

#	Section	Commenter	Comment	Board Response
1	1735(a)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	As written this definition assumes that all FDA approved drugs have a diluent, resultant strength, and storage time. This will not always be the case.	Board staff have reviewed the comment and agree that the language could be clarified. The Board amended the language to address comments.
2	1735(c)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	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.	Board staff have reviewed the change and do not recommend a change to the regulation text. Staff notes that there are multiple grades of water referenced in USP, depending on the intended use. Staff note that section 1735.4(b) further identifies the types of water.
3	1735(d)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	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 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.	Board staff have considered the comment and do not recommend a change to the proposed text. Staff note that as written, the language provides flexibility for a clinician to use their professional judgment when determining if a compound is essentially a copy. Should the Board amend the language to include the recommended text, the Board would be limiting this flexibility and a clinician's professional judgment.
4	1735(d)	Philip Smyth Medisca	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	Board staff have considered the comment and do not recommend a change to the proposed text. Staff note that as written, the language provides flexibility for a clinician to use their professional judgment when determining if a compound is essentially a copy. Should the Board amend the language to include the recommended language, the Board would be limiting this flexibility and a clinician's professional judgment.

			definition allows for better compliance and understanding of the term.	
5	1735(d)	Tommy Mai Huntington Health	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)).	Board staff have considered the comment and do not recommend a change to the proposed text. Staff note that as written, the language provides flexibility for a clinician to use their professional judgment when determining if a compound is essentially a copy. Should the Board amend the language to include the recommended language, the Board would be limiting this flexibility and a clinician's professional judgment.
6	1735(d)	Wendy Waldman Torrance Memorial Medical Center	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)).	Board staff have considered the comment and do not recommend a change to the proposed text. Staff note that as written, the language provides flexibility for a clinician to use their professional judgment when determining if a compound is essentially a copy. Should the Board amend the language to include the recommended language, the Board would be limiting this flexibility and a clinician's professional judgment. https://www.fda.gov/files/drugs/published/Compounded-Drug-Products-That-Are-Essentially-Copies-of-a-Commercially-Available-Drug-Product-Under-Section-503A-of-the-Federal-Food--Drug--and-Cosmetic-Act-Guidance-for-Industry.pdf.
7	1735(d)	Melanie Horn Sutter Health Also Provided at Reg Hearing	The CCR section 1735.1 (k) definition of "essential copy" effective January 2017 matches the proposed 1735.(d) standard and i FD&C Act for 503A and 503B, however, the CCR definition lacks specificity for California pharmacies to differentiate compounded drugs from an "essentially a copy" without further clarifying language.	Board staff have reviewed the comment and do not recommend any changes based on the comment. The example provided would not be essentially a copy under the current proposed regulation as there is a clinically significant difference for this specific pediatric patient. Pharmacists must remain knowledgeable of current practice standards and legal requirements of the industry when exercising their professional judgment.

		The definition makes the determination to same active pharmaceutical ingredient (API) without other determinations such as strength, dosage form and route of administration. For example, a neonate requiring a CNSP liquid oral suspension prepared from capsules. Under the current definition, this and all other dosage form change CNSPs would be an essentially a copy with the same API as a commercial product. The defined exception is the determination by the prescribing practitioner but if a California compounder intends to rely on such a determination to establish that a compound is not essentially a copy, the CCR 1735.1 (f) (B) requires documentation of the determination by physician, compounder, and dispensing pharmacist. To enhance clarity, recommend revising the definition to explicitly consider factors such as strength, dosage form and rout of administration when determining whether a compounded preparation qualifies as an "essentially a copy" to differentiate CNSPs from essential copies thus eliminating unnecessary documentation from a prescribing practitioner for all CNSPs. (d) "Essentially a copy" of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (API(s)), <u>same, similar, or an easily substitutable dosage strength, same dosage form, and the same route of administration as the commercially available drug product,</u> 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.	
8	1735(f)	Marie Cottman Pacific Compounding	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."	Staff have reviewed the comment and do not recommend any changes to the proposed text based on the comment. Staff note that the regulation requires the establishment of a beyond-use date to ensure the quality of the product to that date, not just through the time of dispensing.
9	1735.1	Paul Lofholm	no comment except I do not know why Blood products are contained herein?	Staff have reviewed the comment and do not believe any changes are necessary. Staff note that there are some CNSPs that may contain blood products, for example, a facial cream that contains the patient's own blood.
10	1735.1(a) should be 1735.5(a)	K. Scott Guess	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	Staff believe the commenter is referring to proposed section 1735.5(a) as opposed to section 1735.1(a), which is referenced in the comment. Staff have reviewed the comment and do not recommend any change to the

