops with a 60 day BUD at room temperature. After factoring in approximately 2 weeks for sterility testing our patients can get a prescription that is stable at room temperature with at least 45 days left on it's beyond use date. However, with the proposed regulation which would require compounding with the sterile commercially available atropine ophthalmic drops our beyond use date would drop to 30 days at room temperature. After factoring in the time it takes to complete sterility testing our patients would only be able to receive the product with approximately 2 weeks left on the beyond use date. Needing to refill a chronic prescription every 14 days is a challenging barrier to overcome with patients which may lead them to using a product past it's beyond use date putting them at a greater risk. Another option would be for us to assign a 45 day beyond use date with refrigerated

		storage requirements. Although this would allow our patients approximately 30 days left on the beyond use date after sterility testing, the need to maintain refrigerated storage conditions can be challenging for families who need to safely transport their medication when traveling. Instead of imposing a blanket regulation, I urge you to take into consideration the effects this may have on patients and their ability to readily and continuously access sterile compounded products.

Valor Compounding Pharmacy Lauren Honda and Thao Tran-Kam lhonda@vcprx.com, ttran@vcprx.com		
Section, Subdivision	**Proposed Language**	**Recommendation / Comment**
1736.9 (d)	(d) all API and excipient components used to compound a CSP shall be manufactured by an FDA-registered facility, be accompanied by a Certificate of Analysis (COA), and suitable for use in sterile pharmaceuticals. A COA that includes the compendial name, the grade of the material, and the appliable compendial designations on the COA, must be received and evaluated prior to use, unless components are commercially available drug products. When the COA is received from a supplier, it must provide the name and address of the manufacturer. API and excipient components provided with a COA without this data shall not be used in a CSP.	As a compounding pharmacist, I understand that vetting chemical suppliers is of the utmost importance to ensure the quality and safety of the final CSP that is delivered to patients. However, I would like to express that we have encountered challenges in obtaining the name and address of the manufacturer from several of our major chemical suppliers. Despite our efforts to request this information these suppliers have been unable to provide this information as they hold it to be proprietary information. In light of the difficulties our facility has had in obtaining the manufacturer name and address from some suppliers, we have put SOPs into place which state that when appropriate a supplier that is able to provide the manufacturer name and address will be considered a first-tier supplier and used over a manufacturer that is not able to provide that information. This allows us to consider best practices while still being able to source chemicals from alternative secondary suppliers when our first-tier suppliers are unable to source a chemical we need for compounding. I ask you to consider how this regulation might impact patients' access to CSPs, given that certain chemicals necessary for compounding are only available from suppliers that we have historically not been able to acquire the manufacturer name and address from.
1735.12 (b)	(b) The Board shall be notified in writing within 72 hours of the facility's	In the interest of maintaining compliance with this proposed

	receipt of a complaint of a potential quality problem or the occurrence of an adverse drug event involving a CNSP.	language, I would recommend that The Board consider clarifying if the 72 hours mentioned would be in terms of business hours. Thank you for your consideration.
1737.14 (b)	(b) When furnishing an antineoplastic HD, a sufficient supply of gloves that meet the ASTM D-6978 standard to allow for appropriate administration, handling, and disposal of HD drugs by the patient or patient's agent shall be provided.	Having been a designated person, I greatly appreciate The Board's concern for patient education and safety surrounding hazardous drug handling. Guidelines for administering hazardous drugs have generally applied to in-patient settings. As written, the proposed language would extend to hazardous compounded prescriptions dispensed to the patient or patient's agent in an outpatient setting. If that is the intention of The Board, then compounding pharmacies dispensing hazardous compounded medications would benefit from an example written by The Board to define what a sufficient supply of gloves would be.

Institution/Contact Name	Providence Little Company of Mary Medical Centers Torrance and San Pedro	Muno Bholat, Pharm.D. Pharmacist-in-Charge muno.bholat@providence.org
Section, Subdivision	**Proposed Language**	**Recommendation / Comment**
1736.2(d)	(d) Compounding personnel or persons with direct oversight over compounding personnel who fail any aspect of the aseptic manipulation ongoing training and competency evaluation shall not be involved in compounding or oversight of the preparation of a CSP until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs. A person with only direct oversight over personnel who fails any aspect of the aseptic manipulation ongoing training and competency evaluation may continue to provide only direct oversight for no more than 14 days after a failure of any aspect while applicable aseptic manipulation ongoing training and competency evaluation results are pending.	In agreement with the initial statement of reasons' justification of no more than a 14-day period to allow for a transition if necessary to avoid disruption in compounding while training and evaluation are still pending, this same concern for patient safety while the facility has a chance to make other arrangements, should also be applied to compounding personnel upon the failure of ongoing training and competency evaluation. Since this section reflects an immediate repeat of training and competency evaluation upon receiving results indicating a failure, it acknowledges that this would likely be the initial action taken for a failure. We recommend that compounding personnel be allowed to continue compounding during the same 14-day period allowed those with direct oversight only. Then, in the event that this initial repeat evaluation also fails, both compounding personnel and those with direct oversight will be restricted from performing any compounding or direct oversight until after successfully passing training and competency in the deficient area(s). Keeping patient safety in mind, disrupting the ability for an acute care hospital pharmacy to provide continuity of sterile compounding to patients 24 hours a day could delay delivery of care to critically ill patients. Workload, workflow, and staffing coverage would be negatively impacted and may take time to arrange without disrupting compounding and patient care. Allowing a transition period for compounding personnel with their initial failure of ongoing training and competency will minimize the negative impact on patient safety.

		Recommend modifying the wording to: *"(d) Compounding personnel or persons with direct oversight over compounding personnel who fail any aspect of the aseptic manipulation ongoing training and competency evaluation shall have no more than 14 days after a failure to successfully pass ~~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. If training and competency are not passed after the 14 days, personnel shall not be involved in compounding or direct oversight of the preparation of a CSP, until successfully passing applicable aseptic manipulation ongoing training and competency as detailed in the facility's SOPs.* *~~A person with only direct oversight over personnel who fails any aspect of the aseptic manipulation ongoing training and competency evaluation may continue to provide only direct oversight for no more than 14 days after a failure of any aspect while applicable aseptic manipulation ongoing training and competency evaluation results are pending.~~"*
1737.5(c)	(c) Where a pass-through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking. A pass-through is not allowed between the C-SEC into an unclassified space.	In some facilities, a passthrough is located between the C-SEC and the hazardous drug storeroom (which meets USP<800> requirements to be negative pressure with at least 12 air changes per hour and externally ventilated). - This pass-through allows for transport of hazardous drugs (HDs), HD CSPs, and HD waste into and out of the negative pressure buffer room to minimize the spread of HD contamination. - This facility design also limits the contamination of the anteroom since HDs are not transported directly through the anteroom. This in turn also minimizes contamination to the positive buffer

		room and other areas outside of the anteroom. There is no requirement in USP for hazardous drug storerooms to be classified rooms. USP<800> Glossary definition of pass-through: "An enclosure with interlocking doors that is positioned between two spaces for the purpose of reducing particulate transfer while moving materials from one space to another. A pass-through serving negative-pressure rooms needs to be equipped with sealed doors." This acknowledges the reduction in particulate transfer and requires sealed doors between negative-pressure rooms. The proposed language would prohibit use of a pass-through between a C-SEC and an unclassified hazardous drug storeroom even if the HD storeroom and pass-through meet the USP <800> requirements. The USP<800> requirements are devised to minimize contamination with HDs and particulate transfer into the C-SEC. Where a pass-through is between the C-SEC and HD storeroom, the negative-pressure, externally ventilated HD storeroom provides an added buffering space between the sterility of the C-SEC and the outside area even if the HD storeroom is unclassified. The pass-through itself also provides a barrier from particles making their way into the C-SEC. And being negative-pressure and externally ventilated, the HD storeroom provides limitation to the outside space from being contaminated with HDs. The proposed regulation would require these facilities to transport HDs through the anteroom instead of through the pass-through. Thus the risk of contamination of the anteroom greatly increases and being positive

		pressure, air and contaminants from the anteroom have a greater chance of blowing out into the outside area, outside of the cleanroom suite. Facilities designed with the pass-through between the C-SEC and HD storeroom, could require construction to upgrade HVAC air-handling systems to meet ISO 7 classification for the HD storeroom. Construction may also be required to remove a passthrough or seal it off to not be used. In these cases, many steps would be needed and take time to complete – including construction, certification of the rooms, and potential relicensing. we would recommend that the Board allow for waivers to be applied if there is a subsequent delay in compliance with the new regulations when they go into effect. Recommend modifying the wording to: *"(c) Where a pass-through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking. ~~A pass-through is not allowed between the C-SEC into an unclassified space.~~"* Additional recommendation: If a pass-through is not allowed between a C-SEC into an unclassified HD storeroom, we would ask the Board for consideration to allow licensed facilities to apply for a construction waiver for this section or a delay in implementing this section. This would factor in the time delays and allow physical changes to the facilities' structure and HVAC air handling needed to comply with the law change.

June 1, 2024

Dear Board of Pharmacy,

I am Marie Cottman, 1997 UCSF graduate and licensed California Pharmacist with twenty-years of experience as a compounder, PIC, and retail sterile compounding pharmacy owner. I've spoken to this Board on many occasions in consideration of proposed new compounding regulations and I am thankful for the opportunity to do so again.

We have a mutual goal of ensuring high quality, effective compounded medications are provided to patients in California. As such, any regulations promulgated by this Board should serve to achieve this goal and do so with a rigor of scientific evidence that supports the rationale for implementation. Where possible, these new regulations should balance the value of the improvement in care against the inevitable costs that will ultimately be passed on to the consumer.

While I appreciate the efforts BOP staff, Inspectors, and the Compounding Committee have put into the proposed regulations, I have several concerns about the lack of clarity in how a PIC is to achieve compliance with them and, in some instances, the lack of scientific reasoning that justifies their need.

I have long advocated against adopting Chapters of USP as law because they are written as guidance for standards of practice, not as regulations to be cited for non-compliance. In fact, many USP Standards are worded with "should" to encourage individual discretion and accommodate the variability that exists in real world compounding practices. I acknowledge the frustration inspectors have with this flexibility, as it makes it difficult to achieve effective enforcement changes in licensees.

It cannot be understated that simply changing a guidance statement from "should" to "shall" is not sufficient rulemaking, nor is it being a responsible steward for the protection of the public. As a PIC, I accept the responsibility to ensure compliance with BOP Regulations. As Board Directors, you have a responsibility to ensure that new regulations are in plain language and have clarity of how a licensee is to comply with the regulation. This is hard work, and takes diligent consideration of what is being expected of your licensee to protect the public.

Unfortunately, on numerous occasions in the proposed regulations, there are "shall" requirements given for terms and conditions that are subjective in nature. Having longitudinal experience with participating in the CA BOP promulgation of regulations over the decades, I've seen numerous minor and major revisions of these regulations, and the effect of hasty implementation of them. It is my strong assessment that the proposed regulations simply are not yet ready for publication.

Our mutual goal is to maintain access for the public to safe, high quality pharmacy services. Please be diligent in your review of the comments provided by your licensees and be cautious with the regulations that you approve.

Thank you for taking my comments and suggestions into consideration,

Marie Cottman, Pharm.D.
Owner/PIC
Pacific Compounding Pharmacy
1889 W March Ln
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Comments from Marie Cottman, Pharm.D. Owner, PIC and DP Pacific Compounding Pharmacy, Stockton, CA		
Subdivision	Proposed Language	Comment/Concern/Recommendations
Article 4.5 Section 1735 (f)	*(f) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, or the absence of APIs other than those listed on the label, or the absence of inactive ingredients other than those listed on the master formulation record as specified in USP Chapter 795.*	**COMMENT**: I agree with the sentiment of this statement and understand that this is being retained and renumbered, however I recommend adding "at the time of dispensing" into the section. **RATIONALE**: Once the preparation is in the patient's hands I cannot control if the product was left open on the counter and if dust, mold, smoke, or other substances entered the preparation. I have heard of patients who add their own sweeteners or flavors, which I should not be held accountable for. Once the preparation leaves the pharmacy, I can no longer control what happens to it. **RECOMMENDATION**: (*f) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, or the absence of APIs other than those listed on the label, or the absence of inactive ingredients other than those listed on the master formulation record <u>at the time of dispensing</u> as specified in USP Chapter 795."*
Article 4.5 Section 1735.1(f)(1)(B)	*In addition to the standards in the USP Chapter 795, the nonsterile compounding of a CNSP shall meet the following requirements of this section.* *(f) In addition to prohibitions and requirements for compounding established in federal law, no CNSP shall be prepared that:* *(1) Is essentially a copy of one or more commercially available drug products, unless: (B) the compounding produces a clinically significant difference for the medical need of an identified individual patient, as determined by:* *(i) the prescribing practitioner,* *(ii) the compounding pharmacist, and* *(iii) the dispensing pharmacist(s).*	**COMMENT:** It is already established in Federal Guidelines and the proposed definition 1735 9(d) that the prescriber makes the determination of what is "essentially a copy." But if that is not sufficient, then "clinically significant difference" needs to be defined. Concern to consider: if the prescriber, compounding RPh and dispensing RPh all agree, but an inspector doesn't, who is right and for what reason? Further, the compounding pharmacist and the dispensing pharmacist are often the same individual, so they get 2 votes **RATIONALE:** Federal statute Section 503A of the FD&C Act states that "the term 'essentially a copy of a commercially available drug product' does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, ***as determined by the prescribing practitioner,*** between the compounded drug and the comparable commercially available drug." Pharmacists still have to use common sense and not violate any of our own rules and regulations. **RECOMMENDATION:** Allow Federal statute 503A of the FD&C Act to stand on its own.

Article 4.5 Section 1735.1(f)(2)	*In addition to the standards in the USP Chapter 795, the nonsterile compounding of a CNSP shall meet the following requirements of this section.* *(f) In addition to prohibitions and requirements for compounding established in federal law, no CNSP shall be prepared that:* *(2) Is made with any component not suitable for use in a CNSP for the intended patient population, unless allowable under the Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA).*	**COMMENT:** Based on your statement of reasons, it appears clear that this is only intended for vet patients, however, the full statement applies to all CNSP compounding (including human). **RATIONALE:** As proposed "*no CNSP shall be prepared that (2) Is made with any component not suitable for use in a CNSP for the intended patient population*," If it does apply to human compounding, compounders would constantly be unable to provide CNSPs to patients in need, limiting accessibility to compounded medications. a) It would prevent me from providing a combination APAP-Hydrocodone liquid to a liver transplant patient because APAP is contraindicated with liver disease. When we are providing a lower concentration of APAP than any of the commercially available products with good pain control. b) It would prevent compounding plavix for a 4 year old when the UCSF Pediatric Cardiologist feels it is the best solution for her medical issues because plavix is not intended for use in pediatrics (only approved for adult use). c) Anything compounded for "off-label use" could be construed as not suitable for that patient. **RECOMMENDATION:** Clarify this is for animal/veterinary CNSPs by modifying the language: *(2) Is made with any component not suitable for use in a CNSP for the intended ~~patient~~ animal population, unless allowable under the Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA)*.
Article 4.5 Section 1735.1(h)	*In addition to the standards in the USP Chapter 795, the nonsterile compounding of a CNSP shall meet the following requirements of this section.* *(h) In addition to the provisions provided in section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning proper use, storage, handling, and disposal of the CNSP and related supplies furnished.*	**COMMENT:** This is repetitive of other regulations already in place. Further, consultation regulations should be consistent across all medications dispensed, not limited to compounded preparations and thus Section 1707.2 should be modified rather than creating new regulations limited only to CNSPS.. **RATIONALE:** Regarding *"...proper use, storage…"* the referenced Section 1707.2 subsections (c) and (d) both require consultation that includes proper use and storage. Disposal is not currently a consultation requirement, but CNSPs are not that different from capsules, creams, troches, and liquids that are dispensed by non-compounding pharmacies. If this is a true patient safety issue, then it should be addressed in ALL consultations, not just CNSPs. **RECOMMENDATION:** Remove section 1735.1 (h) and initiate the rulemaking process to update 1707.2 for additional consultation requirements.

Article 4.5 Section 1735.2 (b)	*In addition to the standards in the USP Chapter 795, the compounding of CNSPs shall meet the following requirements:* *(b) A pharmacist responsible for, or directly supervising, the compounding of CNSPs, shall demonstrate proficiency in skills necessary to ensure the integrity, strength, quality, and labeled strength of a CNSP as described in the facility's SOPs as referenced in section 1735.11.*	**COMMENT:** This is a duplicate of what is already stated in USP 795 as a MUST statement. **RATIONALE:** USP <795> states in Section 2. Paragraph 4 "*Before beginning to compound CNSPs independently or have direct oversight of compounding personnel, personnel **must** complete training and be able to demonstrate knowledge of principles and competency of skills for performing nonsterile manipulations as applicable to their assigned tasks*." In the Initial Statement of Reasons it is clear that the BOP is not intending to re-write what is already in USP 795; the word change from competency of skills to proficiency in skills is insignificant and open to interpretation by both compounders and inspectors alike. Further, you already hold the compounding pharmacists accountable to "*the integrity, strength, quality, and labeled strength of a CNSP"* in section 1735.8. **RECOMMENDATION:** Remove section 1735.2 (b) as it is redundant.
Article 4.5 Section 1735.2 (c)	*(c) Compounding personnel or persons with direct oversight over personnel performing compounding, who fail any aspect of ongoing training and evaluation shall not be involved in compounding or oversight of the preparation of a CNSP until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs.*	**COMMENT:** I agree that a compounder who fails a competency for [dosage form A] should not continue to make [dosage form A] and should receive additional training to pass competency measures. Remediation is required by USP 795 Section 14, paragraph 2. But the way this section is written, it will remove compounding personnel from ALL compounding (not just dosage form A) when an issue is identified. This section is overly restrictive! Imagine this scenario: A tech who starts training on basic liquids, becomes proficient and compounds for patients. Then that same tech struggles with the competency for capsules. He *"failed an aspect of ongoing training"* and thus they cannot participate in ANY compounding!?!?! This is silly. **RATIONALE:** Compounding training is multifaceted and complex! Many training programs, like pharmacy school, will start with core skills training and then build from there. If a new compounder struggles and fails on Dosage Form C, that does not necessarily mean that they will have issues with Dosage form A. (the training needs to assess for this, though) Removing compounders from ALL compounding until the identified deficiency is resolved may take days or weeks, depending on the issue. This will impair the pharmacies ability to provide CNSPs in a timely manner and impede access to the patients of California. This regulation may also force Compounding Pharmacy owners (who are willing to stay in the compounding business) to over-hire staff, for the "just in case" situation where a competent tech is removed from workflow for a specific failed competency; this will also raise prices for patients and continue to impede access. Further, if this regulation passes, it will encourage DPs to do only minimal assessments of staff to meet the letter of the law because it will be too costly (dollars, stress, patient dissatisfaction) to remove compounders from the daily work flow. Lastly, In USP 795, section 14, paragraph 2, the USP clearly requires that the DP create a policy to address *"Personnel training, competency assessments, and qualification*

Article 4.5 Section 1735.2 (c) con't		*records including corrective actions for any failures*." **RECOMMENDATION:** Allow USP 795 Section 14, paragraph 2 to stand as is and delete Section 1735.2 (c). If that will not satisfy, then please reword to: *c) Compounding personnel or persons with direct oversight over personnel performing compounding, who fail any aspect of ongoing training and evaluation shall not be involved in that specific dosage form compounding ~~or oversight of the preparation of a CNSP~~ until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs.*
Article 4.5 Section 1735.2 (d)	*(d) 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 facility's SOPs as referenced in section 1735.11. Documentation must be maintained demonstrating compliance with this section.*	**COMMENT:** This is a duplication of USP language and should not be included as it only creates confusion on what additional requirement it is trying to allude to. **RATIONALE:**USP Section 2 states " "*All personnel who compound or have direct oversight of compounding CNSPs **must** be initially trained and qualified by demonstrating knowledge and competency according to the requirements in this section (2. Personnel Training and Evaluation) before being allowed to perform their job functions independently*." The trainer will have oversight of compounding CNSPs and thus must also be initially trained and demonstrate competency. USP 797 Chapter 11, it states "*Facilities preparing CNSPs **must** develop SOPs on all aspects of the compounding operation. All personnel who conduct or oversee compounding activities must be trained in the facility's SOPs and be responsible for ensuring that they are followed."* And in Chapter 14 states "*All facilities where CNSPs are prepared **must** have and maintain written or electronic documentation to demonstrate compliance with the requirements in this chapter. This documentation must include, but is not limited to, the following:* *Personnel training, competency assessments, and qualification records including corrective actions for any failures."* **RECOMMENDATION:** Remove, it is repetitive and does not add anything that is not already a MUST in USP 795.
Article 4.5 Section 1735.3 (a)	*a) Prior to admitting any personnel into a compounding area, the supervising pharmacist shall evaluate whether compounding personnel is experiencing any of the following: rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection, or any other medical condition, to determine if such condition could contaminate a CNSP or the environment*	**COMMENT/CONCERN:** 1) This should be removed because 795 requires in Section 3, paragraph 1 "*Individuals must evaluate whether they have a personal risk of potentially contaminating the compounding environment and CNSP (e.g., personnel with rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infection). Individuals must report…*" 2) Who does this actually apply to? The statement starts with "any personnel" and moves to "compounding personnel" then finishes with "personnel." Is it anyone (certifiers, clerical staff and compounders)? Is it just compounding staff? Or is it all staff?

Article 4.5 Section 1735.3 (a) con't	*("contaminating condition"). After such evaluation and determination, the supervising pharmacist shall not allow personnel with potentially contaminating conditions to enter the compounding area*	**RATIONALE:** The BOP statement of reason for adding this section is "*This addition is needed for patient safety to prevent contamination of the CNSP. Contamination of a CNSP could occur from these situations from a cough, sneeze, skin flake, or other activity into the CNSP, which would pose a threat to patient safety.*" I disagree that having the supervising pharmacist standing at the door evaluating personnel will be any more effective than the requirement of USP 795 Section 3, Paragraph 1 (cited above). a) the supervising RPh does not want to accuse staff of not self-reporting and does on want to do physical exams). c) If you don't trust the licensees who are doing the compounding to *self report (AS REQUIRED)*, how can you trust the supervising pharmacist to report? This is redundant from what is already ***required as a MUST*** in USP 795. **RECOMMENDATION:** Remove.
Article 4.5 Section 1735.3 (c)	*(c) Disposable garb shall not be shared by staff and shall be discarded if soiled and after each shift. All garb removed during a shift must remain in the compounding area.*	**COMMENT:** Confusing as written, as it appears to say that discarded garb never leaves the compounding area. (With 5 compounders wearing new garb at least daily, my compounding lab will fill up with discarded garb VERY quickly if I cannot remove it from the lab! LOL) **RATIONALE:**Most of this is clear in USP 795 Section 3.3, paragraph 3. "*Garb should be removed when leaving the compounding area. When personnel exit the compounding area, garb, except for gowns, should be discarded. Disposable garb must not be laundered. If gowns are worn, they may be reused if not damaged or soiled. If gowns are to be reused, they must remain in the compounding area, and should only be reused during the same shift. The facility's SOPs must describe cleaning and sanitization procedures for reusing goggles, respirators, and other reusable equipment.*" **RECOMMENDATION:** For clarity this should read "*(c) Disposable garb shall not be shared by staff and shall be discarded if soiled and after each shift. All garb removed <u>with the intent to be reused</u> during a shift must remain in the compounding area."*
Article 4.5 Section 1735.3 (e)	*In addition to the standards set forth in Chapter 795, the following requirements apply to nonsterile compounding.* *(e) Non-disposable garb shall be cleaned with a germicidal cleaning agent and sanitized with 70% isopropyl alcohol before re-use.*	**COMMENT:** This is addressed in UPS 795 Section 3.3 "*The facility's SOPs must describe cleaning and sanitization procedures for reusing goggles, respirators, and other reusable equipment."* In the statement of reasons it explains, "This language is necessary to require the appropriate cleaning of non-disposable garb with both a germicide and sanitizing agent consistent with the Chapter to prevent cross contamination." But the language is still undefined… what does "re-use" mean– used by another employee? the next day? or every time it is removed for an itch or bathroom break? **RATIONALE:** At some point, the DP will have to have discretion to create reasonable P&Ps. Without an official definition of what "re-use" means, this is a requirement up to interpretation.

Article 4.5 Section 1735.3 (e) con't		As a pharmacist compounder, my compounding day is interrupted frequently for phone calls, consultations, and overseeing other compounding staff. I may need to leave the compounding lab, and thus remove non-disposable garb many times in 1 day. I am concerned for the health of my skin if I have to clean the goggles every time I remove them and "re-use" them. Further, I'm concerned that it will take up as much as 3-5 minutes to do the cleaning process correctly and that workflow and patient access will ultimately be delayed. **RECOMMENDATION:** Remove this and let it stand that each facility MUST have this in their SOPs as required by USP 795, Section 3.3. If you really think that the DPs cannot write appropriate SOPs, then completely re-word this to provide a guideline for what you want in the SOP: "The facility's SOPs must describe cleaning and sanitization procedures and frequency for *reusing goggles, respirators, and other reusable equipment* that includes at least a germicidal cleaning agent and 70% IPA.
Article 4.5 Section 1735.4 (a)	*(b) Purified water, distilled water, or reverse osmosis water shall be used for rinsing equipment and utensils.*	**COMMENT:** This is very clearly a "shall" in place of the should in USP 795, but it also creates an unexpected limitation. As explained in the statement of reasons, this "shall" is to prevent the use of Tap Water for rinsing. **RATIONALE:** If the point is to not use tap water, just say it! However, sterile water should also be included as an option. We have found that sterile water in liter bags is more cost effective than USP grade purified, distilled, or reverse osmosis water. And did you know that USP grade purified water costs about $80 per gallon + shipping and handling? **RECOMMENDATION:** Re-word to include all grades of water equal to or better than Purified Water. "*(b) Purified water, ~~distilled water, or reverse osmosis~~ or better grade of water shall be used for rinsing equipment and utensils."*
Article 4.5 Section 1735.6 (b)	*b) Any component used to compound a CNSP shall be used and stored in accordance with all federal laws and regulations and industry standards, including the manufacturers' specifications and requirements.*	**COMMENT:** This is excess and compounders don't need another "reminder" of storage compliance. **RATIONALE:** From the statement of reasons, "This subdivision serves to remind the public that the use and storage of compounding components must adhere to a host of standards to ensure the integrity of the components and patient safety." This is incongruent with "*The goal of the board's regulations is not to duplicate provisions of federal law or USP language, but to clarify or make more specific the requirements"*. Additional note, appropriate storage is discussed in USP 795 no less than 16 times! There is no lack of requirement to store components correctly. **RECOMMENDATION:** Remove.

Article 4.5 Section 1735.7 (c)	*In addition to the standards set forth in Chapter 795, the following requirements apply to nonsterile compounding.* *(c) A compounding record (CR) shall be a single document developed in compliance with USP Chapter 795, and includes the following additional elements:* *(5) The identity of each person performing the compounding, the person who has direct oversight of compounding, and the pharmacist verifying the final drug preparation.*	**QUESTION:** Who, other than a pharmacist, is a person who can have direct oversight over compounding? **RATIONALE:** Just seeking clarification. I understand that "each person" is language from UPS 795 which applies to anywhere compounding may occur (MD office, vet office, etc), but in writing new regulations specific to pharmacy, who could this "person" be, other than a pharmacist? **RECOMMENDATION:** Use language consistent with pharmacy regulations *(5) The identity of each person performing the compounding, the ~~person~~ pharmacist who has direct oversight of compounding, and the pharmacist verifying the final drug preparation.*
Article 4.5 Section 1735.8	*A pharmacist performing or supervising the nonsterile compounding is responsible for the integrity, strength, quality, and labeled strength of a CNSP until the beyond-use date indicated on the label provided the patient or the patient's agent follows the label instructions provided on the CNSP for storage and handling after receiving the CNSP.*	**COMMENT:** USP requires that all compounding individuals are responsible for the CNSP. Why write in language that only holds the supervising pharmacist responsible? **RATIONALE:** In multiple locations, additional compounding personnel have been identified as responsible for the CNSP including section 1735.1(f)(1)(B) you referenced both the compounding pharmacist and the dispensing pharmacist… and section 1735.7 (c) you referenced " the person who has direct oversight of compounding, and the pharmacist verifying " Since the dispensing pharmacist will see the final label, but the compounding or supervising pharmacist may not (consider batch made CNSPs), the dispensing pharmacist who initializes the final label should be responsible for the information on the patient's label. **RECOMMENDATION:** Re-word. *A pharmacist performing or supervising the nonsterile compounding is responsible for the integrity, strength, quality, and labeled strength of a CNSP until the beyond-use date indicated on the label<u>. The dispensing pharmacist is responsible for the integrity, strength, quality, and labeled strength of a CNSP until the beyond-use date indicated on the patient's label</u> provided the patient or the patient's agent follows the label instructions provided on the CNSP for storage and handling after receiving the CNSP.*
Article 4.5 Section 1735.9 (a)&(b)	*(a) A CNSP's label shall include the following: (1) Route of intended administration, and* *(2) Name of compounding facility and name of dispensing facility (if different).* *(b) A CNSP's labeling shall include:* *(1) Any special handling instructions,* *(2) Any applicable warning statements, and* *(3) Name, address, and phone number of the compounding facility if the CNSP is to be sent*	**COMMENT:** These requirements should not be limited to CNPS, but rather applied to all medications dispensed to improve patient safety. **RATIONALE:** In the statement of reasons, "The board determined that the labeling requirements must be mandatory; adequate labeling is essential for dispensed medication to ensure patient safety." However, by creating this new regulation specific to CNSPs, you are ONLY 'ensuring the safety' of patients receiving compounds (a very small percentage of the prescriptions dispensed in California). If this is deemed "mandatory" by the board, it should be included in section 4076, with all the other

Article 4.5 Section 1735.9 (a)&(b) con't	*outside of the facility or healthcare system in which it was compounded.*	prescription labeling requirements so that 100% of patients have the benefit of this safety measure. Additionally, 4187.1 for correctional facilities, 4199 for veterinary food animals, 4427.6(h) and 4119.11(d)(8) for ADPS, 1707.4 for refill pharmacies, 1710 for hospital pharmacies, 4068.7 for emergency room dispensing, and 4077 (b) and 4170 (a)(4) for prescriber dispensing are all ONLY required only to label in accordance with 4076. So including 1735.9 (a)&(b) would not apply to any of their labels! **RECOMMENDATION:** Remove and initiate rulemaking to improve Section 4076 to include these requirements in order to protect the safety of patients in California.
Article 4.5 Section 1735.10 (b)	*(b) A CNSP's BUD shall not exceed any of the following: (1) The chemical and physical stability data of the active pharmaceutical ingredient (API) and any added component in the preparation, (2) The compatibility and degradation of the container–closure system with the finished preparation (e.g., possible leaching, interactions, and storage conditions),*	**COMMENT:** Look to the definition in Section 1 of USP 795 "For purposes of this chapter, nonsterile compounding is defined as combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance to create a nonsterile preparation." In other words, the art of compounding creates novel, unique preparations to meet a patient's specific need– often there is NO DATA! Please allow USP 795 Section 10.2 to stand as it is otherwise novel and unique solutions to patient problems that have never been looked at before will no longer be potential compounding options for desperate patients and providers. **RATIONALE:**USP 795 states in Section 10.2 paragraph 2 "*When establishing a BUD for a CNSP, compounders must consider parameters that may affect quality, including but not limited to the following:* *Chemical and physical stability properties of the API and any added substances in the preparation (e.g., if the API and added substances in the preparation are known to rapidly degrade over time and/or under certain storage conditions, reduce the strength of the preparation, or produce harmful impurities)* *Compatibility of the container closure system with the finished preparation (e.g., leachables, interactions, adsorption, and storage conditions)* *Degradation of the container closure system, which can lead to a reduction in integrity of the CNSP"* This is already a MUST that these things be ***considered***, but compounding is often the LAST RESORT for a patient to receive a medication that can provide relief of symptoms, and there is not always data available. If individuals regulated under the BOP have to have data for EVERYTHING compounded, but other professions do not, then you will find pharmacies eventually will not be where medications are compounded, but rather the other professions with only USP to follow will compound affordably for the patients of California (and completely unregulated by the BOP). **RECOMMENDATION:** Remove**.**

Article 4.5 Section 1735.10 (c)	*(c) If antimicrobial effectiveness testing results provided by a current FDA-registered drug establishment or outsourcing facility or published in current peer-reviewed literature sources are used, the reference in its entirety (including the raw data and testing method suitability) shall be readily retrievable in accordance with Business and Professions Code section 4081 for three years from the last date the CNSP was dispensed.*	**COMMENT:** This needs clarification because it is not clear WHY this is included. It would be very difficult to comply with as raw data is usually considered proprietary and most companies will not share it. If a pharmacy dispenses a preparation from an outsourcing facility, are you requiring that we obtain the antimicrobial effectiveness raw data information in order to use their labeled BUD? Or are you trying to make sure that if we use an outsourced compound as a component in a CNSP prepared at my pharmacy, then I have to have their data? Or something else? **RATIONALE:** Each compounding wholesaler (PCCA, Medisca, Fagron, etc) makes their own hormone cream base that has been through antimicrobial effectiveness testing. Do I now have to obtain the raw data and the original method suitability for that component even though the CoA for that component has appropriate data regarding antimicrobial effectiveness? Is this information only for **extending** a BUD for an aqueous formulation? What is the point of using FDA registered and inspected drug establishments if the 503A pharmacy then has to double check their data? **RECOMMENDATION:** Remove, it is unclear where this will be applied to enforcement actions.
Article 4.5 Section 1735.11 (a)(2)(A) and (a)(2)(C)	*(a) The facility's standard operating procedures (SOPs) for nonsterile compounding shall be followed and shall:* *(2) Also describe the following:* *(A) Methods by which the supervising pharmacist will ensure the quality of CNSPs.* *(C) The methods a pharmacist will use to determine and approve the ingredients and the compounding process for each preparation before compounding begins.*	**COMMENT:** Subsections (a)(2)(A) and (a)(2)(C) are requiring 2 new SOPs that are covered by several other SOPs required throughout USP 795 and thus they become redundant and repetitive. and several IF, after following all these other required SOPs, the quality of the CNSP is not ensured, another SOP to describe the method to "ensure the quality" will not be sufficient! **RATIONALE:** Ensuring the quality and methods to approve ingredients and the compounding process are addressed by several required SOPs including: Section 6: *Equipment **must** be suitable* Section 6.2 *The compounding facility **must** have written SOPs for the selection and inventory control of all components from receipt to use in a CNSP.* Section 6.2.3 *Compounding personnel **must** ascertain **before** use that components are of the correct identity based on the labeling and have been stored under required conditions in the facility*. Section 8 *All release inspections **must** be included in the facility's documentation (see 7. Master Formulation and Compounding Records and 11. SOPs). All checks, inspections, and any other required tests to ensure the quality of the CNSP **must** be detailed in the facility's MFR.* Section 8.1 *At the completion of compounding, before releasing and dispensing, the CNSP **must** be visually inspected to determine whether the physical appearance of the CNSP is as expected (e.g., color, texture, physical uniformity). Some CNSPs, as noted in their MFR, also **must** be visually checked for certain characteristics (e.g., emulsions must be checked for phase separation). The CNSP **must** be visually inspected to*

Article 4.5 Section 1735.11 (a)(2)(A) and (a)(2)(C) Con't		*confirm that the CNSP and its labeling match the CR and the prescription or medication order. The inspection also **must** include a visual inspection of container closure integrity (e.g., checking for leakage, cracks in the container, or improper seals).* Section 12, paragraph 2: A *facility's QA and QC programs **must** be formally established and documented in the facility's SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with the requirements in this chapter (〈795〉) and the laws and regulations of the applicable regulatory jurisdiction*. **RECOMMENDATION:** Remove these SOPs are redundant.
Article 4.5 Section 1735.11 (a)(2)(B)	*(B) Procedures for handling, compounding, and disposal of infectious materials. The SOPs shall also describe the facility's protocols for cleanups and spills in conformity with local health jurisdictional standards, if applicable.*	**COMMENT:** This is a reuse and renumber from existing law 1751.3(17) Sterile Compounding Policies and Procedures That should be removed. **RATIONALE:** "Infectious materials" typically is a reference to bacteria, viruses, parasites, etc which might/could include untested blood samples. The term infectious materials never comes up in USP 795 and blood is not considered an appropriate component for nonsterile compounding. Infectious materials should not be allowed in a nonsterile compounding facility. **RECOMMENDATION:** If you are aware of nonsterile infectious material compounding that is happening, please reword with both a qualifier for who needs to have this and clarification that will define 'infectious materials'. Proposed wording:(B) <u>If compounding with infectious materials (such as …..), *the SOPs shall also describe the facility's* procedures for handling, compounding, ~~*and*~~ disposal, ~~*of infectious materials. The SOPs shall also describe the facility's protocols for*~~ *cleanups, and spills in conformity with local health jurisdictional standards, if applicable.*</u>
Article 4.5 Section 1735.11 (a)(2)(D)	*In addition to the standards set forth in Chapter 795, the following requirements apply to nonsterile compounding.* *(a) The facility's standard operating procedures (SOPs) for nonsterile compounding shall be followed and shall:* *(2) Also describe the following:* *(D) The method for complying with any other requirements specifically required to be addressed in the facility's SOPs as described in this article.*	**COMMENT:** This is far too vague to even know where to begin to comply. "An SOP shall be followed and describe the method for complying with any other requirements specifically required to be addressed." What does it mean???? **RATIONALE:** Per the statement of reasons, "The goal of the board's regulations is not to duplicate provisions of federal law or USP language, but to clarify or make more specific the requirements." What is specific about this? "Any other" is as non-specific as it gets. The phrase "requirements specifically required" is redundant and confusing all at the same time. Further, isn't the point of an SOP (Standard Operating Procedure) to define the method to comply with the requirements? **RECOMMENDATION:** Remove Section 1735.11 (a)(2)(D) as it does not provide clarity nor improve patient safety. If there is a SPECIFIC goal for this, it needs to be better worded so the licensees have comprehension of how to comply.