			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.	proposed regulation. Staff note the documentation of the cleaning process as described in the proposed language is appropriate and consistent with the actions necessary to maintain and clean the compounding environment. Staff note that operationalizing the requirements could be quite simple, including a prepared log that already has the items listed. Staff performing the cleaning could then document the date, time, and place a check box or other indication next to the products used.
11	1735.1(a)	John Gray Kaiser Permanente	"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. Nonsterile compounding is performed by or under the <u>direct supervision and control</u> of a licensed pharmacist pursuant to a patient specific prescription, unless otherwise specified in this article.	Staff have reviewed the comment and recommend a change to clarify the language to reaffirm the Board's expectation that the level of supervision encompasses direct supervision and control.
12	1735.1(b)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy 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." 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 expiration 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	Staff have considered the comment and recommend a change to the language. Specifically, staff recommend removing 1735.1(b) to avoid the potential overexpansion of the definition of nonsterile compounding to removing a dangerous drug from a manufacturer's bottle and placing it in a prescription vial.

			logical. Recommend to move away from this guidance and to not use chapters over 1000 as regulation.	
13	1735.1(b)	Rheta Silvas Kaweah Health	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>	After consideration of comments, staff recommend removing 1735.1(b), because it is appropriately addressed within the USP Chapter.

			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?	
14	1735.1(e)	K. Scott Guess	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.	Staff have reviewed the comment and do not recommend any substantive change; however, staff do recommend a minor nonsubstantive change to amend "fairly" to "reasonably." The day supply provisions are related only to office furnishing for veterinary patients. Staff are recommending a change to the days supply for antibiotics for veterinary patients, not based solely on this comment. (See 1735.1(e)(2))
15	1735.1(e)(2)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	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. We are requesting a carve-out (similar to that of ophthalmic agents) for antibiotic medications.	Staff have considered the comment and are recommending a change to the proposed regulation text to allow for the dispensing of a 14-day course of an antibiotic for an animal patient.
16	1735.1(e)(2)	Michael Blaire	The commenter expressed concern about the veterinarian's compounding to 7 days as the standard course of antibiotics is 10 to 14 days. He indicates an animal will show improvement after 5 days, so the animal owner will not fill the prescription for the remaining days, which will lead to reinfections. Some states allow in-office use with no restrictions, and others allow 14	Staff have considered the comment and are recommending a change to the proposed regulation text to allow for the dispensing of a 14-day course of an antibiotic for an animal patient.

			days. The commenter requests an increase to 14 days.	
17	1735.1(f)	Keck Medicine of USC	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 tablets 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 [sic], 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	Staff have considered the change and do not recommend changes to the proposed regulation text. Staff note that the proposed language, as written, would not prohibit a pharmacist from compounding the suspension based on the facts as described in the comment since there is a clinically significant difference for that identified patient.

			language to "In addition to prohibitions and requirements for compounding established in federal law, no CNSP ~~should~~ <u>shall</u> be prepared that".	
18	1735.1(f)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	Prior version cited 21CFR353a, and replacing the citation with "federal law" is vague and could apply to any federal law.	Board staff have reviewed the comment and do not recommend changes based on the comment; however, staff note that the comment reflects that licensees may not be fully aware of their obligation to comply with all relevant federal laws. Staff note Business and Professions Code section 4301(j) establishes as unprofessional conduct violations of any state or federal law related to controlled substances and dangerous drugs. As such, staff are recommending changes to the language to ensure licensees have this understanding.
19	1735.1(f)	A. VanOstrand Him and Hers	Commenter expressed concern about the requirements for Essentially a copy and 2 separate pharmacists needing to sign off.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. Additional information related to this issue is found in responses in line 7 and line 30. Related to essentially a copy) Staff note that a compounding pharmacist may not have access to the patient's record to make a determination that the compounding product is the appropriate treatment. Staff note that all pharmacists have a professional obligation to patient care, which includes the selection of the drug therapy being provided to their patient.
20	1735.1(f)(1)(A)	CSHP	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~~ <u>should</u> be prepared that: (1) Is essentially a copy of one or more	Board Staff have considered the change and do not recommend changes. Staff notes further that the proposed regulation text is consistent with the Board's current regulation, CCR Section 1735(d)(3). Staff note that the proposed language, as written, would not prohibit a pharmacist from compounding the suspension as described in the comment based on the facts described in the comment, since there is a clinically significant difference for that identified patient. Staff note that a drug product that is not available by a wholesaler is not a shortage as the product may be available from other wholesalers or directly from the manufacturer.

			commercially available drug products, unless: (A) <u>that drug product is not available by the manufacturer or wholesaler</u> , 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	
21	1735.1(f)(1)(A)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	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. 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.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. Pharmacists must remain knowledgeable of current practice standards and legal requirements of the industry while exercising their professional judgment, including any guidance for the industry, including those issued by the FDA related to veterinary patients.
22	1735.1(f)(1)(A)	UCSF Also submitted at Reg Hearing	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	Staff have considered the change and do not recommend changes to the proposed regulation text. Staff notes further that the proposed regulation text is consistent with the Board's current regulation, CCR Section 1735(d)(3). Staff note that referring only to nationally recognized sources for drug shortages is necessary to ensure members of the regulated public rely only on the same authorized sources. The sources specified in the proposed regulation text are consistent with current industry practice.

			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 <u>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</u>	
23	1735.1(f)(1)(A)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health	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 shortage² and recent manufacturer bankruptcies (i.e. Akorn, Apotex) it is becoming more challenging for Health-Systems to obtain commercially available	Staff have considered the change and do not recommend changes to the proposed regulation text. Staff note that referring only to nationally recognized sources for drug shortages is necessary to ensure members of the regulated public rely only on the same authorized sources. The sources specified in the proposed regulation text are consistent with current industry standards and practices. Staff notes further that the proposed regulation text is consistent with the Board's current regulation, CCR Section 1735(d)(3).

			products. 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) <u>that drug product is not available by the manufacturer or wholesaler</u>, 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	
24	1735.1(f)(1)(A)	Walgreens	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	Staff have considered the change and do not recommend changes to the proposed regulation text. Staff note that referring only to nationally recognized sources for drug shortages is necessary to ensure members of the regulated public rely only on the same authorized sources. The sources specified in the proposed regulation text are consistent with current industry practice. Staff notes further that the proposed regulation text is consistent with the Board's current regulation, CCR Section 1735(d)(3).

			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	
25	1735.1(f)(1)(A)	Melanie Horn Sutter Health	ASHP and FDA drug shortage lists can have a lag between the posted shortage and a disruption in supply. In 2023, the Akorn recall was posted after the State Board notification of the company shut down with multiple unlisted drug shortages already impacting supply. Wholesalers frequently cannot supply critical medications, especially in a pre-shortage situation. California code restrictions in place prevent compounding during these supply disruptions and contribute to heightened risk and safety concerns for patients unable to access medication therapies. Documentation of inability to acquired due to wholesaler not able to supply documentation is a solution recommended. Compounding to meet an immediate need when a commercially available dosage form is	Staff have considered the change and do not recommend changes. Staff note that referring to nationally recognized sources for drug shortages is necessary for patient safety. Staff highlight that the example provided in the comment would not be considered "essentially a copy" under the current proposed regulation as there is a clinically significant difference for this specific patient. Pharmacists must remain knowledgeable of current practice standards and legal requirements for the profession when exercising their professional judgment.

		not stocked but is not done so in regular or inordinate amounts is a necessary exclusion to provide patient access and continuity of care through compounded preparations. If not done so based on establishing a routine pattern or in inordinate quantities deemed by the board creating a clear exemption. An example is treating <i>Clostridioides difficile</i> with compounded from sterile vancomycin vial manufactured products to make an oral suspension where a rural or small facility will not routinely order the commercial medication it does not routinely utilize but would be remiss to delay or withhold the compounding treatment to initiate therapy. Recommended new language: (A) the drug product is deemed not commercially available, appearing in an American Society of Health-System Pharmacists (ASHP) or FDA Drug Shortages Database that is in short supply at the time of compounding, ~~and at the time of dispensing,~~ or <u>(B) the drug product is not commercially available due to inability to supply by the manufacturer or wholesaler.</u> <u>(C) the drug product is unavailable to dispense and the CNSP is not compounded regularly or in inordinate amounts.</u> (D) the compounding produces a clinically significant difference for the medical need of an identified individual patient, as determined by the prescribing practitioner. <u>If such determination has not been documented on the prescription by the prescriber, the</u> (ii) the compounding pharmacist, and or (iii) the dispensing pharmacist(s)	

			<u>Shall ensure that the determination is documented on the prescription.</u> (C) Documentation describing the conditions in (1)(A) , (1)(B), (1)(C) and <u>1 (D)</u> is maintained in a readily retrievable format	
26	1735.1(f)(1)(A)	Wendy Waldman Torrance Memorial Medical Center	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. 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	Staff have considered the change and do not recommend changes to the proposed regulation text. Staff note that referring only to nationally recognized sources for drug shortages is necessary to ensure members of the regulated public rely only on the same authorized sources. The sources specified in the proposed regulation text are consistent with current industry practice. Staff notes further that the proposed regulation text is consistent with the Board's current regulation, CCR Section 1735(d)(3).

			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) <u>that drug product is not available by the manufacturer or wholesaler</u> , 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...	
27	1735.1(f)(1)(B)	Philip Smyth Medisca	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.	The Board reviewed the comment and made changes to the proposed regulation text to remove the requirement that could have potentially required two pharmacists to make independent determinations. Staff notes further that the commenter is asking a question regarding documentation requirements. Documentation requirements will be pharmacy-specific.
28	1735.1(f)(1)(B)	Walgreens	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 <u>appropriate</u> by: (i) the prescribing practitioner, <u>or</u> (ii) the compounding pharmacist, <u>and</u> ~~(iii) the dispensing pharmacist(s).~~	The Board reviewed the comment and made changes to the proposed regulation text to remove the requirement that could have potentially required two pharmacists to make independent determinations. Staff note that all pharmacists have a professional obligation to patient care, which includes the selection of the drug therapy being provided to their patient.
29	1735.1(f)(1)(B)	Marci Bencomo Pacifica Compounding	The commenter disagrees with the requirement for two pharmacists to make the determination that a compound produces a clinically significant difference for the patient as it is redundant, and federal guidelines require the	The Board reviewed the comment and made changes to the proposed regulation text to remove the requirement that could have potentially required two pharmacists to make independent determinations. Staff note that all pharmacists have a professional obligation to patient

			prescribing practitioner to make the determination.	care, which includes the selection of the drug therapy being provided to their patient.
30	1735.1(f)(1)(B)	Rheta Silvas Kaweah Health	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	The Board reviewed the comment and made changes to the proposed regulation text to remove the requirement that could have potentially required two pharmacists to make independent determinations. Staff note that all pharmacists have a professional obligation to patient care, which includes the selection of the drug therapy being provided to their patient.