Article 4.5 Section 1735.11 (a)(2)(E)	*(E) The validated processes for storage, shipping containers and transportation of temperature sensitive CNSPs to preserve quality standards for integrity, quality and labeled strength.*	**COMMENT:** This is redundant and repetitive as it is addressed several other places in USP and new proposed regulations. **RATIONALE:** Other sections that address "*validated processes for storage, shipping containers and transportation of temperature sensitive CNSPs to preserve quality standards for integrity, quality and labeled strength."* Include: Section 1.1.4 Oversight by designated person(s): *The compounding facility must designate one or more individuals to be responsible and accountable for the performance and operation of the facility and personnel for the preparation of CNSPs. The responsibilities of the designated person(s)include but are not limited to:* ***Establishing****, monitoring, and documenting procedures for the* ***handling and storage of CNSPs*** *and/or components of CNSPs* Section 2 Training. *Knowledge and competency must be demonstrated initially and at least every 12 months in at least the following core competencies:* ***Handling and transporting*** *components and CNSPs* Section 13.1 T*he facility's SOPs* ***must*** *describe packaging of CNSPs. Personnel should select and use packaging* ***materials that will maintain the physical and chemical integrity and stability of the CNSPs****. Packaging materials* ***must protect CNSPs*** *from damage, leakage, contamination, and degradation, while simultaneously protecting personnel from exposure.* And new CA reg 1735.2(b) *A pharmacist responsible for, or directly supervising, the compounding of CNSPs, shall demonstrate proficiency in* ***skills necessary to ensure the integrity, strength, quality, and labeled strength of a CNSP*** *as described in the facility's SOPs as referenced in section 1735.11.* **RECOMMENDATION:** Remove, it is redundant with no added substance or specificity.
Article 4.5 Section 1735.12 (b)	*(b) The Board shall be notified in writing within 72 hours of the facility's receipt of a complaint of a potential quality problem or the occurrence of an adverse drug event involving a CNSP.*	**COMMENT:** Please define for your licensees what the BOP wants to know… if a patient receives a high strength bleaching cream and has redness and peeling on their face, is that an ADR or a side effect? And how do you define a "potential quality problem?" This could just be a lack of response to treatment, right? Shouldn't the pharmacy initiate an investigation into a "potential quality problem" prior to disrupting you the BOP staff? This regulation needs much clarification and specific language. **RATIONALE:** Patient's often are paying cash for compounds. If it doesn't work in 3 days, they may call and report a "potential quality problem" when either a) they haven't allowed enough time for therapeutic effect or b) the doctor erred on a lower dose prescription that may not work. There are no guarantees that any medication will work for any one patient; think simple NSAIDs– why does IBU work for one patient and Naprosyn for another, but not vise versa. Is that a potential quality issue with the manufactured product? No. However, if a patient were to report to the board that they reported to me that their bleaching cream did not lighten their dark spots within a week,

Article 4.5 Section 1735.12 (b) Con't		and I didn't see it as a potential quality problem, would I be cited and fined for not reporting the "issue" within 72 hours, I believe yes. Quality issues and ADR examples should be defined clearly to prevent both the pharmacy and the Board from spending too much time on non-issues. Also need to clarify HOW and to WHOM this is reported to the board. **RECOMMENDATION:** Restructure and define what needs to be reported to the board. If it could be a normal side effect, will it qualify as an ADR? Allow the pharmacy to conduct an initial assessment of a potential quality problem– even define the steps you want completed (review Logged formula, interview all staff involved with the compounding process, review specific steps with the compounder to determine if there was deviation, interview the patient to see if it was mis-handled, etc.) And create a requirement for reporting high level issues that really are quality based.
Article 4.5 Section 1735.11 (c)	*(c) All complaints related to a potential quality problem with a CNSP and all adverse events shall be reviewed by the pharmacist-in-charge within 72 hours of receipt of the complaint or occurrence of the adverse event. Such review shall be documented and dated as defined in the SOPs..*	**COMMENT:** I sincerely understand the urgency of reviewing ADRs and quality issue, but is it not effective to limit the review process ONLY to the PIC. **RATIONALE:** What if a PIC is on vacation, out of the country for 5 days (or more)? Must they interrupt their time off communicate with the Board? Could they not delegate the review and communication to the Board to someone onsite handling the issue? Please open this up to the PIC, the DP, or a compounding pharmacist if you must keep the 72 hour limit. **RECOMMENDATION:** Reword *(c) All complaints ~~related to a potential~~ determined to be an actual quality problem with a CNSP and all adverse events shall be reviewed by ~~the pharmacist-in-charge~~ a pharmacist within 72 hours of receipt of the complaint or occurrence of the adverse event. Such review shall be documented and dated as defined in the SOPs.*
Article 4.5 Section 1735.13	*CNSP Packaging and Transporting.* *In addition to the standards set forth in Chapter 795, the facility shall ensure appropriate processes for storage, shipping containers and temperature sensitive CNSPs as provided for in the facility's SOPs.*	**COMMENT:** There is no "in addition" here. This is repetitive of USP 795 Section 13. **RATIONALE:** Chapter 795 Section 13 *The facility's SOPs **must** describe packaging of CNSPs. Personnel should select and use* *packaging materials that will maintain the physical and chemical integrity and stability of the CNSPs. Packaging materials must protect CNSPs from damage, leakage, contamination, and degradation, while simultaneously protecting personnel from exposure.* And Section 13.2 *If transporting CNSPs, the facility must have written SOPs to describe the mode of transportation, any special handling instructions, and whether temperature monitoring devices are needed.* And proposed 1735.8 "*A pharmacist performing or supervising the nonsterile compounding is responsible for the integrity, strength, quality, and labeled strength of a*

Article 4.5 Section 1735.13 Con't		*CNSP until the beyond-use date indicated on the label provided the patient or the patient's agent follows the label instructions provided on the CNSP for storage and handling after receiving the CNSP.* " **RECOMMENDATION:** Recommendation: remove this as it is already required by other proposed language and it only confuses the issue.
Article 4.5 Section 1735.14.(b)	*(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.*	**COMMENT:** The intent of this is to keep an audit trail, but the wording becomes a bit confusing as well as difficult to comply with. **RATIONALE:** The first sentence is clear, but the next one "*Prior versions of each record must be maintained in a readily retrievable format and include the changes to the document,..."* doesn't make sense. A prior (earlier) version will not have the current nor future changes recorded on it. And we need clarity on how long to keep this audit trail. **RECOMMENDATION:** (reword for clarity) (*b) Records created shall be created and maintained in a manner to provide an audit trail for revisions and updates of each record document for at least 3 years from the date of the revision. Prior versions of each record must be maintained in a readily retrievable format. Each revision must include the changes to the document, identification of the individual who made the change, and the date of each change.*
STERILE		
Article 4.6 Section 1736.1(e)(1)(A)	*(e) In addition to prohibitions and requirements for compounding established in federal law, no CSP may be compounded that:* *(1) Is essentially a copy of one or more commercially available drug products, unless:* *(A) that drug product appears in an American Society of Health-System Pharmacists (ASHP) or FDA Drug Shortages Database that are in short supply at the time of compounding and at the time of dispensing, or*	**COMMENT:** The FDA requirement is simply on the shortage list. Adding additional language may create confusion. **RATIONALE:** California language should be precisely the same as FDA language on this topic to prevent confusion of discrepancies in enforcement. The text of the 503A exemption only states you cannot compound essentially a copy of a commercially available drug product. The text of 503A does not reference the drug shortage list. FDA guidance does not consider a drug to be commercially available if it appears on the "FDA drug shortage list." The FDA defines "appears on the list" as being if the drug is on the drug shortages database list and shows its status as "currently in shortage". **RECOMMENDATION:** *(1) Is essentially a copy of one or more commercially available drug products, unless:* *(A) that drug product appears in an American Society of Health-System Pharmacists (ASHP) or FDA Drug Shortages Database ~~that are in short supply~~ and the drug status is "currently in shortage" at the time of compounding and at the time of dispensing, or*

Article 4.6 Section 1736.1(e)(1)(B)	*(B) the preparation produces a clinically significant difference based on the medical need of an identified individual patient, as determined by:* *(i) the prescribing practitioner,* *(ii) the compounding pharmacist, and (iii) the dispensing pharmacist(s).*	**COMMENT:** It is already established in Federal Guidelines and the proposed definition 1736(e) that the prescriber makes the determination of what is "essentially a copy." But if that is not sufficient, then "clinically significant difference" needs to be defined. Concern to consider: if the prescriber, compounding RPh and dispensing RPh all agree, but an inspector doesn't, who is right and for what reason? Further, the compounding pharmacist and the dispensing pharmacist are often the same individual, so they get 2 votes **RATIONALE:** Federal statute Section 503A of the FD&C Act states that "the term 'essentially a copy of a commercially available drug product' does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, ***as determined by the prescribing practitioner,*** between the compounded drug and the comparable commercially available drug." Pharmacists still have to use common sense and not violate any of our own rules and regulations. **RECOMMENDATION:** Allow Federal statute 503A of the FD&C Act to stand on its own
Article 4.6 Section 1736.1(e)(2)	*(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).*	**COMMENT:** Based on your statement of reasons, it appears clear that this is only intended for vet patients, however, as written, this statement applies to all CSP compounding (including human). Also, there is no definition for "component not suitable for use in a CSP" creating great vagueness and opportunity for multiple interpretations that can range from issues related to ingredient quality to how a prescriber intends to use it, clinically. **RATIONALE:** As proposed, a pharmacist, or an inspector, determining that a component is "not suitable" for the intended population is infringing on a prescribers prerogative to decide what they want to use to treat their patient. Other language exists to ensure ingredient quality, potency, and integrity of the CSP. This language creates confusion, lack of specificity, and opportunity for vague interpretations and should be stricken or reworded to achieve the specific regulatory oversight desired. **RECOMMENDATION:** Remove or clarify this applied to animal compounding. Clarify this is for animal/veterinary CNSPs by modifying the language: *(2) Is made with any component not suitable for use in a CNSP for the intended ~~patient~~ animal population, unless allowable under the Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA).*

Article 4.6 Section 1736.1(e)(3)	*(3) Is made with a non-sterile component for which a conventionally manufactured sterile component is available and appropriate for the intended CSP.*	**COMMENT:** This says that one cannot use bulk-powder for CSP if a manufactured sterile component is appropriate. However, there is no definition of "appropriate" to provide clarity for a PIC to know if they are compliant with this regulation. **RATIONALE:** There may be instances where the package size available for a commercial product is so ridiculously large (e.g. needing only 1 ml out of a 250ml IV infusion bag) or so the packaging is so small (0.5ml vials) that it would requiring 10's of vials to get sufficient volume for the preparation. The PIC should have discretion to choose if a bulk ingredient is "acceptable." **RECOMMENDATION:** Remove.
Article 4.6 Section 1736.1(g)	*(g) In addition to the provisions 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.*	**COMMENT:** This is repetitive of other regulations already in place. Further, consultation regulations should be consistent across all medications dispensed, not limited to compounded preparations and thus Section 1707.2 should be modified rather than creating new regulations limited only to CSPs. **RATIONALE:** Regarding *"...proper use, storage…"* the referenced Section 1707.2 subsections (c) and (d) both require consultation that includes proper use and storage. Disposal is not currently a consultation requirement, but CNSPs are not that different from capsules, creams, troches, and liquids that are dispensed by non-compounding pharmacies. If this is a true patient safety issue, then it should be addressed in ALL consultations, not just CNSPs. **RECOMMENDATION:** Remove section 1735.1 (h) and initiate the rulemaking process to update 1707.2 for additional consultation requirements.
Article 4.6 Section 1736.1(h)	*(h) CSPs with human whole blood or human whole blood derivatives shall be produced in compliance with Health and Safety Code section 1602.5.*	**COMMENT:** HSC 1602.5 requires biologic licensure which is granted by CA DPH Laboratory Field Services to provide blood products. However, their regulations ***do not*** include compliance with USP <797> and thus they do not require their licensed entities to comply with 797. This creates a completely uneven playing field that ensures that patients will get substandard less expensive preparations from individuals not regulated by the board of pharmacy. **RATIONALE:** Entities licensed under HSC 1602.5 are actively making drug products (autologous serum eye drops) when they are not licensed pharmacies. They fill prescriptions, compound preparations; dispense these to patients, and bill insurers for their services. They do not comply with USP<797> and offer eye drops with 6-month expiration dates for unpreserved, blood components.

Article 4.6 Section 1736.3(a)	*(a) The pharmacist overseeing compounding shall not allow personnel with potentially contaminating conditions to enter the designated compounding area.*	**COMMENT:** The term “potentially contaminating” condition is not defined and is open to broad interpretation. **RATIONALE:** Without clarity, a PIC cannot be compliant with a “shall” term unless the conditions for compliance are clear. Absent such clarity, it is appropriate that the regulation language be a “should” statement to provide the necessary latitude for PIC discretion. **RECOMMENDATION:** *(a) The pharmacist overseeing compounding ~~shall not allow~~ should use their judgement to prevent personnel with potentially contaminating conditions to enter the designated compounding area.*
Article 4.6 Section 1736.4(c)	*(c)(1) Designated compounding area(s) shall typically be maintained at a temperature of 20° Celsius or cooler. (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.*	**COMMENT:** Having “shall” and “typically” in the same sentence is contradictory. **RATIONALE:** A PIC cannot be compliant with something “typically” and have it state that it “shall” be a certain temperature. **RECOMMENDATION:** *(c)(1) Designated compounding area(s) ~~shall~~ should typically be maintained at a temperature of 20° Celsius or cooler. (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.*
Article 4.6 Section 1736.4(e)	*(e) Except as provided in subsection (d), dynamic interactions between areas and rooms with classified air shall be controlled through a heating, ventilation, and air condition (HVAC) system.*	**COMMENT:** Passive airflow connections between classified areas is required based on the physics of airflow and HVAC system operation. **RATIONALE:** The movement of air from one classified space to another must include passive movement between spaces, as the HVAC system can only directly affect airflow in the ductwork. Once air enters a wide open space, properties of fluid dynamics, gravity, and air-pressure differentials affect where air moves and how. The connections between rooms does not include powered vents, and gaps in door ways prevent complete separation of air from one room to another. By definition, passive air flow occurs whenever a door opens between the rooms. **RECOMMENDATION:** *(e) Except as provided in subsection (d), dynamic interactions between areas and rooms with classified air shall be controlled through a heating, ventilation, and air condition (HVAC) system and passive air exchange vents of appropriate design.*

Article 4.6 Section 1736.4(f)	*(f) No CSP shall be compounded if the compounding environment fails to meet criteria specified in law or the facility's SOPs.*	**COMMENT:** This is so general, it does not allow for potential monitoring deviations that are corrected to enable ongoing operations. **RATIONALE:** For example, if surface testing indicates excessive CFU in an ante area, this would then stop all activity in the compounding suite. The intent in monitoring is to identify an excursion (aka "failure to meet criteria") then take remediation actions and continue to monitor for ongoing excursions. As written, one excursion in temperature, monitoring, pressure, humidity, missed floor cleaning, would trigger a stoppage of all compounding, even if the excursion was deemed not a substantial risk by the PIC. There are numerous regulations around identifying and mitigating these excursions, and discretion if given to the PIC to evaluate these and decide accordingly if compounding should be performed. This regulation is vague and redundant. **RECOMMENDATION:** Remove.
Article 4.6 Section 1736.6(a)	(a) At a minimum of every 6 months, air and surface sampling results shall be identified to at least the genus level, regardless of the CFU count to trend for growth of microorganisms. Investigation must be consistent with the deviation and must include evaluation of trends.	**COMMENT:** This is just not always possible, I believe that is why USP 797 States "an attempt must be made to identify any microorganisms recovered to the genus level" **RATIONALE:** Is there a scientific basis for requiring this? Why is the language of 797 insufficient when it calls for "an attempt MUST be made"? Growing microorganisms can be tricky and identification may only be to the Class Level, not Genus depending on the conditions. It is out of the PICs control as to if the organism CAN be identified to the Genus level. Holding the PIC/DP accountable to this requirement of "shall be identified" is unreasonable. As stated in 797, an attempt must be made, is reasonable. **RECOMMENDATION:** Remove. Allow 797 to stand as is.
Article 4.6 Section 1736.6(b)	*(b) Environmental sampling shall be done in compliance with Controlled Environment Testing Association's Certification Application Guide USP <797> Viable Environmental Sampling & Gowning Evaluation (CAG-009, Revised October 2022), which is hereby incorporated by reference.*	**COMMENT:** This requires licensees to obtain membership with a private entity ($295/yr) just to view the documents (CETA membership). The entity openly states they are intended only as guidance documents. As such, they are not appropriate for use as regulatory compliance documents. Also, the current CAG-009 document available for viewing was revised in 2020. The item referenced is not even available to determine if compliance can be achieved. **RATIONALE:** Having "shall" language being used on documents that are guidance and suggestive in nature creates vague language that makes it impossible for a PIC to determine if they are in compliance, or not, with CA BOP regulations. **RECOMMENDATION:** *(b) Environmental sampling ~~shall~~ should be done in compliance with Controlled Environment Testing Association's Certification Application Guide USP <797> Viable Environmental Sampling & Gowning Evaluation (CAG-009, Revised October 2022), which is hereby incorporated by reference.*

Article 4.6 Section 1736.8	*In addition to the requirements in USP Chapter 797, the following requirement applies to sterile compounding. Introducing items into the SEC and PEC shall comply with the SOPs as required in section 1736.17.*	**COMMENT:** This is redundant of the language in 1736.17(d) **RATIONALE:** Redundant of proposed 1736.17(d), which says "(d) The SOPs shall specify the process and products to be used on any equipment and other items entering from an unclassified area into the clean side of the anteroom, entering a PEC, and entering the SCA." **RECOMMENDATION:** Remove regulation.
Article 4.6 Section 1736.9(d)	*(d) All API and excipient components used to compound a CSP shall be manufactured by an FDA-registered facility, be accompanied by a Certificate of Analysis (COA), and suitable for use in sterile pharmaceuticals. A COA that includes the compendial name, the grade of the material, and the applicable compendial designations on the COA, must be received and evaluated prior to use, unless components are commercially available drug products. When the COA is received from a supplier, it must provide the name and address of the manufacturer. API and excipient components provided with a COA without this data shall not be used in a CSP.*	**COMMENT:** There is no definition of what constitutes "suitable for use in sterile pharmaceuticals" **RATIONALE:** Without a definition of what "suitable for use in sterile compounding" means, a PIC cannot determine if they are compliant with this regulation. It is appropriate to have specifics about what kind of documentation is required, and the information that is required on the document. Including a "shall" statement for a subjective assessment to determine if something is "suitable" is too vague to be included in the compliance regulations and should be removed. **RECOMMENDATION:***(d) All API and excipient components used to compound a CSP shall be manufactured by an FDA-registered facility, be accompanied by a Certificate of Analysis (COA)~~, and suitable for use in sterile pharmaceuticals~~. A COA that includes the compendial name, the grade of the material, and the applicable compendial designations on the COA, must be received and evaluated prior to use, unless components are commercially available drug products. When the COA is received from a supplier, it must provide the name and address of the manufacturer. API and excipient components provided with a COA without this data shall not be used in a CSP.*
Article 4.6 Section 1736.9(e)	*(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.*	**COMMENT:** There is a profound contradiction in assuring public safety with this regulation. It prevents compounding with drugs the FDA is allowing to be done while its expert committees make decisions about them. At the same time, it gives any public health official in CA the power to allow a compounding pharmacy to use any bulk ingredient it deems appropriate for a specific patient. **RATIONALE:** As worded, this prevents pharmacies from using on the FDA's Category 1 Bulk drug substances under evaluation list (503A updated updated 5/2024). As a result, patients will go out of state or have things shipped-in from unlicensed out of state providers. This does little to improve the safety of California patients. At the same time, it allows a compounder to "get permission" from any public health official to use any bulk drug substance on a patient specific basis. One quick web search for what is a "public health official" showed "*Public health official means a local health officer, the Director of the Bureau of Health, Department of Health and Human Services, or any designated employee or agent of the Department of Health and Human Services."*

Article 4.6 Section 1736.9(e) Con't		**RECOMMENDATION:** *(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, on the FDA Category 1 Bulk Drug Substances list, unless authorized by a public health official in an emergency use situation for a patient-specific compounded sterile preparation.*
Article 4.6 Section 1736.11(c)(6)	*(6) When applicable, endotoxin level calculations and results.*	**COMMENT**: I outsource endotoxin testing and the calculations are handled by the vendor. How do you define "when applicable"? How can I show calculations that I am not doing? **RATIONALE:** Vague definition of "when applicable" and the calculations and results are determined by the vendor of the service… Below a certain level is the current standard of practice, not provided the exact level measured or the corresponding calculations, which involve a variety of sample dilutions, measurement, then extrapolation of the levels. This is why labs are registered with the FDA, to ensure the services provided are compliant. As a client using those services, we have neither the expertise nor insight to their proprietary procedures to fully validate the results we are collecting. How far does the BOP expect an RPH to go to validate a vendor? Do we inspect FDA manufacture plants for tablet production? Or commercially available injections? **RECOMMENDATION:** *(6) When applicable, endotoxin ~~level calculations and~~ testing results*
Article 4.6 Section 1736.13(a)(2)	*(a) A CSP label shall include all of the following:* *(2) The solution utilized, if applicable;*	**COMMENT:** Having a "shall" requirement for the label to indicate the solution in the CSP may not be practical to achieve in some situations. **RATIONALE:** Not all CSPs are simple solutions that can be detailed on the label. IV admixtures are often simply D5 or NS and can be listed. However eyedrops can be complex mixtures of solvents, lubricants, stabilizers, salts, buffers, and pH adjustments. Often, these are labeled as "aqueous" for water based or "emulsion" for oil in water solutions, or "in oil". This amount of detail on the label should be a point of discretion by the RPH to reflect, as practically as possible, information sufficient for the end user (patient, provider, etc). **RECOMMENDATION:** *a) A CSP label ~~shall~~ should include all of the following: (1) Route of intended administration;(2) The solution utilized, if applicable;*
Article 4.6 Section 1736.13(a)(4)	*(4) Name of compounding facility and dispensing facility (if different).*	**COMMENT:** Having one pharmacy put another pharmacy's name on its product has multiple issues regarding accuracy and liability**.** **RATIONALE:** Having one pharmacy put another pharmacy's identifying information on the label is problematic. Different registered names, spellings, specific location

Article 4.6 Section 1736.13(a)(4) Con't		(basement or clinic). Maybe the compounding pharmacy doesn't know what facility it will ultimately be dispensed by, or what if it changes? Who updates the information? Is it mislabelled? Delays in care and mismatched records. If a pharmacy dispenses something made by another pharmacy, then require that pharmacy to also label the product with identifying information. The burden should be on the dispensing pharmacy, who acquires it, to label it with their information. **RECOMMENDATION:** *(4) Name of compounding facility ~~and dispensing facility (if different)~~.*
Article 4.6 Section 1736.13(b)	*(b) Any CSP dispensed or ready to be dispensed to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5.*	**COMMENT: It is** Redundant to state they must comply with a regulation that is already required to be compliant with in another section. **RATIONALE:** It starts with "(a) A pharmacist shall not dispense a prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:" Since, by definition, a compound can only leave a pharmacy under order of a prescription (dispensed), not distributed, then 4076(a) automatically attached to every item made and dispensed. No need to restate the requirement. "Or ready to be dispensed" prevents preparation in anticipation of dispensing. Similarly, 1707.5 defines label requirements for items dispensed to patients. By definition, anything leaving the pharmacy must be dispensed (pursuant a prescription) and meet this requirement. It is unnecessarily redundant here. **RECOMMENDATION:** Remove regulation.
Article 4.6 Section 1736.14	*1736.14 Establishing Beyond-Use Dates. In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.*	**COMMENT:** Redundant of USP <1163> **RATIONALE:** As stated above in 1736.17(a)(1) requiring compliance with USP<1163> that also states Is the intent of this to be more restrictive than USP <1164> by excluding the option for "an extrapolation of above based on professional judgment"? See next page

Article 4.6 Section 1736.14 Con't		**DOCUMENTATION** The purpose of documentation is to provide a record of all aspects of compounding operations and procedures that are described in this chapter, in ⟨795⟩, and in ⟨797⟩. Information on the compounding record should ideally be entered as the tasks are performed or as testing data is received. Compounding records should be reviewed for accuracy, completeness (as appropriate) and approved by QA personnel, prior to dispensing. Additionally, beyond-use dating and sterility studies, where appropriate, should be documented by reference to at least one of the following: • Stability studies published in peer-reviewed literature, • In-house or laboratory conducted stability and/or sterility studies, • National compendia, or • An extrapolation of above based on professional judgment. **RECOMMENDATION:** Remove regulation.
Article 4.6 Section 1736.14(a)(1-3)	*(a) A CSP's beyond-use date (BUD) shall not exceed: (1) The chemical and physical stability data of the active pharmaceutical ingredient(s) 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); and* *(3) The shortest remaining expiration date or BUD of any of the starting components.*	**COMMENT:** This is applying USP language for extending compounding BUDs beyond normal 45 day limits and applying it to any compounded preparation. This will completely paralyze all custom compounding, as the data being required is not available for all CSP, or combinations of CSPs (ie TPNs) **RATIONALE:** It is using language from USP that is defined for extending a BUD beyond table 13 (45 days frozen, etc) and putting this requirement on all BUDs being assigned. This is completely untenable as a pharmacy, as much of this is not known, especially to the specifications prescribed. Without lab testing on your formula and Pharma level investments into sophisticated analysis, standard packaging experience cannot be applied, or can be but becomes at the discretion of an inspector to interpret and apply their expectations. One cannot operate a business on such vague regulatory requirements. Does not allow for short dated items, like pH adjusting solutions. In addition, if the starting component does not have a validated stability and container system bud, then how does one apply it to the finished component? USP already address this adequately and does not need additional regulations from CA BOP for compounders to do stability and container closure testing on products with BUDs within the limits set by USP <797> **RECOMMENDATION:** Delete regulation.

Article 4.6 Section 1736.14(c))	*(c) Prior to furnishing a CSP, the pharmacist performing or supervising sterile compounding is responsible for ensuring that sterility and endotoxin testing for BUD determination is performed and has received and reviewed the results. Results must be within acceptable USP limits. Test results must be retained as part of the compounding record.*	**COMMENT:** Are you intending for this to apply to ALL CSPs? Currently, not all CSPs require this testing. This is an impractical requirement that will prevent all hospital, home infusion, and retail compounding from happening in a timely manner. **RATIONALE:** This restricts all CSP compounding, even hospital IV Add mixtures and TPNs to performing sterility and endotoxin tests prior to dispensing. By definition, sterile to sterile do not require this in 797, but this would be more restrictive. If a result does not have an established acceptable limit, such as endotoxins for eye drops or for sterile topical applications, then one cannot even comply with this requirement. **RECOMMENDATION:** Delete and rewrite to achieve the desired regulatory oversight goals.
Article 4.6 Section 1736.16(a)	*(a) A compounded stock solution intended for use in a CSP must comply with all provisions of this article and USP Chapter 797 Category 1, Category 2, or Category 3.*	**COMMENT:** Without a definition of "stock solution" it is unclear what provisions must be compliant with. **RATIONALE:** Does this mean prior to use? Does it have to be sterility testing prior to being used in the final CSP. It is vague and does not provide clarity of what it intended. There's no definition of "stock solution" If a CSP is made in multiple steps, is each ingredient considered "stock solution"? This is clearly written to address some scenarios, but without being specific on the conditions, it leaves broad interpretation and discretion, which simply creates uncertainty for PICs, difficulty understanding when compliance has been obtained, and a business risk that will further drive owners away from practice and decrease patient access and increase costs. **RECOMMENDATION:** Discard and rewrite to achieve the desired regulatory oversight.
Article 4.6 Section 1736.18(a)(1)	*(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 CSP is discovered to be outside the expected standards for integrity, quality, or labeled strength.*	**COMMENT:** Recalls are not scheduled events. **RATIONALE:** Recalls are not scheduled actions. Remove "scheduled" and simply have "a written procedure for action in the event…" **RECOMMENDATION:** *(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,~~ actions in the event any CSP is discovered to be outside the expected standards for integrity, quality, or labeled strength.*

Article 4.6 Section 1736.18(b)	*(b) Recalls and adverse event reporting must be completed in compliance with relevant provisions of law.*	**COMMENT:** Redundant of other regulations. **RATIONALE:** Redundant. No need for a regulation that states you must comply with another regulation? **RECOMMENDATION:** Remove regulation.
Article 4.6 Section 1736.19	*1736.19 CSP Handling, Storage, Packaging, Shipping, and Transport. In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.* *Packaging materials shall protect CSPs from damage, leakage, contamination, degradation, and adsorption while also preventing transportation personnel from inadvertent exposure.*	**COMMENT:** Issues of compound stability and container reactivity don't fit this section on transport integrity. **RATIONALE:** From Wikipedia: "Adsorption is the adhesion[1] of atoms, ions or molecules from a gas, liquid or dissolved solid to a surface.[2]" CSP transport packaging has no effect on the compound adsorption to the container it is in. This is part of container closure considerations. The word should be removed. Contamination and degradation are also components of container closure considerations and should not be included in this section on handling, storage and transportation. **RECOMMENDATION:** *1736.19 CSP Handling, Storage, Packaging, Shipping, and Transport. In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding. Packaging materials shall protect CSPs from damage, leakage, ~~contamination, degradation, and adsorption~~ while also preventing transportation personnel from inadvertent exposure.*
Article 4.6 Section 1736.21	*1736.21 Compounding Allergenic Extracts. In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.*	**COMMENT:** As this section applies to Allergenic Extracts, the regulation should be specific in its language and not broadly applied to all sterile compounding. **RECOMMENDATION:** *1736.21 Compounding Allergenic Extracts. In addition to the requirements in USP Chapter 797, the following requirements apply to sterile <u>allergen</u> compounding.*
Article 4.6 Section 1736.21(a)	*(a) Any allergenic extract compounding shall take place in a dedicated PEC. No other CSP may be made in this PEC.*	**COMMENT:** Logically unsound, arbitrary and with no basis in scientific fact. **RATIONALE:** This is nonsensical. To state that no other CSP can be made in a PEC suggests that there is contamination that happens that **cannot** be remediated. If this is the case, then having allergen extracts made in a horizontal laminar flow hood exposes the entire buffer room to allergen extracts that cannot be remediated, so one should not allow any compounding to happen in a room where any allergen is compounded. Likewise, if they are required to be made in a vertical flow biologic safety cabinet, then it would then presume to have the assumed contamination of garb that a hazardous chemo

Article 4.6 Section 1736.21(a) Con't		compound would, where gloves are assumed to be contaminated and changed between chemicals. Thus should not gloves also be changed between compounding. And since garb is presumed to be contaminated and discarded with every use, should not garb with allergens be similarly considered contaminated. And in this logic, if you cannot use a hood where allergens would have been compounded, and the buffer area and gowns are presumed contaminated in hazardous compounding, the same contamination should be assumed in allergen compounding. To prevent exposure to HD chemo patients, who are presumed immunocompromised, that should not the regulations say you cannot use a buffer room used for allergen compounding for any other compounding. And what about cross contamination between allergen patients. If I cannot decontaminate the PEC sufficiently to do compounding of non-allergens, then am I not exposing one allergen patient to another allergen patient's mixture? There is no scientific, measurable, quantifiable assay or data to justify this practice. And, when given that this kind of compounding is routinely done on the counter top in an allergies office, and just recently have they even begun to start training their office clerks on aseptic technique, to put such an onerous, unscientific regulation in practice is irresponsible of the BOP. **RECOMMENDATION:** Remove.
Article 4.6 Section 1736.21(b)	*(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 Chapter 797.*	**COMMENT:** Inconsistent with environmental risk design of USP <797>. **RATIONALE:** What is the scientific basis for limiting the compounding of one kind of drug to a particular category? The categories are established based on the risk of contamination based on the intensity of environmental controls and monitoring activities, not the ingredients being used in the environment. **RECOMMENDATION:** Remove and rewrite to achieve desired regulatory oversight.
Article 4.6 Section 1736.21(c)	*(c) Any compounded stock solution shall comply with the requirements established in USP Chapter 51, Antimicrobial Effectiveness Testing and the requirement established in USP Chapter 1207, Sterile Product Packaging – Integrity Evaluation related to container closure. A compounding record is required for any compounded stock solution.*	**COMMENT:** As this section applies to allergy extracts, the regulation should be specific in its language. **RECOMMENDATION:** *(c) Any compounded stock <u>allergy</u> solution shall comply with the requirements established in USP Chapter 51, Antimicrobial Effectiveness Testing and the requirement established in USP Chapter 1207, Sterile Product Packaging – Integrity Evaluation related to container closure. A compounding record is required for any compounded stock solution.*

HAZARD		
Article 4.7 Section 1737	*A licensee performing hazardous drug (HD) compounding shall comply with this article as well as the non-sterile and sterile compounding requirements, as applicable, in Article 4.5 and Article 4.6.*	**COMMENT:** This is merely a reminder that provides no substance, clarity, nor does it improve protection of the public. **RATIONALE:** It is clear from CCR 4126.8. *The compounding of drug preparations by a pharmacy for furnishing, distribution, or use in this state shall be consistent with standards established in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary, including relevant testing and quality assurance.* As the reference to Article 4.5 and 4.6 are not complete to all applicable rules and regulations related to HD compounding, this is not very useful and will **not** ensure compliance with all compounding rules and regulations. **RECOMMENDATION:** Remove.
Article 4.7 Section 1737.1	*In addition to providing consultation in compliance with section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning handling and disposal of an HD or related supplies furnished.*	**COMMENT:** This is repetitive of other regulations already in place and HD medications are NOT limited to compounded preparations. Consultation regulations should be consistent across all HD medications dispensed, Section 1707.2 should be modified rather than creating new regulations limited only to compounds. **RATIONALE:** Regarding *"...proper use, storage…"* the referenced Section 1707.2 subsections (c) and (d) both require consultation that includes proper use and storage. Disposal is not currently a consultation requirement, but CNSPs are not that different from capsules, creams, troches, and liquids that are dispensed by non-compounding pharmacies. If this is a true patient safety issue, then it should be addressed in ALL consultations, not just CNSPs. **RECOMMENDATION:** Remove section 1731.1 and initiate the rulemaking process to update 1707.2 for additional consultation requirements.
Article 4.7 Section 1737.3 Article 4.7	*Each premises where HDs are handled shall ensure that all employees are aware of the types of HD exposures that may occur as referenced in the USP Chapter 800. This shall be documented in SOPs and training documents.*	**COMMENT:** I agree that handling HDs is an employee safety issue, but I don't agree that licensees need another "reminder" as explained in the "Statement of Reasons." This is redundant and repetitive of what is required in CCR It is a minimum requirement of USP 800 that entities have Safe Work Practices, Ensure competency of personnel, "types of exposures" are listed in Section 3 and Table 1, and the **required** Hazard Communication Program outlined in Section 8 discusses the training of all of the above.

Section 1737.3 Con't		**RATIONALE:** Chapter 800 Section 1 *"Entities that handle HDs must incorporate the standards in this chapter into their occupational safety plan. The entity's health and safety management system must,* ***at a minimum,*** *include:* • ***A list of HDs*** • *Facility and engineering controls* • *Competent personnel* • ***Safe work practices*** • *Proper use of appropriate Personal Protective Equipment (PPE)* • *Policies for HD waste segregation and disposal "* Chapter 800 Section 4 Paragraph 1. "*Each entity must have a designated person who is qualified and trained to be responsible for developing and implementing appropriate procedures; overseeing entity compliance with this chapter and other applicable laws, regulations, and standards;* ***ensuring competency of personnel;*** *and ensuring environmental control of the storage and compounding areas."* Chapter 800 Section 4 Paragraph 4. *"****All personnel who handle HDs are responsible for understanding the fundamental practices*** *and precautions and for continually evaluating these procedures and the quality of final HDs to prevent harm to patients, minimize exposure to personnel, and minimize contamination of the work and patient-care environment"* Chapter 800, Section 8. "*Entities are required to establish policies and procedures that ensure worker safety during all aspects of HD handling.* *The entity must develop SOPs to ensure effective training regarding proper labeling, transport, storage, and disposal of the HDs and use of Safety Data Sheets (SDS), based on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).*" **RECOMMENDATION:** Remove, it is redundant.
Article 4.7 Section 1737.5 (c) Article 4.7	*(c) Where a pass-through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking. A pass-through is not allowed between the C-SEC into an unclassified space.*	**COMMENT:** Pass-through to an unclassified space is not excluded by USP 800 Glossary definition. Consider applying the same language as allowed in 1735.5 (a) to certify that the room maintains ISO 7 classification. What is the scientific basis for this regulatory restriction? Did an expert committee assembled by the CA BOP evaluate this and make a consensus statement that justifies why it is more restrictive than the expert committee of the USP? **RATIONALE:** A pass-through can be tested for microbial growth, just like any other surface in the controlled space. It can be certified to maintain appropriate controls with the gasketed and interlocking doors. Appropriate cleaning of the pass-through has the potential to be effective at minimizing

Section 1737.5 (c) Con't		contamination risks and certification can verify that ISO 7 classification can be maintained while the pass-through is utilized. **RECOMMENDATION:** Modify language. *(c) Where a pass-through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking. ~~A pass-through is not allowed between the C-SEC into an unclassified space.~~ If a pass-through connects to an unclassified space, it must be either a HEPA purge type or biannual certification shall document that the C-SEC room can continuously maintain an ISO 7 classification throughout the opening and closing of the pass-though. Specific standard operating procedures (SOPs) shall be written to address the maintenance of the ISO 7 classification.*
Article 4.7 Section 1737.5 (e)	*(e) Facility room pressure monitoring equipment shall be placed consistent with CETA Guidelines CAG-003:2022. SOPs shall address corrective and remedial actions in the event of pressure differentials and air changes per hour excursions.* *(f) Containment Supplemental Engineering Controls (CSTDs) shall not be used to extend the in-use time, BUD, or expiration of any manufactured product or HD CSP.*	**COMMENT:** Section (e) needs to be clarified that it is only applicable to sterile HD rooms as the referenced CETA guidelines are specifically for sterile, controlled environments. **RATIONALE:** Upon reviewing *CETA Guidelines CAG-003:2022 (chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://coeta.memberclicks.net/assets/application-guides/CAG-003%20Final_Signed.pdf)* And section 2.1 specifically states that it is not for non-sterile facilities. **RECOMMENDATION:** Clarify that 1735.5 is for sterile areas only. *(e) Sterile Facility room pressure monitoring equipment shall be placed consistent with CETA Guidelines CAG-003:2022. SOPs shall address corrective and remedial actions in the event of pressure differentials and air changes per hour excursions in the sterile areas.*
Article 4.7 Section 1737.6 (a)	*(a) The SOPs of a premises where HDs are handled shall address environmental wipe sampling for HD surface residue, its frequency, areas of testing, levels of measurable contamination, and actions when those levels are exceeded.* *(b) When any actionable level of contamination is found, at a minimum the following shall occur as described in the SOPs:* *(1) Reevaluate work practices;* *(2) Reevaluate the appropriateness of deactivation, decontamination, and cleaning agents;* *(3) Re-train personnel on deactivation, decontamination, and cleaning; and*	**COMMENT:** While I acknowledge that wipe sampling for HD residue is mentioned in USP 800, it is not a requirement; likely for the same rational as the explanation included the Statement of Reasons "*there are currently no studies demonstrating the effectiveness of a specific number or size of wipe samples in determining levels of HD contamination."* Thus, HD wipe sampling requirements that include "actionable detection" are premature and should not be required by the board. **RATIONALE:**. Without industry level standards or effectiveness, any HD wipe process required by the board is faulty from the start! Further, if the licensee is required to "take action" based off of a process that is clearly not validated and known to be ineffective becomes an exercise in futility and frustration! Pharmacy owners, DPs, PICs, and pharmacists are not experts in HD chemical detection, nor in effective deactivation other than what is provided by the industry experts who, admittedly, have not yet identified a specific process that provides a reproducible result to quantify/measure the level of HD contamination much less identify

	(4) Re-train personnel on donning and doffing appropriate personal protective equipment (PPE).	or define a clinical relevance if a level is detected. Further interpretation of data that is inconsistent or not well controlled due to a host of potential influencing factors (including quantity of initial contamination, light exposure, temperature, wipe material and size, sample surface, chemical degradation properties, etc.) is beyond the scope of the responsible parties' training and expertise. The Statement of Reasons assertion that "the facility must establish their specific procedures based on their business practices. While there is no standard, the facility must still perform the sampling to check for contamination and take action to clean any contaminated areas." is instructing DPs and PICs to pick a random process out of thin air and pretend that it will generate data that indicates "measurable contamination" which will then warrant an effective remediation "plan of action." **RECOMMENDATION:** Remove the actionable levels, but retain the practice of looking for contamination. *(a) The SOPs of a premises where HDs are handled shall address environmental wipe sampling for HD surface residue, its frequency, areas of testing, ~~levels of measurable contamination, and actions when those levels are exceeded.~~* *~~(b) When any actionable level of contamination is found, at a minimum the following shall occur as described in the SOPs:~~* *~~(1) Reevaluate work practices;~~* *~~(2) Reevaluate the appropriateness of deactivation, decontamination, and cleaning agents;~~* *~~(3) Re-train personnel on deactivation, decontamination, and cleaning; and~~* *~~(4) Re-train personnel on donning and doffing appropriate personal protective equipment (PPE).~~* *(b) Results of the testing should be maintained including the testing wipe system used, the date of testing, record of who completed the sampling, the location of the sampling, and which HD was identified (or supposed to be identified).* *(c) Results of the testing will be used to educate HD compounding staff about surface contamination as described in the facilities SOPs.*
Article 4.7 Section 1737.7(c)	(c) Outer gloves used for HD compounding shall be changed between each different HD preparation.	**COMMENT:** This is a very wasteful process overall, but incredibly expensive in the clean room setting that may increase the risk of issues with gloving in the sterile C-PEC. Differentiating between a clean room setting and the nonsterile setting is recommended. **RATIONALE:** When HD compounding in the non-sterile space with powders and creams, though it is wasteful, changing gloves between each preparation is acceptable to prevent cross-contamination. There are no CSTDs that are available to prevent exposure to HD powders when compounding. However, in the sterile environment, there are CSTDs that minimize pressure issues, leaks, and accidental exposures very significantly! Changing gloves in the ISO-5 space takes a few minutes and generates an outer plastic wrap, an inner paper wrap, and 2 gloves each time. A sterile HD compounder may be making upwards of 5-10 compounds per hour… you can envision

		the waste and expense. **RECOMMENDATION:** modify text to differentiate non-sterile and sterile HD gloving practices. (c) *Outer gloves used for nonsterile HD compounding shall be changed between each different HD preparation. Outer gloves used for sterile HD compounding shall be changed in compliance with 1737.7 (b).*
Article 4.7 Section 1737.7(d)	*(d) PPE shall be removed to avoid transferring contamination to skin, the environment, and other surfaces. PPE worn during compounding shall be disposed of in the proper waste container before leaving the C-SEC. SOPs shall detail the donning and doffing of PPE and where it takes place in the C-SEC.*	**COMMENT:** No issue with this in the non-sterile C-SEC, but removing garb in the sterile C-SEC (buffer room) will increase the risk of contaminating the C-SEC with human skin and hair! Differentiate between non sterile and sterile area PPE processes. **RATIONALE:** USP 797 states in section 3.3 "*When preparing Category 2 or Category 3 CSPs, all garb should be donned in a classified area before entering the buffer room*." Further, USP 797 section 4.1.2 "*Typically, personnel hand hygiene and garbing procedures, staging of components, and other activities that potentially generate higher levels of particulates are performed in the anteroom.*" There is a specific situation outlined in USP 797 Section 5.3.2 where an HD sterile compounding area may be entered through a non-HD buffer room, special consideration is required to prevent contamination of the non-HD buffer area. **RECOMMENDATION:** Add language to clarify difference between non sterile and sterile area donning and doffing procedures including the specific situation in Section 5.3.2. *(d)(1) In non sterile HD compounding areas, PPE shall be removed to avoid transferring contamination to skin, the environment, and other surfaces. PPE worn during compounding shall be disposed of in the proper waste container before leaving the C-SEC. SOPs shall detail the donning and doffing of PPE and where it takes place in the C-SEC.* *(d)(2) In sterile HD compounding areas with an anteroom connected directly to an HD C-SEC, PPE shall be removed in the anteroom to minimize particulate generating activities in the C-SEC. PPE worn during HD compounding shall be disposed of in the proper waste container before leaving the HD anteroom. SOPs shall detail the donning and doffing of PPE.* *(d)(3) If the negative-pressure HD buffer room is entered through the positive-pressure non-HD buffer room, a line of demarcation must be defined within the negative-pressure buffer room for donning and doffing PPE.PPE must be removed to avoid transferring contamination to skin, the environment, and other surfaces. PPE worn during compounding shall be disposed of in the proper waste container before leaving the HD C-SEC. SOPs shall detail the donning and doffing of PPE and where it takes place in the HD C-SEC.*
Article 4.7	*(b) All personnel responsible for handling HDs*	**COMMENT:** I agree that a compounder who fails a competency for [dosage form A]

Section 1737.9(b)	*who fail any aspect of training in handling HDs shall not handle HDs until after successfully passing reevaluations in the deficient area(s), as detailed in the facility's SOPs.*	should not continue to make [dosage form A] and should receive additional training to pass competency measures. And remediation is required by both USP 795 Section 14, paragraph 2 and USP 797 Section 20, paragraph 2. But the way proposed 1737.9 (b) is written, personnel will be removed from ALL HD handling (not just dosage form A and maybe not just compounding) when an issue is identified. This section is overly restrictive! **RATIONALE:** Compounding training is multifaceted and complex! Many training programs start with core skills training and then build from there. If a new compounder struggles and fails on Dosage Form C, that does not necessarily mean that they will have issues with Dosage form A. (the training needs to assess for this, though) Removing personnel from ALL HD handling until the identified deficiency is resolved may take days or weeks, depending on the issue. This will impair the facilities' ability to provide compounds in a timely manner and <u>delay access to compounded medications to the patients of California</u>. This proposed regulation may also force Pharmacy owners (who are willing to stay in the compounding business) to hire additional staff, for the "just in case" situation where personnel is removed from workflow for a specific failed competency; this will also raise prices for patients and continue to impede access. Further, if this regulation passes, it will encourage DPs to do only minimal assessments of staff to meet the letter of the law because it will be too costly (dollars, stress, patient dissatisfaction) to remove personnel from the daily operations Lastly, In USP 795, section 14, paragraph 2, the USP clearly requires that the DP create a policy to address *"Personnel training, competency assessments, and qualification records including corrective actions for any failures*." **RECOMMENDATION:** Allow USP 795 Section 14, paragraph 2 USP Section 20, paragraph 2.to stand as is and delete Section 1737.9 (b). If that will not satisfy, then please reword 1737.9 (b) to: *(b) All personnel responsible for handling HDs who fail any aspect of training in handling HDs shall <u>continue to perform the failed HD competency or other dependent competencies</u> ~~not handle HDs~~ until after successfully passing reevaluations in the deficient area(s), as detailed in the facility's SOPs.*
Article 4.7 Section 1737.10 Article 4.7	*All HD APIs and antineoplastic HDs shall be shipped and received from the supplier in segregated impervious plastic and labeled "Hazardous Drugs" on the outside of the delivery container.*	**COMMENT:** The pharmacy receiving the HD API or chemo just does not have control over how the HDs are shipped by the supplier and thus no control over how they are received! The pharmacy **does** have control over how HDs are shipped out. You can make a separate regulation for the wholesalers that they too have to comply with these processes. **RATIONALE:** Common sense? We can only control what we do, not what others do… **RECOMMENDATION:** modify this proposed regulation:

Section 1737.10 (Con't)		1737.10 *All HD APIs and antineoplastic HDs shall be shipped ~~and received from the supplier in segregated~~ or transported in separate impervious plastic and labeled "Hazardous Drugs" or "Chemotherapy" the outside of the delivery container.* 1737.10 (a) As soon as an HD API or antineoplastic is identified during receiving, personnel will comply with SOPs for receiving HDs, including facility SOPs that address how to contain HDs to prevent accidental exposure.
Article 4.7 Section 1737.11 (a)	*(a) Any compounded HD preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5.*	**COMMENT:** Proposed 1737.11 (a) is merely restating 4076 and 1707.5. It does not clarify, specify, or protect public safety more than the original language. **RATIONALE:** This proposed 1737.11 (a) is not even clarifying USP 800. **RECOMMENDATION:** Remove, it is redundant.
Article 4.7 Section 1737.11 (b)	*(b) All HD APIs and antineoplastic HDs shall be transported from the facility in an impervious plastic container and labeled as HD on the outside of the container.*	**COMMENT:** Proposed 1737.11(b) appears to be the same as 1737.10 with a minor change in wording "shipped" rather than "transported." For brevity, combine into one sentence. **RATIONALE:** 1737.10 "*All HD APIs and antineoplastic HDs shall be shipped and received from the supplier in segregated impervious plastic and labeled "Hazardous Drugs" on the outside of the delivery container."* 1737.11(b) All HD APIs and antineoplastic HDs shall be transported from the facility in an impervious plastic container and labeled as HD on the outside of the container. **RECOMMENDATION:** *All HD APIs and antineoplastic HDs shall be shipped or transported from the facility in an impervious plastic container and labeled as HD on the outside of the container.*
Article 4.7 Section 1737.13(a)	*(a) A disposable preparation mat shall be placed on the work surface of the C-PEC when compounding HD preparations. Where the compounding is a sterile preparation, the preparation mat shall be sterile. The preparation mat shall be changed immediately if a spill occurs, after each HD drug, and at the end of daily compounding activity.*	**COMMENT:** There is no definition of a "spill" in USP 800, nor in the proposed regs. **RATIONALE:** Without a definition of "spill," compliance becomes subjective. If a staticy powder is on the prep mat and not in the weight boat, is that a spill? Is it only a "spill" when it reaches a certain weight, volume, or surface area? Objective conditions for compliance cannot be established to meet the rigidity of the "shall" terms of this regulation. **RECOMMENDATION:** Define what constitutes an HD spill; until then let USP 800 Section 13, paragraph 4 stand as "should."
Article 4.7	*(b) Only one HD preparation may be handled in a*	**COMMENT:** A variety of products may take significant time to reconstitute (15 to 30

Section 1737.13(b)	*C-PEC at one time.*	min). **RATIONALE:** It's reasonable to prepare multiple, same type, closed preparations at the same time to enable efficient operations, provided the space is organized so compounding errors do not occur. It is not necessary to specify, in regulation, this level of compounding activity specificity. This should fall to the professional judgment of the licensees (RPhs and DPs). **RECOMMENDATION:** *(b) Only one <u>type of</u> HD preparation may be handled in a C-PEC at one time.*
Article 4.7 Section 1737.14(a)(1)	*In addition to the standards in USP Chapter 800, Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article.* *(a) When dispensing an HD to a patient or patient's agent for administration, the pharmacy shall:* *(1) Place the HD in a decontaminated impervious plastic container with an HD label on the outside of the container;*	**COMMENT:** There is no definition of a "decontaminated impervious plastic container." What is the definition of decontaminated? What constitutes a plastic container? A pliable 2 mil baggie? A stiff 6mil baggie? Hard plastic? Double bag? Would a new container have to be decontaminated, too? **RATIONALE:** Without definition of what a decontaminated impervious plastic container is, compliance cannot be determined by a PIC. **RECOMMENDATION:** (a) When dispensing an HD to a patient or patient's agent for administration, the pharmacy shall: (1) Place the HD in a ~~decontaminated impervious plastic container~~ <u>container suitable for hazardous items to prevent HD exposure</u>, with an HD label on the outside of the container;
Article 4.7 Section 1737.14(a)(2)	*and (2) For an antineoplastic HD, attach and prime all tubing and attach a CSTD when appropriate.*	**COMMENT:** This proposed regulation is overly restrictive. Not all antineoplastic HDs are infused. Some are injected IM, others IV push, and some administered as ophthalmic injections or drops. **RATIONALE:** Not all antineoplastic HDs are prepared for infusion and thus compliance with this regulation will be impossible unless limited to infusions. Additionally, there may be situations where an infusion bag should not be spiked prior to transport to prevent leakage in transport. Nursing procedures exist at facilities where antineoplastic infusions are administered for antineoplastic HD bag spiking and handling. **RECOMMENDATION:** *(2) For an antineoplastic HD <u>infusion</u>, attach tubing <u>if appropriate</u> and prime ~~all~~ tubing <u>if appropriate</u> and attach a CSTD when appropriate.*
Article 4.7	*(b) When furnishing an antineoplastic HD, a*	**COMMENT:** Not every dispense situation requires provision of gloves. Changing the

Section 1737.14(b)	*sufficient supply of gloves that meet the ASTM D-6978 standard to allow for appropriate administration, handling, and disposal of HD drugs by the patient or the patient's agent shall be provided.*	language to allow PIC discretion is appropriate. **RATIONALE:** There are many instances where a sterile HD is furnished to a provider (e.g. clinic, pharmacy, infusion nurse) who has their own internal procedures for handling, gowning, gloving, and disposal of administration supplies. The items provided by the compounding pharmacy may not be known or congruent with those procedures. Also, not all patients want to get their administration supplies from the compounding pharmacy, depending on item preference, cost, and insurance coverage. Also, as written, it could be inferred that the "shall be provided" is done at no cost to the patient. **RECOMMENDATION:** *(b) When furnishing an antineoplastic HD, a sufficient supply of gloves that meet the ASTM D-6978 standard to allow for appropriate administration, handling, and disposal of HD drugs by the patient or the patient's agent ~~shall be provided.~~ <u>should be made available, when needed</u>.*
Article 4.7 Section 1737.15(b)	*(b) Agents used for deactivation, decontamination, cleaning, and disinfecting all areas and equipment involved in HD handling shall be applied through the use of wipes wetted with the appropriate solution and shall not be applied or delivered to the wipe by use of a spray bottle to avoid spreading HD residue.*	**COMMENT:** This overly restricts the ability to purchase and use products as provided by manufacturers. **RATIONALE:** USP 800 specifies that solutions should not be applied by wipes, not solutions sprayed onto the surface being cleaned, as the spray could spread HD contaminants. There is no logic to the prevention of using a sprayer bottle to saturate a clean wiper, then using that wiper on the surface being cleaned. It is also reasonable to argue that using a sprayer to apply a solution onto a wiper provides more even coverage over a palm-sized area than pouring solution onto a single spot on the wiper, which also risks spillage over and possible slipping hazards from the less controlled pouring of the cleaning solution and it not being fully absorbed by the wipe. **RECOMMENDATION:** (b) Agents used for deactivation, decontamination, cleaning, and disinfecting all areas and equipment involved in HD handling shall be applied through the use of wipes wetted with the appropriate solution and shall not be applied or delivered to the ~~wipe~~ surface by use of a spray bottle to avoid spreading HD residue.