			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.	
31	1735.1(f)(1)(B)	Marie Cottman Pacific Compounding	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.	Staff note that as written, the language provides flexibility for a clinician to use their professional judgment when determining if a compound is essentially a copy by determining if a change will produce a clinically significant difference. The Board reviewed the comment and made changes to the proposed regulation text to remove the requirement that could have potentially required two pharmacists to make independent determinations. Staff note that FDA guidance documents help establish the standard of practice for compounders. Staff note that pharmacists must remain knowledgeable of current practice standards and legal requirements of the industry while exercising their professional judgment. Staff note that all pharmacists have a professional obligation to patient care, which includes the selection of the drug therapy being provided to their patient.

			RECOMMENDATION: Allow Federal statute 503A of the FD&C Act to stand on its own.	
32	1735.1(f)(1)(B)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	Is it necessary to have two pharmacists involved? What if the compounding pharmacist is also the dispensing pharmacist? How would the pharmacy document pharmacist(s) assessment of the reason for compounding? 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.	The Board reviewed the comment and made changes to the proposed regulation text to remove the requirement that could have potentially required two pharmacists to make independent determinations.
33	1735.1(f)(2)	Marie Cottman Pacific Compounding	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	Board staff have reviewed the comment and agree that additional clarification of the proposed regulation language is appropriate.

			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~~ <u>animal</u> population, unless allowable under the Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA).	
34	1735.1(f)(2)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	As written, this eliminates the compounding 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 FDA GFI 256 in their approach to animal compounding and maintain patient access.	Staff have reviewed the comment and do not recommend changes to the proposed regulation text. Staff note that FDA guidance documents establish the standard of practice for compounders. Staff note that pharmacists must remain knowledgeable of current practice standards and legal requirements while exercising their professional judgment.
35	1735.1(h)	John Gray Kaiser Permanente	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. <u>When a CNSP is furnished to a patient or patient's agent</u>, 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,	Staff have reviewed the comment and agree that additional clarification to the language is appropriate to more specifically describe when patient consultation is required. Staff is offering recommended language.

			handling, and disposal of the CNSP and related supplies furnished.	
36	1735.1(h)	Marie Cottman Pacific Compounding	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.	Board staff have considered the comment and do not recommend changes based solely on this comment. Staff note that changes to CCR 1707.2 are outside of the scope of the regulation. Should the Board seek to amend CCR 1707.2, at that time the Board will consider if consultation should also encompass disposal information on manufactured drug products.
37	1735.1(h)	CSHP	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	Staff have reviewed the comment and agree that additional clarification to the language is appropriate to more specifically describe when patient consultation is required. Staff is offering recommended language to address the comment.

			healthcare professional. Proposed Exemption Language: <u>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.</u>	
38	1735.1(h)	Tommy Mai Huntington Health	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: <u>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.</u>	Staff have reviewed the comment and agree that additional clarification to the language is appropriate to more specifically describe when patient consultation is required. Staff is offering recommended language to address the comment.
39	1735.1(h)	Rheta Silvas Kaweah Health	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 relevant to oral patient consultation to include	Staff have reviewed the comment and agree that additional clarification to the language is appropriate to more specifically describe when patient consultation is required. Staff is offering recommended language to address the comment.

			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.	
40	1735.1(h)	Melanie Horn Sutter Health	Limit consultation to CNSPs dispensed directly to the patient and not for other healthcare dispensing scenarios where patient does not store, handle, or dispose the CNSP. <u>When a CNSP is dispensed to a patient or patient's agent</u>, 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.	Staff have reviewed the comment and agree that additional clarification to the language is appropriate to more specifically describe when patient consultation is required. Staff is offering recommended language to address the comment.
41	1735.1(h)	Wendy Waldman Torrance Memorial Medical Center	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.	Staff have reviewed the comment and agree that additional clarification to the language is appropriate to more specifically describe when patient consultation is required. Staff is offering recommended language to address the comment.