Article 4.7 Section 1737.15(c)	*(c) SOPs shall include procedures for deactivation and decontamination of the HD preparation container closure and shall be approved by the pharmacist-in-charge or professional director of a clinic, as applicable.*	**COMMENT:** This proposed regulation suggests completing decontamination of a finished CSP closure system which would include applying deactivation/decontamination solution(s) to the IV bag, ports, and attached tubing. This is completely impractical and there is no information about the compatibility of IV bag and tubing sets to not absorb the decontamination solutions required to complete such a task. **RATIONALE:** USP 800 states that there is no single deactivator for all HDs, but the goal is “complete surface decontamination.” 800 also references the EPA-registered oxidizers, but the EPA search engine does not have any results for this term. Studies, in fact, have shown some chemotherapy agents become more cytotoxic after being treated with oxidizers, so even though the original chemical was not detected, the new chemical entity formed by the “deactivation” process was more cancerous. Since there is no definition of “deactivation” nor a list of EPA products that have approved labeling to be effective at “deactivating” a drug, nor is there an ability for a PIC to determine if they are compliant with “deactivation” regulatory requirements, the language should not be in the regulations. Additionally, wiping down HD CSPs, after they have been compounded, is not a standard of practice and potentially exposes the patient to unknown hazards with no scientific basis showing that CSP containers have contaminations that need to be addressed. **RECOMMENDATION:** *Remove as we cannot verify compatibility nor guarantee that the deactivation/decontamination products don't CAUSE harm to patients.*

END OF DOCUMENT

Mark Johnston, R.Ph
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5/30/24

California Board of Pharmacy,

I am writing to you in my capacity as Executive Director of Pharmacy Regulatory Affairs for CVS Health ("CVS") and its family of pharmacies. CVS Health, the largest pharmacy health care provider in the United States, is uniquely positioned to provide diverse access points of care to patients in the state of California through our integrated offerings across the spectrum of pharmacy care that includes over 1,000 pharmacies located within California. We appreciate the opportunity to submit comments on the Board's proposed compounding regulations.

Article 4.7 Hazardous Drugs

USP 800 contains a broad carve-out for facilities that do not engage in hazardous drug compounding and thus only dispense hazardous drugs in manufactured dosage forms, however proposed Article 4.7 does not contain such a carve-out. Subjecting community pharmacies to 1737.6, 1737.7, 1737.9 and 1737.10 is impractical, costly, and overly burdensome, with no proven benefit to public safety. Therefore, CVS Health requests the following amendment to each of the rules above:

In addition to the standards in USP Chapter 800, Hazardous Drugs – ~~Handling~~ Compounding in Healthcare Setting shall meet the following requirements of this article.

While proposed 1737.12 and 1737.13 obviously pertain to just compounding and not dispensing of manufactured dosage forms, for consistency our suggestion is to also amend these, as red lined above.

Proposed 1737.17 requires an SOP when handling hazardous drugs. Specifically, 1737.17(3) requires the SOP to address "designation of HD areas", but USP 800 does not require separate areas when only dispensing manufactured dosage forms. 1737.17(5) also requires the SOP to address "storage", but again, USP 800 does not require special storage for manufacturer's bottles. Therefore, CVS Health requests the following amendments:

1737.17. Documentation and Standard Operating Procedures (SOPs). *In addition to the standards in USP Chapter 800 Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article.*

(a) Any premises engaged in the compounding or handling of HDs shall maintain and follow written SOPs.

(b) The SOPs for compounding or handling HDs shall include at least the following:

(1) Hazard communication program

(2) Occupational safety program

(3) Designation of HD areas or separate counting trays/spatulas

(4) Receipt

(5) Storage for HD removed from manufacturer's packaging

CVS Health believes the use of "designated person" within Article 4.7 should be optional and not mandatory, as a PIC should have the right to assume all "designated person" responsibilities themselves. Certainly, a PIC should be able to retain responsibility and accountability for the performance and operation of a pharmacy, including the responsibilities and accountabilities that relate to the handling of hazardous drugs.

CVS Health develops policies at a corporate level and standardizes them across 1,000+ California pharmacies, for PICs to implement and assure adherence. At CVS Health, a corporate person (or even a department) is the "designated person", as the term is used in proposed 1737.4, 1737.8, & 1737.17. At CVS Health such a "designated person" is not approved by a PIC, and such a "designated person" is not responsible and accountable for the performance and operation of any pharmacy. Therefore, CVS Health requests the following amendments:

1737.2. List of Hazardous Drugs. *In addition to the standards in the USP Chapter 800, Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article.*

(a) The facility's list of HDs as required by USP Chapter 800 must be reviewed and approved by the designated person and/or the pharmacist-in-charge (PIC), professional director of a clinic, or designated representative-in-charge, as applicable. The designated person ~~must~~ may be a single individual approved by the pharmacist-in-charge to be responsible and accountable for the performance and operation of the facility and personnel as related to the handling of hazardous drugs, or in the case of a chain pharmacy the designated person may be a corporate person or department, with the PIC remaining responsible and accountable for the performance and operation of the pharmacy. The designated person shall not exceed the scope of their issued license. When the designated person is not a pharmacist, the PIC must review all practices related to the operations of the facility that require the judgment of a pharmacist. Approval shall be documented at least every 12 months.

(b) If an assessment of risk approach is taken as authorized in USP Chapter 800, it shall be approved by the designated person and/or the pharmacist-in-charge, professional director of a clinic, or designated representative-in-charge, as applicable.

APhA, ASHP, and NABP convened a summit titled "Implementing Solutions: Building a Sustainable, Healthy Pharmacy Workforce and Workplace," on June 20–21, 2023, in Arlington, VA. The summit called on participants to implement various actionable solutions, including boards of pharmacy. Among other actions, the Implementing Solutions report tasks boards of pharmacy to "Identify unnecessary regulatory burdens and workplace requirements that take time away from activities that could improve the safety of patients and the well-being of pharmacy staff."

CVS Health believes that maintaining employee lists, which may be subject to frequent change, is an example of a burden that your own association has asked you not to promulgate. We believe that spill control can be adequately handled within the framework of the SOP mandated by proposed 1737.17(b)(15). Therefore, we request the striking of proposed 1737.16 in its entirety.

~~*1737.16. Spill Control. In addition to the standards in USP Chapter 800, Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article. The premises shall maintain a list of properly trained and qualified personnel able to clean up an HD spill. An SOP shall outline how such a qualified person will be available at all times while HDs are handled.*~~

A prohibition on the use on an unclassified pass-through may create risk of microbial contamination due to the additional movement throughout the ISO classified space that trigger additional requirements to perform disinfection procedures. Therefore, CVS Health requests the following amendment:

1737.5. Facilities and Engineering Controls. *In addition to the standards in USP Chapter 800, Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article.*

(c) Where a pass-through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking. ~~A pass-through is not allowed between the C-SEC into an unclassified space.~~

Counseling: in Articles 4.5-4.7

Existing regulation 1707.2 creates a Duty to Consult, and at best, proposed regulations 1737.1, 1736.1(g) and 1735.1(h) are misplaced. While 1702.2(c) only lists two categories of mandatory counseling, these pending regulations would create a third. 1707.2(d) lists seven additional categories of consultation for which a pharmacist may use professional judgment to decide when to utilize such counseling components. CVS believes that patients may become concerned about ingesting a drug that is termed hazardous, potentially discontinuing therapy. Therefore, we believe that counseling on hazardous drug disposal should be left to the professional judgment of the pharmacist; otherwise, we fear that this pending regulation might cause a greater public safety risk than it is attempting to solve. Additionally, disposal laws are complicated and vary by drug and by geography in California, including by counties and municipalities. Drug disposal is also regulated by the EPA and the FDA. These pending regulations are essentially requiring pharmacists to provide legal advice on proper disposal, for which we are not well educated. Therefore, CVS Health requests the following amendments:

1737.1. Introduction and Scope. *In addition to the standards in the USP Chapter 800, Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article. In addition to providing consultation in compliance with section 1707.2, whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral consultation shall be provided to the patient and/or patient's agent concerning handling ~~and disposal~~ of an HD or related supplies furnished.*

1736.1. Introduction and Scope*. This article applies to compounded sterile preparations (CSP)s as defined in USP Chapter 797, titled Pharmaceutical Compounding – Sterile Preparations. In addition to the standards in the USP Chapter 797, the preparation of a CSP shall meet the following requirements of this article.*

(g) In addition to the provisions in Section 1707.2, whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral consultation shall be provided to the patient and/or patient's agent concerning proper use, storage, and handling ~~and disposal~~ of the CSP and related supplies furnished.

1735.1. Introduction and Scope*. In addition to the standards in the USP Chapter 795, the nonsterile compounding of a CNSP shall meet the following requirements of this section.*

(h) In addition to the provisions provided in section 1707.2, whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral consultation shall be provided to the patient and/or patient's agent concerning proper use, storage, and handling~~, and disposal~~ of the CNSP and related supplies furnished

Article 4.6 Sterile Compounding

Proposed regulation 1736.6 does not account for the fact that people will introduce an acceptable amount of airborne particulate, as determined by USP experts, and this is especially true in the anti-room and the buffer room (ISO 8 and 7). According to USP 797, based upon scientific expert review, ISO 7 and

8 areas are expected to have a CFU count > 1CFU. In the absence of specifying a particular ISO space in 1736.6, any time more than 1 CFU of any microorganism is found, a microbiologist analysis of the organism is triggered, which will occur with great frequency and create unwarranted cost. Realizing this requirement doesn't apply anywhere across the country and that the Board is supplanting their opinion with those of seasoned experts, CVS Health request the following amendment, which is in excess of USP Chapter 797 requirements:

1736.6 Microbiological Air and Surface Monitoring.

In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.

(a) At a minimum of every 6 months, air and surface sampling shall occur and results shall be identified to at least the genus level when surface sampling exceeds >1 CFU in an ISO Class 5 area, >5 CFU in an ISO Class 7 area, and >50 CFU in an ISO Class 8 area and when air sampling exceeds >1 CFU in an ISO Class 5 area , >5 CFU in an ISO Class 7 area, and >50 CFU in an ISO Class 8 area ~~regardless of the CFU count to trend for growth of microorganisms~~. Investigation must be consistent with the deviation and must include evaluation of trends.

Article 4.5: Nonsterile Compounding:

CVS Health applauds the Board to for eliminating current rule 1735.8(c), which requires "routine testing and analysis of compounded drug preparations" and replacing with proposed 1735.11's requirement to comply with USP Chapter 1163, which allows the compounder to use their clinical discretion and professional judgment in determining the need for routine testing and analysis.

Sincerely,

Mark Johnston, R.Ph

Senior Director

Pharmacy Regulatory Affairs

Institution: Westcliff Compounding Pharmacy
Contact: Mike Pavlovich, Pharm.D.

Section, Subdivision	Proposed Language	Recommendation/Comment

Section 1736.1(e)(4)

(e) In addition to prohibitions and requirements for compounding established in federal law, no CSP may be compounded that:
(4) Requires end product sterilization unless sterilization occurs within the same licensed compounding location.

Recommendation/Comment Omit/delete all language in (4)

When this issue was first raised during the September 2019 Compounding Committee meeting, I and several others voiced similar concerns, and even forwarded comments to the attention of the Compounding Committee, and subsequently to EO Sodergren some time thereafter. In neither case did I receive a response from any representative of the Board. Thus, I am compelled to comment here and ask that these comments be considered.

We happen to employ electron beam to sterilize naltrexone pellets, the only sterile product we currently compound. This dosage form is in demand in the opiate/alcohol addiction and rehabilitation community. If these regulations were to be adopted, it would prohibit us from continuing to compound it as we have since early 2016 would be a great loss to patients with problems of dependence and there are very few providers anywhere.

Oral naltrexone has a very poor track record of compliance for opiate addiction and Vivitrol is comparatively expensive (AWP of nearly $1600/dose), has a duration of action between only 21-28 days, and compliance is also not great. Having a dosage form that can be administered in a minor surgery, even under local anesthesia, that can provide serum levels for between 3 to 6 months is a significant therapeutic advantage. On numerous occasions, including very recently, where doctors and patients have expressed that the use of our compound has "saved their life".

My eBeam provider is Steri-tek, located in Fremont. I had suggested to former EO Herold that she might speak to or visit the facility to increase the Board's understanding of the process. Apparently, her retirement came first.

The website can be found here: https://steri-tek.com/
Steri-Tek is an ISO 11137 and ISO 13485 certified, FDA registered, DEA registered as well as State of California Medical Device and Drug Manufacturing licensed facility serving the medtech, biotech, pharmaceutical and other industries.

As you may know, an implantable pellet is an anhydrous formulation, is highly stable, and is not suitable for sterilization by any means available in the pharmacy - wet methods such as steam would degrade the product and not generate sufficient heat (despite the fact Pfizer has sterilized their Testopel product by autoclave for many years) and dry heat methods would destroy these

dosage forms. Irradiation (gamma, electron beam or X-ray) provides distinct advantages. However, these methods are neither practical or suitable for occurring in the licensed pharmacy. Herein lies the conflict with the proposed language.

Some of the benefits are listed here:

– E-beam sterilization is an FDA approved process. It is recognized and accepted by international standards organizations,
– It can penetrate a variety of product packaging materials including foils,
– It can cause no damage to sterile seals on packaging,
– It allows to control of temperature during irradiation process,
– Well-controlled dose range can be achieved,
– The process is cost effective but the construction of the e-beam sterilization institution is expensive, and not suitable for placement inside a pharmacy.
– It is a fast process (like a minute) in very small lots which effects the efficacy of the procedure and for immediate access to fully sterilized and shippable product, (We are further required to perform a USP <71> sterility test despite this fact)
– It gives dose very rapidly for protecting the properties of the product,
– It has minimal effect on atmosphere. The only effect is the formation of slight amount of ozone,
– For the sterilization procedure, validation guidance documents can be used for the implementation and start up.

As far as why I selected eBeam for terminal sterilization, after considerable research, the cost, convenience and speed of the process appeared to suit my practice best. A "dry" method that could be used to sterilize the final product in its ultimate container without need for further manipulation, would not degrade the product, and was relatively inexpensive. As you know, USP <797> essentially advocates for the use of terminal sterilization since its potential SAL is 1000 times greater than other methods that can be performed in the pharmacy. The chain of custody for products is well-documented and the facility is licensed by multiple entities, state and federal, and tamper-evident measures are applied to all packages. There would be no interest on the facility's part to either contaminate or divert. Aside from testosterone, I know of no other controlled substance that is prepared in a pellet form. Our compounds are not controlled substances but are accounted for similarly.

Without the availability of terminal sterilization, we would not be able to function and patients would suffer. We have worked extremely hard and for a very long time to produce a consistent and safe sterile product. We have never failed a sterility, endotoxin or potency test. I urge your reconsideration of this important regulation and ask that it be struck down entirely as stated.

Section, Subdivision	Proposed Language	Recommendation/Comment

1736.10 (e)

(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.

Recommendation/Comment

Omit/delete all language in (e) or use relevant USP <1229> sections as were used for other sterilization methods.

Since electron beam sterilization is a superior method that contributes to product and patient safety, prohibiting its use would be a serious step backwards. I suggest these proposed regulations be rescinded, or at the very least amended to include methods outlined in <797>, and <1229> or to establish criteria necessary for terminal sterilizers to qualify as approved by the Board.

I respectfully disagree with the statement “the pharmacy would not be completing all steps of the compounding process”. Sterilization, particularly terminal sterilization, occurs once the compounding has been completed and the CSP is properly packaged in the final container. It is a distinctly separate process.

I further disagree with the Economic Impact Assessments, as jobs and businesses may well be eliminated.

Paul W. Lofholm, PharmD, FACA
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415-845-6160

PharmacyRulemaking@dca.ca.gov

Comments regarding Title 16. Board of Pharmacy Proposed Regulations

Its my understanding that approved labeling applies to manufactured products only and not compounded prescriptions. Board of Pharmacy spells out labeling requirements.
Diluent applies to CSP and not CNSPs
Essential Copies applies to a specific product or USP monograph and all its ingredients
Quality essentially means what's on the label is what is in the preparation [plus or minus 10%]

1735.1 no comment except I do not know why Blood products are contained herein?
1735.2 Quality Control and quality assurance OK
Container closure for CNSP- are you saying the existing pharmaceutical supplies are not meeting the compounding standards when it comes to CNSP? Data? likewise criteria for equipment selection, basis?
How does one clean non-disposable garb before re-use?
1735.4 sink requirements and water requirements are reasonable though a dishwasher plumbing can be a problem.
1735.5 Cleaning and Sanitizing
(a) usually this is covered in the SOP and so is (b)_
1735.6 Industry standards mean labeled requirements?
1735.7 Master Formulation and Compounding Records
© (1) basis for time documentation for CNSP?
1735.8 Release Inspections and Testing- Release inspection=verification by Pharmacist, Testing Is part of the QA program specified in the SOP-usually each dosage form prepared annually and A percent compounded more frequently by each compounder; in the CSP realm it will be done with each batch
1735.9 Labeling The route is inherent on the prescription label
1735.10 Establishing BUD container-closure system does not apply to CNSP based on accepted standards of pharmaceutical containers and USP requirements as the standard
1163 is advisable only and not required
1735.11 SOPs 1163 is advisable only
1735.12 QA and QC 1163 is advisable only, Reporting time should be 7 days considering investigation time however a serious complaint involving serious harm or death should be reported in 24 hrs.
1735.12 CNSP Packaging and Transporting This is really a process validation
1735.14 Documentation Records strike for at least, 3 years.

Sterile Compounding
1736. Definitions
1736.1 If a shortage occurs and is not on the ASHP list, what does the pharmacist do?
There should be other sources to document or the pharmacist documents the shortage in their Facility.
1736.3 Garbing Donning and doffing garb shall not occur in the anteroom at the same time, seems problematic to me, install traffic lights?
Is the location of the sink need clarification?
1736.7 Cleaning: documentation is part of the SOP
1736.9 Equipment, Supplies and Components What to do is the API is manufactured in a non-FDA facility or one not registered by CA BOP, is there room of a COA requirements or other?
1736.10 Sterilization and Depyrogenation reference to 1228 is advisory, basically sterilization processes must be validated and meet SOP for sterilization
Hazardous Drugs
It appears to me that this section is institutionally-based and not typically of a NSCP. While the principles apply in general and anti-neo plastics are seldom compounded, hormones are
Usually these preparations are compounded in powder-containment hoods.

Generally, my observation is the CNSP proposed regulations have been written to follow the CSP regulations. It appears to be over restrictive given the benefit to risk of the patient. Furthermore, the proposed regulations will drive up costs: supplies increased, training increased, insurance increased, lack of trained personnel, and overall cost to achieve a new level of quality. The result will be decreased access to compounding services to the people of California

Paul Lofholm, PharmD, FACA
6-3-2024

From: Mahan, Paul <paul.b.mahan@petnetsolutions.com>
Sent: Monday, May 13, 2024 10:46 AM
Subject: RE: Request Assigned Inspector for LSC 100848 & 101146 exp 7/1/2024

Hey Christine,

I have some excerpts in black and my comments in blue below for the draft regulation. Let me know if you have any questions or if you need anything else.

Thanks,

Paul

From proposed regulation:

(b) The temperature shall be monitored either manually or by a continuous recording device in the SRPA and classified areas each day that processing is performed.

From <825>:
The temperature and humidity must be monitored in the SRPA or area containing a hot-cell, and if in a classified area the
pressure must monitored, each day that preparations are made, either manually or by a continuous recording device. These
include:

The draft regulation should harmonize with <825> in that temperature and humidity monitoring should take place in the area containing a hot-cell.

From proposed regulation:

The board shall be notified in writing within 72 hours of a complaint involving a radiopharmaceutical.

This should exclude delivery mishaps, unless they are related specifically to pharmacy practice errors (e.g., mislabeling or mispackaging errors by the pharmacy personnel causing the delivery mishap).

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Date May 31, 2024
Subject Notice of Proposed Regulatory Action Concerning: Compounded Drug Products
Recipient California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Dear Board Members:

Thank you for the opportunity to comment on the Notice of Proposed Regulatory Action Concerning: Compounded Drug Products issued by the California State Board of Pharmacy.

Medisca is a global leader in the procurement, repackaging, and distribution of pharmaceutical ingredients and technology with a vast portfolio of over 2,000 products complemented by a library of 10,000+ customized medication formulas, expertise, and services in pharmaceutical compounding, continuing healthcare education, analytical testing, and more.

We recognize the California Board of Pharmacy's commitment to patient safety and we fully align to patient safety being of upmost importance and priority. However, we are concerned that some of the proposed changes to the national standards recently updated by the United States Pharmacopeia may impose additional workload and costs on pharmacies without demonstrable benefits to patient safety. The USP Compounding Expert Committee, composed of experts in the compounding field, developed these changes to USP chapters 795 and 797 over years of work and input from the compounding community. We kindly ask that you take into account all scientific rationale utilized in establishing the current chapters and furthermore ask for the Board to bring forward any new recommendations with accompanying supporting data for discussion/collaboration with industry. Attached are our comments on specific provisions of the proposed regulations, referring to the amendments and repeals outlined in the proposal affecting Division 17 of Title 16 of the California Code of Regulations.

Sincerely,

Philip Smyth
Director, Global Public Affairs
Medisca

Section, Subdivision	Proposed Language	Recommendation/Comment
Notice of Proposed Action Concerning: Compounded Drug Products	Fiscal Impact	The majority of compounding pharmacies are small businesses and these changes will likely have a significant financial impact on their operations. We ask that a thorough financial impact report be completed to fully understand the cost of compliance.

1735 (d)	“Essentially a copy” of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (APIs) as the commercially available drug product, except that It does not include any preparation in which there has been a change made for an identified individual patient that produces for that patient a clinically significant difference, as determined by the prescribing practitioner, between that compounded preparation and the commercially available drug product.	We ask that California align its definition of "essential copy” with the FDA's definition. The FDA defines an “essential copy” as the same API, same route of administration, and same, similar, or easily substitutable strength, and same characteristics as two or more commercially available drug products. Aligning the California definition with the FDA definition allows for better compliance and understanding of the term.
1735.1(f)(1)(B)	Considers a compounded preparation “essentially a copy” unless the compounding produces a clinically significant difference for the medical need of an identified individual patient, as determined by: the prescriber, the compounding pharmacist and the dispensing pharmacist.	This definition is unnecessarily narrow. We ask that it align with USP’s definition for clarity. In addition, the requirement of two pharmacist approval is redundant when prescribed by a practitioner. It is not clear what, if any, documentation is required by the pharmacy.

1735.2(a)	Training and competency procedures for all personnel who compound or have direct oversight of personnel performing compounding, verifying, and/or handling a CNSP shall address the following topics…	Containment closure and equipment is often predetermined by the PIC or compounding specialist and recorded in the Master Formulation Record. Training and competency in this should not necessarily be a requirement of a compounder.
1735.3(e)	Non-disposable garb shall be cleaned with a germicidal cleaning agent and sanitized with 70% of alcohol before use.	It is unclear as to whether non-disposal garb can be effectively cleaned with a germicidal cleaner and how to properly sanitize all non-disposable garb. Fabric garb, for instance.
1735.7(c)(1)	The date and time of compounding, which is the time when compounding of the CNSP started, and which determines when the assigned BUD starts	The specific time is now required to be documented and reflected in the assigned BUD seems a bit precise and unnecessary. This requirement seems to conflict with 1735.10(a) for assigning BUD.
1736.1(b)	CSPs for direct and immediate administration as provided in the Chapter shall only be compounded in those limited situations where the failure to administer such CSPs could result in loss of life or intense suffering of an identifiable patient….	There are many other times that CSPs should be compounded for direct and immediate administration other than loss of life or intense suffering. USP removed the emergency situation requirement for immediate-use CSPs. An example of when this might be required is during the shortage of lidocaine with epinephrine. Clinics could use available ingredients (lidocaine vials, epinephrine vials) to compound multiple syringes for single use in multiple patients over a 4- hour period. This medication is often needed for infiltration and nerve block.

1736.1(e)	“Essentially a copy” of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (APIs) as the commercially available drug product, except that It does not include any preparation in which there has been a change made for an identified individual patient that produces for that patient a clinically significant difference, as determined by the prescribing practitioner, between that compounded preparation and the commercially available drug product.	We ask that California align its definition of "essential copy” with the FDA's definition. The FDA defines an “essential copy” as the same API, same route of administration, and same, similar, or easily substitutable strength, and same characteristics as two or more commercially available drug products. Aligning the California definition with the FDA definition allows for better compliance and understanding of the term.
1736.1(e)(1)(A,B,C)	Is essentially a copy of one or more commercially available drug products, unless:	The FDA defines an “essential copy” as the same API, same route of administration, and same, similar, or easily substitutable strength, and same characteristics as two or more commercially available drug products. Aligning the California with the FDA definition allows for better compliance and understanding of the definition.
1736.1(e)(4)	Requires end-product sterilization unless sterilization occurs within the same licensed compounding location.	This would limit the ability to produce products relying on e-beam or gamma-irradiation for validated terminal sterilization as they cannot be performed onsite. Can we have additional clarity on how this would make an end product safer?

1736.9(d)	All API and excipient components used to compound a CSP shall be manufactured by an FDA-registered facility, be accompanied by a Certificate of Analysis (COA), and suitable for use in sterile pharmaceuticals. A COA that includes the compendial name, the grade of the material, and the applicable compendial designations on the COA, must be received and evaluated prior to use, unless components are commercially available drug products. When the COA is received from a supplier, it must provide the name and address of the manufacturer. API and excipient components provided with a COA without this data shall not be used in a CSP.	Excipients are different than APIs. USP explored this topic extensively through a panel and workshop with industry experts on the topic of excipient quality. They decided on the below language. We ask that the same language be used: [excipients] should be manufactured by an FDA-registered facility - If a component cannot be obtained from an FDA-registered facility, the designated person(s) must select an acceptable and reliable source (see Good Distribution Practices for Bulk Pharmaceutical Excipients ⟨1197⟩). The compounding facility must establish the identity, strength, purity, and quality of the ingredients obtained from that supplier by reasonable means. Reasonable means may include but are not limited to visual inspections, evaluation of a COA supplied by the manufacturer, and/or verification by analytically testing a sample to determine conformance with the COA or other specifications

1736.9(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.	This is in opposition to FDA guidance which allows for the compounding of products on the interim Bulks List (category 1). We ask that California align with federal guidance to avoid gaps in care.
1736.10(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.	This would prevent the use of e-beam or gamma-irradiation sterilization methods, which are performed off-site at validated facilities. We ask that this be allowed for.
1736.14(c)	Prior to furnishing a CSP, the pharmacist performing or supervising sterile compounding is responsible for ensuring that sterility and endotoxin testing for the BUD determination is performed and has received and reviewed the results. Results must be within acceptable USP limits. Test results must be retained as part of the compounding record.	Sterility testing can take more than 2 weeks for results to be reported. USP removed the requirement for these results to be reviewed before the release of a CSP as long as proper recall procedures were in place. With the new BUDs being so short, patients would have very little time to use their CSPs before they would expire.

1737.6(a)(b)	The SOPs of a premises where HDs are handled shall address environmental wipe sampling for HD surface residue, its frequency, areas of testing, levels of measurable contamination, and actions when those levels are exceeded.	There are no standards for contamination action levels for HD drugs. Wipe sampling is recommended in USP 800 but not required, as there is no consensus on what to do with the results.

Comments on Proposed CA Compounding Regulations

Rick Rhoads, Pharm.D.

June 3, 2024

Institution/Contact Name	Rick Rhoads, Pharm.D.	
Section/Subdivision	**Proposed Language**	**Recommendation/Comment**
1735.2 Personnel Training and Evaluation	(c) Compounding personnel or persons with direct oversight over personnel performing compounding, who fail any aspect of ongoing training and evaluation shall not be involved in compounding or oversight of the preparation of a CNSP until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs.	(c) Compounding personnel or persons with direct oversight over personnel performing compounding, who fail any aspect of ongoing training and evaluation shall not be involved in compounding or oversight of compounding related to the sections failed until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs. ***Reason:*** *Nonsterile compounding personnel are often trained on each dosage form in addition to the core competencies required by USP <795>. Based on this wording, if an employee fails a new dosage form (eg. they are currently trained on compounding creams and then later begin to learn compounding capsules), they would be barred from compounding creams. I think this could have a negative unintended consequence of pharmacies choosing less*

		stringent training with fewer domains for fear of employees becoming disqualified from doing any compounding at all.
1735.7 Master Formulation and Compounding Records	(c) A compounding record (CR) shall be a single document developed in compliance with USP Chapter 795, and includes the following additional elements: (1) The date and time of compounding, which is the time when compounding of the CNSP started, and which determines when the assigned BUD starts. (2) The manufacturer, lot number, and expiration date for each component. (3) The assigned internal identification number, which shall be unique for each CR. (4) The total quantity compounded, which shall include the number of units made and the volume or weight of each unit	(c) A compounding record (CR) shall be a single document developed in compliance with USP Chapter 795, and includes the following additional elements: (1) The date or date and time of compounding, if the BUD is listed in hours. The time of preparation is ~~which is the time~~ when compounding of the CNSP started, and which determines when the assigned BUD starts. (2) The manufacturer, lot number, and expiration date for each component. (3) The assigned internal identification number, which shall be unique for each CR. (4) The total quantity compounded, which shall include the number of units made and the volume or weight of each unit, if immediately packaged into the final dispensing container. ***Reason:*** *This language is helpful to clarify that the date*

		and/or time of compounding refers to when the compounding process started. However, this language may be confused to mean that the BUD must specify a day and time (eg. Discard after 06/15/2023 at 1PM). However, most BUDs are assigned in days only, which would make the start time irrelevant. The time compounded would only be applicable when the BUD is listed in hours, which is very rare for CNSPs. ***Reason:*** *It is common to package bulk CNSPs into multiple containers at the time of dispensing. This language could inadvertently create a new requirement to package into the final containers only at the time of compounding. This would dramatically change the practice of compounding and dispensing CNSPs.*
1735.10 Establishing Beyond Use Dates	(c) If antimicrobial effectiveness testing results provided by a current FDA-registered drug establishment or outsourcing facility or published in current peer-reviewed literature sources are used, the reference in its entirety (including the raw data	(c) If antimicrobial effectiveness testing results provided by a current FDA-registered drug establishment or outsourcing facility or published in current peer-reviewed literature sources are used, the reference ~~in its entirety (including the raw data and testing method suitability)~~ shall be readily

	and testing method suitability) shall be readily retrievable in accordance with Business and Professions Code section 4081 for three years from the last date the CNSP was dispensed.	retrievable in accordance with Business and Professions Code section 4081 for three years from the last date the CNSP was dispensed. ***Reason:*** *Requiring compounders to obtain raw data worksheets would limit their ability to utilize data from 3rd party sources, which is an important tool to offset the tremendous cost of performing these tests on CNSPs (eg. $2-5k per formula). It would also call into question whether it is acceptable to utilize USP compounded preparation monographs because USP does not publish raw data worksheets.*
1736.1 Introduction and Scope	~~3) Is made with a non-sterile component for which a conventionally manufactured sterile component is available and appropriate for the intended CSP.~~	***Reason:*** *This language could become unnecessarily problematic for Category 3 compounders. It is unclear how inspectors will determine when commercially available products are mandated to use as components. This is very challenging for compounders to predict, especially when significant financial and time investments are put into stability studies (Approx $30-$50k and 6-12 months per formula). Also, the availability of each manufactured product changes, which can*

		result in different excipients, concentrations, and pHs. This can change the stability and compatibility of the formulation. Lastly, the benefit to quality would be unclear when using a commercially available product along with other nonsterile API and excipients. I believe the newest revision of USP <797> adequately addresses the risk associated with utilizing nonsterile ingredients.
1736.9 Equipment, Supplies, and Components	(d) All API and excipient components used to compound a CSP shall be manufactured by an FDA-registered facility, be accompanied by a Certificate of Analysis (COA), and suitable for use in sterile pharmaceuticals. A COA that includes the compendial name, the grade of the material, and the applicable compendial designations on the COA, must be received and evaluated prior to use, unless components are commercially available drug products. When the COA is received from a supplier, it must provide the name and address of	(d) All API and excipient components used to compound a CSP shall be manufactured by an FDA-registered facility, be accompanied by a Certificate of Analysis (COA), and suitable for use in sterile pharmaceuticals. A COA that includes the compendial name, the grade of the material, and the applicable compendial designations on the COA, must be received and evaluated prior to use, unless components are commercially available drug products. When the COA is received from a supplier, it must provide the name and address of the manufacturer. API and excipient components provided with a COA without this data shall

	the manufacturer. API and excipient components provided with a COA without this data shall not be used in a CSP	not be used in a CSP, unless the manufacturer name and address are retrieved from the supplier and documented on the COA. ***Reason:*** *It would helpful to allow compounders to obtain this information from the supplier, if missing from the COA. In my experience, this information is not usually printed on the COA.*
1736.11 Master Formulation and Compounding Records	(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.	(1) The date, or date and time of preparation, if the BUD is listed in hours. The time of preparation is the time when compounding the CSP started, which also determines when the assigned BUD starts. ***Reason:*** *This language is helpful to clarify that the date and/or time of compounding refers to when the compounding process started. However, this language may be confused to mean that the BUD must specify a day and time (eg. Discard after 06/15/2023 at 1PM). However, most BUDs are assigned in days only, which would make the start time irrelevant. The time compounded would only be applicable when the BUD is listed in hours.*

1737.5 Facilities and Engineering Controls	(c) Where a pass-through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking. A pass-through is not allowed between the C-SEC into an unclassified space.	(c) Where a pass-through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking. A pass-through is not allowed between ~~the~~ an ISO classified C-SEC for sterile compounding into an unclassified space. ***Reason:*** *Nonsterile compounding areas are not ISO classified, so the last sentence should only apply to ISO classified sterile compounding areas.*
1737.5 Facilities and Engineering Controls	(d) Where a pass-through door is installed or replaced in a secondary engineering control after [OAL insert effective date] the pass-through door shall be a HEPA purge type.	~~(d) Where a pass-through door is installed or replaced in a secondary engineering Control after [OAL insert effective date] the pass-through door shall be a HEPA purge type.~~ ***Reason:*** *HEPA purge type pass-throughs are typically utilized to maintain ISO classification when transferring material from unclassified to classified sterile compounding spaces. These would not be appropriate for nonsterile HD rooms (eg. HD to non-HD room) because they are not ISO classified. Also, depending on the type of purge type pass-through, it could exacerbate HD*

		contamination of the rooms. Please consider removing.
1737.13 Compounding	(a) A disposable preparation mat shall be placed on the work surface of the C-PEC when compounding HD preparations. Where the compounding is a sterile preparation, the preparation mat shall be sterile. The preparation mat shall be changed immediately if a spill occurs, after each HD drug, and at the end of daily compounding activity.	(a) A disposable preparation mat shall be placed on the work surface of the C-PEC when compounding antineoplastic HD preparations. For non-antineoplastic HD preparations, an assessment of risk may be performed for alternative work practices. Where the compounding is a sterile preparation, the preparation mat shall be sterile. The preparation mat shall be changed immediately if a spill occurs, after each HD drug, and at the end of daily compounding activity. ***Reason:*** *This is would greatly impact the work practices of compounders, and may not be beneficial for all dosage forms and hazard types. Please consider either removing or requiring for antineoplastic HDs only. Mats could be considered in an assessment of risk for all other hazard types (which is utilized in USP <800>).*

Public Comment to proposed text in Title 16, California Code of Regulations

Add new sections 1735 et seq of Title 16, Division 17, Article 4.5 of the California Code of Regulations
Add new sections/Article 1736 et seq of Title 16, Division 17, Article 4.6 of the California Code of Regulations
Add new sections/Article 1737 et seq of Title 16, Division 17, Article 4.7 of the California Code of Regulations
Add new sections/Article 1738 et seq of Title 16, Division 17, Article 4.8 of the California Code of Regulations

Institution: Contact:	Kaweah Health Medical Center Rheta Silvas, Pharm.D., Inpatient Assistant Director of Pharmacy	
Section	Proposed Language	Recommendation/Comments
1735.1(b)	Repackaging of a conventionally manufactured drug product is not considered compounding if compliant with USP Chapter 1178, Good Repackaging Practices.	Recommend: strike this language and before re-introducing have a deeper discussion with pharmacy stakeholders in a variety of practice settings. Rationale: The language proposed differs from what was presented at the February 2023 Board of Pharmacy Enforcement and Compounding Committee meeting. The February 2023 language specified that repackaging of a drug product is not considered compounding but must be compliant with USP 1178. The recently proposed language specifies that repackaging is not considered compounding if compliant with USP <1178>. On review of USP <1178>, the …"chapter is "intended to provide guidance to those engaged in repackaging *oral solid drug products*"…further, the section Establishing Expiration Date includes criteria that should be considered by **repackagers** when assigning an expiration date. The chapter defines **repackagers** in the glossary as "an establishment that repackages drugs and sends them to a second location anticipation of need. Repacking firms repackage for distribution (e.g., for resale to distributors, hospitals, or other pharmacies, a function that is beyond the regular practice of a pharmacy". Requiring compliance with USP <1178> would thereby establish state enforceability of the cross referenced USP standards (USP <659> Packaging and Storage Requirements and <671> Containers – Performance Testing). Additional time for pharmacy practice stakeholders would be beneficial to gain perspective and clarify what nonsterile compounding provisions would be required for repackaging. For example, would creation of a MFR be required to repackage an oral solid from a commercially available bulk container? Would measuring and mixing be a required competency for personnel that repackage an oral solid from a commercially available bulk container?

1735.1 f(1)(B)	(B) The compounding produces a clinically significant difference for the medical need of an identified individual patient, as determined by: (i) The prescribing practitioner, (ii) the compounding pharmacist, and (III) the dispensing pharmacist	Recommend: strike (B)(ii) and (B)(iii) to keep consistent with Title 21 Chapter 9 Subchapter V Part A § 353a definition of the term "essentially a copy of a commercially available drug product". The definition is as follows: For purposes of paragraph (1)(D), the term "essentially a copy of a commercially available drug product" does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product. Recommend: clarify the following: 1. if the expectation would be that the "determination" as referenced in the proposed language would be made for each time the preparation was compounded or for the initial prescription 2. If the expectation would be that the compounding pharmacist AND the dispensing pharmacist contact the prescriber to confirm the prescriber has determined the compounding produces a clinically significant difference for the medical need of an identified individual or the determination by the prescriber is assumed based on the generation of the prescription Concerns: Without complete medical information necessary for the pharmacist (compounding and/or dispensing pharmacist) to make the determination as proposed in 1735.1(f)(1)(B)(ii)(iii), there could be unnecessary delays and/or barriers to the patient receiving a medication that is vital to their care. Rationale: the determination "the compounding produces a clinically significant difference for the medical need" is best made by the prescriber. The compounding pharmacist and dispensing pharmacist may not have complete medical information necessary to make this determination.
1735.1(h)	1735.1 In addition to the standards in the USP Chapter 797, the compounding of CNSPs shall meet the following requirements:	Recommend: add this language to 1707.2 or add language to clarify settings in which it is applicable. Rationale: adding this language to 1735.1 expands compliance requirements

	(h) In addition to the provisions provided in section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning proper use, storage, handling and disposal of the CNSP and related supplies furnished.	relevant to oral patient consultation to include pharmacies that are compounding CNSPs that are not dispensed to a patient as is the case in the hospital setting where drugs are furnished by the hospital pharmacy to be administered to the patient.
1735.2(a)	(a) Training and competency procedures for all personnel who compound or have direct oversight of personnel performing compounding, verifying, and/or handling a CNSP shall address the following topics: (1) Quality assurance and quality control procedures, (2) Container closure and equipment selection, and (3) Component selection and handling	Recommend: revise to "Training and competency procedures for all personnel who compound or have direct oversight of compounding CNSPs shall address the following topics"…. Rationale: Personnel not involved with compounding or having direct oversight of compounding may **handle** a CNSP (e.g. individuals administering the CNSP, individuals handling the CNSP at the cash register, individuals delivering the CNSP to a patient) but the training and competency described in 1735.2(a)(1)(2)(3) described in the proposed revision are not relevant to the job duties.
1735.3(a)	1735.3 In addition to the standards set forth in Chapter 795, the following requirements apply to nonsterile compounding. (a) Prior to admitting any personnel into a compounding area, the supervising pharmacist shall evaluate whether compounding personnel is experiencing any of the following: rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection, or any other medical	Recommend: allow the standards set forth in Chapter <795> section 3 to stand without additional requirements (preferred). Alternatively, consider the following: 1. set a minimum daily requirement for the supervising pharmacist to evaluate this (e.g. at the beginning of the shift) with a requirement that the individuals entering the compounding area notify if there are changes that arise during the course of their shift that would preclude them from entering the compounding area. 2. Revise the proposed language in 1735.3(a) as follows: Prior to admitting any personnel into a compounding area for the purpose of compounding, the supervising pharmacist shall….. Rationale: the proposed regulation may be practical and achievable in an outpatient compounding pharmacy. Pharmacies in other settings (retail,

	condition, to determine is such condition could contaminate a CNSP of the environment ("contaminating condition"). After such evaluation and determination, the supervising pharmacist shall not allow personnel with potentially contaminating conditions to enter the compounding area.	hospital) must have a designated compounding area that meets the standards set forth in USP Chapter <795> section 4.1 but it may be in a designated area of the pharmacy that has other activities performed when compounding is not occurring. To have a supervising pharmacist evaluate for "contaminating conditions" *each* time personnel is admitted to the compounding area is not practical and serves no clear benefit to the consumer it may adversely impact the consumer to repeatedly through the course of a shift evaluate conditions that are not subject to change in the course of a shift.
1735.3 (c)	1735.3 In addition to the standards set forth in Chapter 795, the following requirements apply to nonsterile compounding. (b) Disposable garb shall not be shared by staff and shall be discarded if soiled and after each shift. All garb removed during a shift must remain in the compounding area.	Recommend revise the proposed language as follows: When disposable gown re-use is permitted in the SOP, disposable gowns shall only be re-used within the same work day by the same person if the gown is retained in the compounding area when not in use and is not visibly soiled. Rationale – USP Chapter <795> indicates that garb, except for gowns, should be discarded. Not aware of any disposable garb that would be appropriate to re-use except for gowns. Depending on an organization's hazardous drug assessment of risk, nonsterile compounding of a hazardous drug may be performed in a C-SEC or C-SCA in which case the outer disposable gown is discarded but inner gown may be re-used but would not be retained in the nonsterile compounding area. Proposed 1735.3(b) dictates that the garb be discarded "after each shift" which may conflict with the organizational SOP. The language "all garb removed during a shift must remain in the compounding area" implies that the garb removed remains in the compounding area indefinitely.
1735.4 (a)	1735.4 Building and Facilities – In addition to the standards set forth in Chapter 795, the following requirements apply to nonsterile compounding. (a) A sink used for compounding or hand hygiene shall not be part of a restroom or a water closet.	Recommend: revise proposed language as follows – A sink used for cleaning of any equipment used in nonsterile compounding, hand hygiene when entering the compounding area for the purpose of compounding, or compounding shall not be part of a restroom or water closet. Rationale- the requirement for the sink location for hand hygiene should be qualified (given context). One should perform hand hygiene in the restroom after using the facilities.

1735.5 (a)	1735.5 Cleaning and Sanitizing - In addition to the standards set forth in Chapter 795, the following requirements apply to nonsterile compounding. (a) The facility's documentation of each occurrence of the cleaning and sanitizing of the compounding area shall include the identity of the person completing the cleaning and sanitizing, as well as the product name(s) of the cleaning and sanitizing agent(s) used.	Recommend: revise proposed language as follows - The facility's documentation of each occurrence of **routine** cleaning and sanitizing of the compounding area shall include the identity of the person completing the cleaning and sanitizing, as well as the product name(s) of the cleaning and sanitizing agent(s) used. Rationale: documentation of ***each*** occurrence of cleaning and sanitizing would be impractical depending on the nonsterile compounding volume. In the setting of sterile compounding, this would be akin to documenting each instance the work surface is sanitized with sterile 70% isopropyl alcohol before and after each compound and as needed throughout the compounding process.
1735.6 (b)	1735.6 –Equipment and Components - In addition to the standards set forth in Chapter 795, the following requirements apply to nonsterile compounding. (b) Any component used to compound a CNSP shall be used and stored in accordance with all federal laws and regulations and industry standards, including the manufactures' specifications and requirements.	Recommend the following: 1. delete the word "used" 2. clarify "industry standards". Rationale: it may be acceptable to use a component for nonsterile compounding in a manner that is not consistent with the manufactures' specifications as is the case of a literature supported unlabeled use of a medication. Unclear what was intended when using this term in the language. The term "industry standard" is ambiguous.
1735.9 (c)	1735.9 – Labeling - In addition to the standards set forth in Chapter 795, the following requirements apply to nonsterile compounding. (c) Any CNSP dispensed to a patient or readied for dispensing to a	Recommend: revise proposed language as follows – The **prescription container** of any CNSP dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5. Rationale: adding the proposed language could imply that the prescription container labeling requirements outlined in B&PC 4076 and 1707.5 are

	patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5.	applicable to CNSPs compounded and furnished by the hospital pharmacy for administration to a patient.
1735.10 (b)	1735.10 – Establishing Beyond-Use Dates - In addition to the standards set forth in Chapter 795, the following requirements apply to nonsterile compounding. (b) A CNSP's BUD shall not exceed any of the following (2) The compatibility and degradation of the container-closure system with the finished preparation (e.g., possible leaching, interactions, and storage conditions).	Recommend: revise the proposed language as follows – A CNSP's BUD shall not exceed any of the following (2) The compatibility and degradation of the container-closure system with the finished preparation (e.g., possible leaching, interactions, and storage conditions), **where such information is available**. Rationale: a BUD limit based on the criteria included in the proposed language may be warranted in some nonsterile compounding settings. In the acute care setting, where nonsterile compounding is generally limited and less complex the BUD considerations are largely driven by the reference that supports the nonsterile compounding process for a specific preparation. Specific information about compatibility and degradation of the container-closure system is not frequently described in the reference.
1735.11 (a)(2)(D)	1735.11 – Standard Operating Procedures (SOPs) - In addition to the standards set forth in Chapter 795, the following requirements apply to nonsterile compounding. (a) The facility's standard operating procedures (SOPs) for nonsterile compounding shall be followed and Shall: (2) Also describe the following: (D) The method for complying with any other requirements specifically required to be addressed in the facility's SOPs as	Recommend: strike or clarify the proposed language so the intent is clear. Rationale – the language is ambiguous.

	described in this article.	
1735.11 (a)(2)(E)	1735.11 – Standard Operating Procedures (SOPs) - In addition to the standards set forth in Chapter 795, the following requirements apply to nonsterile compounding. (a) The facility's standard operating procedures (SOPs) for nonsterile compounding shall be followed and Shall: (2) Also describe the following: (E) The validation process for storage, shipping containers and transportation of temperature sensitive CNSPs to preserve quality standards for integrity, quality and labeled strength.	Recommend: clarify when a validation process for storage, shipping containers, and transportation are required for temperature sensitive CNSPs. Would a pharmacy that compounds sterile preparation be required to implement a validation process for the ***storage*** of each temperature sensitive CNSP?
1735.12(c)	1735.12 – Quality Assurance and Quality Control - In addition to the standards set forth in Chapter 795, the following requirements apply to nonsterile compounding. (b) All complaints related to a potential quality problem with a CNSP and all adverse events shall be reviewed by the pharmacist-in-charge within 72 hours of receipt of the complaint or occurrence of the adverse event. Such review shall be	Recommend: revise the proposed language to include the word "drug" after the word "adverse". Add to the definition adverse drug event. Rationale: adverse event is a broader term and unlikely the intent of the language.

	documented and dated as defined in the SOPs.	
1736.1 (b)	1736.1 – Introduction and Scope – This article applies to compounded sterile preparations (CSP)s as defined in USP Chapter 797, titled Pharmaceutical Compounding – Sterile Preparations. In addition to the standards in the USP Chapter 797, the preparation of a CSP shall meet the following requirements of this article. (b) CSPs for direct and immediate administration as provided in the Chapter shall only be compounded in those limited situations where the failure to administer such CSP could result in loss of life or intense suffering of an identifiable patient. Any such compounding shall be only in such quantity as is necessary to meet the immediate need of the patient. Documentation for each such CSP shall include identification of the CSP, compounded date and time, number of units compounded, the patient's name and patient's unique identifier and the circumstance causing the immediate need of the patient.	<u>Recommend</u>: clarify the following – 1. applicability of the proposed language. Are the documentation requirements outlined specific to sterile compounding personnel employed by the pharmacy or any healthcare professional (within the bounds of their scope)? 2. if the proposed language would limit the "repackaging" of a sterile product immediately prior to administration to the situations outlined in the proposed language (loss of life or intense suffering). For example, straight draw of insulin from the vial into a syringe by the nurse just prior to administration. <u>Concerns</u>: pharmacy oversight and assuring compliance of non-pharmacy personnel with the documentation requirements would be challenging given the emergency circumstances that prompt the need. Meeting the critical needs of the patient is the focus of the healthcare team; the documentation would be apt to be overlooked.

	Such documentation may be available in the patient's medical record and need not be redocumented by the compounding staff if already available.	
1736.1 (d)	1736.1 – Introduction and Scope - This article applies to compounded sterile preparations (CSP)s as defined in USP Chapter 797, titled Pharmaceutical Compounding – Sterile Preparations. In addition to the standards in the USP Chapter 797, the preparation of a CSP shall meet the following requirements of this article. (c) A reasonable quantity of a CSP compounded drug preparation may be furnished to a veterinary office for use by the veterinarian this is sufficient:	Recommend: strike "compounded drug preparation". Rationale: this verbiage is preceded by the abbreviation CSP and is redundant.
1736.1 (e)(1)(B)(i)(ii)(iii)	1736.1 – Introduction and Scope - This article applies to compounded sterile preparations (CSP)s as defined in USP Chapter 797, titled Pharmaceutical Compounding – Sterile Preparations. In addition to the standards in the USP Chapter 797, the preparation of a CSP shall meet the following requirements of this article. (e)(1) Is essentially a copy of one or more commercially available drug	Recommend: strike 1736.1(e)(1)(B)(ii) and (B)(iii) to keep consistent with Title 21 Chapter 9 Subchapter V Part A § 353a definition of the term "essentially a copy of a commercially available drug product". The definition is as follows: For purposes of paragraph (1)(D), the term "essentially a copy of a commercially available drug product" does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product. Recommend: clarify the following: 1. if the expectation would be that the "determination" as referenced in the proposed language would be made for each time the preparation was

	products. Unless: (B) the preparation produces a clinically significant difference based on the medical need of an identified individual patient as determined by: (i) the prescribing practitioner (ii) the compounding pharmacist, and (iii) the dispensing pharmacist(s).	compounded or for the initial prescription 2. If the expectation would be that the compounding pharmacist AND the dispensing pharmacist contact the prescriber to confirm the prescriber has determined the compounding produces a clinically significant difference for the medical need of an identified individual or the determination by the prescriber is assumed based on the generation of the prescription <u>Concerns</u>: Without complete medical information necessary for the pharmacist (compounding and/or dispensing pharmacist) to make the determination as proposed in 1736.1(e)(1)(B)(ii) and (iii), there could be unnecessary delays and/or barriers to the patient receiving a medication that is vital to their care. <u>Rationale</u>: the determination "the compounding produces a clinically significant difference for the medical need" is best made by the prescriber. The compounding pharmacist and dispensing pharmacist may not have complete medical information necessary to make this determination
1736.1 (g)	1736.1 – Introduction and Scope - This article applies to compounded sterile preparations (CSP)s as defined in USP Chapter 797, titled Pharmaceutical Compounding – Sterile Preparations. In addition to the standards in the USP Chapter 797, the preparation of a CSP shall meet the following requirements of this article. (g) In addition to the provisions in Section 1707.2, consultation shall be provided to the patient and/or patients agent concerning proper use, storage, handling and disposal of the CSP and related supplies furnished.	<u>Recommend:</u> add this language to 1707.2 or add language to clarify settings in which it is applicable. <u>Rationale</u>: adding this language to 1736.1 expands compliance requirements relevant to oral patient consultation to include pharmacies that are compounding CSPs that are not dispensed to a patient as is the case in the hospital setting where drugs are furnished by the hospital pharmacy to be administered to the patient.

1736.2 (b)	1736.2 – Personnel Training and Evaluation – In addition to the standards set forth in USP Chapter 797, the following requirements apply to sterile compounding. (b)Initial and ongoing aseptic manipulation training and competency documentation shall include the Primary Engineering Control (PEC) type and PEC unique identifier used during the evaluation. Aseptic manipulation competency evaluation and requalification shall be performed using the same procedures, type of equipment, and **materials** used in aseptic compounding. Aseptic qualifications from one premises may be used for another premises if all of the following conditions are met:	Recommend: clarify the term "materials" by adding to the sterile compounding definitions (CCR 1736). Rationale: the term "materials" is ambiguous.
1736.2 (d)	1736.2 – Personnel Training and Evaluation - In addition to the standards set forth in USP Chapter 797, the following requirements apply to sterile compounding. (d)Compounding personnel or persons with direct oversight over compounding personnel who fail any aspect of the aseptic manipulation ongoing training and competency evaluation shall not be involved in compounding or oversight of the preparations of a	Recommend: reconsider strict removal of compounder personnel from compounding duties until such time as they successfully pass training and competency in the deficient area(s). Recommend extending the 14 day grace for personnel that provide only direct oversight of compounding. Rationale: concern about ability to meet sterile compounding needs of patients in the acute care setting given the impact this requirement could have on staffing levels. If the failed competency was a media fill test, 14 days is the minimum time needed for incubation of a media fill test though the lab results may take longer to obtain. Should the failure be a media fill test, a 14 day grace may allow for results of media fill test if the test was done on the day the failed results are received. It is not always possible to complete a retest that timely as personnel may be on paid time off, on leave of absence at the time

	CSP until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs. A person with only direct oversight over personnel who fails any aspect of the aseptic manipulation ongoing training and competency evaluation may continue to provide only direct oversight for no more than 14 days after a failure of any aspect while applicable aseptic manipulation ongoing training and competency evaluation results are pending.	the failed results are received.
1736.2 (e)	1736.2 – Personnel training and Evaluation - In addition to the standards set forth in USP Chapter 797, the following requirements apply to sterile compounding. (d) Any persons 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 facility's SOP. **Documentation** demonstrating compliance with training and competency must **be maintained**.	Recommend: include a record retention requirement for maintenance of competency documentation or refer to applicable regulation. Alternatively, strike the language "documentation demonstrating compliance with training and competency must be maintained" as this is covered in CCR 1751.1.
1736.3 (c)	1736.3 – Personnel Hygiene and Garbing - In addition to the standards set forth in USP Chapter 797, the following requirements	Recommend: Strike the language "garb shall be donned in an anteroom or immediately outside the segregated compounding area". Recommend: revise language to ….."or in the SCA" to be consistent with USP

	apply to sterile compounding. (c) Garb shall be donned in an anteroom or immediately outside the segregated compounding area (SCA). Donning and doffing garb shall not occur in the anteroom at the same time unless the facility's SOP define specific processes that must be followed to prevent contamination.	Chapter <797> section 3.2 in the paragraph below Box 3 (this glove requirement is a little hidden gem). Rationale: allow compounding pharmacies to determine the best location for donning of gloves based on their facility design as long as they are donned in a classified space (not in a C-PEC/PEC) or in the SCA. Note: USP Chapter <797> requires that gloves be donned in a classified room or SCA. The proposed language specifies "immediately outside the SCA".
1736.4 (a)	1736.4 – Facilities and Engineering Controls - In addition to the standards set forth in USP Chapter 797, the following requirements apply to sterile compounding. (a) A sink used for compounding or hand hygiene shall not be part of a restroom or water closet.	Recommend: revise proposed language as follows – A sink used for cleaning of any equipment used in sterile compounding, hand hygiene when entering the sterile compounding area for the purpose of compounding, or compounding shall not be part of a restroom or water closet. Rationale: the requirement for the sink location for hand hygiene should be qualified (given context). One should perform hand hygiene in the restroom after using the facilities.
1736.4 (f)	1736.4 – Facilities and Engineering Controls - In addition to the standards set forth in USP Chapter 797, the following requirements apply to sterile compounding. (e) No CSP shall be compounded if the compounding environment fails to meet criteria specified in law or the facility's SOPs.	Recommend: strike the proposed language. Rationale: There are many circumstances where CSPs can continue to be safely compounded until such time as the compounding environment achieves the criteria specified in law or the facilities SOP. For example, a HEPA filter in the buffer room ceiling requires replacement. BUD assignments can be reduced to the maximum allowed for a SCA in the interim to allow continuation of compounding operations without jeopardizing the health and safety of patients. Ceasing compounding in some cases would be counter to consumer protection.
1736.6 (b)	1736.6 – Microbial Air and Surface Monitoring - In addition to the standards set forth in USP Chapter 797, the following requirements	Recommend: clarify if the intent is to require the qualified technician (i.e. third party certifier) to comply with CAG-009 or anyone performing environmental sampling. If the former, recommend modifying the language accordingly.

	apply to sterile compounding. (b) Environmental sampling shall be done in compliance with Controlled Environment Testing Association's Certification Application Guide USP <797> Viable Environmental Sampling & Growth Evaluation (CAG-009, Revised October 2022), which is hereby incorporated by reference.	
1736.9 (c)	1736.9 – Equipment, Supplies, and Components - In addition to the standards set forth in USP Chapter 797, the following requirements apply to sterile compounding. (c) Any component used to compound a CSP shall be used and stored in accordance with all state and federal laws and manufacturer's specifications and requirements.	Recommend: revise the proposed language deleting the word "used". Rationale: it may be acceptable to use a component for sterile compounding in a manner that is not consistent with the manufactures' specifications as is the case of a literature supported unlabeled use of a medication. Unclear what was intended when using this term in the language.
1736.11 (c)	1736.11 – Master Formulation and Compounding Records - In addition to the standards set forth in USP Chapter 797, the following requirements apply to sterile compounding. (c)A compounding records (CR) shall be a single document. The document shall satisfy the requirements of USP Chapter 797,	Recommend: revise the proposed language to "The compounding record shall satisfy the requirements of USP Chapter 797 and also contain the following"… Rationale: The proposed language is congruent with a *paper-based* recordkeeping process. As facilities are moving towards implementing IV workflow management systems, the information required for recordkeeping as described in 1735.3(a)(2)(A-J) is captured/stored electronically. The stored electronic information is readily retrievable in the pharmacy.

	and also contain the following:	
1736.14 (a)(2)	1736.14 – Establishing Beyond-Use Dates - In addition to the standards set forth in USP Chapter 797, the following requirements apply to sterile compounding. (a)(2) The compatibility of the container-closure system with the finished preparation (e.g., possible leaching, interactions, and storage conditions);and	Recommend revise the proposed language as follows – A CSP's beyond-use date (BUD) shall not exceed: (2) The compatibility and degradation of the container-closure system with the finished preparation (e.g., possible leaching, interactions, and storage conditions), **where such information is available; and**. Rationale – a BUD limit based on the criteria included in the proposed language may be warranted in some sterile compounding settings. In the acute care setting, BUD considerations are largely driven by the reference that supports the sterile compounding process for a specific preparation. Specific information about compatibility and degradation of the container-closure system is not frequently described in the reference.
1736.17(a)(2)(D)	Standard Operating Procedures (SOPs) for sterile compounding shall be followed and shall:… (D) The method for complying with any other requirements specifically defined in the SOPs.	Recommend: strike or clarify the proposed language so the intent is clear. Rationale – the language is ambiguous. SOPs have many requirements. It would be challenging to specify a method for complying with all the requirements of the SOP. Seeking to better understand the intent and expectation with practical examples.
1736.18(b)	Recalls and adverse event reporting must be completed in compliance with relevant provisions of law.	Recommend: revise the proposed language to include the word "drug" after the word "adverse". Add to the definition adverse drug event. Rationale: adverse event is a broader term and unlikely the intent of the language.
1736.18(c)	In addition to subsection (b0, all complaints made to the facilitate related to a potential quality problem with a CSP and all adverse events shall be reviewed by the pharmacist-in-charge within 72 hours of receipt of the complaint or	Recommend: revise the proposed language to include the word "drug" after the word "adverse". Add to the definition adverse drug event. Rationale: adverse event is a broader term and unlikely the intent of the language.

	occurrence, such review shall be documented and dated as defined in the SOPs.	
1737.5(c)	Where a pass-through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking. A pass-through is not allowed between the C-SEC into an unclassified space.	Recommend: an OAL effective date for the pass-through prohibition between the C-SEC into an unclassified space. Rationale: there are newly constructed or existing clean room suites at considerable costs in the state of California that incorporate this design feature as it is not prohibited by USP Chapter <800> and is not prohibited under the OSHPD Advisory Guide for Sterile Compounding Pharmacies for hospital facilities (OSHPD 1 Buildings). In a clean room suite with an ISO-7 Anteroom shared between an ISO 7 Positive Pressure Buffer Room and ISO 7 Negative Pressure Buffer Room, optimal placement of a pass-through is between the Negative Pressure Buffer room and adjacent unclassified space and/or placement between the Negative Pressure Buffer room and adjacent unclassified negative pressure hazardous drug storage room. There are contamination control benefits afforded from this design in that the design limits entry in/out of the anteroom thereby limiting the introduction of microbial contamination into the anteroom which is then introduced into the negative pressure buffer room as a result of the pressure relationship between the 2 rooms. The benefit of a pass-through between the negative pressure buffer room and adjacent unclassified negative pressure room storage room is it avoids the storage of bulk HD refrigerated and non-refrigerated inventory in the negative pressure buffer room optimizing microbial contamination control while minimizing the risk of HD exposure by better controlling material transfer.
1737.7(d)	PPE shall be removed to avoid transferring contamination to skin, the environment, and other surfaces. PPE worn during compounding shall be disposed of in the proper waste container before leaving the C-SEC. SOPS shall detail	Recommend: include the word “outer” before the second instance of the word PPE. Rationale: If PPE is doffed before leaving the C-SEC, personnel would then be on the clean side of the ante-room wearing no garb.

	the donning and doffing of PPE and where it takes place in the C-SEC.	
1737.11(a)	Any compounded HD preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code 4076 and section 1707.5.	Recommend: revise proposed language as follows – The **prescription container** of any compounded HD preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5. Rationale: adding the proposed language could imply that the prescription container labeling requirements outlined in B&PC 4076 and 1707.5 are applicable to compounded HD preparations furnished by the hospital pharmacy for administration to a patient.
1737.13	A disposable preparation mat shall be placed on the work surface of the C-PEC when compounding HD preparations. Where the compounding is a sterile preparation, the preparation mate shall be sterile. The preparation mat shall be changed immediately if a spill occurs, after each HD drug, and at the end of daily compounding activity.	Recommend: revised the proposed language to read "a disposable preparation mat shall be placed on the work surface of the C-PEC when compounding HD preparations without the use of a closed system transfer device or when use of a closed system transfer device is not possible as is the case when withdrawing an HD from an ampule. Recommend to clarify "after each drug" (may be missing a word or two?). Rationale: Requiring the use of a disposable preparation pad does introduce more opportunity for microbial contamination, increases supply and labor costs (costs associated with material transfer and terminal cleaning of supplies and the resources to do the work) and if the prep pad is too large, may interfere with airflow to the front or back air grilles of the BSC. Because a pad may absorb small spills, it could be a source of HD contamination for anything placed on it.
General comment	CCR Headers	Consider including the terms Nonsterile Compounding or Sterile Compounding where applicable in the CCR Headers (e.g. CCR 1735 would read "Nonsterile Compounding Definitions" instead of Compounding Definitions. This would make it easier to navigate the table of contents in the law book.

Alliance for Pharmacy Compounding

Compounding the Joy of Living®

June 3, 2024

Seung Oh, President
Anne Sodergren, Executive Officer
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Dear President Oh, Director Sodergren, and Board Members:

Thank you for the opportunity to comment on the **Notice of Proposed Regulatory Action Concerning: Compounded Drug Products** issued by the California State Board of Pharmacy.

The Alliance for Pharmacy Compounding is the national trade association for the pharmacy compounding industry, representing more than 500 compounding pharmacies and facilities across the U.S., including more than 4,000 compounding pharmacists and technicians in both 503A and 503B settings, as well as prescribers, educators, researchers, and suppliers.

Our comments on specific provisions of the proposed regulations are attached here and refer to the amendments and repeals outlined in the proposal affecting Division 17 of Title 16 of the California Code of Regulations.

We have serious concerns about certain provisions of the Board's proposed regulations and theongoing failure of the Board to root its regulation and enforcement of compounding in applicable law and science. The effects of the Board's regulation of sterile compounding in particular, may be serving to drive sterile compounding pharmacies out of California and de prive California patients access to essential compounded medications. In short:

1. The Board is proposing regulation of sterile compounding that goes beyond nationally recognized and accepted standards, has provided no evidence of how that additional regulation makes patients safer, and has failed to respond to requests that it explain theneed for the additional reguation.
2. The Board asserts that the proposed regulations will have no economic impact, a demonstrably erroneous assertion that indicates the Board did not conduct a proper eco nomic impact analysis of the proposed regulations on California-based small business sterile compounding pharmacies, which will certainly need to make necessary investme nts to come into compliance.

3. The Board has failed to conduct a proper analysis of the impact of the proposed regulations on California patients and their ability to access essential sterile compounded medications.
4. The Board has been nonresponsive to requests for clarification of its regulations and inspection protocols, leaving licensees without a clear understanding of what compliance with Board regulation looks like.
5. The Board has used taxpayer dollars to attempt to enforce non-existent regulation and to enact punitive action against some sterile compounding pharmacies for offenses that have no bearing on patient safety – cases which have resulted in legal actions in which courts have ruled in favor of pharmacies.

We elaborate on these concerns below.

The Board's proposals exceed national standards but do not demonstrate how additional regulation protects patients.

We are deeply concerned about the Board's proposal, some provisions of which go well beyond what is required in federal law and what is recommended in the compounding standards of the United States Pharmacopeia. The Board's mission is to protect its citizens, of course, but the Board has failed to demonstrate how proposed regulatory changes that exceed the carefully considered USP standards keep patients safer. Indeed, with its proposal the Board seems to embrace more regulation for the sake of regulation, without regard to the impacts of that regulation on patients who depend on compounded medications. The regulatory amendments you have proposed will almost certainly limit patient access to compounded medications – medications that in the judgment of their prescriber are necessary.

As you know,

We do support alignment of California regulation with USP <795>, <797> and <800> standards, which are normative in most other states.

Because the USP Chapters are the recognized standard across the nation, we strongly urge that the Board step back from proposed regulation that exceeds those standards, particularly if the Board is unable to demonstrate how its proposals make patients safer.

The Board did not conduct a proper economic analysis of the proposed regulations on pharmacies.

Without question, the proposed regulations will require small-business pharmacies to incur significant expense to come into compliance. Many are prepared to make investments to be compliant with the USP chapters. But the Board's representation that the proposed regulations will have no financial or economic impact is simply incorrect. There are significant costs of compliance. In addition, we believe an unintended consequence of implementation of your

proposed changes will be to drive some California compounding pharmacies to cease sterile and/or hazardous drug compounding – a move that will affect not only California patient access to compounded sterile drugs but could also result in layoffs of pharmacy personnel and elimination of jobs. That potential economic impact must be recognized.

We urge the Board to conduct stakeholder interviews or perform other data-gathering in order to determine the real financial and economic impact of these proposed changes – the costs of compliance, of course, but also the potential economic impact on pharmacies that may cease operation and the lost jobs that may result.

The Board did not conduct a proper analysis of the impact of the proposed regulations on California patients and their access to compounded sterile preparations.

As we note in our detailed comments, some of the proposed provisions will likely place certain types of compounded medications out of reach of California patients, such as compounded allergenic extract injections. Other proposals, particularly the prohibition on compounding substances that appear on the FDA's interim bulk substances list, will result in an immediate loss of access to essential medications — methylcobalamin and glutathione, for instance — for many California patients.

As stated earlier, we believe the Board has failed to show how its proposed additional standards will improve the safety of compounded medications. Indeed, the Board's proposal does not balance patient access with patient safety. Closer alignment with federal guidelines and USP chapters will better serve the needs of California patients and compounding pharmacies alike.

The Board has been nonresponsive to our simple requests for clarification of its regulations and inspection protocols.

In recent years, the California Board has cultivated an environment of uncertainty in its understanding and interpretation of current regulation, failing to provide clarity when asked or, in some instances, even to respond at all. That absence of bright-line understanding of the meaning of a regulation and how the Board defines compliance puts licensees in a no-win situation when inspected, having to guess whether they will be deemed compliant or not.

Pharmacy compounders are conscientious and want to comply with state and federal law and regulation, but to do so, they must understand not only the purpose of the regulation but also the Board's interpretation of that regulation.

We believe that adding additional state-specific regulatory requirements on top of widely accepted USP standards will only deepen that environment of confusion and uncertainty the Board has cultivated.

At a minimum, if your proposals are enacted, we strongly urge that the California Board of Pharmacy engage in thorough and extensive training and education of licensees of any new regulations to help assist pharmacies in attaining full compliance and protecting patient health. Licensees should not be kept in a posture of having to guess how California regulators are going to interpret one regulation or another.

The Board has a history of going after licensees for minor infractions – often expending taxpayer dollars, only to lose in court.

The Board's ongoing "throw the book at them" enforcement mindset has resulted in onerous disciplinary action – including loss of license and stiff financial penalties – against conscientious licensees for minor violations that do not impact patient safety. In several of those instances, the cases have landed in courts and the judges have ruled in favor of the pharmacy. These represent a stunning misuse of both the Board's power and the taxpayer resources with which it is entrusted.

We are supportive of the Board's role in protecting California citizens, but we bemoan the ongoing lack of discernment in the Board's wielding of its authority. We have no confidence that adding new, excessive regulation will improve that situation. In fact, we only think it will further encourage the Board to act imperiously and punitively.

As mentioned, our comments on specific proposed regulatory proposals is attached here and should be considered part of this comment letter.

Please do not take our pointed criticism of the Board's actions as disrespect. We do understand and respect the seriousness and complexity of the Board's role in protecting Californians. But that very seriousness and complexity should spur the Board to take care that its regulations and actions are not only rooted in both science and practicality, but that they are consistent, coherent, and fair. We urge the Board to either justify the patient safety benefits of proposals that exceed national standards or to revise the proposal to match the applicable USP chapters.

Thank you for this opportunity to comment. Should you have any questions or require further information, please do not hesitate to contact me at scott@a4pc.org.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer

Comments of The Alliance for Pharmacy Compounding Regarding The Notice of Proposed Regulatory Action Concerning: Compounded Drug Products		
Section, Subdivision	**Proposed Language**	**Recommendation/Comment**
Notice of Proposed Action Conc erning: C ompounded Drug Products	Fiscal Impact and Related Estimates	The board indicates that the proposed changes will not have a significant adverse economic impact, including the inability of California businesses to compete with businesses in other states. The board makes these statement s without conducting interviews gathering stakeholder feedback. The board also indicates that it does not have data to determine if its licensees are "small businesses," which of course, many are. Holding pharmacies to a higher standard than is required by FDA and USP will cost these pharmacies, including those that are small businesses, more money to comply. The term "Small Business" is defined in California Code. The California Board of Pharmacy has over 40 inspectors who physically visit those establishments regulated by the Board. It can be assumed that Board Inspectors have the capability to determine which licensed entities they visit would qualify as a "Small Business." We respectfully request that the Board of Pharmacy refrain from implementing these proposed regulations until an actual economic impact analysis can be performed, determining the adverse effect the proposed

		regulations will have on small businesses.
1735(a)	"Approved labeling" means the Food and Drug Administration's (FDA's) approved labeling in acc ordance with sections 201.56 and 201.57 of title 21, Code of Federal Regulations that inc lude FDA approved information for the diluent, the resultant strength, the c ontainer closure system, and storage time.	As written, this definition assumes that all FDA-approved drugs have a diluent, resultant strength, and storage time. This will not alway s be the case.
1735(c)	"Diluent" means a liquid with no pharmacological activity used in recon stitution, such as purified water or sterile water.	If this is specifically related to manufactured products, it will work. If this is used when speaking to compounded preparations, it must specify that it is referring to USP grade purified water or USP grade sterile water. USP grade water is required as a component of nonsterile compounds.
1735 (d)	"Essentially a copy" of a commercially available drug product means a preparation that includes the same active pharmaceutial ingredient(s) (APIs) as the commercially available drug product, except that It does not include any preparation in which there ha s been a change made for an identified individual patient that produces for that patient a clinically significant difference, as determined by the prescribing practitioner,	The FDA defines an "essential copy" as the same API; same route of administration; same, similar, or easily substitutable strength; and same characteristics as the combination of two or more commercially available drug products in the 503A copies guidance. The proposed definition makes many compounded medications copies of manufactured drugs for simply sharing the same API. Recommend aligning with the FDA approach.

	between that c ompounded preparation and the commercially available drug product.	
1735.1 (b)	Repackaging of a conventionally manufactured drug product is not consideredcompounding if compliant with USP Chapter 1178, *Good Repackaging Practices*.	USP chapters over 1000 are not written for compliance purposes. See this quote from the USP General Notices: "General chapter s numbered 1000 to 1999 are for informational purposes only. They contain no mandatory tests, assay s, or other requirements applicab le to any official article, regardless of citation in a general chapter numbered below 1000, a monograph, or these General Noti ces." Generally pharmacists can dispense an oral capsule or tablet and the patient can store it in a prescription bottle for up to one year provided that the e xpiration date of the product is at least that long. Following the guidance in USP 1178, the same drug could only be given no more than 6 months of dating and many times this could be shorter. This is not logical. Recommend to move away from this guidance and to not use chapters over 1000 as regulation.
1735.1 (e)(2)	For furnishing of not more than a 7-day supply, as fairly estimated by the prescriber, and documented on the purchase order or other doc umentation submitted to the pharmacy prior to furnishing.	Finishing a course of medication, like antibiotics, is important, and many pet owners will not fill the remainder of the prescription if a full course is not provided. Veterinarians should be able to provide a full course of antibiotic agents to the owners of the animals for which they are prescribed. APC is requesting a carve-out (similar to that for

		ophthalmic agents) for antibiotic medications.
1735.1 (f)	In addition to the prohibitions and requirements for compounding established in federal law, no CNSP shall be prepared that:	Prior version cited 21CFR353a. Replacing the citation with "federal law" is vague and could apply to any federal law.
1735.1(f)(1)(A,B,C)	Is essentially a copy of one or more commercially available drug products, unless:	There is no accommodation for veterinary compounds, which are regulated under different provisions of federal law. A reference should be made to the appropriate guidance, and a section should be added to allow for compounded preparations being sold for veterinary office use where the API appears on the lists of approved or under consideration APIs for veterinary u se. Subpoint A indicates that the drug must be on shortage 'at the time of compounding and at the time of dispensing'. There should be a transition period from the time of the end of shortage. We recommend a 30-day transition period.
1735.1(f)(1)(B)	Considers a compounded preparation "essentially a copy" unless the compounding produces a clinically significant difference for the medical need of an identified individual patient, as determined by: the prescriber, the compounding pharmacist and the dispensing pharmacist.	Is it necessary to have two pharmacists involved? What if the compounding pharmacist is also the dispensing pharmacist? This is not a pharmacist's job. Furthermore, it puts the pharmacist in an adversarial position to the prescriber, questioning the prescriber's judgement. How would the pharmacy document pharmacist(s) assessment of the reason for compounding?

1735.1(1)(B)	The compounding produces a clinically significant difference for the medical need of an identfied individual patient, as determined by: the prescribing practitioner; the compounding pharmacist, and the dispensing pharmacist(s).	This language as a statement could require all 3 people involved to document their determination of the clinical need for the compounded preparation. If the physician has said/documented the need, then additional determination and ultimately documentation by the two pharmacists creates unnecessary work that pulls away from time that could be better used for patient care activities.
1735.1(f)(2)	Is made with any component not suitable for use in a CNSP for the intended patient population, unless allowable under the Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA).	As written, this eliminates the c ompounding of drugs for animals from API because AMDUCA does not address this. The statement says that it has to be specifically allowed under AMDUCA, and AMDUCA does not address this topic. California should align with FDA GFI 256 in their approach to animal compounding to maintain patient access.
1735.2(a)	Training and competency procedures for all personnel who compound or have direct oversight of personnel performing compounding, verifying, and/or handling a CNSP shall address the following topics…	There are many people that may handle the CNSP (lab assistants, dispensary technicians, shipping associates) who do not need to be trained on topics such as c ontainer closure, equipment selection, and component selection and handling.
1735.2(c)	Compounding personnel or persons with direct oversight over personnel performing compounding, who fail any aspect of ongoing training and evaluation shall not be involved in compounding or oversight of the preparation of a CNSP until after successfully passing training and competency in the deficient	Having people that fail any aspect of training be removed from compounding is too broad. A more nuanced approach needs to be taken based on what training was failed. If the person fails washing their hands properly, they should be excluded from c ompounding entirely. If they fail c ompounding of capsules, it does not generally mean they could not continue to compound

	area(s) as detailed in the facility's SOPs.	suspensions provided that they had passed the training for that do sage form. Wording should be amended to allow the supervising pharmacist to determine the appropriate course of action based on the training needed and the training that was not passed.
1735.3(a)	Prior to admitting any per sonnel into a compounding area, the supervising pharmacist shall evaluate them.	Is it reasonable for every employee to check in with a pharmacist at the beginning of the day to check them for rashes, oozing sores, conjunctivitis, etc.? It is typical in GMP facilities that it is a requirement of each person to report these symptoms to management as opposed to the pharmacist responsible to inspect each person and admit them to c ompounding. Requiring the pharmacist to inspect their team prior to compounding for all the listed items will create HR-related c hallenges and is not realistic.
1735.3(c)	Disposable garb shall not be shared by staff and shall be discarded if soiled and after each shift. All garb removed during a shift must remain in the compounding area.	As written, this would allow for the reuse of any and all disposable garb during a shift. Of the dispo sable garb items, only the dispo sable gown should be reused.
1735.3(e)	Non-disposable garb should be cleaned with a germicidal cleaning agent and sanitized with 70% isopropyl alcohol before re-use.	It is possible that the proposed language was intended for items such as goggles. However, it is possible that some pharmacies may have non-disposable garb, including gowns, which are laundered either by the pharmacy or by third party services. These gowns would be typically cleaned with the combination of agents specified in the proposed language. Clarity should be created in the wording of this language as to what non-

		disposable garb this is expected to be used with.
1735.4(b)	Purified water, distilled water, or reverse osmosis water shall be used for rinsing equipment and utensils.	USP 795 offers this as a should statement and is not required. Should this be required as written it should also allow for other waters of equal or better quality such as sterile water for irrigation or sterile water for injection.
1735.4(c)	CNSP shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the law or the facility's SOPs.	Recommend specifying the following as: • Vermin (e.g., insects, rodents) or other animals (e.g., dogs) or evidence of their presence (e.g., urine, feces) in the production area or adjacent areas • Visible microbial c ontamination (e.g., bacteria, mold) in the production area or adjacent areas Foreign matter in the production area (e.g., rust, glass shavings, hair s, paint chips) • Producing drugs while construction is underway in a nearby area without adequatecontrols to prevent contamination of the production area and product • Standing water or evidence of water leakage in the production area or adjacent areas • Handling bulk drug substances or drug products that are hazardous, sensitizing, or highly potent (e.g., hormones) with inadequate controls to prevent cross-contamination. • Using active ingredients, inactive ingredients, or processing aides, that have or

		may have higher levels of impurities compared to c ompendial or pharmaceutical grade equivalents (e.g., ingredients with potentially harmful impurities, ingredients labeled with “not for pharmac eutical use” or an equivalent statement)
1735.7(c)(1)	The date and time of c ompounding, which is the time when compounding of the CNSP started, and which determines when the assigned BUD starts	Time becomes relevant when BUDs are relatively short (<72 hours). This would be highly unc ommon for CNSPs. Recommend that the language be updated to only include the day that the CNSP was compounded.
1735.7(c)(2)	The manufacturer, lot number, and expiration date for each c omponent.	The manufacturer of each component is a trade secret that is not required to be disclosed by federal law or federal regulation. Suggest changing the word manufacturer to supplier.
1735.7(c)(4)	The total quantity c ompounded, which shall include the number of units made and the volume or weight of each unit.	Compounding software programs typically require the metric quantity of a batch prepared, but do not document the quantity of each individual unit.
1735.10(b)(1)	The chemical and physical stability data of the active pharmaceutical ingredient (API) and any added component in the preparation.	Components such as pH adjusters should be excluded from impacting the BUD of the formulation. These are typically made fresh, used, and disposed of. If the pharmacy were to document a 1-day BUD for the pH adjuster, then this language as written would cause the final preparation to have a 1-day BUD. Recommend aligning with USP’s approach to exclude pH adjusters from the determination of the BUD.