42	1735.1 (h)	Mark Johnston CVS Health Also provided at Reg Hearing	Commenter indicates that section 1702.2(c), Duty to Consult, only lists two categories of mandatory counseling and the pending regulations would create a third. Additionally, 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. Commenter states that 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. Commenter believes the pending regulations are essentially requiring pharmacists to provide legal advice on proper disposal, for which they are not well educated. Commenter requests the following edit: (h) In addition to the provisions provided in section 1707.2, <u>whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral</u> consultation shall be provided to the patient and/or patient's agent concerning proper use, storage, <u>and</u> handling, ~~and disposal~~ of the CNSP and related supplies furnished.	Staff have reviewed the comment and recommend no changes to the language based on the comment. Staff notes that it is recommending changes to the language based on other comments received. Staff further notes that appropriate consultation with a patient will incorporate patient-centered language easily understandable to the patient and notes that information on proper disposal could, for example include, "Our pharmacy offers drug take back services. It is recommended that you place unused medications in our drug take back bin."
43	1735.1 (i)	Melanie Horn Sutter Health Also Provided	Recommend for clarity to harmonize the terminology used in 1735.1 (i) and 1736.1 (h), match the wording to the Board's intent (i.e.,	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Staff notes that federal law does not allow for pharmacy

		at Reg Hearing	for production, preparation, and/or handling). 1736.1 (h) states "CSPs with human whole blood or human whole blood derivatives shall be produced in compliance with Health and Safety Code section 1602.5." The California Code, Health and Safety Code - HSC § 1602.5 address the production of human blood/blood derivatives. "(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:...." USP 797 1.1.2 differentiates between "human" and "patient" to recognize that the requirement does not apply to licensed BLAs for manufactured derivatives like IVIG, Albumin, cryoprecipitate, and clotting factors. To enhance clarity, recommend explicitly excluding these manufactured derivatives to recognize compounding of these products. (i) Human whole blood or human whole blood derivatives used in CNSPs shall be ~~prepared~~ <u>produced</u> in compliance with Health and Safety Code section 1602.5 <u>or supplied as a commercial biologic product licensed as a Fractionated Plasma Products.</u> Reference: https://www.fda.gov/vaccines-blood-biologics/approved-blood-products/fractionated-plasma-products	compounding of biologic products. Staff note that the FDA has released guidance in this area. Staff note that FDA guidance documents establish the standard of practice for compounders. It is incumbent on licensed professions to remain current on guidance's issued to ensure compliance with provisions established. The guidance document is available at https://www.fda.gov/files/drugs/published/Mixing--Diluting--or-Repackaging-Biological-Products-Outside-the-Scope-of-an-Approved-Biologics-License-Application.pdf
44	1735.2	Paul Lofholm	Quality Control and quality assurance OK Container closure for CNSP- are you saying the existing pharmaceutical supplies are not	Staff have reviewed the comments and do not recommend changes to the proposed language. Staff note that the commenter appears to be asking questions

			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?	and the tenor of the comments are unclear. Staff refer the commenters to the Initial Statement of Reasons to gain an understanding about the rational for the proposed regulation language.
45	1735.2(a)	Rheta Silvas Kaweah Health	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.	Staff have reviewed the comment and recommend a change to the language to address the comment. Staff recommend removing the requirement for training for individuals who are only handling completed compounded preparations.
46	1735.2(a)	Philip Smyth Medisca	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.	Staff have reviewed the comments and do not recommend any changes based solely on the comment. Staff note that while the PIC may determine the appropriate container closure for use, compounding staff need to have foundational knowledge to safely use the container closure system selected.
47	1735.2(a)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	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 container closure and equipment selection and component selection and handling.	Staff have reviewed the comment and recommend a change to the language to address the comment. Staff recommend the removal of the requirement for training by individuals who are just handling the completed compounded preparation.
48	1735.2(b)	Marie Cottman Pacific Compounding	COMMENT: This is a duplicate of what is already stated in USP 795 as a MUST statement. RATIONALE:	Staff have considered the comment and agree with the commenter that section 1735.2(b) can be removed from the proposed text.

			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.	
49	1735.2(c)	Marci Bencomo Pacifica Compounding	If someone fails a training element, the restriction from all compounding does not make sense as it would have a substantial impact to small compounding locations.	Board staff have considered the comment and do not recommend changes to the proposed regulation text based solely on this comment. Staff are offering recommended changes to the section, to focus on the core competencies established in the USP Chapter.
50	1735.2(c)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	Having people that fail any aspect of training having to 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 compounding entirely. If they fail compounding of capsules it does not generally mean they could not continue to compound suspensions provided that they had passed the training for that dosage form. Wording should be amended to allow the supervising pharmacist to determine the appropriate course of action based on the	Board staff have considered the comment and do not recommend changes to the proposed regulation text based solely on this comment. Staff are offering recommended changes to the section, to focus on the core competencies established in the USP Chapter.

			training needed and the training that was not passed.	
51	1735.2(c)	Marie Cottman Pacific Compounding	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! 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	Board staff have considered the comment and do not recommend changes to the proposed regulation text based solely on this comment. Staff are offering recommended changes to the section, to focus on the core competencies established in the USP Chapter.