1735.10(b)(2)	(e.g. possible leachables, interactions, and storage conditions.)	Leachables per USP are extensive studies that cost several hundred thousand dollars for each drug product. It is not reasonable for compounding pharmacy to study leachables.
1735.11(1)	Comply with USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding	USP chapters over 1000 are not written for compliance purposes. See this quote from the USP General Notices: "General chapters numbered 1000 to 1999 are for informational purposes only. They contain no mandatory tests, assays, or other requirements applicable to any official article, regardless of citation in a general chapter numbered below 1000, a monograph, or these General Notices."
1735.11(a)(2)(E)	The validated processes for storage, shipping containers and transportation of temperature sensitive CNSPs to preserve quality standards for integrity, quality and labeled strength.	The statement “validated processes” is unclear and undefined.
1735.12(a)	The facility’s quality assurance program shall comply with section 1711 and the standards contained in USP Chapter 1163, entitled *Quality Assurance in Pharmaceutical Compounding.* In addition, the program shall include the following:	USP chapters over 1000 are not written for compliance purposes. See this quote from the USP General Notices: "General chapters numbered 1000 to 1999 are for informational purposes only. They contain no mandatory tests, assays, or other requirements applicable to any official article, regardless of citation in a general chapter numbered below 1000, a monograph, or these General Notices."
1735.12(b)	The Board shall be notified in writing within 72 hours of the facility’s receipt of a complaint	Adverse events are expected as a potential occurrence with the use of a drug and may not represent a

	of a potential quality problem or the occurrence of an adverse drug event involving a CNSP.	quality-related problem with the compounded medication. As written, the board will have to hear about every adverse effect related to a CNSP whether it is related to the quality of the CNSP or not. This type of reporting may drown out the reports the board needs to be aware of for a CNSP that has a quality problem. Suggest that this be changed to have the reporting occur when the adverse drug event is related to a quality problem and is not an adverse event that is generally expected to occur with the use of the drug. Pharmacies should investigate potential quality problems. It will take longer than 72 hours to conduct those investigations, as well. The board will be notified of occurrences prior to them being able to be fully investigated.
1735.13	In addition to the standards set forth in USP 795, the facility shall ensure appropriate processes for storage, shipping containers and temperature sensitive CNSPs as provided for in the facility's SOPs.	The statement "validated processes" is unclear and undefined.
1736 (g)		See 1735 (f) above
1736.1(e)	"Essentially a copy" of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (APIs) as the commercially available drug product, except that It does not include any preparation in which there has been a change made for an identified individual patient	The FDA defines an "essential copy" as the same API; same route of administration; same, similar, or easily substitutable strength; and same characteristics as the combination of two or more commercially available drug products. Recommend that California align with FDA's description used in the 503A copies guidance.

	that produces for that patient a clinically significant difference, as determined by the prescribing practitioner, between that compounded preparation and the commercially available drug product.	
1736.1(b)	CSPs for direct and immediate administration as provided in the Chapter shall only be compounded in those limited situations where the failure to administer such CSPs could result in loss of life or intense suffering of an identifiable patient….	There are many other times that CSPs should be compounded for direct and immediate administration other than loss of life or intense suffering. USP removed the emergency situation requirement for immediate-use CSPs. An example of when this might be required is during the shortage of lidocaine with epinephrine. Clinics could use available ingredients (lidocaine vials, epinephrine vials) to compound multiple syringes for u se in multiple patients over a 4-hour period. This medication is often needed for infiltration and nerve block.
1736.1(e)(1)(A,B,C)	Is essentially a copy of one or more commercially available drug products, unless:	There is no accommodation for veterinary compounds, which are regulated under different provisions of federal law. A reference should be made to the appropriate guidance, and a section should be added to allow for compounded preparations being sold for veterinary office use where the API appears on the lists of approved or under consideration APIs for veterinary use.
1736.1(e)(2)	Is made with any component not suitable for use in a CNSP for the intended patient population, unless allowable under the Animal Medicinal	As written, this eliminates the compounding of drugs for animals from API because AMDUCA does not address this. The statement says that it must be specifically

	Drug Use Clarification Action of 1994 (AMDUCA).	allowed under AMDUCA, and AMDUCA does not address this topic. California should align with FDA GFI 256 in their approach to animal compounding to maintain patient access.
1736.1(e)(3)	Is made with a non-sterile component for which a c onventionally manufactured sterile component is available and appropriate for the intended CSP.	In some cases, starting with the non-sterile component would be more appropriate (excipients in the conventionally manufactured product, tonicity, concentration). Depending on batch size and c ompounding set-up, using a c onventionally manufactured sterile product as opposed to bulk ingredients could cause more sterility issues and potency variability among units prepared (e.g., exponentially increased manual manipulations by repetitively entering vials or bags to transfer a portion of liquid to the finished preparation increases the potential for contamination and variability as these processes are primarily manual.) Additionally, starting with non- sterile ingredient s already shortens the BUD of the final product. Does “conventinally manufac tured” mean commercially available?
1736.1(e)(4)	Requires end-product sterilization unless sterilization occurs within the same lic ensed compounding location.	This would prevent the use of e- beam or gamma-irradiation sterilization methods, which are performed off-site at validated facilities. Can the board demonstrate the harm caused to patient care by offsite sterilization?
1736.2(d)	Compounding personnel or persons with direct oversight	The person with direct oversight who fails will need more than 14

	over compounding personnel who fail any aspect of the aseptic manipulation ongoing training and competency evaluation shall not be involved in compounding or oversight of the preparation of a CSP until after successfully passing training and competenc y in the deficient area(s) as detailed in the facility's SOPs. A person with only direct oversight over personnel who fails any aspect of the aseptic manipulation ongoing training and competency evaluation may continue to provide only direct oversight for no more than 14 days after a failure of any aspect while applicable aseptic manipulation ongoing training and competency evaluation results are pending.	days after the failure if this involves a media-fill failure. The incubation of a media-fill takes 14 days at a minimum per 797. Unless the person can do a media-fill on the same day that their media-fill failure is known, they will not be able to continue to provide that direct oversight for some number of days. Recommend that this time be e xtended to 21 days. Similar to the comment in nonsterile compounding, removing people from performing all compounding due to a failure in any training area is not appropriate. A more nuanced approach should be used. If a per son fails in their use of an auto clave, they could still compound solutions that are prepared aseptically or by filtration, assuming that they passed all training and competency for those processes. The supervising pharmacist needs to be able to determine areas of training and competency that would cause the compounder to be c ompletely removed from all c ompounding of CSPs.
1736.3		Refer to 1735.3(a) above
1736.6(a)	At a minimum of every 6 months, air and surface sampling results should be identified to at least the genus level. Investigation must be c onsistent with the deviation and must include evaluation of trends.	The second sentence is not clear. What deviation is this referring to? Is there an assumption that the sampling will result in a deviation or there will be results exceeding the action limits?
1736.9(d)	All API and excipient components used to	Most excipient components are sold by FDA-registered

	compound a CSP shall be manufactured by an FDA-registered facility, be acc ompanied by a Certificate of Analysis (COA), and suitable for use in sterile pharmaceuticals. A COA that includes the compendial name, the grade of the material, and the applicable c ompendial designations on the COA, must be received and evaluated prior to use, unless components are commercially available drug products. When the COA is received from a supplier, it must provide the name and address of the manufacturer. API and excipient components provided with a COA without this data shall not be used in a CSP.	wholesalers but are not manufactured by FDA-registered facilities. FDA registration is required of manufacturers of food, beverages, dietary supplements, cosmetics, animal and veterinary products, medical devices, drug products, tobacco products, radiation-emitting devices, and biologics. What is meant by “suitable for use in sterile pharmaceuticals?” Additionally, not all wholesalers or repackagers include the original manufacturer name or address on the COA, as they assert that is a trade secret. Trade secrets should be protected under California law.
1736.9(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 sub stance 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.	21 CFR 216 only includes items on the Final FDA bulks list, and not anything on the interim bulks list (category 1 items). Removal of the ability to use these agents in a C SP will harm California patients who require these medications, and who cannot get them otherwise.
1736.10	The entire section references various USP chapters numbered over 1000.	From USP's General Notices: "General chapters numbered 1000 to 1999 are for informational purposes only. They contain no mandatory tests, assays, or other requirements applicable to any official article, regardless of citation in a general chapter numb ered below 1000, a

		monograph, or these *General Notices."*
1736.10(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.	This would prevent the use of e- beam or gamma-irradiation sterilization methods, which are performed off-site at validated facilities.
1736.12(b)	A pharmacist performing or supervising sterile compounding is responsible for ensuring validation of an alternative method for sterility testing is done in compliance with USP Chapter 1223, Validation of Alternative Microbiological Methods, and shall receive and maintain documentation of the method-suitability for each CSP formulation for which the alternate method is used.	This places the burden of ensuring validation of an alternative method for sterility testing is done in compliance with USP Chapter 1223 on the pharmacist. Validation should be provided by the Analytical Laboratory performing the alternative method and maintained by the pharmacy as part of the compounding record.
1736.12(c)	A pharmacist performing or supervising sterile compounding is responsible for ensuring injectable CSPs made from nonsterile components, regardless of Category, are tested to ensure that they do not contain excessive bacterial endotoxins, as established in USP Chapter 85, Bacterial Endotoxins. Results must be reviewed and documented in the compounding records prior to furnishing.	For Category 2 CSPs that are not sterility tested, it is impractical and would hinder patient care to wait for endotoxin testing to release the CSP. In addition, CSPs that use nonsterile starting c omponents and are not sterility te sted only have a 4-day BUD. Typical endotoxin testing would not be available before the end of the BUD.
1736.13(a)(2)	The solution utilized, if applicable.	Clarify what this means.
1736.14(a)(1)	The chemical and physical stability data of the active pharmaceutical ingredients(s)	Components such as pH adjusters should be excluded from impacting the BUD of the formulation. These are typically

	and any added substances in the preparation.	made fresh, used, and disposed of. If the pharmacy were to document a 1-day BUD for the pH adjuster, then this language as written would cause the final preparation to have a 1-day BUD. Recommend aligning with USP's approach to exclude pH adjusters from the determination of the BUD.
1736.14(a)(2)		Refer to 1735.10(b)(2) above
1736.14(c)	Prior to furnishing a CSP, the pharmacist performing or supervising sterile compounding is responsible for ensuring that sterility and endotoxin testing for the BUD determination is performed and has received and reviewed the results. Results must be within acceptable USP limits. Test results must be retained as part of the compounding record.	Sterility testing can take more than 2 weeks for results to be reported., and patients may need access to the compounded preparations before testing results are available. Restricting formulations to release after testing creates a situation where patients could be denied a medication if testing cannot be performed fast enough to prevent suffering or patient harm.
1736.17(g)	There shall be written proc edures for qualification of storage, shipping containers and transportation of temperature sensitive CSPs to preserve quality standards for integrity, quality, and labeled strength.	The statement "validated processes" is unclear and undefined. What does the Board consider to be a validated process? Temperature mapping, thermal mapping, or must standardized tests be used (International Safe Transit Association standards 3A, 20, 7D and 7E or the ASTM International Standard D3103)?
1736.18(c)	In addition to subsection (b), all complaints made to the facility related to a potential quality problem with a CSP and all adverse events shall be reviewed by the pharmacist-in-charge within 72 hours of receipt of the complaint or occurrence. Such review shall	Adverse events are expected as a potential occurrence with the use of a drug and may not represent a quality related problem with the compounded medication. As written, the board will have to hear about every adverse effect related to a CNSP, whether or not it is related to the quality of the

	be documented and dated as defined in the SOPs.	CNSP. This type of reporting may drown out the reports that the board needs to be aware of for a CNSP that has a quality problem. Suggest that this be changed to have the reporting occur when the adverse drug event is related to a quality problem and is not an adverse event that is generally expected to occur with the use of the drug. Pharmacies should investigate potential quality problems. It will take longer than 72 hours conduct those investigations, as well. The board will be notified of occurrences prior to them being fully investigated.
1736.21(a)	Any allergenic extract compounding shall take place in a dedicated PEC. No other CSP may be made in this PEC.	Compounding of allergenic extracts per USP may be done in a PEC or a dedicated Allergenic Extracts Compounding Area. The PEC is not required to be used only for allergenic extracts. This requirement is onerous and will restrict access of this vital medication therapy.
1736.21(b)	Compounding of allergenic e xtracts are limited to patient-specific prescriptions and the conditions limited to Category 1 and Category 2 CSPs as spec ified in USP Chapter 797.	Allergenic extracts are in a c ategory of their own, and USP allows up to a one-year BUD after preparation without sterility testing. If pharmacies have to treat them as a category 1 or 2 CSP, the short BUDs will prevent patient access. Additionally, this is more onerous than FDA's approac h to compounding these preparations, as discussed in their Biologics guidance document.
1736.6(a)(b)	The SOPs of a premises where HDs are handled shall address environmental wipe sampling for HD surface residue, its frequency, areas of testing,	There are no standards for c ontamination action levels for HD drugs. Wipe sampling is recommended in USP 800 but not

	levels of measurable contamination, and actions when those levels are exceeded.	required, as there is no consensus on what to do with the results.
1737.7 (d)	PPE shall be removed to avoid transferring contamination to skin, the environment, and other surfaces. PPE worn during compounding shall be disposed of in the proper waste container before leaving the C-SEC. SOPs shall detail the donning and doffing of PPE and where it takes place in the C-SEC	As written, this assumes that there is only a positive pressure anteroom which would require the PPE to be removed in the C - SEC. Some facilities have a negative pressure anteroom where the PPE could be removed so that it does not have to be removed in the negative pressure buffer room. These facilities with a negative pressure anteroom also have a positive pressure gowning room.
1737.9 (b)	Personnel responsible for handling HDs who fail any aspe ct of training in handling HDs shall not handle HDs until after successfully passing reevaluations in the deficient area(s), as detailed in the facility's SOPs.	As noted in other areas of compounding, failing one area of training may not mean that a person should be removed from handling of HDs entirely. The supervising pharmacist needs discretion to determine if the area failed should cause complete removal of the individual.
1737.13(a)	A disposable preparation mat shall be placed on the work surface of the C-PEC when compounding HD preparations. Where the c ompounding is a sterile preparation, the preparation mat shall be sterile. The preparation mat shall be c hanged immediately if a spill occurs, after each HD drug, and at the end of daily c ompounding activity.	Change "the mat must be sterile" to "the mat must be cleaned with germicidal cleaner and then sanitized with sterile 70% IPA prior to use."
1737.14(b)	When furnishing an antineoplastic HD, a sufficient supply of gloves that meet the ASTM D-6978 standard to allow for appropriate	Who bears liability if the patient refuses to pay for the glove s? Who bears liability if the patient does not use the gloves that shall be made available for purchase?

	administration, handling, and disposal of HD drugs by the patient or the patient's agent shall be provided.	

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Section, Subdivision	**Proposed Language**	**Recommendation / Comment**
Non-Sterile Compounding		
1735.1. Introduction and Scope. Subsection (f)(1)(A)	(A) the drug product appears in an American Society of Health-System Pharmacists (ASHP) or FDA Drug Shortages Database that are in short supply at the time of compounding and at the time of dispensing, or	**Comment:** • The ASHP and FDA Drug Shortages Database is not always a timely source for detecting fluctuations in the drug supply chain. Drug supply shortages often impact community or hospital pharmacies before being reported on the ASHP/FDA Drug Shortages list. • Shortages and allocations can also be specific to a wholesaler rather than occurring on a national scale. Current regulations, as they stand, could prohibit pharmacies from compounding products in these instances, potentially causing delays in patient care, particularly in acute care settings. **Recommendation:** • It is recommended that the board add language allowing pharmacies to compound products when there is evidence of drug allocation or shortages at the wholesaler or supplier level. Please see proposed revision below. **1735.1. Introduction and Scope. Subsection (f)(1)(A)** *The drug product appears in an American Society of Health-System Pharmacists (ASHP) or FDA Drug Shortages Database that are in short supply at the time of compounding and at the time of dispensing, or the pharmacy can provide evidence of interruption in inventory supply (such as invoices to show allocation or back order from wholesaler) at the time of compounding or*

Sterile Compounding		
CCR 1736.1 Introduction and Scope. Subsection (b):	(b) CSPs for direct and immediate administration as provided in the Chapter shall only be done in those limited situations where the failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need. Documentation for each such CSP shall include identification of the CSP, compounded date and time, number of units, the patient's name and patient's unique identifier and the circumstance causing the immediate need. Such documentation may be available in the patient's medical record and need not be redocumented by the compounding staff if already available.	**Comment:** • Immediate-use compounding is frequently required in the Emergency Department and during hospital code situations. The proposed documentation requirements seem unlikely to enhance patient care or safety immediately and may introduce delays in an already high-stress, high-risk environment. As currently written, the regulations add another layer of complexity for participating pharmacists, potentially diverting their attention from triaging, participating in the code, and providing patient care. **Recommendation:** • We recommend the board consider modifying the language to accommodate administration documentation. ***1736.1 Sterile Compounding Scope. Subsection (b)*** *(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 patient harm ~~loss of life or intense suffering~~. Any such compounding shall be only in such quantity as is necessary to meet the immediate need. Documentation of administration of CSP shall be recorded in patent's medical record if given. ~~Documentation for each such CSP shall include identification of the CSP, compounded date and time, number of units, the patient's name and patient's unique identifier and the circumstance causing the immediate need. Such documentation may be available in the patient's medical record and need not be redocumented by the compounding staff if already available~~*

CCR 1736.1 Introduction and Scope. Subsection (e)(1)(A)	(A) that drug product appears in an American Society of Health-System Pharmacists (ASHP) or FDA Drug Shortages Database that are in short supply at the time of compounding and at the time of dispensing, or	**Comment:** • The ASHP and FDA Drug Shortages Database is not always a timely source for detecting fluctuations in the drug supply chain. Drug supply shortages often impact community or hospital pharmacies before being reported on the ASHP/FDA Drug Shortages list. • Shortages and allocations can also be specific to a wholesaler rather than occurring on a national scale. Current regulations, as they stand, could prohibit pharmacies from compounding products in these instances, potentially causing delays in patient care, particularly in acute care settings. **Recommendation:** • It is recommended that the board add language allowing pharmacies to compound products when there is evidence of drug allocation or shortages at the wholesaler or supplier level. Please see proposed revision below. **1735.1. Introduction and Scope. Subsection (e)(1)(A)** *that drug product appears in an American Society of Health-System Pharmacists (ASHP) or FDA Drug Shortages Database that are in short supply at the time of compounding and at the time of dispensing, or the pharmacy can provide evidence of interruption in inventory supply (such as invoices to show allocation or back order from wholesaler) at the time of compounding or*
CCR 1736.6 Microbiological Air and Surface monitoring. Subsection (a)	(a) At a minimum of every 6 months, air and surface sampling results shall be identified to at least the genus level, regardless of the CFU count to trend for growth of microorganisms. Investigation must be consistent with the deviation and must include evaluation of trends.	**Comment:** • There is concern regarding the feasibility of the proposed language, if identification is needed down to any CFU level it could potentially overwhelm current lab/resource capacity, especially with surface sampling requirement changing to every month. The proposed language also does not provide clear action on what to do with this information. **Recommendation:** • Recommend the Board to consider adopting USP 797 standard and use the USP797 proposed action levels for surface sampling as cut off for genus level identification. Recommend modified language below. **1736.6 Microbiological Air and Surface monitoring. Subsection (a)** *At a minimum of every 6 months, air and surface sampling results shall be identified to at least the genus level based on facility SOP action level, ~~regardless of the CFU count~~ to*

		trend for growth of microorganisms. Investigation must be consistent with the deviation and must include evaluation of trends.
CCR 1736.14 Establishing Beyond-Use Dates. Subsection (c)	(c) Prior to furnishing a CSP, the pharmacist performing or supervising sterile compounding is responsible for ensuring that sterility and endotoxin testing for BUD determination is performed and has received and reviewed the results. Results must be within acceptable USP limits. Test results must be retained as part of the compounding record.	**Comment:** • This section could be interpreted that there must be sterility and endotoxin testing done for any BUD determination. • Sterility and bacterial endotoxin testing is usually a send out test, contracted to an outside lab, the process could take up to a week. One example where such practice would cause delay in acute care setting is the compounding of formalin for treatment of persistent hemorrhagic cystitis. **Recommendation:** recommend modified language below **1736.14 Establishing Beyond-Use Dates. Subsection (c)** *(c) Prior to furnishing a CSP, the pharmacist performing or supervising sterile compounding is responsible for ensuring that applicable sterility and endotoxin testing for BUD determination is performed per USP and has received and reviewed the results. Results must be within acceptable USP limits. Test results must be retained as part of the compounding record.*
CCR 1736.21 Compounding Allergenic Extracts subsection (a)	(a) Any allergenic extract compounding shall take place in a dedicated PEC. No other CSP may be made in this PEC.	**Comments:** • Requiring a dedicated PEC would potentially constrict pharmacy workflow and displace resources that could cause a delay in patient care where PEC is needed. We ask the board to consider adopting the USP 797 language as is and allow the use of Allergenic Extracts Compounding Area (AECA) for allergenic extracts and BUD determination. **Recommendations:** recommend modified language below *(a). Any allergenic extract compounding shall take place in a dedicated PEC or be compounded in an Allergenic Extracts Compounding Area (AECA). No other CSP may be made in this PEC if allergenic extract is compounded until appropriate cleaning is conducted per regulation or facility SOP.*

Hazardous drugs		
CCR 1737.1 Introduction and Scope	In addition to providing consultation in compliance with section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning handling and disposal of an HD or related supplies furnished.	**Comments:** • Section 1707.2 (b)(2) does not require consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, however there are outpatient ambulatory infusions centers where CSP is being administered by a healthcare professional where this may be interpreted to include such facilities. **Recommendation:** recommend modified language below **CCR 1737.1 Introduction and Scope** *In addition to providing consultation in compliance with section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning handling and disposal of an HD or related supplies furnished unless the CSP is being administered by a healthcare professional.*
CCR 1737.5 Facilities and Engineering Controls. Subsection (c)	(c) Where a pass-through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking. A pass-through is not allowed between the C-SEC into an unclassified space.	**Comment:** A method to transport HDs, HD CSPs, and HD waste into and out of the negative pressure buffer room to minimize the spread of HD contamination. This may be accomplished by use of a pass-through chamber between the negative-pressure buffer area and adjacent space per USP 800. **Recommendation:** Recommend align with USP 800 section 5.3.2. as this current language would prohibit the usage of pass through and add additional delay and interruption to patient care. ***CCR 1737.5 Facilities and Engineering Controls:*** *(c) Where a pass-through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking. ~~A pass-through is not allowed between the C-SEC into an unclassified space.~~ 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. The pass-through chamber must be included in the facility's certification to ensure that particles are not compromising the air quality of the negative-pressure buffer room.*
CCR 1737.10. Receiving.	All HD APIs and antineoplastic HDs shall be shipped and received from the supplier in segregated impervious plastic and labeled "Hazardous Drugs" on the outside of the	**Comment:** This section appears to imply that all HD (reproductive, non-antineoplastic hazardous drugs) needs to be segregated by the wholesaler. Per USP, each organization is responsible for creating their own hazardous drug list based on risk assessment and it

	delivery container.	would be challenging for wholesaler to have this aligned with each individual organization unless the Board publish a standardized list. **Recommendations**: recommend modified language below ***1737.10. ~~Receiving.~~ Shipping and Handling*** *All HD APIs and antineoplastic HDs shall be shipped ~~and received~~ from the supplier in segregated impervious plastic and labeled "Hazardous Drugs" on the outside of the delivery container. Pharmacy shall develop facility SOP for appropriate handling and receiving procedure per USP.*

Section, Subdivision	Proposed Language	Recommendation / Comment
Non-Sterile Compounding		
CCR 1735 Compounding Definitions. Subsection (d)	(d) "Essentially a copy" of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (API(s)) as the commercially available drug product, except that it does not include any preparation in which there has been a change made for an identified individual patient that produces for that patient a clinically significant difference, as determined by the prescribing practitioner, between that compounded preparation and the comparable commercially available drug product	**Rationale:** • The proposed language does not distinguish commercially available drug products with the same active pharmaceutical ingredient(s) (API(s)) with drug dosage form(s). • To make it clear that drug dosage forms not available commercially can be compounded for patient specific clinical needs. **Recommendation:** Recommend that the board amend the definition of "essentially a copy" to include "the same dosage form" alongside the same active ingredient(s) (API(s)).
CCR 1735.1 Introduction and Scope. Subsection (f) (1) (A):	(f) In addition to prohibitions and requirements for compounding established in federal law, no CNSP shall be prepared that: (1) Is essentially a copy of one or more commercially available drug products, unless: (A) the drug product appears in an American Society of Health-System Pharmacists (ASHP) or FDA Drug Shortages Database that are in short supply at the time of compounding and at the time of dispensing, or	**Rationale:** • The ASHP and FDA drug shortage lists do not always reflect real-time drug shortages. For example, the 2023 Akorn recall was posted after the State Board notified about the company shutdown, which led to multiple drug shortages. Health systems have monitoring strategies in place to track these drug shortages in real-time from drug manufacturers or wholesalers before these drugs are added to the ASHP and FDA drug shortage lists. • Additionally, wholesalers often run out of supply of critical medications, leading to pre-shortage situations. The inability to procure medications or restrictions on compounding in these events can contribute to heightened risk and safety concerns for patients. With the growing number of medications going on shortage and recent manufacturer bankruptcies (e.g., Akorn, Apotex), it is becoming increasingly challenging for health systems to obtain commercially available products. • References: **Recommendation:** • Recommend that the board include language concerning recent drug shortages not reflected on the ASHP and FDA lists, as well as the

		unavailability of medications from wholesalers, to ensure health systems maintain compliance with requirements. ○ ***1735.1 Introduction and Scope. Subsection (f) (1) (A):*** *(f) In addition to prohibitions and requirements for compounding established in federal law, no CNSP shall be prepared that:* *(1) Is essentially a copy of one or more commercially available drug products, unless:* *(A) that drug product is not available by the manufacturer or wholesaler, appears on an ASHP (American Society of Health-System Pharmacists), or FDA list of drugs at the time of compounding and at the time of dispense, or*
CCR 1735.1 Introduction and Scope. Subsection (h):	(h) In addition to the provisions provided in section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning proper use, storage, handling, and disposal of the CNSP and related supplies furnished.	**Rationale:** • Section 1707.2 (b)(2) does not require consultation for inpatients of a healthcare facility licensed under section 1250 of the Health and Safety Code. However, there are outpatient ambulatory infusion centers where CNSPs are administered by a healthcare professional. **Recommendation:** • Recommend that the BOP clarify CCR 1736.1 subsection (h) to specify that this regulation does not apply to CNSPs administered and dispensed to patients by a healthcare professional. • **Proposed Exemption Language**: Health facilities defined in Section 1250 of the Health and Safety Code are exempt from this requirement if prescriptions are administered by a licensed healthcare professional.
CCR 1735.7 Master Formulation and Compounding Records subsection (c):	(c) A compounding record (CR) shall be a single document developed in compliance with USP Chapter 795, and includes the following additional elements:	**Rationale:** • Current documentation practices in Health-System pharmacies utilize electronic record keeping systems/software to meet compounding record requirements, which may limit the ability to provide the information in a single document. **Recommendation:** • Recommend the Board consider modifying the language as follows: *(c) Compounding record requirements shall be readily retrievable to comply with USP Chapter 795 and includes the following additional elements:*

CCR 1735.7 Master Formulation and Compounding Records. subsection (c)(2):	(c)(3) The manufacturer, lot number, and expiration date for each component for the CSP.	**Rationale:** • The existing language in CCR 1735.3 includes a provision for compounded sterile preparations (CSPs) in health facilities to mitigate delays in care for acutely ill patients, such as those with infections, cancer, critical care needs, etc.. The current language 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:** • In order to avoid disruptions in care for acutely ill patients, it is suggested that the board contemplate incorporating similar exemption language into subsection (c)(2) of 1735.7 Master Formulation and Compounding Records., subsection (c)(2): *The manufacturer, lot number, and expiration date for each component.(i) Exempt from the requirements in this paragraph are non-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 1735.9 Labeling subsection (b):	(c) Any CNSP dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5.	**Rationale:** • At present, health facilities, defined according to Section 1250 of the Health and Safety Codes, are exempt from requirements regarding patient-centered labels.

		Recommendations: • To align with existing regulations, it is recommended to include exemption language in the proposed language for HSC 1250 (a) licensed facilities. This exemption is justified as compounded medications administered to patients are conducted by healthcare personnel authorized to administer medications, rather than being dispensed for outpatient use. • ***CCR 1735.9 Labeling subsection (c):*** *(c) Any CNSP dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5. (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.*
1735.12. Quality Assurance and Quality Control. Subsection (b)	(b) The Board shall be notified in writing within 72 hours of the facility's receipt of a complaint of a potential quality problem or the occurrence of an adverse drug event involving a CNSP.	**Rationale:** A requirement of 72 hours may not provide sufficient time for health-systems to investigate and notify the necessary regulatory bodies in cases where it occurs over the holiday weekend. **Recommendation** *(b) The Board shall be notified in writing within 3 business days ~~72 hours~~ of the facility's receipt of a complaint of a potential quality problem or the occurrence of an adverse drug event involving a CNSP.*
1735.12. Quality Assurance and Quality Control. Subsection (c)	(c) All complaints related to a potential quality problem with a CNSP and all adverse events shall be reviewed by the pharmacist-in-charge within 72 hours of receipt of the complaint or occurrence of the adverse event. Such review shall be documented and dated as defined in the SOPs.	**Rationale:** • A 72-hour requirement might not offer adequate time for health systems to investigate and notify the requisite regulatory bodies, particularly if the incident occurs over a holiday weekend. **Recommendation** • *(c)All complaints related to a potential quality problem with a CNSP and all adverse events shall be reviewed by the pharmacist-in-charge within 3 business days ~~72 hours~~ of receipt of the complaint or occurrence of the adverse event. Such review shall be documented and dated as defined in the SOPs.*
Sterile Compounding		
CCR 1736.1 Introduction and Scope. Subsection (b):	(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	**Rationale:** • During a patient emergency like a code blue or rapid resuscitation event in a hospital, the need for additional documentation will cause a delay in providing urgently required medication to prevent loss of life.

	suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need. Documentation for each such CSP shall include identification of the CSP, compounded date and time, number of units, the patient's name and patient's unique identifier and the circumstance causing the immediate need. Such documentation may be available in the patient's medical record and need not be redocumented by the compounding staff if already available.	• The current language may lead to substantial unintended consequences, such as organizational decisions to have nursing staff compound medications to avoid the risk of delays in drug administration, which could pose life-threatening situations. **Recommendation:** • We suggest the board consider removing the documentation requirement due to concerns regarding patient safety. • ***1736.1 Sterile Compounding Scope. Subsection (b)*** *(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 patient harm ~~loss of life or intense suffering~~. Any such compounding shall be only in such quantity as is necessary to meet the immediate need. ~~Documentation for each such CSP shall include identification of the CSP, compounded date and time, number of units, the patient's name and patient's unique identifier and the circumstance causing the immediate need. Such documentation may be available in the patient's medical record and need not be redocumented by the compounding staff if already available~~*
CCR 1736.1 Introduction and Scope. Subsection (e) (1) (A):	(e) In addition to prohibitions and requirements for compounding established in federal law, no CSP may be compounded that: (1) Is essentially a copy of one or more commercially available drug products, unless: (A) that drug product appears in an American Society of Health-System Pharmacists (ASHP) or FDA Drug Shortages Database that are in short supply at the time of compounding and at the time of dispensing, or	**Rationale:** • The ASHP and FDA drug shortage lists may not consistently reflect real-time shortages. For instance, the 2023 Akorn recall was announced after the State Board notification of the company shutdown, leading to multiple drug shortages. Health systems employ monitoring strategies to track these shortages in real-time directly from drug manufacturers or wholesalers, preempting the inclusion of these shortage drugs on the ASHP and FDA drug shortage lists. • Additionally, wholesalers themselves often run out of supply of critical medications (pre-shortage situations). Inability to procure medications or restrictions to compound in these events would have contribute to heightened risk and safety concerns for patients. With the growing number of medications going on shortage2 and recent manufacturer bankruptcies (i.e., Akorn,

		Apotex) it is becoming more challenging for Health-Systems to obtain commercially available products. **Recommendation:** • Suggest the board include language addressing recent drug shortages not captured on the ASHP and FDA lists, along with unavailability from wholesalers, to ensure health systems adhere to requirements. • ***1736.1 Sterile Compounding Scope. Subsection (e) (1) (A):*** *(e) 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 is not available (cannot be purchased) by the manufacturer or wholesaler, appears on an ASHP (American Society of Health- System Pharmacists), or FDA list of drugs at the time of compounding ~~and at the time of dispense~~, or*
CCR 1736.1 Introduction and Scope. Subsection (g):	(g) In addition to the provisions provided in Section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning proper use, storage, handling and disposal of the CSP and related supplies furnished	**Rationale:** • Section 1707.2 (b)(2) does not mandate consultation for inpatients of a healthcare facility licensed under section 1250 of the Health and Safety Code. Nevertheless, there are outpatient ambulatory infusion centers where compounded sterile preparations (CSPs) are administered by healthcare professionals. **Recommendation:** • Suggest that the BOP offer clarification for CCR 1736.1 subsection (g), specifying that the regulation does not apply to compounded sterile preparations (CSPs) administered and dispensed to patients by a healthcare professional. • **Proposed Exemption Language**: *(g) In addition to the provisions provided in Section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning proper use, storage, handling and disposal of the CSP and related supplies furnished.* *(i) Excluded from this requirement are health facilities, as defined in Section 1250 of the Health and Safety Code, provided that the prescriptions are administered by a licensed healthcare professional*

CCR 1736.1 Introduction and Scope. Subsection (h):	(h) CSPs with human whole blood or human whole blood derivatives shall be produced in compliance with Health and Safety Code section 1602.5.	**Rationale:** • The existing Health and Safety Code section 1602.5 states: (a) "No person shall engage in the production of human whole blood or human whole blood derivatives unless the person is licensed under this chapter and the human whole blood or human whole blood derivative is collected, prepared, labeled, and stored in accordance with both of the following:" • The proposed regulation, as it stands, may create confusion by enforcing a law that does not apply to any human whole blood or human whole blood derivative already manufactured by a pharmaceutical company (e.g., Albumin, Factor products, IVIG, etc.). **Recommendation:** • Recommend that the board revise the proposed language to clarify that the regulation does not apply to compounded sterile preparations (CSPs) made with human blood or derivatives manufactured by pharmaceutical companies. • *(h) CSPs with patient's own whole blood or human whole blood derivatives from the patient shall be produced in compliance with Health and Safety Code section 1602.5.*
CCR 1736.2 Personnel Training and Evaluation. Subsection (b)	Initial and ongoing aseptic manipulation training and competency documentation shall include the Primary Engineering Control (PEC) type and PEC unique identifier used during the evaluation. Aseptic manipulation competency evaluation and requalification shall be performed using the same procedures, type of equipment, and materials used in aseptic compounding. Aseptic qualifications from one premises may be used for another premises if all of the following conditions are met: (1) The Standard Operating Procedures (SOPs) required by section 1736.17 related to compounding are identical. (2) The Secondary Engineering Control (SEC) facility designs are sufficiently similar to accommodate the use of the same SOPs. (3) The PECs are of the same type and	**Rationale:** • The current USP 797 chapter does not require the PEC unique identifier to be documented for personnel training. Requiring a PEC unique identifier only adds to the additional documentation burden. **Recommendation:** • Recommend that the Board of Pharmacy consider eliminating the requirement for the "PEC unique identifier." • **Proposed Regulation Revision:** *Initial and ongoing aseptic manipulation training and competency documentation shall include the Primary Engineering Control (PEC) type ~~and PEC unique identifier~~ used during the evaluation.*

	sufficiently similar to accommodate the use of the same SOPs describing use and cleaning.	
CCR 1736.2 Personnel Training and Evaluation. Subsection (d)	(d) Compounding personnel or persons with direct oversight over compounding personnel who fail any aspect of the aseptic manipulation ongoing training and competency evaluation shall not be involved in compounding or oversight of the preparation of a CSP until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs. A person with only direct oversight over personnel who fails any aspect of the aseptic manipulation ongoing training and competency evaluation may continue to provide only direct oversight for no more than 14 days after a failure of any aspect while applicable aseptic manipulation ongoing training and competency evaluation results are pending	**Rationale:** • Several factors may contribute to the failure of staff in aseptic technique training and competency evaluation, such as environmental testing failure and engineering control failure. Prohibiting compounding personnel from compounding without an assessment of these contributing factors and timeframe could significantly disrupt patient treatment and jeopardize the health system's ability to operate. **Recommendation:** • Recommend adopting the facility's Standard Operating Procedure (SOP) for an action plan that outlines the steps to be taken when compounding personnel fail any aspect of aseptic manipulation during ongoing training and competency evaluation. • **Proposed Regulation Revision:** *(d) ~~Compounding personnel or persons with direct oversight over compounding personnel who fail any aspect of the aseptic manipulation ongoing training and competency evaluation shall not be involved in compounding or oversight of the preparation of a CSP until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs. A person with only direct oversight over personnel who fails any aspect of the aseptic manipulation ongoing training and competency evaluation may continue to provide only direct oversight for no more than 14 days after a failure of any aspect while applicable aseptic manipulation ongoing training and competency evaluation results are pending~~ The facility's Standard Operating Procedure (SOP) shall incorporate an action plan that addresses compounding personnel or individuals with direct oversight over compounding who fail any aspect of the ongoing training and competency evaluation for aseptic manipulation.*
CCR. 1736.4 Facilities and Engineering Controls Subsection (c)	(1) Designated compounding area(s) shall typically be maintained at a temperature of 20° Celsius or cooler.	**Rationale:** • According to USP Chapter 797, it is recommended to maintain a temperature of 20° Celsius or cooler for staff comfort within the classified compounding areas where multiple layers of PPE are worn. • The term "designed compounding area" is defined by CCR 1736 as a restricted location within a facility that limits access, where only activities and items

		related to compounding are present. This definition encompasses both classified compounding areas and segregated compounding areas. • If the language remains unchanged, stating "shall typically," it could have significant consequences for many health systems. Many would need to make substantial changes to their Heating, Ventilation, and Air Conditioning (HVAC) systems to comply with this requirement. Additionally, numerous classified compounding rooms and segregated compounding areas store medication at room temperature, which must adhere to the temperature range defined in USP Chapter 659 as 20°–25°C (68°–77°F). **Recommendation:** • Recommend removing this requirement and have pharmacies follow USP 797 standards for temperature requirement. Recommend the Board of Pharmacy consider removing the requirement of CCR. 1736.4 subsection (c).
CCR. 1736.4 Facilities and Engineering Controls Subsection (f)	(f) No CSP shall be compounded if the compounding environment fails to meet criteria specified in law or the facility's SOPs.	**Rationale:** • The proposed law, coupled with CCR 1736.1 Introduction and Scope, Subsection (b), could have grave implications for patients. For instance, if a designated compounding area fails to meet the criteria specified in the law, hospitals might be unable to compound medications for immediate use. Consequently, this could force them to cease operations, unable to deliver the necessary level of patient care. **Recommendation:** • Recommend that the Board of Pharmacy consider eliminating CCR 1736.4 subsection (f) and instead adhere to the standards outlined in USP 797.
CCR 1736.6 Microbiological Air and Surface monitoring. Subsection (a)	(a) At a minimum of every 6 months, air and surface sampling results shall be identified to at least the genus level, regardless of the CFU count to trend for growth of microorganisms. Investigation must be consistent with the deviation and must include evaluation of trends.	R**ationale:** • USP 797 recommends identifying sampling results on a genus level for actionable Colony Forming Units (CFUs) that exceed action levels. However, current evidence and infection control practices do not support the idea that tracking genus level below actionable levels will yield data that reduces patient risks. Nonetheless, this approach will lead to increased costs and workload. **Recommendation:** • *(a) At a minimum, every 6 months, air and surface sampling results shall be identified to at least the genus level, ~~regardless of~~ when the CFU count*

		exceeds action level to trend for growth of microorganisms. Investigation must be consistent with the deviation and must include evaluation of trends.
CCR 1736.11 Master Formulation and Compounding Records subsection (c):	(c) A compounding record (CR) shall be a single document. The document shall satisfy the requirements of USP Chapter 797, and also contain the following:	**Rationale:** • Health-system pharmacies currently rely on electronic record-keeping systems/software to fulfill compounding record requirements. However, this reliance on electronic systems may limit the ability to present all the necessary information in a single document. **Recommendation:** • Recommend the Board consider modify the language to: *(c) Compounding record requirements shall be readily retrievable to comply with USP Chapter 797 and includes the following additional elements:*
CCR 1736.11 Master Formulation and Compounding Records. subsection (c)(3):	(c)(3) The manufacturer, lot number, and expiration date for each component for the CSP.	**Rationale:** • Current language in CCR 1735.3 below has a provision for CSPs compounded in health facilities to prevent delays in care to acutely ill patient, i.e., infections, cancer, critical care, etc. The current language 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): *(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 1736.11 Master Formulation and Compounding Records. subsection (c)(5):	(c) (5) The identity of each person performing the compounding, that has direct oversight of compounding, and pharmacist verifying the final drug preparation.	**Rationale:** • In current compounding practices at health-system pharmacies, the pharmacist overseeing compounding also verifies the final drug preparation. The requirement for three different individuals will present challenges for smaller hospitals in California due to their limited staff. This situation may lead to delays in patient care and have a negative impact on safety. **Recommendation:** • recommend that the Board of Pharmacy clarify the intent of this requirement or consider adding language allowing one individual to fulfill both the requirements of direct oversight of compounding and verifying final drug preparations.
CCR 1736.13 Labeling subsection (a):	(a) A CSP label shall include all of the following: (1) Route of intended administration; (2) The solution utilized, if applicable; (3) Instructions for administration; (A) For an admixed CSP, the rate of infusion, or range of rates of infusion as prescribed, or the duration for the entire CSP to be administered.	**Rationale:** • Most health-systems utilize electronic health record (EHR) system that can provide the required label components in readily retrievable format. Not all admixture CSPs are infused. **Recommendations:** • Recommend modifying the language to include: *(a) A CSP label shall include all of the following and these can also be readily retrievable from the EHR:* *(1) Route of intended administration;* *(2) The solution utilized, if applicable;* *(3) Instructions for administration;* *(A) For an admixed CSP that are to be infused, the rate of infusion, or range of rates of infusion as prescribed, or the duration for the entire CSP to be administered.*
CCR 1736.13 Labeling subsection (b):	(b) Any CSP dispensed or ready to be dispensed 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 align with current regulations, it is recommended to include exemption language in the proposed language for HSC 1250 (a)

		licensed facilities. This is because compounded medications are administered to patients by authorized healthcare personnel and are 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.*
CCR. 1736.14 Establishing Beyond-Use Dates subsection (c)	(c) Prior to furnishing a CSP, the pharmacist performing or supervising sterile compounding is responsible for ensuring that sterility and endotoxin testing for BUD determination is performed and has received and reviewed the results. Results must be within acceptable USP limits. Test results must be retained as part of the compounding record.	**Rationale:** • According to USP 797, endotoxin and sterility testing must be performed in certain cases for category 2 or 3 compounded sterile preparations (CSPs). **Recommendations:** • To align with the USP 797 recommendations, we suggest the following revision to this section: *(c) Prior to furnishing a CSP, the pharmacist performing or supervising sterile compounding is responsible for ensuring that sterility and endotoxin testing (when applicable) for BUD determination is performed and has received and reviewed the results.*
CCR. 1736.17 Standard Operating Procedures (SOPS) subsection (a)(2)(c)	(a)(2)(c) The methods a pharmacist will use to determine and approve the ingredients and the compounding process for each preparation before compounding begins;	**Rationale:** • Many health systems currently use IV room workflow systems with barcode scanning to verify components before allowing technicians to proceed with compounding. Additionally, due to pharmacy recruitment challenges, it would be difficult for health systems to conduct manual individual checks for a large number of CSPs before and after compounding. This adds an addition step that does not add any safety components. **Recommendations:** • The methods a pharmacist will use to determine and approve the ingredients and the compounding process for each preparation before compounding begins; *(i) A sterile compounding workflow system may be utilized for verification of correct components used for preparing a CSP.*