			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 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.	
52	1735.2(c)	Rick Rhoads University Compounding	(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 <u>related to the sections failed</u> 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	Board staff have considered the comment and do not recommend changes to the proposed regulation text based solely on this comment. Staff are offering recommended changes to the section, to focus on the core competencies established in the USP Chapter.

			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.	
53	1735.2(c)	Jasmine Parker Pacific Compounding	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.	Board staff have considered the comment and do not recommend changes to the proposed regulation text based solely on this comment. Staff are offering recommended changes to the section, to focus on the core competencies established in the USP Chapter.
54	1735.2(d)	Marie Cottman Pacific Compounding	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	Staff have considered the comment and do not recommend changes to the language. Staff note that the individual providing the training must have a more thorough knowledge that encompasses not only how to perform a task, but also for example why something must be done to protect patients.

			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.	
55	1735.3(a)	John Gray Kaiser Permanente	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." 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.	Board staff have reviewed the comments related to this issue and are recommending changes to the proposed text to address the comments and some of the confusion that appears to be stemming from the provisions of Chapter 795 requirements and the Board's proposed regulation text.

			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.	
56	1735.3(a)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	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 compounding. USP 795 requires individuals to report their conditions to the designated person. We suggest amending the proposed rule using language from USP. Requiring the pharmacist to inspect their team prior to compounding for all of the listed items will create HR related challenges and is not realistic.	Board staff have reviewed the comments related to this issue and are recommending changes to the proposed text to address the comments and some of the confusion that appears to be stemming from the provisions of Chapter 795 requirements and the Board's proposed regulation text.
57	1735.3(a)	Marie Cottman Pacific Compounding	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	Staff have reviewed the comment and recommend a change to the language to provide clarification. Commenter appropriately highlighted that the language needs to apply to any personnel entering the compounding area.

			finishes with "personnel." Is it anyone (certifiers, clerical staff and compounders)? Is it just compounding staff? Or is it all staff? 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.	
58	1735.3(a)	Rheta Silvas Kaweah Health	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	Board staff have reviewed the comments related to this issue and are recommending changes to the proposed text to address the comments and some of the confusion that appears to be stemming from the provisions of Chapter 795 requirements and the Board's proposed regulation text.

			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, 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.	
59	1735.3(a)	Melanie Horn Sutter Health	The USP 795 chapter details 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. The Initial Statement of Reasons, the Board claims that this regulation is necessary "to prevent contamination of the CNSP." but allows for documented accommodations. Mitigation and accommodation of listed, specific conditions can be accomplished such as a rash between the toes of an enclosed shoe, a recent ankle tattoos that has a bandage cover and under clothing and PPE but as written these are specific contaminating conditions that are excluded. Recommend less	Board staff have reviewed the comments related to this issue and are recommending changes to the proposed text to address the comments and some of the confusion that appears to be stemming from the provisions of Chapter 795 requirements and the Board's proposed regulation text.

			prescriptive detail and outline that the medical condition be of concern to impact the CNSPs or the environment and decide. Since designation of the area is required, recommend using the terminology. 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 a medical condition (such as but not limited to conjunctivitis, active respiratory infection) 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.	
60	1735.3(b)	Walgreens	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	Board staff have considered the comment and do not recommend changes to the proposed text. Staff note that a closed system processing device is only required in the chapter when there is a exposure to staff. Use of a gown and face mask reduce the higher risk of exposure to staff and higher risk of contamination to the compounding environment and CNSP.

			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~~ <u>Appropriate PPE</u> shall be used whenever a closed system processing device is required.	
61	1735.3(c)	Rheta Silvas Kaweah Health	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.	Staff have reviewed the comment and recommend changes to the language to provide clarity consistent with the recommendations from the commenter.
62	1735.3(c)	Melanie Horn Sutter Health	The term "All" garb establishes an unclear standard for the disposition of the which specific garb removed used for CNSP compounding must remain in the compounding area. As written "All garb" is	Staff have reviewed the comment and do not recommend changes based solely on this comment; however, staff are recommending changes to this subdivision.

			inclusive of disposable, reusable, discarded and garb being stored for reuse and does not meet the intent. Single-use disposable garb used during a shift that is disposed does not remain in the compounding area. <u>All Disposable garb removed and stored for reuse during a shift must remain in the designated compounding area.</u>	
63	1735.3(c)	Marie Cottman Pacific Compounding	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 with the intent to be reused during a shift must remain in the compounding area."	Staff have reviewed the comment and do not recommend changes based solely on this comment; however, staff are recommending changes to this subdivision.

64	1735.3(c)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	As written, this would allow for the reuse of any and all disposable garb during a shift. Of the disposable garb items, only the disposable gown should be reused.	Board staff have reviewed the comment and recommend a change to the language not based solely on this comment.
65	1735.3(e)	Marie Cottman Pacific Compounding	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. 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	Board staff have considered the comment and recommend changes to the language, although not based solely on these comments.

			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.	
66	1735.3(e)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	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 that includes 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.	Board staff have considered the comment and recommend changes to the language, although not based solely on these comments.
67	1735.3(e)	Walgreens	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 <u>with methods to minimize environmental contamination.</u> ~~with a germicidal cleaning agent and sanitized with 70% isopropyl alcohol before re-use.~~	Board staff have considered the comment and recommend changes to the language, although not based solely on these comments.

68	1735.3(e)	Philip Smyth Medisca	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.	Board staff have considered the comment and recommend changes to the language, although not based solely on these comments.
69	1735.4	Paul Lofholm	sink requirements and water requirements are reasonable though a dishwasher plumbing can be a problem.	Board staff have reviewed the comment. It appears to be commentary. Staff do not recommend changes to the language based on these comments.
70	1735.4(a)	Jasmine Parker Pacific Compounding	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."	Staff have reviewed the comment and believe the commenter may be referencing 1735.4(b). Staff are recommending changes to Section 1735.4(b); however, these changes are not based on the comments provided.
71	1735.4(a)	Rheta Silvas Kaweah Health	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.	Board staff have reviewed the comment and do not recommend changes to the proposed text. Staff note that compounding personnel washing their hands after using the restroom does not meet the standards for proper hand hygiene prior to compounding. As an example, compounding personnel leaving the restroom would then be touching a door knob to open the door, creating the potential to contaminate their hands.
72	1735.4(a) should be 1735.4(b)	Marie Cottman Pacific Compounding	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	Board staff believe the comment is related to 1735.4(b) related to water quality. Board staff are recommending a change based on the comments as staff understand them.

			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."	
73	1735.4(b)	John Gray Kaiser Permanente	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.	Board staff have considered the comment and recommend changes to the language, although not based solely on these comments. Staff note that USP identifies various grades of water, including in Section 4.4 of the Chapter. Staff notes that the quality of water is of significance for patient safety. As an example, tap water may be contaminated with fungus, bacteria, and other elements that could contaminate the equipment used in the preparation of CNSPs.
74	1735.4(b)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	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.	Board staff have considered the comment and recommend changes to the language, although not based solely on these comments.
75	1735.4(b)	Walgreens	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,~~	Board staff have reviewed the comment and do not recommend changes based on this comment. Staff note that USP identifies various grades of water, including in Section 4.3 of the Chapter. Staff notes that the quality of water is of significance for patient safety. As an example, tap water may be contaminated with fungus, bacteria, and other elements that could contaminate the equipment used in the preparation of CNSPs.

			~~distilled water, or reverse osmosis water shall be used for rinsing equipment and utensils.~~	
76	1735.4(c)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	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 contamination (e.g., bacteria, mold) in the production area or adjacent areas • Foreign matter in the production area (e.g., rust, glass shavings, hairs, paint chips) • Producing drugs while construction is underway in a nearby area without adequate controls 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 compendial or pharmaceutical grade equivalents (e.g., ingredients with potentially harmful impurities, ingredients labeled with “not for pharmaceutical use” or an equivalent statement)	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Staff note that pharmacists must use professional judgment. It is not possible to develop a list that encompasses every potential scenario. Staff noted that the commenter appears to have provided information that is contained in a guidance document released by the FDA. As provided in previous comments from staff, professional judgment requires remaining current on guidance issued by the FDA, including those describing insanitary conditions.
77	1735.5	Paul Lofholm	(a) usually this is covered in the SOP and so is (b)	Staff believe that documentation of the cleaning process, as described in the proposed language, is appropriate and consistent with the actions necessary to maintain a clean compounding environment. Staff note that operationalizing the requirements could be quite simple, including a prepared log that already has the items listed. Staff performing the cleaning could then document the date, time, and place a check box or other indication next to the products used.

78	1735.5(a)	Rheta Silvas Kaweah Health	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.	Staff believe that documentation of the cleaning process, as described in the proposed language, is appropriate and consistent with the actions necessary to maintain and clean the compounding environment. Staff note that operationalizing the requirements could be quite simple, including a prepared log that already has the items listed. Staff performing the cleaning could then document the date, time, and place a check box or other indication next to the products used.
79	1735.5(a)	Narinder Singh Santa Clara Valley Healthcare (SCVH) Also provided at Reg Hearing	In the County of Santa Clara outpatient pharmacies, a non-pharmacy staff, Environmental Service (EVS), provides the daily cleaning. Keeping track of each EVS employee is burdensome and adds no value since the pharmacy staff does clean and sanitize the compounding area before each compounding. Request to modify this requirement to "The facility's documentation <u>prior to the</u> compounding occurrence of the cleaning and sanitizing of the compounding area shall ..."	Staff believe that documentation of the cleaning process, as described in the proposed language, is appropriate and consistent with the actions necessary to maintain and clean the compounding environment. Staff note that operationalizing the requirements could be quite simple, including a prepared log that already has the items listed. Staff performing the cleaning could then document the date, time, and place a check box or other indication next to the products used.
80	1735.5(a)	Melanie Horn Sutter Health	Cleaning Logs include each occurrence with identity of individual and detail the cleaning agent(s) and when used. The Board proposed language places additional burden of added documentation of listing multiple cleaning agents used every day. Each occurrence to document a fixed rotation of cleaning agents adds burden that does not introduce added	Staff believe that documentation of the cleaning process as described in the proposed language is appropriate and consistent with the actions necessary to maintain and clean the compounding environment. Staff note that operationalizing the requirements could be quite simple, including a prepared log that already has the items listed. Staff performing the cleaning could then document the