CCR. 1736.17 Standard Operating Procedures (SOPS) subsection (d)	(d) The SOPs shall specify the process and products to be used on any equipment and other items entering from an unclassified area into the clean side of the anteroom, entering a PEC and entering the SCA. These SOPs must define at a minimum what product is to be used, the dwell time required, and how dwell time will be monitored and documented.	**Rationale:** • In many health systems, numerous items enter the sterile compounding spaces, including the PEC. Requiring documentation of monitoring dwell time adds a significant burden to the workload of sterile compounding staff, which could increase the risk of errors in compounding. **Recommendation:** • *d) The SOPs shall specify the process and products to be used on any equipment and other items entering from an unclassified area into the clean side of the anteroom, entering a PEC and entering the SCA. These SOPs must define at a minimum what product is to be used, the dwell time required, and how dwell time will be monitored. ~~and documented.~~*
CCR. 1736.18 Quality Assurance and Quality Control subsection (c)	(c) In addition to subsection (b), all complaints made to the facility related to a potential quality problem with a CSP and all adverse events shall be reviewed by the pharmacist-in-charge within 72 hours of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs.	**Rationale:** • A 72-hour requirement may not provide sufficient time for health systems to investigate and notify the necessary regulatory bodies if an incident occurs over a holiday weekend. **Recommendation:** • *(c) In addition to subsection (b), all complaints made to the facility related to a potential quality problem with a CSP and all adverse events shall be reviewed by the pharmacist-in-charge within 3 business days ~~72 hours~~ of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs.*
CCR 1736.21 Compounding Allergenic Extracts subsection (a)	(a) Any allergenic extract compounding shall take place in a dedicated PEC. No other CSP may be made in this PEC.	**Rationale:** • The new USP 797 chapter mandates that allergenic extracts be compounded in either (1) an ISO Class 5 Primary Engineering Control chamber (PEC) or (2) a dedicated Allergenic Extracts Compounding Area (AECA). Requiring a dedicated PEC for allergenic extracts would result in significant operational and financial burdens. **Recommendations:** • To align with the new USP 797 guidance, it is recommended to revise the language to permit the PEC to be used for other CSPs and not solely for allergenic extracts. • ***CCR 1736.21 Compounding Allergenic Extracts subsection (a):*** *(a) Any allergenic extract compounding shall take place in either a dedicated Allergenic Extracts Compounding Area or a PEC. No other CSP may be made in this PEC at the same time allergenic extract compounding is*

		occurring. Work surface of the PEC must be disinfected immediately after compounding.
Hazardous drugs		
CCR 1737.1 Introduction and Scope	In addition to providing consultation in compliance with section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning handling and disposal of an HD or related supplies furnished.	**Rationale:** • Section 1707.2 (b)(2) does not mandate consultation for inpatients of healthcare facilities licensed under section 1250 of the Health and Safety Code. However, there are outpatient ambulatory infusion centers where compounded sterile preparations (CSP) are administered by healthcare professionals. • If the proposed regulation necessitates consultation for all hazardous medications dispensed and administered in an outpatient infusion center, it will impose a substantial workload on health systems to meet this requirement. **Recommendation:** • Recommend providing clarification for CCR 1737 to specify that the regulation does not apply to compounded sterile preparations (CSPs) administered and dispensed to patients by a healthcare professional. • **Proposed Exemption Language**: *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.*
CCR 1737.2 List of Hazardous Drugs subsection (a) and (b) :	(a) The facility's list of HDs as required by USP Chapter 800 must be reviewed and approved by the designated person and the pharmacist-in-charge (PIC), professional director of a clinic, or designated representative-in-charge, as applicable. The designated person must be a single individual approved by the pharmacist-in-charge to be responsible and accountable for the performance and operation of the facility and personnel as related to the handling of hazardous drugs. The designated person shall not exceed the scope of their issued license. When the designated person is not a pharmacist, the PIC must review all practices related to the operations of the facility that require the	**Rationale:** • Frequently, the designated individual may be the pharmacist-in-charge. **Recommendation:** • Suggest revising the language to permit the Pharmacist-in-charge or designated individual to review and approve the facility's list of hazardous drugs (HDs) annually. • ***CCR 1737.2 List of Hazardous Drugs subsections:*** *(a) The facility's list of HDs as required by USP Chapter 800 must be reviewed and approved by the designated person ~~and~~ or the pharmacist-in-charge (PIC), or professional director of a clinic, or designated representative-in-charge, as applicable. The designated person must be a single individual approved by the pharmacist-in-charge to be responsible and accountable for the performance and operation of the facility and personnel as related to the handling of hazardous drugs. The designated person shall not exceed the*

	judgment of a pharmacist. Approval shall be documented at least every 12 months. (b) If an assessment of risk approach is taken as authorized in USP Chapter 800, it shall be approved by the designated person and the pharmacist-in-charge, professional director of a clinic, or designated representative-in-charge, as applicable.	*scope of their issued license. When the designated person is not a pharmacist, the PIC must review all practices related to the operations of the facility that require the judgment of a pharmacist. Approval shall be documented at least every 12 months.* *(b) If an assessment of risk approach is taken as authorized in USP Chapter 800, it shall be approved by the designated person ~~and~~ or the pharmacist-in-charge, or professional director of a clinic, or designated representative-in-charge, as applicable.*
1737.5 Facilities and Engineering Controls. Subsection (c)	(c) Where a pass-through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking. A pass-through is not allowed between the C-SEC into an unclassified space.	**Rationale:** • USP 800 does not prohibit the use of a pass-through between a classified space and an unclassified space. However, this requirement, without an exemption for previously constructed classified areas, will impose significant financial and operational burdens on institutions that utilize a pass-through to comply with the new regulations. **Recommendation:** • Revise language to remove the requirement and to align with USP 800 to read as follows: • ***CCR 1737.5 Facilities and Engineering Controls:*** *(c) Where a pass-through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking. A pass-through is not allowed between the C-SEC into an unclassified space.* ◦ *A passthrough may be allowed if installed before [OAL insert effective date].* ◦ *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.*
CCR 1737.6 Environmental Quality and Control. Subsection (a)	(a) The SOPs of a premises where HDs are handled shall address environmental wipe sampling for HD surface residue, its frequency, areas of testing, levels of measurable contamination, and actions when those levels are exceeded.	**Rationale:** • USP 800 only recommends performing environmental wipe sampling for HD surface residue routinely. • Currently, there is currently no standard for acceptable limits for HD surface contamination.[1] • Additionally, requiring additional sampling will add an undue burden to test without any concrete actionable limits.

		Reference: 1. Connor et al. Surface wipe sampling for antineoplastic (chemotherapy) and other hazardous drug residue in healthcare settings: Methodology and recommendations. Journal of Occupational and Environmental Hygiene. **Recommendations**: • Suggest the board consider either removing the section entirely or revising the language to use "should" to maintain consistency with USP 800 Chapter. Additionally, providing guidance on specific requirements such as action levels, frequency of testing, and actions to take when actionable levels are reached would be beneficial, considering the absence of standards in this regard. • ***CCR 1737.6 Environmental Quality and Control*** *a) The SOPs of a premises where HDs are handled ~~shall~~ should address environmental wipe sampling for HD surface residue, its frequency, areas of testing, levels of measurable contamination, and actions when those levels are exceeded.*
CCR 1737.7. Personal Protective Equipment (PPE), subsection (c).	(c) Outer gloves used for HD compounding shall be changed between each different HD preparation.	**Rationale:** • Many health-systems use closed system transfer device (CSTD) when compounding antineoplastic HDs. The use of CSTD has shown to significantly reduce overall chemical contamination (12.24% vs. 26.39%).[1] **Reference** 1. Simon N, Vasseur M, Pinturaud M, et al. Effectiveness of a Closed-System Transfer Device in Reducing Surface Contamination in a New Antineoplastic Drug-Compounding Unit: A Prospective, Controlled, Parallel Study. Ahmad A, ed. PLoS One 2016;11:e0159052. Available at: https://dx.plos.org/10.1371/journal.pone.0159052. **Recommendations**: • Revise the proposed language to: *(c) Outer gloves used for HD compounding shall be changed between each different HD preparation if a closed system transfer device (CSTD) is not used.*

CCR 1737.10. Receiving.	All HD APIs and antineoplastic HDs shall be shipped and received from the supplier in segregated impervious plastic and labeled "Hazardous Drugs" on the outside of the delivery container.	**Rationale:** • Health-systems typically do not have control over how hazardous drug active pharmaceutical ingredients (HD APIs) and antineoplastic hazardous drugs (HDs) are shipped, as this process is directly managed by the distributing companies. **Recommendations**: • Consider removing the entire section.
CCR 1737.11. Labeling, Packaging, Transport and Disposal (a):	(a) Any compounded HD preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5.	**Rationale:** • At present, health facilities, as outlined in Section 1250 of the Health and Safety Codes, are exempt from patient-centered label requirements. **Recommendations:** • To align with existing regulations, it is recommended to include exemption language in the proposed language for HSC 1250 (a) licensed facilities. This is because compounded medications administered to patients are handled by healthcare personnel authorized to administer medications and are not dispensed for outpatient use. • ***CCR 1737.9 Labeling subsection (a):*** • *Any compounded HD preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5 (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.*
CCR 1737.13 Compounding subsection (a):	(a) A disposable preparation mat shall be placed on the work surface of the C-PEC when compounding HD preparations. Where the compounding is a sterile preparation, the preparation mat shall be sterile. The preparation mat shall be changed immediately if a spill occurs, after each HD drug, and at the end of daily compounding activity.	**Rationale:** • According to USP 800, a plastic-backed preparation mat is recommended to be placed on the work surfaces of the C-PEC. This mat should be changed immediately in case of a spill and regularly during use, and it should be discarded at the end of daily compounding activity. Additionally, Closed System Transfer Devices (CSTDs) are utilized during the compounding of hazardous drugs (HD) to prevent spills and enhance worker protection. Requiring preparation mats for HD compounding could pose a patient safety concern in the event of a shortage, as institutions may be unable to

		compound HD drugs for patients. **Recommendations**: • Revise language to be consistent with USP 800 requirements: *(a) A disposable preparation mat ~~shall~~ should be placed on the work surface of the CPEC when compounding HD preparations. Where the compounding is a sterile preparation, the preparation mat shall be sterile. The preparation mat shall be changed immediately if a spill occurs, ~~after each HD drug,~~ during decontamination between different HD, and at the end of daily compounding activity.*
CCR 1737.14. Administering subsection (b)	(b) When furnishing an antineoplastic HD, a sufficient supply of gloves that meet the ASTM D-6978 standard to allow for appropriate administration, handling, and disposal of HD drugs by the patient or the patient's agent shall be provided.	**Rationale:** • In health facilities where antineoplastic HD are dispensed and administered by licensed health care professionals who are trained to handle HDs. Supplies such as ASTM D-6978 grade gloves, and HD disposal bins are readily available. **Recommendations:** • Suggest including exemption language for HSC 1250 (a) licensed facilities. This exemption would account for the fact that compounded medications are administered to patients by healthcare personnel who are trained and authorized to handle hazardous drug (HD) medications, and these medications are not dispensed for outpatient use. • *(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.*
CCR 1737.16. Spill Control	The premises shall maintain a list of properly trained and qualified personnel able to clean up an HD spill. An SOP shall outline how such a qualified person will be always available while HDs are handled.	**Rationale:** • In compliance with USP 800, personnel undergo training to handle hazardous drugs (HDs), which encompasses the procedure for cleaning up an HD spill before handling HDs. In healthcare today there are constant staff changes; maintaining an up-to-date list of all qualified personnel to attend an HD spill would be difficult. **Recommendations**: • Recommend the following revision to the following proposed regulation: *~~The premises shall maintain a list of properly trained and qualified personnel able to clean up an HD spill.~~ An SOP shall outline how such a qualified person to clean up an HD spill will be always available while HDs are handled.*
Radiopharmaceutical- Preparation, Compounding, Dispensing, and Repackaging		

CCR 1738.4 Personnel Qualifications, Training, and Hygiene subsection (c)	(c) Aseptic manipulation competency initial training and competency and ongoing training and competency documentation shall include the Primary Engineering Control (PEC's) type and PEC unique identifier used during the evaluation. Aseptic manipulation competency evaluation and requalification shall be performed using the same procedures, type of equipment, and materials used in aseptic compounding.	**Rationale:** • The current USP 825 chapter does not require the PEC unique identifier to be documented for personnel training. Requiring a PEC unique identifier only adds to the additional documentation burden. **Recommendation:** • Recommend the Board of Pharmacy to consider removing the requirement of "PEC unique identifier." **Recommendation:** • *(c) Aseptic manipulation competency initial training and competency and ongoing training and competency documentation shall include the Primary Engineering Control (PEC's) type ~~and PEC unique identifier~~ used during the evaluation. Aseptic manipulation competency evaluation and requalification shall be performed using the same procedures, type of equipment, and materials used in aseptic compounding.*
CCR 1738.5. Facilities and Engineering Controls subsection (d)	(d) Compounding shall not take place in the SRPA.	**Rationale:** • Per USP 825, for compounding sterile radiopharmaceuticals, the ISO 5 PEC must be placed in a classified area. However, non-radiopharmaceutical sterile compounds were not applicable for this restriction in USP 825. Prohibiting all compounding at SRPA would have a significant impact in the workload on health-systems that does not have a dedicated classified room for radiopharmaceuticals as they would not be able to prepare any supportive meds that has an SRPA. **Recommendation** • *(d) Radiopharmaceutical compounding shall not take place in the SRPA.*
CCR 1738.5. Facilities and Engineering Controls subsection (j)	(j) A dynamic airflow smoke pattern test must be performed initially and at least every 6 months for all classified spaces and equipment. All dynamic airflow smoke pattern tests shall be immediately retrievable during inspection. A copy of the test shall be provided to the Board's inspector if requested in accordance with the timeframes set forth in Section 4105 of the Business and Professions Code.	**Rationale:** • USP 825 requires a visual smoke study for classified spaces if there are low air returns. A dynamic airflow smoke pattern test is conducted initially and every 6 months to ensure proper PEC placement and staff maintaining unidirectional airflow (first air). **Recommendation** • Request clarification on the purpose of dynamic airflow smoke pattern test for all classified spaces. In addition, recommend the BOP be consistent with USP 825 recommendations and remove this proposed subsection.

CCR 1738.6. Microbiological Air and Surface Monitoring subsection (b)	(b) In addition to the SOPs at a minimum every 6 months, air and surface sampling results shall be identified to at least the genus level, regardless of the colony forming units (CFU) count, to trend for growth of microorganisms. Trends of microorganism growth must be identified and evaluated.	**Rationale:** • USP 825 recommends identifying sampling results on a genus level for actionable CFUs (CFUs exceeding action levels). BOP language is not consistent with USP 825 recommendations, and in contrast will require health-systems to identify every CFU count at least to the genus level regardless of if they exceeded the CFU action levels. **Recommendation:** • *(b) In addition to the SOPs at a minimum every 6 months, air and surface sampling results shall be identified to at least the genus level, ~~regardless of~~ when the colony forming units (CFU) count exceeds action level to trend for growth of microorganisms. Trends of microorganism growth must be identified and evaluated.*
CCR 1738.10. Preparation subsection (c)	(c) When preparing radiopharmaceuticals with minor deviations ("preparation with minor deviations" as defined in USP Chapter 825) an SOP shall at least define the circumstances that necessitated the deviation and all quality control testing requirements and limits. Such circumstances shall, at a minimum, include patient need or facts that support the deviation that maintains the appropriate quality and purity (radiochemical purity and radionuclidic purity) as specified in individual monographs, and other applicable parameters as clinically appropriate in the professional judgment of the pharmacist.	**Rationale:** • The proposed language is inconsistent with USP 825 recommendations, will require health-systems to incorporate patient need which may not be pertinent information. **Recommendation:** • *(c) When preparing radiopharmaceuticals with minor deviations ("preparation with minor deviations" as defined in USP Chapter 825) an SOP shall at least define the circumstances that necessitated the deviation and all quality control testing requirements and limits. Such circumstances shall, at a minimum, ~~include patient need or~~ facts that support the deviation that maintains the appropriate quality and purity (radiochemical purity and radionuclidic purity) as specified in individual monographs, and other applicable parameters as clinically appropriate in the professional judgment of the pharmacist.*
CCR 1738.14. Quality Assurance and Quality Control subsection (b)	(b) The board shall be notified in writing within 72 hours of a complaint involving a radiopharmaceutical. Recalls and adverse events must be reported to the Board and other agencies in compliance with relevant provisions of law.	**Rationale:** • A requirement of 72 hours may not provide sufficient time for health-systems to investigate and notify the necessary regulatory bodies in cases where it occurs over the holiday weekend. **Recommendation:**

		• (*b) The board shall be notified in writing within ~~72 hours~~ 3 business days of a complaint involving a radiopharmaceutical. Recalls and adverse events must be reported to the Board and other agencies in compliance with relevant provisions of law.*
CCR 1738.14. Quality Assurance and Quality Control subsection (c)	(c) In addition to subsection (b), all complaints related to a potential quality problem with a radiopharmaceutical and all reported adverse events shall be reviewed by the pharmacist-in-charge within 72 hours of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs.	**Rationale:** • A requirement of 72 hours may not provide sufficient time for health-systems to investigate and notify the necessary regulatory bodies in cases where it occurs over the holiday weekend. **Recommendation:** • *(c) In addition to subsection (b), all complaints related to a potential quality problem with a radiopharmaceutical and all reported adverse events shall be reviewed by the pharmacist-in-charge within 3 business days ~~72 hours~~ of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs.*

Dear Executive Director Sodergren and members of the California Board of Pharmacy,

On behalf of all pharmacies owned and operated by Walgreen Co. licensed in the State of California, we thank the Board for the opportunity to comment on the proposed rules. We ask the board to review our comments and concerns regarding the proposed language impacting compounding practices in the state of California.

In general, Walgreens is concerned with any language that extends, expands, duplicates, or conflicts with the current recommended standards of USP General Chapters <795>, <797>, and <800>, as it is unnecessary and overreaching. The recommended standards listed in USP's compounding chapters have been extensively discussed, debated, and challenged to ensure safe compounding practices that can be practically applied. However, the proposed regulations now require pharmacists to understand and reference two sets of standards and regulations impacting compounding practices. This duplication and additional standards will cause confusion, even for pharmacies with extensive compounding experience. As suggested throughout the proposed language, the additional requirements above and beyond the General Chapters of USP, intend to hold California pharmacies to a higher standard than established by the national authorities without evidence of additional patient safety.

We are especially concerned that the proposed language will further limit patient access to compounding services, especially to what was previously known as "simple compounds." Simple compounds are generally known as non-hazardous compounded products that do not require advanced techniques, equipment, or calculations, such as creams, lotions, gels, solutions, suspensions, ointments, or pastes. Most states are utilizing USP as the only standard to reference to ensure patient safety for compounding practices. However, some states are also taking action to carve out "simple compounding" due to the low risk to patient safety and concerns for readily available access to these products. We ask the board to review the language used for Mississippi's compounding regulations as an example of a regulatory agency seeking to balance patient safety with the practical application of compounding practices, see Appendix.

Walgreens thanks the board for reviewing our concerns and ensuring a balance is made for pharmacies in California and to reduce unnecessary regulatory burdens on the practice of pharmacy that may impact patient access to compounded products.

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Section, Subdivision	**Proposed Language**	**Recommendation / Comment**
1735.1. Introduction and Scope.(f)(1)(A)	(A) the drug product appears in an American Society of Health-System Pharmacists (ASHP) or FDA Drug Shortages Database that are in short supply at the time of compounding and at the time of dispensing, or	This language appears to come from an FDA guidance document; however, commercial products become unavailable for patients long before they appear on the referenced databases. Product shortages can be short-term or long-term. It can take months for a product to "officially" appear on the FDA shortage list, as it is self-reported by the manufacturer. However, many times products remain on short-term shortages, backorders, or limited supply causing issues for patients as they struggle to find needed medication. It is not prudent to prohibit products, such as Tamiflu, from compounding until it is on the FDA Drug Shortages Database, as it may significantly impact patient health outcomes to wait for the product's availability. Walgreens suggests the board allow the compounding of a copy or essentially a copy of a commercial product so long

		as there is a therapeutic reason, such as a documented allergy or product shortage. The pharmacy must document the commercial product shortage on the prescription or the Compounding Formulation Record, if applicable. The board should require that pharmacy teams review the American Society of Health-System Pharmacists (ASHP) or Food and Drug Administration (FDA) list of drugs in short supply but not require that this product is listed. **Recommended Language:** (A) the drug product appears in an American Society of Health-System Pharmacists (ASHP) or FDA Drug Shortages Database ~~that~~ or are in short supply at the time of compounding ~~and at the time of dispensing,~~ or
1735.1. Introduction and Scope.(f)(1)(B)	(B) the compounding produces a clinically significant difference for the medical need of an identified individual patient, as determined by: (i) the prescribing practitioner, (ii) the compounding pharmacist, and (iii) the dispensing pharmacist(s).	Pharmacists have a corresponding responsibility to ensure that prescriptions, including compounds, are completed for a legitimate medical purpose. However, as suggested, the language is overreaching and may create conflict and misunderstanding between the prescribing practitioner and the pharmacist involved in the preparation and dispensing of the product. **Recommended language:** (B) the compounding produces a clinically significant difference for the medical need of an identified individual patient, as determined appropriate by: (i) the prescribing practitioner, or (ii) the compounding pharmacist, ~~and~~ ~~(iii) the dispensing pharmacist(s).~~
1735.3. Personnel Hygiene and Garbing.(b)	(b) A gown and face mask shall be used whenever a closed system processing device is required.	We feel that this language is too specific and restrictive. Additionally, it does not address the type of mask required nor does it address the need for gloves, which, although covered in other sections, can lead to confusion. In various settings when compounding items requiring a closed system device, for example, when working in a USP General Chapter <800> compliant room, masks are not always necessary, because the hood serves as a protective piece. For non-hazardous compounds, industrial hygiene studies have been completed that eliminate the need for a mask when working with a closed system device. In USP <795> 6.1, the equipment and components used for compounding a CNPS must be suitable for the specific compounding process. Using general language as proposed, that applies to all types of compounding practices, is problematic and may cause unintended consequences. **Recommended language:** ~~A gown and face mask~~ Appropriate PPE shall be used whenever a closed system processing device is required.
1735.3. Personnel Hygiene and Garbing.(e)	(e) Non-disposable garb shall be cleaned with a germicidal cleaning agent and sanitized with 70% isopropyl alcohol before re-use.	This language is too specific and does not account for the various types of “non-disposable garb”. **Recommended language:** Non-disposable garb shall be laundered, cleaned and sanitized with methods to

		minimize environmental contamination. ~~with a germicidal cleaning agent and sanitized with 70% isopropyl alcohol before re-use~~.
1735.4. Building and Facilities.(b)	(b) Purified water, distilled water, or reverse osmosis water shall be used for rinsing equipment and utensils.	We request that this language be removed as this topic is already addressed in USP <795>. Utilizing purified water, distilled water, or reverse osmosis water for compounding products is necessary, however, it is not necessary for cleaning or rinsing the equipment and utensils used, especially for non-sterile products. **Recommended language:** ~~(b) Purified water, distilled water, or reverse osmosis water shall be used for rinsing equipment and utensils.~~
1735.5. Cleaning and Sanitizing (a) and (b)	(a) The facility's documentation of each occurrence of the cleaning and sanitizing of the compounding area shall include the identity of the person completing the cleaning and sanitizing, as well as the product name(s) of the cleaning and sanitizing agent(s) used.	This is unnecessary and overly burdensome language that does not improve patient safety. Requiring pharmacy teams to follow USP guidelines and instructions for cleaning is sufficient to ensure patient safety. **Recommended language:** (a) The facility's documentation of each occurrence of the cleaning and sanitizing of the compounding area shall include the identity of the person completing the cleaning and sanitizing, ~~as well as the product name(s) of the cleaning and sanitizing agent(s) used~~.
1735.6. Equipment and Components.(a) and (b)	(a) Any equipment used to compound a CNSP shall be used in accordance with the manufacturer's specifications. (b) Any component used to compound a CNSP shall be used and stored in accordance with all federal laws and regulations and industry standards, including the manufacturers' specifications and requirements.	We suggest this language be removed, as it is already addressed in USP <795>, in section 6.1, and if USP <795> is amended, this could lead to contradictory requirements. **Recommended language:** ~~(a) Any equipment used to compound a CNSP shall be used in accordance with the manufacturer's specifications.~~ ~~(b) Any component used to compound a CNSP shall be used and stored in accordance with all federal laws and regulations and industry standards, including the manufacturers' specifications and requirements.~~
1735.7. Master Formulation and Compounding Records. (a)(1)	(1) If a source is referenced to support the assigned beyond-use date (BUD), each source referenced shall be readily retrievable at the time of compounding and shall be maintained for three years from the date each CNSP is dispensed.	UPS monographs are widely referenced for beyond-use date assignments; however, access to these monographs is limited and cost prohibitive for many pharmacies. This requirement would further limit locations that could provide compounding services to patients. Often, if requested by the compounding pharmacist, a copy of the materials supporting the extended BUD will be provided. **Recommended language:** (1) If a source is referenced to support the assigned beyond-use date (BUD), each source referenced shall be available upon request prior to compounding ~~readily retrievable at the time of compounding~~ and shall be retrievable ~~maintained~~ for three years from the date each CNSP is dispensed.
1735.7. Master Formulation and Compounding Records. (c)	(c) A compounding record (CR) shall be a single document developed in compliance with USP Chapter 795, and includes the following additional elements:	The requirement for a "single" document for the compounding record does not account for the use of digital systems that keep the documentation electronic and readily retrievable. When paper records are utilized, pharmacies often have multiple "documents" or pages of

	(1) The date and time of compounding, which is the time when compounding of the CNSP started, and which determines when the assigned BUD starts. (2) The manufacturer, lot number, and expiration date for each component. (3) The assigned internal identification number, which shall be unique for each CR. (4) The total quantity compounded, which shall include the number of units made and the volume or weight of each unit. (5) The identity of each person performing the compounding, the person who has direct oversight of compounding, and the pharmacist verifying the final drug preparation.	information for the full compounding record, and we are concerned with the use of the language "single document" and how it will be interpreted. **Recommended language:** c) A compounding record (CR) shall be a ~~single document~~ developed in compliance with USP Chapter 795, maintained in a retrievable manner, and includes the following additional elements:
1735.10. Establishing Beyond-Use Dates.(c)	(c) If antimicrobial effectiveness testing results provided by a current FDA-registered drug establishment or outsourcing facility or published in current peer-reviewed literature sources are used, the reference in its entirety (including the raw data and testing method suitability) shall be readily retrievable in accordance with Business and Professions Code section 4081 for three years from the last date the CNSP was dispensed.	This language far exceeds what is outlined in USP <795> (see below). Rarely are pharmacies provided access to all the raw data and testing methods. Most often pharmacies only have access to the abstract of the reference and not the full reference. This will, not only invalidate many extended BUDs, but it will also force the majority of compounds containing water into a 14-day, refrigerated BUD. Ora-Plus states that it is preserved right on the label, allowing a 35-day BUD, but pharmacies do not have access to the raw data, so according to this, anything compounded with Ora-Plus is limited to 14 days in a refrigerator. Same with preserved creams, lotions, etc. **USP language**: Alternatively, the designated person(s) may rely on antimicrobial effectiveness testing results provided by an FDA-registered facility or published in peer-reviewed literature as long as the CNSP formulation (including any preservative) and container closure materials of composition are the same as those tested (unless a bracketing study is performed). When a bracketing study is performed, antimicrobial effectiveness testing may be performed on a low concentration and on a high concentration of the active ingredient in the formulation to establish preservative effectiveness across various strengths of the same formulation (e.g., bracketing). The concentration of all other ingredients (including preservatives) must fall within the bracketed range. **Recommended language:** (c) If antimicrobial effectiveness testing results provided by a current FDA-registered drug establishment or outsourcing facility or published in current peer-reviewed literature sources are used, the reference ~~in its entirety (including the raw data and testing method suitability)~~ shall be readily retrievable in accordance with Business and Professions Code section 4081 for three years from the last date the CNSP was dispensed.
1735.11. Standard Operating Procedures	(a) The facility's standard operating procedures (SOPs) for nonsterile compounding shall be followed and shall:	The use of the phrase "the methods" or "the validated processes" is ambiguous and confusing. Pharmacists should use their professional judgment to determine,

(SOPs)(a)(2)(C), (D), and (E)	(1) Comply with USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. (2) Also describe the following: (A) Methods by which the supervising pharmacist will ensure the quality of CNSPs. (B) Procedures for handling, compounding, and disposal of infectious materials. The SOPs shall also describe the facility's protocols for cleanups and spills in conformity with local health jurisdictional standards, if applicable. (C) The methods a pharmacist will use to determine and approve the ingredients and the compounding process for each preparation before compounding begins. (D) The method for complying with any other requirements specifically required to be addressed in the facility's SOPs as described in this article. (E) The validated processes for storage, shipping containers and transportation of temperature sensitive CNSPs to preserve quality standards for integrity, quality and labeled strength.	approve, and supervise the compounding process. The standard operating procedures should be reviewed and understood by the supervising pharmacist, but the method that the pharmacist utilizes to ensure these SOPs should follow the general standard of care of pharmacist supervision. The documentation of the steps taken throughout the compounding process are sufficient for ensuring that appropriate supervision and professional judgement have been used. **Recommended language:** (a) The facility's standard operating procedures (SOPs) for nonsterile compounding shall be followed and shall: (1) Comply with USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. (2) Also describe the following: ~~(A) Methods by which the supervising pharmacist will ensure the quality of CNSPs~~. (B) Procedures for handling, compounding, and disposal of infectious materials. The SOPs shall also describe the facility's protocols for cleanups and spills in conformity with local health jurisdictional standards, if applicable. ~~(C) The methods a pharmacist will use to determine and approve the ingredients and the compounding process for each preparation before compounding begins.~~ ~~(D) The method for complying with any other requirements specifically required to be addressed in the facility's SOPs as described in this article.~~
Microbiological Air and Surface Monitoring 1736.6(a)	(a) At a minimum of every 6 months, air and surface sampling results shall be identified to at least the genus level, regardless of the CFU count to trend for growth of microorganisms. Investigation must be consistent with the deviation and must include evaluation of trends.	As written, we feel that microorganism testing would be required even in the event of negative sampling results. We ask that the board provide clarity that additional testing would not be required to be performed on samples with no growth. **Recommended Language:** (a) At a minimum of every 6 months, air and surface sampling result shall be completed and if growth has been observed it shall identified to at least the genus level, regardless of the CFU count ~~to trend for growth of microorganisms~~. Investigation must be consistent with the deviation and must include evaluation of trends.
Master Formulation and Compounding Records 1736.11	In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.	Our concerns with the Master Formulation and Compounding records remain the same as with non-sterile preparations. UPS monographs are widely referenced for beyond-use date assignments, however access to these monographs are often restricted. If requested due to

	(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 that record includes the following additional elements: (1) If 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.	concerns by the compounding pharmacists, requests can be made to receive a copy of the materials supporting the extended BUD. **Recommended language:** (1) If a source is referenced to support the assigned beyond-use date (BUD), each source referenced shall be available upon request prior to compounding ~~readily retrievable at the time of compounding~~ and shall be retrievable ~~maintained~~ for three years from the date each CNSP is dispensed.
Master Formulation and Compounding Records 1736.11	(c) A compounding record (CR) shall be a single document. The document shall satisfy the requirements of USP Chapter 797, and also contain the following:	The requirement for a "single" document for the compounding record does not account for the use of digital systems that keep the documentation electronic and readily retrievable. When paper records are utilized, pharmacies often have multiple "documents" or pages of information for the full compounding record, and we are concerned with the use of the language "single document" and how it will be interpreted. **Recommended language:** c) A compounding record (CR) shall be a ~~single document~~ developed in compliance with USP Chapter 797, maintained in a retrievable manner, and includes the following additional elements:
1737.2. List of Hazardous Drugs(a)	(a) The facility's list of HDs as required by USP Chapter 800 must be reviewed and approved by the designated person and the pharmacist-in-charge (PIC), professional director of a clinic, or designated representative-in-charge, as applicable. The designated person must be a single individual approved by the pharmacist-in-charge to be responsible and accountable for the performance and operation of the facility and personnel as related to the handling of hazardous drugs. The designated person shall not exceed the scope of their issued license. When the designated person is not a pharmacist, the PIC must review all practices related to the operations of the facility that require the judgment of a pharmacist. Approval shall be documented at least every 12 months.	We suggest that the board update this language to remove the requirement of the required approval of a facility's HD drug list by the Designated Person (DP) **and** the PIC, Director of a clinic, or representative in charge. The review and approval by the designated person is sufficient. The designated person can be any of those roles listed. However, we still feel that all trained team members should review the list and have access to the list. **Recommended Language:** The facility's list of HDs as required by USP Chapter 800 must be reviewed and approved by the designated person, ~~and~~ the pharmacist-in-charge (PIC), professional director of a clinic, or designated representative-in-charge, as applicable. The designated person must be a single individual approved by the pharmacist-in-charge to be responsible and accountable for the performance and operation of the facility and personnel as related to the handling of hazardous drugs. The designated person shall not exceed the scope of their issued license. When the designated person is not a pharmacist, the PIC must review all practices related to the operations of the facility that require the judgment of a pharmacist. Approval shall be documented at least every 12 months.
1737.2. List of Hazardous Drugs.(b)	(b) If an assessment of risk approach is taken as authorized in USP Chapter 800, it shall be approved by the designated person and the pharmacist-in-charge, professional director of	We again ask that the word "and" be stricken. We suggest amending the language to say "or" to allow for multiple subject matter experts to have the ability to authorize the assessment of risk. There are many possible scenarios where there are not two individuals at a pharmacy who

	a clinic, or designated representative-in-charge, as applicable.	have the expertise to provide the approvals and often the pharmacist-in-charge does not have the expertise to provide the informed approval. **Recommended Language:** (b) If an assessment of risk approach is taken as authorized in USP Chapter 800, it shall be approved by the designated person, ~~and~~ the pharmacist-in-charge, professional director of a clinic, or designated representative-in-charge, as applicable.
1737.5. Facilities and Engineering Controls. (e)	(e) Facility room pressure monitoring equipment shall be placed consistent with CETA Guidelines CAG-003:2022. SOPs shall address corrective and remedial actions in the event of pressure differentials and air changes per hour excursions.	This proposed requirement exceeds the standards listed in USP <800> 5.3. Additionally, CAG-003 specifically only applies to the Certification of Sterile Compounding Facilities. This reg applies it broadly to all healthcare settings handling hazardous materials. **Recommended Language:** ~~(e) Facility room pressure monitoring equipment shall be placed consistent with CETA Guidelines CAG-003:2022. SOPs shall address corrective and remedial actions in the event of pressure differentials and air changes per hour excursions.~~
1737.6. Environmental Quality and Control.(a) and (b)	(a) The SOPs of a premises where HDs are handled shall address environmental wipe sampling for HD surface residue, its frequency, areas of testing, levels of measurable contamination, and actions when those levels are exceeded. (b) When any actionable level of contamination is found, at a minimum the following shall occur as described in the SOPs: (1) Reevaluate work practices; (2) Reevaluate the appropriateness of deactivation, decontamination, and cleaning agents; (3) Re-train personnel on deactivation, decontamination, and cleaning; and (4) Re-train personnel on donning and doffing appropriate personal protective equipment (PPE).	While USP addresses the topic of wipe sampling, it specifically highlights that no supporting studies demonstrate the effectiveness of a specific number or size of wipe samples in determining the level of HD contamination. Additionally, there are currently no certifying agencies for vendors of wipe sample kits. USP also states that there is no standard for acceptable limits for HD surface contamination or standards with which to comply. The lack of standardization and guidance for these processes is problematic and should be addressed before this language is included. We suggest the board consider only requiring wipe sampling for entities that work with antineoplastic drugs. A comprehensive safe-handling program for antineoplastic drugs may utilize wipe sampling as a tool to evaluate environmental contamination, and assurances that OHSA standards are followed must always be required. **Recommended language:** (a) The SOPs of a premises where HDs are handled ~~shall~~ may address environmental wipe sampling for HD surface residue, its frequency, areas of testing, levels of measurable contamination, and actions when those levels are exceeded. (b) When any ~~actionable~~ measurable level of contamination is found, at a minimum the following shall occur as described in the SOPs: (1) Reevaluate work practices; (2) Reevaluate the appropriateness of deactivation, decontamination, and cleaning agents;

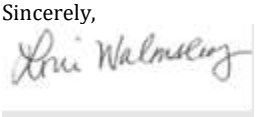
		(3) Re-train personnel on deactivation, decontamination, and cleaning; and (4) Re-train personnel on donning and doffing appropriate personal protective equipment (PPE).
1737.7. Personal Protective Equipment (PPE)(b) and (c)	(b) The outer pair of gloves that meets the ASTM D-6978 standard chemotherapy gloves shall be changed every 30 minutes during HD compounding unless otherwise recommended by the manufacturer's documentation. Documentation from the manufacturer shall be readily retrievable. For sterile HD compounding, both pairs of gloves labeled to meet the ASTM D-6978 standard shall be sterile. (c) Outer gloves used for HD compounding shall be changed between each different HD preparation.	Walgreens requests clarity on what defines "different". For example, if a pharmacist is compounding back-to-back progesterone creams, are those considered different and would require a change in gloves? If so, then c and b in combination will create confusion. We suggest that the board adds language to clarify that their intent is for gloves to be changed when active ingredients are different between compounds, but not necessarily between every compound made. **Recommended language:** (c) Outer gloves used for HD compounding shall be changed between each different HD API preparation.
1737.7. Personal Protective Equipment (PPE)(d)	(d) PPE shall be removed to avoid transferring contamination to skin, the environment, and other surfaces. PPE worn during compounding shall be disposed of in the proper waste container before leaving the C-SEC. SOPs shall detail the donning and doffing of PPE and where it takes place in the C-SEC.	To reduce confusion in this proposed rule, we ask the board to update the language as suggested. **Recommended language:** (d) PPE removal process shall be done in a manner ~~removed~~ to avoid transferring contamination to skin, the environment, and other surfaces. PPE worn during compounding shall be disposed of in the proper waste container before leaving the C-SEC. SOPs shall detail the donning and doffing of PPE and where it takes place in the C-SEC.
1737.10. Receiving.	In addition to the standards in USP Chapter 800, Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article. All HD APIs and antineoplastic HDs shall be shipped and received from the supplier in segregated impervious plastic and labeled "Hazardous Drugs" on the outside of the delivery container.	Pharmacies do not have control over how products are shipped therefore this proposed language is overreaching and should be removed and included in language for the manufacturers. We recommend removing this article. **Recommended language:** ~~In addition to the standards in USP Chapter 800, Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article. All HD APIs and antineoplastic HDs shall be shipped and received from the supplier in segregated impervious plastic and labeled "Hazardous Drugs" on the outside of the delivery container.~~
1737.11. Labeling, Packaging, Transport and Disposal. (b)	In addition to the standards in USP Chapter 800, Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article. (b) All HD APIs and antineoplastic HDs shall be transported from the facility in an impervious plastic container and labeled as HD on the outside of the container.	We ask for clarity on this language, does the ointment jar or capsule vial meet this requirement, or does the board intend to require the dispensing container be in a second, impervious plastic container? **Recommended language:** (b) All HD APIs and antineoplastic HDs shall be packaged and transported from the facility in an impervious plastic container and labeled as HD on the outside of the container.

1737.13. Compounding.	In addition to the standards in USP Chapter 800, Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article. (a) A disposable preparation mat shall be placed on the work surface of the C-PEC when compounding HD preparations. Where the compounding is a sterile preparation, the preparation mat shall be sterile. The preparation mat shall be changed immediately if a spill occurs, after each HD drug, and at the end of daily compounding activity.	The requirement to utilize a plastic-backed preparation mat goes above and beyond USP standards. Many compounding entities already utilize a surface that is smooth, impervious, and non-shedding so they can be cleaned, disinfected, and decontaminated appropriately. Introducing additional materials or tools into the compounding environment also increases the risk of contamination and microorganisms. UPS <800> has specific cleaning directions that make this requirement superfluous. USP also states that you "should", not must, use a mat, and if implemented it may drive the cost of filling these compounded products up significantly. **Recommended language:** In addition to the standards in USP Chapter 800, Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article. (a) A disposable preparation mat ~~shall~~ may be placed on the work surface of the C-PEC when compounding HD preparations. Where the compounding is a sterile preparation, the preparation mat shall be sterile. The preparation mat shall be changed immediately if a spill occurs, after each HD drug, and at the end of daily compounding activity.
1737.14. Administering.	(a) When dispensing an HD to a patient or patient's agent for administration, the pharmacy shall: (1) Place the HD in a decontaminated impervious plastic container with an HD label on the outside of the container; and	We again ask for clarity on this language, does the ointment jar or capsule vial meet this requirement? Or does the board intend to have the dispensing container must be in a second, impervious plastic container? Is the same materials used for shipping the products from the manufacturer to the store sufficient?
1737.14. Administering.	(2) For an antineoplastic HD, attach and prime all tubing and attach a CSTD when appropriate. (b) When furnishing an antineoplastic HD, a sufficient supply of gloves that meet the ASTM D-6978 standard to allow for appropriate administration, handling, and disposal of HD drugs by the patient or the patient's agent shall be provided.	Mandating the supply of gloves for antineoplastic HD compounded products is overreaching. However, we do feel that the dispensing pharmacy and the administering facility should ensure that the appropriate gloves are available for administration. **Proposed language:** (b) When furnishing an antineoplastic HD, the dispensing pharmacy must ensure a sufficient supply of gloves that meet the ASTM D-6978 standard to allow for appropriate administration, handling, and disposal of HD drugs by the patient or the patient's agent is available ~~shall be provided~~.
1737.15. Deactivation, Decontamination, Cleaning, and Disinfecting.	(c) SOPs shall include procedures for deactivation and decontamination of the HD preparation container closure and shall be approved by the pharmacist-in-charge or professional director of a clinic, as applicable.	The designated person of the organization should have the authority to approve the SOPs. **Recommended language:** (c) SOPs shall include procedures for deactivation and decontamination of the HD preparation container closure and shall be approved

		by the designated person, pharmacist-in-charge or professional director of a clinic, as applicable
1737.16. Spill Control.	The premises shall maintain a list of properly trained and qualified personnel able to clean up an HD spill. An SOP shall outline how such a qualified person will be available at all times while HDs are handled.	Spill cleaning should be included in required policies, procedures, and training at pharmacies that handle HD products. We feel that there should be assurances that the individuals who may participate in HD spill clean-up are appropriately trained, however, a separate list of the trained and qualified personnel is not always necessary. **Recommended language:** Unless all pharmacy staff are trained in HD spill control, the premises shall maintain a list of properly trained and qualified personnel able to clean up an HD spill. An SOP shall outline how such a qualified person will be available at all times while HDs are handled.

Once again, Walgreens thanks the board for their attention to our concerns and work to strike a balance when creating regulations that impact the practice of compounding and ensure that readily available access to compounding services for patients in the state of California continues.

Sincerely,



Lorri Walmsley, RPh, FAzPA

Appendix:

TITLE 30: PROFESSIONS AND OCCUPATIONS

PART 3001: MISSISSIPPI PHARMACY PRACTICE REGULATIONS

ARTICLE XXXI COMPOUNDING GUIDELINES

Every pharmacy permitted by the Mississippi Board of Pharmacy engaged in the compounding of pharmaceuticals shall comply with USP 797 and 795 standards. The designated USP representative must be a pharmacist licensed in the State of Mississippi.

1. GENERAL PROVISIONS

A. Prior to engaging in the compounding of pharmaceuticals, a pharmacy shall obtain a compounding certificate from the Mississippi Board of Pharmacy.

i. To obtain a compounding certificate, an applicant must complete a compounding certificate application.

ii. A compounding certificate will expire when the pharmacy permit expires and can be renewed at the time a pharmacy permit is renewed.

iii. Compounding, without obtaining the compounding certificate, shall be grounds for disciplinary action.

iv. Every pharmacy that engages in compounding shall submit a compounding statistical report to the Board on or about January 31st of each year on a form prescribed by the Board.

v. Failure to submit the report as required by this regulation shall be grounds for disciplinary action.

vi. A compounding certificate shall become inactive if a pharmacy fails to compound any prescriptions in a calendar year. A pharmacy may not compound prescriptions with an inactive compounding certificate. A pharmacy may petition the Board to activate a compounding certificate that is inactive.

vii. Any pharmacy with an active compounding certificate is subject to a compounding inspection by the Board.

B. Based on the existence of a pharmacist/patient/practitioner relationship and the presentation of a valid prescription, or in anticipation of prescription medication orders based on routine, regularly observed prescribing patterns, a pharmacy may compound, for an individual patient, medications that are not commercially available in the marketplace. Compounding and manufacturing, as defined within the regulations, are not permitted in the same facility. A pharmacy may not Compound a Drug that appears on the FDA List of Drugs withdrawn or removed from the market for Safety Reasons or on the FDA List of Drug products that present demonstrable difficulties in compounding.

C. For the purpose of this Article, the combining of commercially manufactured, readyto-use products shall be exempt from USP 795 compounding standards under the following conditions:

i. No more than four (4) commercially manufactured ready-to-use products (that have not been manipulated) are used;

ii. Compounding is not done in anticipation of medication orders;

iii. Must follow USP 795 beyond use dates (BUDs);

iv. A valid prescription shall serve as the compounding record;

2

v. The prescription label shall comply with the labeling requirements as set forth in Article XIV of these regulations and also include:

(1) Name of Preparation;

(2) Strength and concentration of each component;

(3) Beyond Use Date;

(4) Special storage requirements, if applicable; and

(5) Cautionary auxiliary labels, if applicable.

D. A pharmacy may compound drugs prior to receiving a valid prescription based on a history of receiving valid prescriptions that have been generated solely within an established pharmacist/patient/practitioner relationship, and provided that they maintain the prescriptions on file for all such products compounded at the pharmacy as required by the Mississippi Board of Pharmacy.

E. Pharmacies shall not offer compounded human drug products to practitioners or to other pharmacies for resale or dispensing. However, patient specific medications may be prepared on behalf of a pharmacy permitted as an Institutional I, Hospital, 3.1 pharmacy for an inpatient at that facility. Pharmacies may compound patient specific medications for office administration by a practitioner.

F. Compounding pharmacies may advertise or otherwise promote the fact that they provide prescription compounding services (e.g., chemicals, devices and information when requested); however, they shall not solicit business by promoting to compound specific drug products (e.g., like a manufacturer).

G. The compounding of inordinate amounts of drugs in anticipation of receiving prescriptions without any historical basis or the distribution of inordinate amounts of compounded products without a patient/practitioner/pharmacist relationship is considered manufacturing.

2. RECORDS

A. The pharmacy shall keep records of all compounded products as required by the Mississippi Board of Pharmacy. Such records shall be readily available for authorized inspection during the retention period at the establishment. These records shall be subject to duplication by photocopying or other means of reproduction as part of any such inspection.

B. Drug Orders: The pharmacist must receive a written, electronic or verbal order from an authorized prescriber before dispensing any compounded product.

i. If the drug order is for an inpatient at an institutional facility, a copy of the patient's medication order may serve as an order for the preparation and dispensing of the compounded product. This and the medication administration record may be maintained as the permanent record in medical records at the

facility.

ii. If the drug order is for an outpatient, the order must be in the form of a prescription document or a patient medication order sheet which contains, at a minimum, the following:

(1) Patient name;

(2) Patient address;

(3) name of medication and strength;

3

(4) Directions for use;

(5) Date;

(6) Prescriber's name;

(7) Physician's address and Drug Enforcement Administration registration number, if applicable;

(8) Refill instructions.

C. Prescriptions for compounded products shall be filed in accordance with the prescription recordkeeping provisions of these regulations. Patient medication order sheets used as authorization for the dispensing of drugs shall be filed in an easily retrievable manner.

3. COMPOUNDING WHEN COMMERCIAL PRODUCTS ARE NOT AVAILABLE

A. A pharmacy may prepare a copy of a commercial product when that commercial product is not available as evidenced by either of the following:

i. Products that appear on a website maintained by the federal Food and Drug Administration (FDA) and/or the American Society of Health Systems Pharmacists (ASHP); or

ii. Products temporarily unavailable from the manufacturer, as documented by invoice or other communication from the distributor or manufacturer.

4. COMPOUNDING FOR VETERINARY USE

A. All compounding for non-human medications must follow USP 795/797 compounding standards.

B. A pharmacy may compound a preparation intended for administration to an animal patient:

i. Pursuant to a patient specific prescription; or

ii. Pursuant to a non-patient specific order from a veterinarian.

C. The label for non-patient specific compounded preparations shall contain, at a minimum, the following:

i. Pharmacy's name, address and telephone number;

ii. Veterinarian's name;

iii. Name of preparation;

iv. Strength and concentration;

v. Lot number;

vi. Beyond use date (BUD);

vii. Special storage requirements, if applicable;

viii. Name or initials of the pharmacist responsible for final check of the preparation.

CSPS
CALIFORNIA SOCIETY of PLASTIC SURGEONS

June 3, 2024

California State Board of Pharmacy
2720 Gateway Oaks Drive
Sacramento, CA 95833

re: Proposed Article 4.6 Sterile Compounding

Dear Members of the California State Board of Pharmacy,

The California Society of Plastic Surgeons (CSPS) appreciates the opportunity to provide comments on the proposed regulations on compounded drug products. Plastic surgeons provide highly skilled surgical services that improve both the functional capacity and quality of life of patients. These services include the treatment of congenital deformities, burn injuries, traumatic injuries, hand conditions, and cancer.

We are concerned the proposed regulations will not allow physicians to buffer lidocaine in-office. As you may know, buffered lidocaine is created when sodium bicarbonate is added to lidocaine with or without epinephrine using aseptic technique to neutralize the pH of the preparation. The buffering of lidocaine significantly decreases the subjective pain of the injection and increases the onset of the local anesthesia for the patient. After the anesthetic takes effect, a surgeon can perform procedures in the least-expensive place of service – the office.

In November 2018, many organizations met with the USP, U.S. Food and Drug Administration, and Centers for Disease Control and Prevention to discuss concerns regarding buffered lidocaine. Buffered lidocaine is routinely prepared in syringes in advance of patient visits with a beyond-use date (BUD) of at least 12 hours to facilitate patient access and patient comfort.

The parties agreed that carving out buffering lidocaine from USP Chapter 797 requirements and developing a separate monograph to enumerate an approved process for buffering lidocaine would meet the agencies' safety concerns, maintain patient comfort and safety, reduce physicians' administrative burden, and ensure continued access.

USP is in the process of finalizing the monograph, which will include the required evidence of safe aseptic practices sufficient to exempt in-office preparation of buffered lidocaine from the onerous requirements that limit dermatologists from providing their patients with necessary treatment.

Because the Board's proposal does not reflect the testing conducted as part of the monograph process, we urge you to refrain from adopting a regulation that would prohibit physician in-office preparation of compounding medications as adopting any regulations at this juncture will critically impact direct patient care. In fact, the Ohio Board of Pharmacy amended its immediate use regulations allowing physicians to prepare buffered lidocaine 12 hours prior to administration in response to evidence provided by our organizations and other stakeholders.

Specifically, we are seeking language to allow a beyond use date of at least twelve-hours and repeal language in Article 4.6 requiring patient-specific prescriptions. This would enable buffered lidocaine to be prepared in advance of patient visits for that day, which ensures valuable time is not taken away from patient interaction.

We appreciate your consideration of our requested changes.

Respectfully,

Gordon K. Lee, MD
President, California Society of Plastic Surgery

June 2, 2024

California State Board of Pharmacy
2720 Gateway Oaks Drive
Sacramento, CA 95833

re: Proposed Article 4.6 Sterile Compounding

Dear Members of the California State Board of Pharmacy,

On behalf of the undersigned organizations representing more than 17,000 dermatologists, we urge the California State Board of Pharmacy **("**Board") to consider our work with the United States Pharmacopeial Convention ("USP") and federal policymakers as outlined below and amend the proposal to preserve a physician's ability to prepare medications in physician offices.

We are seeking language to allow a beyond use date of at least twelve-hours and repeal language in Article 4.6 requiring patient-specific prescriptions. This would enable buffered lidocaine to be prepared in advance of patient visits for that day, which ensures valuable time is not taken away from patient interaction. While we believe the regulation of physician in-office compounding should remain under the purview of the state medical board, it is essential that policymakers work collaboratively to ensure timely access to safe and effective medications for patients.

One in four Americans suffers from a skin disease. Dermatologists diagnose and treat more than 3,000 diseases, including skin cancer, psoriasis, immunologic diseases, and many genetic disorders. As dermatologists on the front lines fighting skin cancer and treating numerous skin diseases, we are advocating for our patients to have access to compounded medications, especially in-office preparations.

In November 2018, many of the undersigned organizations met with the USP, U.S. Food and Drug Administration, and Centers for Disease Control and Prevention to discuss our concerns regarding buffered lidocaine. Buffered lidocaine is routinely prepared in syringes in advance of patient visits with a beyond-use date (BUD) of at least 12 hours to facilitate patient access and patient comfort.

The parties agreed that carving out buffering lidocaine from USP Chapter 797 requirements and developing a separate monograph to enumerate an approved process for buffering lidocaine would meet the agencies' safety concerns, maintain patient comfort and safety, reduce physicians' administrative burden, and ensure continued access.

We have successfully completed a number of required tests through an independent laboratory, which include:

- o <51> Antimicrobial Effectiveness
- o <1207> for Package integrity evaluation:
- o Sterility Tests <71>
- o Bacterial Endotoxin Tests <85>
- o Particulate Matter in Injections <788>
- o pH <791>
- o Stability study time points at T=0, T=6 hours, T=12 hours, T=24 hours, T=3 days, T=7 days at both controlled room temperature and in a refrigerator

USP is in the process of finalizing the monograph, which will include the required evidence of safe aseptic practices sufficient to exempt in-office preparation of buffered lidocaine from the onerous requirements that limit dermatologists from providing their patients with necessary treatment.

Because the Board's proposal does not reflect the testing conducted as part of the monograph process, we urge you to refrain from adopting a regulation that would prohibit physician in-office preparation of compounding medications as adopting any regulations at this juncture will critically impact direct patient care. In fact, the Ohio Board of Pharmacy amended its immediate use regulations allowing physicians to prepare buffered lidocaine 12 hours prior to administration in response to evidence provided by our organizations and other stakeholders.

Thank you in advance for the opportunity to work together to ensure dermatology patients have access to treatment with an in-office prepared product in a timely manner. Should you have any questions, please do not hesitate to contact Lisa Albany, director of state policy for the American Academy of Dermatology Association at (202) 712- 2615 or lalbany@aad.org.

Sincerely,

American Academy of Dermatology Association
American College of Mohs Surgery
American Society for Dermatologic Surgery Association
American Society for Mohs Surgery
California Society of Dermatology & Dermatologic Surgery

Institution/Contact Name	• American Academy of Dermatology Association • American College of Mohs Surgery • American Society for Dermatologic Surgery Association • American Society for Mohs Surgery •	Lisa Albany Director, State Policy AADA 202.712.2615 lalbany@aad.org
Section, Subdivision	**Proposed Language**	**Recommendation / Comment**
Title 16 Proposed Article 4.6, Sterile Compounding		We are seeking language to allow a beyond use date of at least twelve-hours and repeal language in Article 4.6 requiring patient-specific prescriptions. Please see attached comment letter for our rationale.

June 3, 2024

California State Board of Pharmacy
2720 Gateway Oaks Drive
Sacramento, CA 95833

re: Proposed Article 4.6 Sterile Compounding

Dear Members of the California State Board of Pharmacy,

On behalf of the undersigned organizations representing more than 17,000 dermatologists, we urge the California State Board of Pharmacy **("**Board") to consider our work with the United States Pharmacopeial Convention ("USP") and federal policymakers as outlined below and amend the proposal to preserve a physician's ability to prepare medications in physician offices.

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- o Stability study time points at T=0, T=6 hours, T=12 hours, T=24 hours, T=3 days, T=7 days at both controlled room temperature and in a refrigerator

USP is in the process of finalizing the monograph, which will include the required evidence of safe aseptic practices sufficient to exempt in-office preparation of buffered lidocaine from the onerous requirements that limit dermatologists from providing their patients with necessary treatment.

Because the Board's proposal does not reflect the testing conducted as part of the monograph process, we urge you to refrain from adopting a regulation that would prohibit physician in-office preparation of compounding medications as adopting any regulations at this juncture will critically impact direct patient care. In fact, the Ohio Board of Pharmacy amended its immediate use regulations allowing physicians to prepare buffered lidocaine 12 hours prior to administration in response to evidence provided by our organizations and other stakeholders.

Thank you in advance for the opportunity to work together to ensure dermatology patients have access to treatment with an in-office prepared product in a timely manner. Should you have any questions, please do not hesitate to contact Lisa Albany, director of state policy for the American Academy of Dermatology Association at (202) 712- 2615 or lalbany@aad.org.

Sincerely,

American Academy of Dermatology Association
American College of Mohs Surgery
American Society for Dermatologic Surgery Association
American Society for Mohs Surgery

Martinez, Lori@DCA

From: Lee, Bonnie <bonniel6@hs.uci.edu>
Sent: Thursday, May 30, 2024 2:45 PM
To: PharmacyRulemaking@DCA
Subject: Preserve Physician In-Office Preparation of Compounded Medications

To whom it may concern,

As a board-certified dermatologist practicing in California, I urge the California State Board of Pharmacy ("Board") to preserve a physician's ability to prepare medications in physician offices. The use of compounded products allows us to tailor our treatments to the unique needs of our patients in a timely manner, resulting in better outcomes. The proposal will disrupt patient access to medications that have been safely prepared by dermatologists in their offices for years, resulting in needless pain and suffering.

We are seeking amendments to proposed Article 4.6 governing sterile compounding. We urge the Board to allow a beyond use date of at least twelve hours and repeal language in Article 4.6 requiring patient-specific prescriptions. This would enable buffered lidocaine to be prepared in advance of patient visits for that day, which ensures valuable time is not taken away from patient interaction. While we believe the regulation of physician in-office compounding should remain under the purview of the state medical board, it is essential that policymakers work collaboratively to ensure timely access to safe and effective medications for patients.

Thank you for the opportunity to work together to ensure dermatology patients have access to treatment with a compounded medication in a timely manner.

Bonnie Lee, MD| Associate Professor
Departments of Dermatology, and Pathology and Laboratory Services
Director, Dermatology Residency Program
Co-Director of Dermatopathology
University of California, Irvine
101 The City Drive South Building 52, Orange, CA 92868
Tel: 714-456-5556 | Fax: 714-456-8859
bonnie.lee@uci.edu

Martinez, Lori@DCA

From: Bill Resh <billresh@hotmail.com>
Sent: Wednesday, May 29, 2024 3:01 PM
To: PharmacyRulemaking@DCA
Subject: Preserve a physician's ability to prepare medications in physician offices

As a board-certified dermatologist practicing in California, I urge the California State Board of Pharmacy ("Board") to preserve a physician's ability to prepare medications in physician offices. The use of compounded products allows us to tailor our treatments to the unique needs of our patients in a timely manner, resulting in better outcomes. The proposal will disrupt patient access to medications that have been safely prepared by dermatologists in their offices for decades, resulting in needless pain and suffering.

We are seeking amendments to proposed Article 4.6 governing sterile compounding. We urge the Board to allow a beyond use date of at least twelve hours and repeal language in Article 4.6 requiring patient-specific prescriptions. This would enable buffered lidocaine to be prepared in advance of patient visits for that day, which ensures valuable time is not taken away from patient interaction. While we believe the regulation of physician in-office compounding should remain under the purview of the state medical board, it is essential that policymakers work collaboratively to ensure timely access to safe and effective medications for patients. Thank you for the opportunity to work together to ensure dermatology patients have access to treatment with a compounded medication in a timely manner.

Martinez, Lori@DCA

From: Brooke Resh Sateesh, M.D. <brs@sdfamilyderm.com>
Sent: Wednesday, May 29, 2024 4:32 PM
To: PharmacyRulemaking@DCA

As a board-certified dermatologist practicing in California, I urge the California State Board of Pharmacy ("Board") to preserve a physician's ability to prepare medications in physician offices. The use of compounded products allows us to tailor our treatments to the unique needs of our patients in a timely manner, resulting in better outcomes. The proposal will disrupt patient access to medications that have been safely prepared by dermatologists in their offices for years, resulting in needless pain and suffering.

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These limitations would significantly impact the ability to see as many patients, and with a huge shortage of Dermatologists seeing medical dermatology patients this would adversely impact patient care and access.

Thank you for the opportunity to work together to ensure dermatology patients have access to treatment with a compounded medication in a timely manner.

Sincerely,

--
Brooke Resh Sateesh, M.D.

SAN DIEGO FAMILY DERMATOLOGY
www.sdfamilyderm.com
Phone: (619) 267-8303 (619) 579-5115
Text Only: (855) 487-1609

655 Euclid Avenue, Suite 304, National City, CA 91950
222 West Madison Avenue, El Cajon, CA 92020
15725 Pomerado Road, Suite 102, Poway, CA 92064

**Please note we do not reply to medical questions through email. If you have a medical/medication issues, please call the office. If you need a same day/urgent appointment, please call the office. Thank you!

Martinez, Lori@DCA

From: Craig A. Kraffert, MD <ck@ckderm.com>
Sent: Wednesday, May 29, 2024 4:14 PM
To: PharmacyRulemaking@DCA
Subject: Dermatology Care = Patient Access = Bufferred Lidocaine

As a board-certified dermatologist practicing in California, I urge the California State Board of Pharmacy ("Board") to preserve a physician's ability to prepare medications in physician offices. The use of compounded products allows us to tailor our treatments to the unique needs of our patients in a timely manner, resulting in better outcomes. The proposal will disrupt patient access to medications that have been safely prepared by dermatologists in their offices for years, resulting in needless pain and suffering.

We are seeking amendments to proposed Article 4.6 governing sterile compounding. We urge the Board to allow a beyond use date of at least twelve hours and repeal language in Article 4.6 requiring patient-specific prescriptions. This would enable buffered lidocaine to be prepared in advance of patient visits for that day, which ensures valuable time is not taken away from patient interaction. While we believe the regulation of physician in-office compounding should remain under the purview of the state medical board, it is essential that policymakers work collaboratively to ensure timely access to safe and effective medications for patients.

Thank you for the opportunity to work together to ensure dermatology patients have access to treatment with a compounded medication in a timely manner.

Respectfully,

Craig A. Kraffert, MD, FAAD
President, CK Derm
Redding, Chico, Humboldt, Mt. Shasta

Martinez, Lori@DCA

From: Curtis Raskin <curtisraskin@gmail.com>
Sent: Wednesday, May 29, 2024 5:46 PM
To: PharmacyRulemaking@DCA
Subject: Preserve Physician In-Office Preparation of Compounded Medications

As a board-certified dermatologist practicing in California, I urge the California State Board of Pharmacy ("Board") to preserve a physician's ability to prepare medications in physician offices. The use of compounded products allows us to tailor our treatments to the unique needs of our patients in a timely manner, resulting in better outcomes. The proposal will disrupt patient access to medications that have been safely prepared by dermatologists in their offices for years, resulting in needless pain and suffering.

We are seeking amendments to proposed Article 4.6 governing sterile compounding. We urge the Board to allow a beyond use date of at least twelve hours and repeal language in Article 4.6 requiring patient-specific prescriptions. This would enable buffered lidocaine to be prepared in advance of patient visits for that day, which ensures valuable time is not taken away from patient interaction. While we believe the regulation of physician in-office compounding should remain under the purview of the state medical board, it is essential that policymakers work collaboratively to ensure timely access to safe and effective medications for patients.

Requiring dermatologists to administer buffered lidocaine prior to 4 hours of preparation pursuant to a patient specific prescription would impact patient access.

Thank you for the opportunity to work together to ensure dermatology patients have access to treatment with a compounded medication in a timely manner.

Sincerely,

Curtis Raskin, MD, PhD, FAAD

Martinez, Lori@DCA

From: Chung-Yin S Chan <Chung-Yin.S.Chan@kp.org>
Sent: Wednesday, May 29, 2024 3:17 PM
To: PharmacyRulemaking@DCA
Subject: Preserve Physician In-Office Preparation of Compounded Medications

As a board-certified dermatologist and micrographic dermatologic surgeon practicing in California, I urge the California State Board of Pharmacy ("Board") to preserve a physician's ability to prepare medications in physician offices. The use of compounded products allows us to tailor our treatments to the unique needs of our patients in a timely manner, resulting in better outcomes. The proposal will disrupt patient access to medications that have been safely prepared by dermatologists in their offices for years, resulting in needless pain and suffering.

We are seeking amendments to proposed Article 4.6 governing sterile compounding. We urge the Board to allow a beyond use date of at least twelve hours and repeal language in Article 4.6 requiring patient-specific prescriptions. This would enable buffered lidocaine to be prepared in advance of patient visits for that day, which ensures valuable time is not taken away from patient interaction. While we believe the regulation of physician in-office compounding should remain under the purview of the state medical board, it is essential that policymakers work collaboratively to ensure timely access to safe and effective medications for patients.

Requiring dermatologists to administer buffered lidocaine prior to 4 hours of preparation pursuant to a patient specific prescription would impact patient access. On a daily basis, my patients ask why shots hurt less than others, and it is precisely because I am able to offer buffered lidocaine. Wouldn't you want the option to have a less painful procedure when you see your doctor?

Thank you for the opportunity to work together to ensure dermatology patients have access to treatment with a compounded medication in a timely manner.

Chung-Yin Stanley Chan, MD
Department of Mohs Surgery, ELG
916-478-5635
Chung-Yin.S.Chan@kp.org

Martinez, Lori@DCA

From: derrick adams <sawbonesadams@sbcglobal.net>
Sent: Wednesday, May 29, 2024 8:02 PM
To: PharmacyRulemaking@DCA
Subject: 797 regulation opposition

Dear Board Members,

Please do not limit in-office compounding of lidocaine and bicarbonate. We have been doing this safely for generations now. There is no need to further create obstacles and costs for practices, especially private practices.

Repealing the "patient specific prescription" is important as well. If 'batching' lidocaine/bicarb is such a public hazard, where are the bodies? This is an overreach by the Board and will result in McKesson and other wholesalers raising their prices to provide 'safe and approved' compounded medication that we can make for free. Practices are being pressured on so many fronts right now that the private medical practice is an endangered species. Please do not make life on us any more difficult.

Again, if this is such an issue, why has the Board allowed this go on for generations (no exaggeration here)? Practices will not order buffered lidocaine under this new rule and patients, especially pediatric patients, will be subjected to more burning and pain with their injections.

I humbly ask that the Board reconsider this idea and repeal the language.

With Appreciation,

Derrick

Derrick Adams, DO, FAOCD, FAAD
Board Certified Dermatologist
Private Practice

Martinez, Lori@DCA

From: ddicesare orangecoastdermatology.com <ddicesare@orangecoastdermatology.com>
Sent: Wednesday, May 29, 2024 3:00 PM
To: PharmacyRulemaking@DCA
Subject: In Office compounding.

As a board-certified dermatologist practicing in California, I urge the California State Board of Pharmacy ("Board") to preserve a physician's ability to prepare medications in physician offices. The use of compounded products allows us to tailor our treatments to the unique needs of our patients in a timely manner, resulting in better outcomes. The proposal will disrupt patient access to medications that have been safely prepared by dermatologists in their offices for years, resulting in needless pain and suffering.

We are seeking amendments to proposed Article 4.6 governing sterile compounding. We urge the Board to allow a beyond use date of at least twelve hours and repeal language in Article 4.6 requiring patient-specific prescriptions. This would enable buffered lidocaine to be prepared in advance of patient visits for that day, which ensures valuable time is not taken away from patient interaction. While we believe the regulation of physician in-office compounding should remain under the purview of the state medical board, it is essential that policymakers work collaboratively to ensure timely access to safe and effective medications for patients.

Thank you for the opportunity to work together to ensure dermatology patients have access to treatment with a compounded medication in a timely manner.

Daniel A. Di Cesare, M.D.

Martinez, Lori@DCA

From: Daniel Eisen <deisen123@gmail.com>

Sent: Friday, May 31, 2024 12:15 PM
To: PharmacyRulemaking@DCA
Subject: Preserve Physician In-Office Preparation of Compounded Medications

As a board-certified dermatologist practicing in California, I urge the California State Board of Pharmacy ("Board") to preserve a physician's ability to prepare medications in physician offices. The use of compounded products allows us to tailor our treatments to the unique needs of our patients in a timely manner, resulting in better outcomes. The proposal will disrupt patient access to medications that have been safely prepared by dermatologists in their offices for years, resulting in needless pain and suffering.

We are seeking amendments to proposed Article 4.6 governing sterile compounding. We urge the Board to allow a beyond use date of at least twelve hours and repeal language in Article 4.6 requiring patient-specific prescriptions. This would enable buffered lidocaine to be prepared in advance of patient visits for that day, which ensures valuable time is not taken away from patient interaction. While we believe the regulation of physician in-office compounding should remain under the purview of the state medical board, it is essential that policymakers work collaboratively to ensure timely access to safe and effective medications for patients.

Thank you for the opportunity to work together to ensure dermatology patients have access to treatment with a compounded medication in a timely manner.

Best regards,

Daniel Eisen, MD
Professor Clinical Dermatology
University of California Davis

Martinez, Lori@DCA

From: Hutchison, Dana <dmhutchi@hs.uci.edu>
Sent: Thursday, May 30, 2024 7:54 AM
To: PharmacyRulemaking@DCA
Subject: Proposed Article 4.6

As a board-certified dermatologist practicing in California, I urge the California State Board of Pharmacy ("Board") to preserve a physician's ability to prepare medications in physician offices. The use of compounded products allows us to tailor our treatments to the unique needs of our patients in a timely manner, resulting in better outcomes. The proposal will disrupt patient access to medications that have been safely prepared by dermatologists in their offices for years, resulting in needless pain and suffering.

We are seeking amendments to proposed Article 4.6 governing sterile compounding. We urge the Board to allow a beyond use date of at least twelve hours and repeal language in Article 4.6 requiring patient-specific prescriptions. This would enable buffered lidocaine to be prepared in advance of patient visits for that day, which ensures valuable time is not taken away from patient interaction. While we believe the regulation of physician in-office compounding should remain under the purview of the state medical board, it is essential that policymakers work collaboratively to ensure timely access to safe and effective medications for patients.

Thank you for the opportunity to work together to ensure dermatology patients have access to treatment with a compounded medication in a timely manner.

Dana M. Hutchison, MD
Resident Physician, PGY-2
UCI Health - Department of Dermatology
dmhutchi@uci.edu | 619-871-2619

Martinez, Lori@DCA

From: Alessandra Chen <alessandrachenmd@gmail.com>
Sent: Friday, May 31, 2024 11:39 AM
To: PharmacyRulemaking@DCA
Subject: Preserve Physician In-Office Preparation of Compounded Medications

To whom it may concern,

As a board-certified dermatologist practicing in California, I urge the California State Board of Pharmacy ("Board") to preserve a physician's ability to prepare medications in physician offices. The use of compounded products allows us to tailor our treatments to the unique needs of our patients in a timely manner, resulting in better outcomes. The proposal will disrupt patient access to medications that have been safely prepared by dermatologists in their offices for years, resulting in needless pain and suffering.

We are seeking amendments to proposed Article 4.6 governing sterile compounding. We urge the Board to allow a beyond use date of at least twelve hours and repeal language in Article 4.6 requiring patient-specific prescriptions. This would enable buffered lidocaine to be prepared in advance of patient visits for that day, which ensures valuable time is not taken away from patient interaction. While we believe the regulation of physician in-office compounding should remain under the purview of the state medical board, it is essential that policymakers work collaboratively to ensure timely access to safe and effective medications for patients.

Requiring dermatologists to administer buffered lidocaine prior to 4 hours of preparation pursuant to a patient specific prescription would impact patient access.

Thank you for the opportunity to work together to ensure dermatology patients have access to treatment with a compounded medication in a timely manner.

Sincerely,
Alessandra Chen, MD, FAAD
Board-Certified Dermatologist
NPI# 1902367378

Martinez, Lori@DCA

From: Ann Haas <afhaasmd@gmail.com>
Sent: Friday, May 31, 2024 2:27 PM
To: PharmacyRulemaking@DCA
Subject: RE: revisions to USP 797

As a Sacramento dermatologist whose practice is primarily limited to skin cancers and excisional dermatology, I was quite concerned when I read the newly revised USP 797 regulations promulgated by the CA Board of Pharmacy. Frankly, it is an incursion on my ability to practice medicine, to remove my ability to "compound products" (particularly buffered lidocaine) in my office. I have been in practice over 30 years and have been using buffered lidocaine during and after my fellowship. I have had happy patients, no complications and no infections. My experience is not unique; there have been many studies of the safety, sterility and longevity of in-office prepared buffered lidocaine.

The USP has developed a monograph following review of the myriads of rigorous testing required, along with dermatology national organizations. That monograph, which is awaiting USP ratification, asks that physicians are allowed to retain the opportunity to buffer lidocaine in our offices, without a specific patient in mind, and to discard after 12 hours. It would seem reasonable that the CA Board of Pharmacy would wait on making ANY changes to 797, until that monograph has been ratified (or just give us the carve-out).

I have had several patients coming to my office for in office surgical procedures (done under local anesthetic) who have had biopsies done elsewhere with non-buffered lidocaine. The process was so painful and anxiety-provoking that many of them have refused to even try having a subsequent procedure done even with buffered lidocaine in the office and I have had to refer them to one of my general surgery colleagues to have the procedure done in the operating room. Those who were willing to try were extremely tense and anxious, which makes for a stressful day for them and for our office staff. For many geriatric patients and most children, it is impossible to use plain lidocaine for local anesthetic; they simply do not tolerate the discomfort.

Please either adopt the recommendations of the USP regarding buffered lidocaine, or make no changes until the monograph is ratified.

Sincerely,
Ann Haas, M.D., FAAD, FACMS
Sutter Health
Board of Directors, California Society of Dermatology and Dermatologic Surgery (CalDerm)

Martinez, Lori@DCA

From: Jerome Potozkin MD <JP@potozkinmd.com>
Sent: Monday, May 27, 2024 9:27 AM
To: PharmacyRulemaking@DCA
Subject: Compounding

To Whom it May Concern
We are seeking amendments to proposed Article 4.6 governing sterile compounding. We urge the Board to allow a beyond use date of at least twelve-hours and repeal language in Article 4.6 requiring patient-specific prescriptions. This would enable buffered lidocaine to be prepared in advance of patient visits for that day, which ensures valuable time is not taken away from patient interaction. While we believe the regulation of physician in-office compounding should remain under the purview of the state medical board, it is essential that policymakers work collaboratively to ensure timely access to safe and effective medications for patients. I have personally injected tens of thousands of syringes of buffered lidocaine without incident. The medical literature substantiates the safety of in office buffered lidocaine with no documentation of contaminant growth. If this practice is severely limited the only impact that it will have in California is the dramatic increase in pain with injection of non-buffered lidocaine. I invite anyone of the pharmacy board to experience the difference between an injection of buffered vs non-buffered lidocaine in my office. It will be clear as day that the only impact of restrictions on buffered lidocaine is the increased pain and suffering of thousands of Californians.
I thank you for your consideration.
Sincerely-Jerome Potozkin MD

Jerome Potozkin MD
jp@potozkinmd.com
www.mybeautymd.com

Martinez, Lori@DCA

From: Jenny Wang <jennywang@socalskinsurg.com>
Sent: Monday, June 3, 2024 8:00 AM
To: PharmacyRulemaking@DCA
Subject: Dermatologist against changes to in-office compounding

Dear Lori Martinez,

I am a private practice dermatologist based in Los Angeles, CA, and am concerned about the new proposal to change current in-office compounding.

1) We compound Buffered lidocaine regularly at our office, as a way to reduce pain and suffering during common dermatology procedures. Unbuffered lidocaine is painful, and a detriment to good patient care.

2) In order to feasibly maintain this standard of care, we need to allow use of compounded medications beyond 12 hours, and we need to remove the requirement of "patient specific prescriptions" for the use of buffered lidocaine. These requirements are not grounded in evidence based medicine, and would lead to enhanced pain and suffering during common procedures.

3) I have prepared and used buffered lidocaine safely in the office for years, and multiple peer reviewed journals have tested the safety and stability of storage of such products far beyond 12 hours, and closer to several weeks when refrigerated.

Larson PO, Ragi G, Swandby M, Darcey B, Polzin G, Carey P. Stability of buffered lidocaine and epinephrine used for local anesthesia. J Dermatol Surg Oncol. 1991 May;17(5):411-4. doi: 10.1111/j.1524-4725.1991.tb03975.x. PMID: 2030202.

Thank you for your time and consideration,

JENNY WANG, MD, FAAD
Founder & Board-Certified Dermatologist
T: 424-543-0066
C: 240-246-3164
E: *jennywang@socalskinsurg.com*
W: *socalskinsurg.com*

Martinez, Lori@DCA

From: Michael Bradshaw <michaelbbradshaw@gmail.com>
Sent: Wednesday, May 29, 2024 3:05 PM
To: PharmacyRulemaking@DCA
Subject: Preserve Physician In-Office Preparation of Compounded Medications

To Whom It May Concern:

As a board-certified dermatologist practicing in California, I urge the California State Board of Pharmacy ("Board") to preserve a physician's ability to prepare medications in physician offices. The use of compounded products allows us to tailor our treatments to the unique needs of our patients in a timely manner, resulting in better outcomes. The proposal will disrupt patient access to medications that have been safely prepared by dermatologists in their offices for years, resulting in needless pain and suffering.

We are seeking amendments to proposed Article 4.6 governing sterile compounding. We urge the Board to allow a beyond use date of at least twelve hours and repeal language in Article 4.6 requiring patient-specific prescriptions. This would enable buffered lidocaine to be prepared in advance of patient visits for that day, which ensures valuable time is not taken away from patient interaction. While we believe the regulation of physician in-office compounding should remain under the purview of the state medical board, it is essential that policymakers work collaboratively to ensure timely access to safe and effective medications for patients.

Requiring dermatologists to administer buffered lidocaine prior to 4 hours of preparation pursuant to a patient specific prescription would greatly impact patient access.

Thank you for the opportunity to work together to ensure dermatology patients have access to treatment with a compounded medication in a timely manner.

Sincerely,

Michael Bradshaw, MD, FAAD

Insight Dermatology

www.insightderm.com

t. (858) 693-3000

Martinez, Lori@DCA

From: Michael Lin <drlin@michaellinmd.com>
Sent: Wednesday, May 29, 2024 5:30 PM
To: PharmacyRulemaking@DCA
Subject: buffered lidocaine

To whom it may concern,

We need an amendment permitting beyond use date of 12 hours and repeal language requiring "patient specific prescriptions" for buffered lidocaine (this will permit "batching" of buffered lidocaine).

There will be much pain, suffering, expense and detriment to good patient care if these new regulations are adopted.

As a dermatologist, I have been preparing and using buffered lidocaine in the office for years safely and effectively.

Thanks,
Dr. Lin

Martinez, Lori@DCA

From: Shane Hamman <shane.hamman@gmail.com>
Sent: Wednesday, May 29, 2024 3:28 PM
To: PharmacyRulemaking@DCA
Subject: Comments on compounding

As a board-certified dermatologist practicing in California, I urge the California State Board of Pharmacy ("Board") to preserve a physician's ability to prepare medications in physician offices. The use of compounded products allows us to tailor our treatments to the unique needs of our patients in a timely manner, resulting in better outcomes. The proposal will disrupt patient access to medications that have been safely prepared by dermatologists in their offices for years, resulting in needless pain and suffering.

We are seeking amendments to proposed Article 4.6 governing sterile compounding. We urge the Board to allow a beyond use date of at least twelve hours and repeal language in Article 4.6 requiring patient-specific prescriptions. This would enable buffered lidocaine to be prepared in advance of patient visits for that day, which ensures valuable time is not taken away from patient interaction. While we believe the regulation of physician in-office compounding should remain under the purview of the state medical board, it is essential that policymakers work collaboratively to ensure timely access to safe and effective medications for patients.

I am a mohs surgeon doing in office procedures to cure cancer every day. We are able to safely treat many patients in a very affordable manner in an outpatient setting in our office. For patient comfort we buffer lidocaine so that it is not painful. Please understand that hindering our practice to Give patients the medications that we think are in their best interest would hinder our ability to treat patients in the most painless way.

Thank you for the opportunity to work together to ensure dermatology patients have access to treatment with a compounded medication in a timely manner.

M. Shane Hamman MD, FACMS, FAAD

UCSD Health Sciences Assistant Clinical Professor, Non-Salaried
shane.hamman@gmail.com
(619) 988-9906

Martinez, Lori@DCA

From: Shive, Melissa <mshive@hs.uci.edu>
Sent: Wednesday, May 29, 2024 10:24 PM
To: PharmacyRulemaking@DCA
Subject: Preserve a physician's ability to prepare medications in physician offices

To the CA Board of Pharmacy,

As a board-certified dermatologist practicing in California, I urge the California State Board of Pharmacy ("Board") to preserve a physician's ability to prepare medications in physician offices. The use of compounded products allows us to tailor our treatments to the unique needs of our patients in a timely manner, resulting in better outcomes. The proposal will disrupt patient access to medications that have been safely prepared by dermatologists in their offices for years, resulting in needless pain and suffering.

We are seeking amendments to proposed Article 4.6 governing sterile compounding. We urge the Board to allow a beyond use date of at least twelve hours and repeal language in Article 4.6 requiring patient-specific prescriptions. This would enable buffered lidocaine to be prepared in advance of patient visits for that day, which ensures valuable time is not taken away from patient interaction. While we believe the regulation of physician in-office compounding should remain under the purview of the state medical board, it is essential that policymakers work collaboratively to ensure timely access to safe and effective medications for patients.

Thank you for the opportunity to work together to ensure dermatology patients have access to treatment with a compounded medication in a timely manner.

Melissa Shive, MD MPH FAAD

Melissa Shive, MD MPH FAAD
Assistant Clinical Professor
Department of Dermatology
University of California, Irvine

Fellow
American Academy of Dermatology
Excellence in Dermatology™

Martinez, Lori@DCA

From: Parrish Sadeghi <psadeghi99@gmail.com>
Sent: Wednesday, May 29, 2024 3:49 PM
To: PharmacyRulemaking@DCA
Subject: URGENT: The need to preserve physicians' ability to prepare medicaiton in office

Hi,

I am Dr. Parrish Sadeghi, double board-certified dermatologist and Mohs micrographic surgeon practicing in California.
I urge the California State Board of Pharmacy ("Board") to preserve a physician's ability to prepare medications in physician offices. The use of compounded products allows us to tailor our treatments to the unique needs of our patients in a timely manner, resulting in better outcomes. The proposal will disrupt patient access to medications that have been safely prepared by dermatologists in their offices for years, resulting in needless pain and suffering.
We are seeking amendments to proposed Article 4.6 governing sterile compounding. We urge the Board to allow a beyond use date of at least twelve hours and repeal language in Article 4.6 requiring patient-specific prescriptions. This would enable buffered lidocaine to be prepared in advance of patient visits for that day, which ensures valuable time is not taken away from patient interaction. While we believe the regulation of physician in-office compounding should remain under the purview of the state medical board, it is essential that policymakers work collaboratively to ensure timely access to safe and effective medications for patients.
It has been extremely difficult for dermatology practices to even obtain lidocaine since Covid and we continue to deal with this issue to date. Staffing has been an additional burden on practices. If as physicians we were to be limited as to how we prepare and pre-prepare medications in our office, then ultimately the patient care and access will be negatively impacted because we will have to reduce the number of patients we do surgery and procedures on. Unbuffered lidocaine injections are extremely painful and can also potentially prohibit patients from wanting to undergo outpatient dermatologic surgical care.
Thank you for the opportunity to work together to ensure dermatology patients have access to treatment with a compounded medication in a timely manner.

--

Parrish Sadeghi, M.D.
Dermatologic and Mohs Micrographic Surgery
Board Certified - American Academy of Dermatology
Board Certified - American College of Mohs Surgery

Pure Dermatology & Skin Surgery Center
2001 Santa Monica Blvd. #480-W
Santa Monica, CA 90404
(310) 954 -9501
www.PureDermatology.com

Martinez, Lori@DCA

From: steve o <dros777@gmail.com>
Sent: Wednesday, May 29, 2024 4:04 PM
To: PharmacyRulemaking@DCA
Subject: USP 797

To whom it may concern,

As a board-certified dermatologist practicing in California, I urge the California State Board of Pharmacy ("Board") to preserve a physician's ability to prepare medications in physician offices. The use of compounded products allows us to tailor our treatments to the unique needs of our patients in a timely manner, resulting in better outcomes. The proposal will disrupt patient access to medications that have been safely prepared by dermatologists in their offices for years, resulting in needless pain and suffering.

We are seeking amendments to proposed Article 4.6 governing sterile compounding. We urge the Board to allow a beyond use date of at least twelve hours and repeal language in Article 4.6 requiring patient-specific prescriptions. This would enable buffered lidocaine to be prepared in advance of patient visits for that day, which ensures valuable time is not taken away from patient interaction. While we believe the regulation of physician in-office compounding should remain under the purview of the state medical board, it is essential that policymakers work collaboratively to ensure timely access to safe and effective medications for patients.

Thank you for the opportunity to work together to ensure dermatology patients have access to treatment with a compounded medication in a timely manner.

Sincerely,

Steve Oberemok, M.D. FAAD, FACMS

Martinez, Lori@DCA

From: Elan Newman <biodyne@gmail.com>
Sent: Sunday, June 2, 2024 9:41 PM
To: PharmacyRulemaking@DCA
Subject: Pharmacy Rulemaking

As a board-certified dermatologist practicing in California, I urge the California State Board of Pharmacy ("Board") to preserve a physician's ability to prepare medications in physician offices. The use of compounded products allows us to tailor our treatments to the unique needs of our patients in a timely manner, resulting in better outcomes. The proposal will disrupt patient access to medications that have been safely prepared by dermatologists in their offices for years, resulting in needless pain and suffering.

We are seeking amendments to proposed Article 4.6 governing sterile compounding. We urge the Board to allow a beyond use date of at least twelve hours and repeal language in Article 4.6 requiring patient-specific prescriptions. This would enable buffered lidocaine to be prepared in advance of patient visits for that day, which ensures valuable time is not taken away from patient interaction. While we believe the regulation of physician in-office compounding should remain under the purview of the state medical board, it is essential that policymakers work collaboratively to ensure timely access to safe and effective medications for patients.

Studies solidly support the safety of a 12-hour beyond use date for prepared syringes of lidocaine. Indeed, the American Academy of Dermatology, the American Society for Dermatologic Surgery, the American College of Mohs Surgery, and the American Society for Mohs Surgery have all contracted with labs to create a new monograph for the use of buffered lidocaine that is prepared in bulk and by the physician.

Lidocaine that is unbuffered is extremely painful for patients to receive. Ordering buffered lidocaine from a pharmacy is extremely problematic because it has a shelf-life of 7 days, 3-4 of which are spent in transit to the clinic. The proposed rule by the Board of pharmacy would lead to needless pain and suffering for patients as well as raise the cost of health care for practices and patients - without improving patient safety.

To my research, there are no reported cases of patient injury from the buffering of lidocaine by physicians. But there are reports of compounding pharmacies contaminating batches of products and shipping them to hospitals and clinics. I raise this point because

while both physicians and pharmacists have a vested interest in patient safety and quality of care, it is important to recognize that physicians are holding up our part. Furthermore, a board of pharmacists declaring a limit to the scope and practice of medicine for physicians is beyond the mission and jurisdiction of the Board of Pharmacy. This would be unproductive and unhelpful for our patients. We need to move together in a more positive direction and it begins by looking at the facts.

Thank you for the opportunity to work together to ensure dermatology patients have access to treatment with a compounded medication in a timely manner.

-Elan Newman, M.D., FAAD, FASDS

Martinez, Lori@DCA

From: Edward Rohaly <e.george.rohaly@gmail.com>
Sent: Monday, June 3, 2024 2:26 PM
To: PharmacyRulemaking@DCA
Subject: Dermatology In-Office Compounding for in-office use

Persons of the Pharmacy Board:

As a board-certified dermatologist practicing in California, I urge the California State Board of Pharmacy ("Board") to preserve a physician's ability to prepare medications in physician offices. The use of compounded products allows us to tailor our treatments to the unique needs of our patients in a timely manner, resulting in better outcomes. The proposal will disrupt patient access to medications that have been safely prepared by dermatologists in their offices for years, resulting in needless pain and suffering.

We are seeking amendments to proposed Article 4.6 governing sterile compounding. We urge the Board to allow a beyond use date of at least twelve hours and repeal language in Article 4.6 requiring patient-specific prescriptions. This would enable buffered lidocaine to be prepared in advance of patient visits for that day, which ensures valuable time is not taken away from patient interaction. While we believe the regulation of physician in-office compounding should remain under the purview of the state medical board, it is essential that policymakers work collaboratively to ensure timely access to safe and effective medications for patients.

Please note, I have a BS in pharmacy and have exposure to in-hospital Laminar Flow Hoods and the like. We are doing pretty simple things in our offices to better care for our patients.

Thank you for the opportunity to work together to ensure dermatology patients have access to treatment with a compounded medication in a timely manner.

Edward G Rohaly, MD

Martinez, Lori@DCA

From: Jennifer Chen <jenniferkchen@stanford.edu>
Sent: Wednesday, May 29, 2024 3:05 PM
To: PharmacyRulemaking@DCA

As a board-certified dermatologist practicing in California, I urge the California State Board of Pharmacy ("Board") to preserve a physician's ability to prepare medications in physician offices. The use of compounded products allows us to tailor our treatments to the unique needs of our patients in a timely manner, resulting in better outcomes. The proposal will disrupt patient access to medications that have been safely prepared by dermatologists in their offices for years, resulting in needless pain and suffering.

We are seeking amendments to proposed Article 4.6 governing sterile compounding. We urge the Board to allow a beyond use date of at least twelve hours and repeal language in Article 4.6 requiring patient-specific prescriptions. This would enable buffered lidocaine to be prepared in advance of patient visits for that day, which ensures valuable time is not taken away from patient interaction. While we believe the regulation of physician in-office compounding should remain under the purview of the state medical board, it is essential that policymakers work collaboratively to ensure timely access to safe and effective medications for patients.

[Open Box for Additional Text. This can include how requiring dermatologists to administer buffered lidocaine prior to 4 hours of preparation pursuant to a patient specific prescription would impact patient access.]

Thank you for the opportunity to work together to ensure dermatology patients have access to treatment with a compounded medication in a timely manner.

Jennifer Chen, MD

Martinez, Lori@DCA

From: Jeffrey Collins, DO <collinsdermatology@gmail.com>
Sent: Wednesday, May 29, 2024 6:14 PM
To: PharmacyRulemaking@DCA
Subject: In office medication compounding

As a board-certified dermatologist practicing in California, I urge the California State Board of Pharmacy ("Board") to preserve a physician's ability to prepare medications in physician offices. The use of compounded products allows us to tailor our treatments to the unique needs of our patients in a timely manner, resulting in better outcomes. The proposal will disrupt patient access to medications that have been safely prepared by dermatologists in their offices for years, resulting in needless pain and suffering.

We are seeking amendments to proposed Article 4.6 governing sterile compounding. We urge the Board to allow a beyond use date of at least twelve hours and repeal language in Article 4.6 requiring patient-specific prescriptions. This would enable buffered lidocaine to be prepared in advance of patient visits for that day, which ensures valuable time is not taken away from patient interaction. While we believe the regulation of physician in-office compounding should remain under the purview of the state medical board, it is essential that policymakers work collaboratively to ensure timely access to safe and effective medications for patients.

I have been administering buffered lidocaine in the office for many years and have never had a safety issue. Eliminating this will only cause further patient harm as unbuffered lidocaine is more acidic and painful upon injection.

Thank you for the opportunity to work together to ensure dermatology patients have access to treatment with a compounded medication in a timely manner.

Jeffrey Collins, DO

Redwood Empire Dermatology, Santa Rosa, California

Martinez, Lori@DCA

From: Tanya Kormeili MD <drkormeili@gmail.com>
Sent: Wednesday, May 29, 2024 3:04 PM
To: PharmacyRulemaking@DCA
Subject: USP Chapter 797

Who Whom It May Concern:

As a board-certified dermatologist practicing in California, I urge the California State Board of Pharmacy ("Board") to preserve a physician's ability to prepare medications in physician offices. The use of compounded products allows us to tailor our treatments to the unique needs of our patients in a timely manner, resulting in better outcomes. The proposal will disrupt patient access to medications that have been safely prepared by dermatologists in their offices for years, resulting in needless pain and suffering.

We are seeking amendments to proposed Article 4.6 governing sterile compounding. We urge the Board to allow a beyond use date of at least twelve hours and repeal language in Article 4.6 requiring patient-specific prescriptions. This would enable buffered lidocaine to be prepared in advance of patient visits for that day, which ensures valuable time is not taken away from patient interaction. While we believe the regulation of physician in-office compounding should remain under the purview of the state medical board, it is essential that policymakers work collaboratively to ensure timely access to safe and effective medications for patients.

[Open Box for Additional Text. This can include how requiring dermatologists to administer buffered lidocaine prior to 4 hours of preparation pursuant to a patient specific prescription would impact patient access.]

Thank you for the opportunity to work together to ensure dermatology patients have access to treatment with a compounded medication in a timely manner.

--
Tanya Kormeili, MD, FAAD

Derm & Rejuvenation Institute
Board Certified Dermatologist
Clinical Instructor, UCLA

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Santa Monica, CA 90403
Phone: 310-526-8301

www.drkormeili.com
Join me on IG!: @DrKormeili

Martinez, Lori@DCA

From: Walter Wood <whwoodii@gmail.com>
Sent: Friday, May 31, 2024 5:36 PM
To: PharmacyRulemaking@DCA
Subject: California Board of Pharmacy Article 4.6 problem - - modification needed to enable physicians to continue buffering local anesthetic for in office surgery

I urge the California State Board of Pharmacy to preserve the physician's ability to prepare buffered local anesthetic for use in office surgery. The regulation of physician in-office compounding should remain under the purview of the state medical board as it is part of the practice of medicine and surgery. It is essential that policymakers at the medical board and the pharmacy board work collaboratively to ensure timely safe and effective compounded anesthetic for patients during office surgery.

Apparently there is a problem with the language of the California State Board of Pharmacy proposed Article 4.6 governing sterile compounding as it applies to long accepted optimized dermatology office surgery practice. I urge the California State Board of Pharmacy to recognize a time period of at least twelve hours before a compounded local anesthetic needs to be used. There is also a need to remove language in Article 4.6 requiring patient-specific prescriptions for each batch of compounded local anesthetic. Patient specific prescriptions are NOT helpful or necessary because the same compounded formula is repeatedly used. Buffered lidocaine is optimally prepared in the morning and loaded into syringes for use on the same day, which ensures valuable time will not be taken away from patient interaction while the physician prepares the anesthetic. The syringes are prepared in advance and are ready to use when the patient arrives. A patient specific prescription for each batch of buffered local anesthetic would be a waste of time with no safety and no efficacy benefit to patients.

Similar principles apply to many long used compounded topical creams prepared by dermatologists for their patients.

Walter H. Wood, MD, FAAD
Dermatology and Dermatological Surgery
Certified American Board of Dermatology

1709 Berkeley Way
Berkeley, CA 04703

Martinez, Lori@DCA

From: Teresa Fu <teresa.fu@gmail.com>
Sent: Wednesday, May 29, 2024 9:50 PM
To: PharmacyRulemaking@DCA
Subject: keep in-office compounding in California

I am a board-certified practicing dermatologist in California. **I strongly urge the California State Board of Pharmacy ("Board") to preserve a physician's ability to prepare medications in physician offices.** The use of compounded products allows us to tailor our treatments to the unique needs of our patients in a timely manner, resulting in better outcomes. The proposal regarding USP Chapter 797 will disrupt patient access to medications that have been safely prepared by dermatologists in their offices for years (decades!), resulting in needless pain and suffering.

We are seeking amendments to proposed Article 4.6 governing sterile compounding. We urge the Board to allow a beyond use date of at least twelve hours and repeal language in Article 4.6 requiring patient-specific prescriptions. This would enable buffered lidocaine to be prepared in advance of patient visits for that day, which ensures valuable time is not taken away from patient interaction. While we believe the regulation of physician in-office compounding should remain under the purview of the state medical board, it is essential that policymakers work collaboratively to ensure timely access to safe and effective medications for patients.

I have been in practice for nearly 10 years, and have taken care of thousands of patients. Not once have we ever seen an issue with buffered lidocaine (mixed, stored, used, and discarded in accordance with existing guidelines), and it greatly improves patient comfort with minor procedures. Patients tell me the discomfort of undergoing skin biopsy or small surgery done with non-buffered lidocaine is a 7-8 on a scale of 1-10, while buffering reduces that to a 2-3.

Thank you for the opportunity to work together to ensure dermatology patients have access to treatment with a compounded medication in a timely manner.

Teresa Fu, MD
Dermatology, San Carlos Palo Alto Medical Foundation

Written Comments Submitted at Regulation Hearing

June 18, 2024

California State Board of Pharmacy
2720 Gateway Oaks Drive
Sacramento, CA 95833

RE: Proposed Article 4.6 Sterile Compounding

Dear Members of the California State Board of Pharmacy:

On behalf of the more than 700 California members of the American Society for Dermatologic Surgery Association (ASDSA), we are writing to express our concerns regarding the California State Board of Pharmacy (Board) proposed regulations on sterile compounding. Currently as written, these regulations would impede a physician's ability to prepare medications in physician offices negatively impacting patient access to care without a significant improvement in patient safety.

As physicians our number one priority is the health and welfare of our patients. One in four Americans suffers from a skin disease. Dermatologists diagnose and treat more than 3,000 diseases, including skin cancer, psoriasis, immunologic diseases, and many genetic disorders. As dermatologists on the front lines fighting skin cancer and treating numerous skin diseases, we are advocating for our patients to have access to compounded medications, especially in-office preparations.

In order to protect patient safety, we believe it is essential regulations exist to ensure medications are prepared and administered to patients safely. However, it is our belief that the regulation of physician in-office compounding should remain under the purview of the state medical board, while ensuring that policymakers work collaboratively to ensure timely access to safe and effective medications for patients.

We urge the Board to include language allowing a beyond use date (BUD) of at least twelve-hours and repeal language in Article 4.6 requiring patient-specific prescriptions. This would enable buffered lidocaine to be prepared in advance of patient visits for that day, which ensures valuable time is not taken away from patient interaction.

In November 2018, our national organizations met with the United States Pharmacopeial Convention (USP), US Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) to communicate concerns regarding buffered lidocaine as it is routinely prepared in syringes ahead of patient visits with a BUD of at least 12 hours to facilitate patient access and patient comfort. The parties agreed that carving out buffering lidocaine from USP Chapter 797 requirements and developing a separate monograph to enumerate an approved process for buffering lidocaine would meet the agencies' safety concerns, maintain patient comfort and safety, reduce physicians' administrative burden, and ensure continued access.

USP is in the process of finalizing the monograph, which will include the required evidence of safe aseptic practices sufficient to exempt in-office preparation of buffered lidocaine from the onerous requirements that limit dermatologists from providing their patients with necessary treatment. As the Board's proposal does not reflect the testing conducted as part of the monograph process, we urge you to refrain from adopting a regulation that would prohibit physician in-office preparation of compounding medications as adopting any regulations at this juncture will critically impact direct patient care. In fact, the Ohio Board of Pharmacy amended its immediate use regulations allowing physicians to prepare buffered lidocaine 12 hours prior to administration in response to evidence provided by our organizations and other stakeholders.

To best protect the citizens of California and to ensure quality care, we urge you to reconsider the proposed regulations regarding sterile compounding and amend the proposal to preserve a physician's ability to prepare medications in physician offices. Should you have any questions please contact Kristin Hellquist, ASDSA Chief Advocacy Officer, at khellquist@asds.net.

Sincerely,

The Undersigned California ASDSA Members:

Seth Matarasso, MD, President (San Francisco, CA Resident)
American Society for Dermatologic Surgery Association

Glynis Ablon, MD, Manhattan Beach, CA
Jeffrey Binstock, MD, Mill Valley, CA
Daniel Eisen, MD, Sacramento, CA
Richard Glogau, MD, San Francisco, CA
Ann Haas, MD, Fair Oaks, CA
Amelia Hausauer, MD, Campbell, CA
Elan Newman, MD, San Diego, CA
Jerome Potozkin, MD, Alamo, CA
Patricia Wong, MD, Palo Alto, CA

Good morning, all,

My name is Dan Baxter, and I am the executive director of the California Veterinary Medical Association. I want to touch on two items here today, one specific to the proposed amended regulations and then another, more general point.

As to the former, I want to convey the CVMA's appreciation for the modifications to the regulatory package under consideration today, and specifically the addition of relevant language to subdivision (e) to Section 1735.1 and subdivisions (c) and (d) to Section 1736.1. The inclusion of the seven- and 28-day compounding supply authorizations for veterinarians address the concerns that the CVMA had previously expressed, and we are grateful that those concerns were taken into account in fashioning a going-forward regulatory framework. In particular, I want to acknowledge the work of Chair Serpa for her efforts in that regard.

My general point is unfortunately less positive, and has to do with the reality of what veterinarians needing critical compounded medications are currently facing out in the field. And that reality is very stark.

Specifically, veterinarians in many instances are unable—either altogether or in a suitably timely fashion—to procure compounded medications for animal treatment. A few examples of unavailable medications are:,

(a) Antifungal ophthalmic ointments, essential for the treatment of ocular issues in horses and other animals;
(b) Thyrotropin Releasing hormone, a critical diagnostic tool for a common equine disease; and
(c) Controlled substances for use as office stock.

It should be noted that these aforementioned medications are unavailable in FDA-approved forms, either altogether or in a form that can be administered effectively to animals, leaving compounding as the only vehicle by which these medications can be adequately procured. We have talked to representatives from the few veterinary compounding pharmacies left in California, and they report to us that their concerns over Board of Pharmacy enforcement is deterring them from providing several needed medications, including those I previously mentioned. So, despite the fact that the law actually permits—both currently and with the proposed new language—compounding pharmacies to provide those medications to veterinary practitioners, they are unwilling to do so because of Board enforcement authority and activity.

As a result, California veterinarians are the only ones in the country to not have multiple critical medications available to them to treat their patients, and California's animals are suffering for it.

If Board of Pharmacy representatives wish to discuss this matter with the CVMA further, we would welcome a meeting that could include the Veterinary Medical Board.

CALIFORNIA COA ORTHOPAEDIC ASSOCIATION
1246 P Street
Sacramento, CA 95814

Seung Oh, PharmD, Chair
Members
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95883

Via email: PharmacyRulemaking@dca.ca.gov

Dear Chair Oh and Members,

The California Orthopaedic Association represents nearly 2,000 orthopaedic surgeons practicing in all practice settings throughout California. On behalf of the California Orthopaedic Association and our members, we write in concerned opposition to the recommendation of adoption of USP 797 to end in-office compounding.

As an orthopaedic surgeon, our commitment to patient care and safety is paramount. One crucial aspect of our practice involves the administration of medications such as corticosteroids, which would often be mixed into the same sterile syringe with local anesthetics, such as lidocaine and/or bupivacaine. It is unclear if this is considered "compounding", but we wanted to share how important this aforementioned practice is.

The importance of mixing local anesthetics with other medications, such as corticosteroids for orthopaedic patients:

1. Patient Tolerance:
   It can be painful for patients to receive musculoskeletal injections without local anesthesia.
2. Diagnostic Information:
   While there may be a longer term goal of decreasing a patient's inflammation and pain in a joint, bursa or tendon sheath by means of administration of a corticosteroid, the co-administration of a local anesthetic can also give useful diagnostic information about the anatomic source of the patient's pain, by seeing if the pain decreases in the first few minutes, given the rapid onset of action of local anesthetics such as lidocaine. A rapid, significant reduction in pain would confirm the site that was injected is a significant source

of the patient's pain. This allows for a refined diagnosis and for a more precise surgical plan to be developed, should the injection fail to solve the patient's problem in the long term.

3. Precise Patient Care
   When a physician mixes local anesthetics with cortisone, they can tailor the ratio of the mix to that specific patient. These mixes are typically done individually for each patient.

In conclusion, mixing local anesthetics with other medications, such as corticosteroids, for orthopaedic patients is a sterile, important and patient-specific process that is commonly performed multiple times each day in an orthopaedic office. As such, we respectfully request that no further regulatory requirements or barriers be created around this process.

We are unaware of any history of adverse events from the above mentioned sterile mixing of local anesthetics with other medications such as corticosteroids. Thus, we oppose regulatory changes that would restrict or encumber an orthopaedic surgeon's ability to mix these medications in his or her office.

Please reconsider proposed regulations which would hinder this ability.

Should you have any further questions feel free to contact us at: admin@coa.org or 916-454-9884. Thank you for your consideration of this request.

Sincerely,

Russell Nord, M.D., Chair
COA's Legislative Committee

Comments by Grant Miller, DVM (practicing Equine veterinarian in California) on Board of Pharmacy compounding regulations.

Mystique before her ocular fungal infection:

In September of 2023, Mystique began showing signs of a corneal ulcer in her left eye. The veterinarian treated it with a normal course of treatments (antibiotics/ anti-inflammatories) but quickly realized that this was an atypical infection due to the lack of response to therapy and the aggressive nature of the progression.

Fungal eye infections are rare in California horses due to the arid climate. They are characterized by multifocal punctate ulcers that rapidly progress through the cornea to colonize the stromal layers. The infection rapidly progresses through the layers to perforate descemet's membrane, resulting in significant pain, anterior flare, uveitis and blindness.

Effective treatment can only be achieved by topical administration of antifungal ophthalmic ointments and only if the infection is treated quickly. Systemic antifungals are ineffective.

At the time of Mystique's infection in September of 2023, ophthalmic preparations used to treat fungal keratitis in horses were not available in California. They are: miconazole, itraconazole, natamycin, or voriconazole. Of the few remaining veterinary compounding pharmacies in the state, none of them would compound this medication at the time. And today, only ONE compounding pharmacy offers an antifungal ophthalmic. It is itraconazole and it only just recently became available. It is only available pursuant to a patient-specific prescription and for a variety of reasons, this can result in delays in treatment.

For Mystique, the timing of this single drug becoming available was too little, too late. Her veterinarian tried to find antifungal medication in California, and even searched at out of state pharmacies. None of them would offer it to her because she practiced in California.

California is the only state in which veterinarians are reporting that they cannot obtain multiple medications to treat patients.

The owner had an antifungal medication shipped to Las Vegas. She drove from her home in Indio to her family address in Las Vegas, picked up the medication, and drove it back to California. But by then, Mystique was blind in her left eye.

This is Mystique's blind eye following her inability to get treated with an antifungal ophthalmic medication in California:

Mystique will require special management for the remainder of her life. Setting aside the fact that she is now blind, her eye can become painful at times and requires special protection from the wind, dust, and bright light. She now wears a special UV protectant mask essentially at all times during daylight hours and often sometimes also at night.

Mystique spent 47 days in a hospital wearing a black-out mask with an indwelling subpalpaebral lavage system that delivered medications (serum, antibiotics, tissue-plasminogen activase, and others) to her eye every two to three hours on a 24-hour basis. Her hospitalization cost the owner $27,000.

If the eye was treated with a topical antifungal medication, it could have been treated at home by the owner, administering medication three to four times daily for about a month. She would have made a complete recovery and the overall cost would have been likely less than one tenth the cost of Mystique's hospitalization and treatments.

Finally, the economic losses to the consumer are devastating in the loss of value of the horse (Mystique is a world-class Olympic level jumping horse):

This is both eyes before she went blind

MMS
7:24 PM

7:24 PM How much is she worth?

I'm going to print out pictures and give them to the board of pharmacy when I tell them her story. When did she get the fungal infection?

7:25 PM

Haha 😂😅 when she had two eyes? $500k

7:26 PM

7:26 PM Do you think you could sell her for that now?

Oh no I couldn't sell her at all now, she's a forever horse now. Thankfully she's a mare, I'll probably breed her one day.

7:27 PM

Thank you. Send me the photo post injury. Was it in 2021?

7:28 PM 2022?

She got the eye infection end of September 2023, saw an ophthalmologist October 2, was

This is but one example of harm being done to animals in this state as a result of your Board actions.

And why do I say that? For the following simple reasons:

1) There are no other states in the United States of America in which veterinarians are reporting that they cannot obtain medications to treat their patients.
2) When we ask compounding pharmacies why California specifically cannot get medications, it is not USP that they point to, but rather, it is to your board regulations and enforcement activity.

We have come to you on multiple occasions and told you formally with comment letters and through public comments at your meetings that the California veterinary profession is experiencing significant issues in obtaining several medications to treat their patients.

Today, I wanted to show you the result of your consumer protection efforts. Has your Board done right by Mystique? Did you serve her owner well? Are you treating the veterinary profession with the respect that it deserves?

While your decision to extend NSP office stock and increase availability of ophthalmics for office use is applauded, we are concerned that it falls far short of meeting the needs of animals in California if veterinary compounding pharmacies are disincentivized from doing business here in the first place.

We are asking you to fix this. Please do something so that veterinarians have access to vital medications needed to treat their patients.

Thank you.

Martinez, Lori@DCA

From: Peter Rullan <prullan@yahoo.com>
Sent: Sunday, June 2, 2024 11:13 AM
To: PharmacyRulemaking@DCA
Subject: Preserve Physician In-Office Preparation of Compounded Medications

June 3, 2024

California State Board of Pharmacy 2720 Gateway Oaks Drive Sacramento, CA 95833

re: Proposed Article 4.6 Sterile Compounding

Dear Members of the California State Board of Pharmacy,

On behalf of the undersigned organizations representing more than 17,000 dermatologists, we urge the California State Board of Pharmacy ("Board") to consider our work with the United States Pharmacopeial Convention ("USP") and federal policymakers as outlined below and amend the proposal to preserve a physician's ability to prepare medications in physician offices.

We are seeking language to allow a beyond use date of at least twelve-hours and repeal language in Article 4.6 requiring patient-specific prescriptions. This would enable buffered lidocaine to be prepared in advance of patient visits for that day, which ensures valuable time is not taken away from patient interaction. While we believe the regulation of physician in-office compounding should remain under the purview of the state medical board, it is essential that policymakers work collaboratively to ensure timely access to safe and effective medications for patients.

One in four Americans suffers from a skin disease. Dermatologists diagnose and treat more than 3,000 diseases, including skin cancer, psoriasis, immunologic diseases, and many genetic disorders. As dermatologists on the front lines fighting skin cancer and treating numerous skin diseases, we are advocating for our patients to have access to compounded medications, especially in-office preparations.

In November 2018, many of the undersigned organizations met with the USP, U.S. Food and Drug Administration, and Centers for Disease Control and Prevention to discuss our concerns regarding buffered lidocaine. Buffered lidocaine is routinely prepared in syringes in advance of patient visits with a beyond-use date (BUD) of at least 12 hours to facilitate patient access and patient comfort.

The parties agreed that carving out buffering lidocaine from USP Chapter 797 requirements and developing a separate monograph to enumerate an approved process for buffering lidocaine would meet the agencies' safety concerns, maintain patient comfort and safety, reduce physicians' administrative burden, and ensure continued access.

We have successfully completed a number of required tests through an independent laboratory, which include:

o <51> Antimicrobial Effectiveness
o <1207> for Package integrity evaluation:
o Sterility Tests <71>
o Bacterial Endotoxin Tests <85>
o Particulate Matter in Injections <788>
o pH <791>
o Stability study time points at T=0, T=6 hours, T=12 hours, T=24 hours, T=3 days, T=7 days at both controlled room temperature and in a refrigerator

USP is in the process of finalizing the monograph, which will include the required evidence of safe aseptic practices sufficient to exempt in-office preparation of buffered lidocaine from the onerous requirements that limit dermatologists from providing their patients with necessary treatment.

Because the Board's proposal does not reflect the testing conducted as part of the monograph process, we urge you to refrain from adopting a regulation that would prohibit physician in-office preparation of compounding medications as adopting any regulations at this juncture will critically impact direct patient care. In fact, the Ohio Board of Pharmacy amended its immediate use regulations allowing physicians to prepare buffered lidocaine 12 hours prior to administration in response to evidence provided by our organizations and other stakeholders.

Thank you in advance for the opportunity to work together to ensure dermatology patients have access to treatment with an in-office prepared product in a timely manner. Should you have any questions, please do not hesitate to contact Lisa Albany, director of state policy for the American Academy of Dermatology Association at (202) 712- 2615 or lalbany@aad.org.

Sincerely,

Peter P Rullan, MD, FAAD

Member of:

American Academy of Dermatology Association American College of Mohs Surgery
American Society for Dermatologic Surgery Association American Society for Mohs Surgery
California Society of Dermatology & Dermatologic Surgery

Martinez, Lori@DCA

From: Crystal Frost <crystalfrostmusic@gmail.com>
Sent: Tuesday, June 18, 2024 12:32 PM
To: PharmacyRulemaking@DCA
Subject: My Testimony for CA Pharmacy Board at 6/18/24 Meeting

To Whom it May Concern:

My name is Crystal A. Frost, PhD, and I am a patient based in Los Angeles, CA. I want to thank the board for this opportunity to share my experience.

I'd like to protect many freedoms of compounding pharmacies, but because time is limited, I'll focus on defending patient access specifically to intravenous and nebulized glutathione treatments, which the board has proposed banning. Many of California's firefighting heroes shared testimonies attesting to the healing powers of glutathione today, so I am here to represent the many OTHER high-risk communities who suffer from illnesses relating to toxicity who have also had their quality of life restored by lifesaving intravenous Glutathione.

In my case, IV glutathione saved my life in 2021 and 2022 when I acquired severe mold toxicity or Mycotoxicity while also battling Neuroborreliosis, or Neurological Lyme Disease. My detox pathways were so impaired that I also wasn't detoxing heavy metals, and tested positive for obscenely high levels of thallium and literally off-the-charts levels of gadolinium, which is the heavy metal used to make MRI contrast, of which I had received several during the diagnostic period of my illness. As a healthy fitness guru who only ate organic, my atypical illness could not be attributed to lifestyle choices.

Conventional treatments were failing and I had no choice but to quit working. A recently engaged 31-year-old, I'd dropped to 98 pounds and exhibited symptoms of early dementia such as forgetting my own phone number and forgetting my own friends' names. My brain SPECT scan conducted in March 2021 corroborated this when it showed moderate-severe encephalitis and inflammation of my temporal lobes. At this point I could barely walk and I began experiencing fevers and anaphylaxis every single day because the toxic burden was simply too high.

My now husband and I came to realize this could take my life. Immune modulators proved useless because this complex illness had already effectively destroyed my immune system. Antifungals proved useless because the mycotoxins were responsible, not mold spores themselves. Taking oral detoxification agents was laughably ineffective because the toxic burden was largely in my brain, and oral detox medicines aren't well-absorbed systemically nor do they easily cross the blood-brain barrier. Finally after seeing more than 20 doctors, an integrative MD advised me to try IV glutathione, explaining that our bodies produce this master antioxidant on our own, but I would not be able to produce nearly enough of it to save myself.

I began weekly, sometimes twice weekly infusions and the relief was noticeable within the first month but only got better. Around the 6 month mark, I was no longer experiencing fevers or anaphylaxis. I had been unable to

walk more than 2 blocks and could now walk 2 miles. I still get glutathione IVs for maintenance because my detox pathways are still impaired.

You may argue patients can just take glutathione orally, but this antioxidant is notoriously difficult to absorb orally, especially for patients with impaired gut health who can't absorb many nutrients in the gut. Oral glutathione is simply not a viable alternative for the severely ill. Glutathione also has anti-inflammatory processes that provide natural pain relief, making the detox process less burdensome and making pain medicine much less necessary, at least in my case.

Intravenous Glutathione has proved itself lifesaving for many with impaired detox pathways who need to clear dangerous toxins from their body. This applies to people with mold toxicity, heavy metal toxicity, microplastics, and chronic bacterial infections like neuroborreliosis where dead, toxic bacteria need to be eliminated from the body. Preventing patient access to IV glutathione would effectively ruin and end many lives. In fact, glutathione is so effective for so many that banning it is actually suggestive of an ulterior motive to embolden Big Pharma, boost cancer patient numbers, and prevent patients from being less dependent on drug therapy. Please, please reconsider. Many lives depend on it.

Thank you so much for giving me this opportunity to share my testimony.

Sincerely,

Crystal A. Frost, PhD
Writer | Researcher | Composer
crystalfrostmusic@gmail.com
424-901-9790

Martinez, Lori@DCA

From: Light Your Sparkle <lightyoursparkle@gmail.com>
Sent: Tuesday, June 18, 2024 4:04 PM
To: PharmacyRulemaking@DCA
Subject: attention Lori Martinez

ATTENTION BOARD: REGARDING STERILE COMPOUNDS/PHARMACY RULE MAKING

Casey Hersch, MSW, LCSW

Davis, CA 95616

lightyoursparkle@gmail.com

June 18, 2024 (presented this testimony at hearing and am sending copy)

My name is Casey Hersch, professionally I am a licensed clinical medical social worker so I hear from patients often and it is my job to give patients a voice---but day to day I am a patient who suffers from an autoimmune disease called Crohn's disease.

Listening to the testimony, it is apparent to me that those opposing the use of sterile compounds are focused on money and inconvenience. In terms of safety, I have been a consumer of sterile compounds for over twenty years and as a patient I have never been subjected to any dangers, contamination, or infection as a result. However, I must note that numerous times, conventional pharmaceuticals have placed my life in grave danger. First, I encourage the board to give patients a voice---we are an underrepresented population because our voices have been silenced by the perceived power of big pharma, conventional physicians, and corporate medical facilities.

My life and survival with a disease that millions of Americans live with is contingent on my ability to obtain sterile compounds (glutathione, B12, vitamin C, etc). My body, like so many, cannot absorb nutrition nor process nutrition in the normal ways. I depend on B12 injections, IV therapies to give me the best chance I have at staying alive. These past years I have been restricted from receiving certain compounded life saving medications and from being able to get Intramuscular shots that I require for my longevity.

Access to sterile compounds have not only kept me alive, but have prevented me from being hospitalized. I don't want to be hospitalized. I want to stay in the comforts of my own home and to be cared for by my team of integrative physicians who know my body and needs best. Not to mention, access to sterile compounds has always been more affordable to me despite my insurance not covering them and my still having to pay out of pocket.

I urge the board to use my testimony as a voice for all the patients who are too sick to attend, too tired and defeated to attend, and too oppressed to believe that we actually have a say as to what we put into our bodies and have access. On behalf of sick and suffering patients, I urge the board to help us retain the right to make decisions and have access to

sterile compounds that significantly improve our quality of lives. If we lose this right then our life quality deteriorates and for me, I die.

Regards,

Casey Hersch, MSW, LCSW

Martinez, Lori@DCA

From: Sodergren, Anne@DCA
Sent: Tuesday, June 18, 2024 10:13 AM
To: Johnston, Mark D.
Cc: PharmacyRulemaking@DCA
Subject: FW: testimony
Attachments: compounding trstimony.docx

Copied is the appropriate email for submission.

From: Johnston, Mark D <Mark.Johnston@CVSHealth.com>
Sent: Tuesday, June 18, 2024 10:09 AM
To: Sodergren, Anne@DCA <Anne.Sodergren@dca.ca.gov>
Subject: testimony

Sorry, I missed the e-mail address to submit the attached testimony, so I'm sending directly to you. .

My name is Mark Johnston, and I have been a CA licensed pharmacist for 33 years. Today, I represent CVS Health.

USP 800 contains a broad carve-out for facilities that do not engage in hazardous drug compounding and thus only dispense hazardous drugs in manufactured dosage forms, however proposed Article 4.7 does not contain such a carve-out. In our submitted, written comments, we identify 6 sections of Article 4.7 which we believe should only pertain to compounding, as well as requesting changes to the required SOP to clarify that the storage and filling of a prescription with manufactured hazardous drugs does not have to occur within a separate designated area.

CVS Health believes the use of "designated person" within Article 4.7 should be optional and not mandatory, as a PIC should have the right to assume all "designated person" responsibilities themselves. Certainly, a PIC should be able to retain responsibility and accountability for the performance and operation of a pharmacy, including the responsibilities and accountabilities that relate to the handling of hazardous drugs.

CVS Health develops policies at a corporate level and standardizes them across 1,000+ California pharmacies, for PICs to implement and assure adherence. At CVS Health, a corporate person (or even a department) is essentially the "designated person", as the term is used in Article 4.7. At CVS Health such a "designated person" is not approved by a PIC, and such a "designated person" is not responsible and accountable for the performance and operation of any pharmacy. Therefore, CVS's written comments request that the Board vacate the view that oversight of hazardous drug compounding and handling is separate and distinct within each individual pharmacy.

Last year, APhA, ASHP, and NABP convened a summit, which called on participants to implement various actionable solutions, including boards of pharmacy. Among other actions, the Implementing Solutions report tasks boards of pharmacy to "Identify unnecessary regulatory burdens and workplace requirements that take time away from activities that could improve the safety of patients and the well-being of pharmacy staff." CVS Health believes that maintaining employee lists, which may be subject to frequent change, is an example of a burden that your own association has asked you not to promulgate.

Also, CVS Health believes that a prohibition on the use on an unclassified pass-through may create risk of microbial contamination due to the additional movement throughout the ISO classified space. Therefore, we request that a pass-through into an unclassified space remain allowed.

CVS believes that patients may become concerned about ingesting a drug that is termed hazardous, potentially discontinuing therapy. Therefore, we believe that counseling on hazardous drug disposal should be left to the professional judgment of the pharmacist, and we have again suggested changes in our written comments.

Article 4.6, sterile compounding, does not account for the fact that people will introduce an acceptable amount of airborne particulate, as determined by USP experts, and this is **especially t**rue in the anti-room and the buffer room (ISO 8 and 7). According to USP 797, based upon scientific expert review, ISO 7 and 8 areas are expected to have a CFU count > 1CFU. In the absence of specifying a particular ISO space in 1736.6, any time more than 1 CFU of any microorganism is found, a microbiologist analysis of the organism is triggered, which will occur with great frequency and create unwarranted cost. Realizing this requirement doesn't apply anywhere across the country, CVS Health has requested amendments, which mimic USP Chapter 797 requirements for ISO 7 and 8 areas but retain your proposed, more stringent CFU count for ISO 5 areas.

Lastly, CVS Health applauds the Board to for eliminating current rule 1735.8(c), which requires "routine testing and analysis of compounded drug preparations" and replacing it with proposed 1735.11's requirement to comply with USP Chapter 1163, which allows the compounder to use their clinical discretion and professional judgment in determining the need for routine testing and analysis.

My name is Erik Clausen. I'm a CA licensed pharmacist and former compounding pharmacy owner. I have been a practicing compounding pharmacist for 15+ years. In 2021 as I surveyed the compounding regulatory landscape, I was seriously concerned about my ability to remain compliant with – at the time – proposed USP changes as well as the impact of GFI 256. Even before these draft regs, the cost of compliance was becoming so significant that I didn't see a clear path forward. As a small independent operator, I looked at the state of the industry, and, like many others, I decided to get out of ownership. I sold the pharmacy that I had worked so hard to build. My story is not unique. I know dozens of other independent pharmacies that made similar decisions. Some had no option to sell and just closed their doors. Last year, the buyer of my pharmacy made a similar decision and sadly, closed the doors of my former pharmacy forever. I tell this story because in the Initial Statement of Reasons, the Board stated in print – and I quote -

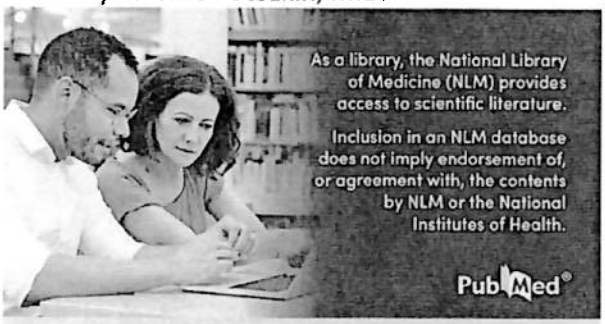
"The Board has made the initial determination that the proposed regulations will not have significant statewide adverse economic impact directly affecting the business including the inability of CA businesses to compete with business in other States. The initial determination is based on the absence of testimony to that effect during the public discussion and development of the proposed regulation. "

I had to read that last sentence twice to be sure I read it correctly. I have sat in these hearing rooms for years and have heard compounding pharmacist after compounding pharmacist try to explain what these regulations and prior regulations will do to our practices and our patients. The costs we would be forced to bear, the rising prescription costs our patients would be forced to pay, or the decrease in compounding access. It appears many of our concerns have not been heard. I assure you there **will** be an economic impact from these proposed regulations - as has been outlined by many others today. There **will** be an impact to patients. That impact may be economic in the form of even higher prices, or it may be one of declining access as more pharmacies close. I don't know. And apparently, based on the Initial Statement of Reasons, neither do you. Based on testimony today, there may be many areas of unintended consequences resulting from these regulations. More needs to be done to consider the many implications this will have on providers, on pharmacies, and the patients that rely on compounded preparations. I strongly urge the Board to consider delaying these regulations, to officially retire the old regs and adopt USP, and if there is a desire to move these regs forward, actually and truly engage stakeholders to understand the full impact these proposed regs would have on the practice of compounding pharmacy or consider moving the rulemaking process to the Sunset Review.

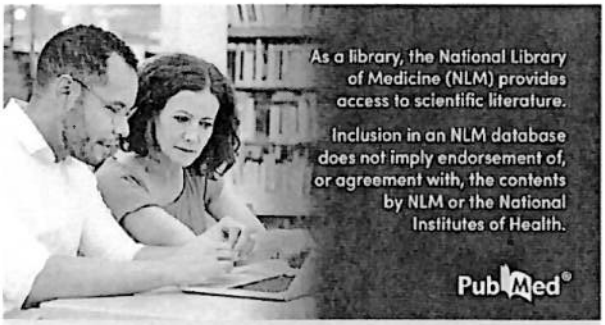
Martinez, Lori@DCA

From: Jerome Potozkin MD <JP@potozkinmd.com>
Sent: Monday, June 17, 2024 3:19 PM
To: PharmacyRulemaking@DCA
Subject: Hearing of June 18, 2024

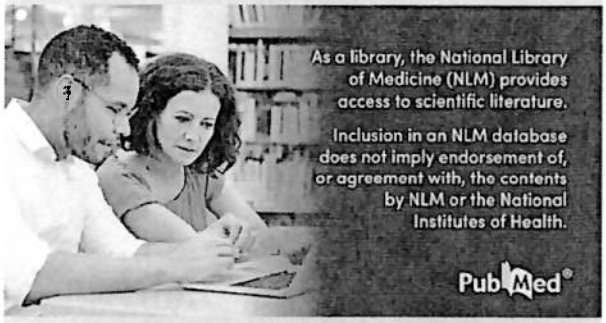
To Whom it May Concern
I plan on testifying at the hearing of 6/18/24 and will be representing the California Derm Society, myself as a board-certified dermatologist as well as the many patients my colleagues and I serve in the state of California. Proposed regulations create an unnecessary burden with respect to the use of buffered lidocaine. It has been common practice and indeed the standard of care for dermatologists (and other physicians) to buffer lidocaine with sodium bicarbonate (10:1) as this drastically eliminates the pain of the injections. Published data shows the safety of this practice as well as the fact that there is no bacterial or fungal growth for as long as 30 days. I have personally injected hundreds of thousands of syringes of buffered lidocaine throughout my career without incident. My colleagues and I have injected millions of syringes of buffered lidocaine without incident. This practice occurs in physician offices and small practices without access to a licensed pharmacist. Adding burdensome regulation with respect to buffered lidocaine will not protect patients. It will have one of two outcomes: 1. It will only serve to increase the pain and suffering of our patients because we are forced to abandon the practice of buffering lidocaine due to overly burdensome regulations or it will create a band of scofflaw physicians who flaunt the regulations in an effort to minimize the pain and suffering of out patients.
Sincerely-Jerome Potozkin, M.D.



[Neutralization of lidocaine-adrenaline. A simple method for less painful application of local anesthesia] - PubMed
nlm.nih.gov



Adjusting the pH of lidocaine for reducing pain on injection - PubMed
nlm.nih.gov



Safety of Prefilled Buffered Lidocaine Syringes With and Without Epinephrine - PubMed
nlm.nih.gov

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Martinez, Lori@DCA

From: Ryan Cassata <ryancassata@gmail.com>
Sent: Tuesday, June 18, 2024 12:17 PM
To: PharmacyRulemaking@DCA
Subject: Glutathione Statement

To Whom this May Concern,
My name is Ryan Cassata. I am a patient in Los Angeles. I have been chronically ill since October with tick born illnesses and autoimmune disease. I have been getting Glutathione IVs since February of this year. My therapies are often harsh on my body and Glutathione has helped me to tolerate the rest of my treatments that I would otherwise have to halt, slowing my recovery. Glutathione is an essential part of my treatment. If these treatments are made unavailable, it will negatively impact my body's capacity to heal.

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Ryan Cassata
www.ryancassata.com