			compliance to performing a thorough and detailed cleaning task. The facility's documentation ~~of each occurrence~~ of the cleaning and sanitizing of the compounding area shall include <u>the product name(s) of the cleaning and sanitizing agents used</u>. The documentation for each <u>cleaning occurrence</u> shall identify ~~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.~~	date, time, and place a check box or other indication next to the products used.
81	1735.5(a) & (b)	Walgreens	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.~~	Staff believe that documentation of the cleaning process, as described in the proposed language, is appropriate and consistent with the actions necessary to maintain and clean the compounding environment. Staff note that operationalizing the requirements could be quite simple, including a prepared log that already has the items listed. Staff performing the cleaning could then document the date, time, and place a check box or other indication next to the products used. Further, staff note that the commenter references 1735.5 (b) but did not provide comments specific to the subdivision.
82	1735.6	Paul Lofholm	Industry standards mean labeled requirements?	Board staff have reviewed the comment and do not recommend any change to the language. Board staff recommend that the commenter review the Initial Statement of Reasons to gain an understanding of the rationale related to this section. Staff note that Section 1735.6 is related to equipment and components.
83	1735.6(a) & (b)	Walgreens	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~~	Board staff have reviewed the comments and do not recommend changes to the proposed text. Staff note that as included in the Initial Statement of Reasons, these requirements ensure equipment is being used properly and consistent with its intended use and not for untested or other purposes that could be ineffective or pose a risk to patient safety. Furthermore, storing components inappropriately can compromise the components,

			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.~~	thereby creating a risk to the safety and efficacy of the CNSP. For example, a component stored under inappropriate temperature conditions could result in an adulterated product under state and federal law.
84	1735.6(b)	Rheta Silvas Kaweah Health	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.	Staff have reviewed the comment and do not recommend changes to the proposed regulation text. Staff note that the term "used" is consistent with the language in the USP Chapter. Staff further note that pharmacists must remain knowledgeable of current practice standards and legal requirements while exercising their professional judgment. This extends to knowledge of appropriate industry standards.
85	1735.6(b)	Marie Cottman Pacific Compounding	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.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on the comment. As this is a common violation found in pharmacies, staff believe inclusion of the proposed regulation text is appropriate.

			RECOMMENDATION: Remove.	
86	1735.7	Narinder Singh Santa Clara Valley Healthcare (SCVH) Also provided at Reg Hearing	Assigning the BUD based on start time is unnecessarily stringent and wasteful. At the start of compounding the product has not been made yet. The language should be modified to "the time when compounding of the CNSP <u>completed</u> ,"	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Staff note that the recommended change from the commenter would be contrary to USP requirements that state that the BUD is determined from the start of the compounding process.
87	1735.7(a)(1)	Walgreens	USP 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 <u>available upon request prior to compounding</u> ~~readily retrievable at the time of compounding~~ and <u>shall be retrievable</u> ~~maintained~~ for three years from the date each CNSP is dispensed.	Board staff have considered the comment and do not recommend change based on comment. Board staff note that the information may be stored in different locations; however, when requested, the compounding record must be produced to the Board that includes are of the required information in a single document.
88	1735.7(a)(1) should be 1735.7(c)(1)	K. Scott Guess	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	Board staff have reviewed the comment and believe the comments are related to 1735.7(c)(1). Board staff do not recommend any changes. Staff note that the USP Chapter 795 establishes either the date or date and time for nonsterile compounding; however, the date AND time are required in Chapter 797. The Board's proposed regulation text ensures consistency between CNSPs and CSPs, standardizing the process for pharmacies.

			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.	
89	1735.7(c)	Melanie Horn Sutter Health	USP 795 does not place restriction on a single document and electronic workflow management systems operate similar technology to consider harmonizing the CR requirement for USP 795 & USP 797 for clarity and support automated workflow solutions with forcing functions to capture and detail the required information readily. The current electronic health record and most other safety automated workflow technologies have some limitations in their ability to produce a single document, but all information is readily obtained and held withing the management system. Mandating a single "document" requires transitioning from electronic automated capture to collating elements that the software does not keep within a single document but is within a single electronic record. A compounding record (CR) <u>shall be retrievable and contains the required information</u> developed in compliance with USP Chapter 795, and includes the following additional elements:	Board staff have considered the comment and recommend a change to this section, although not based solely on this comment. Board staff note that the information may be stored in different locations; however, when requested, the compounding record must be produced to the Board that includes all of the required information in a single document. It is important for the board be able to review all the required information together for individual compounded preparations and not have to guess or wade through unrelated documents that may not have been relied upon. Staff are offering recommended language to clarify.
90	1735.7(c)	Rita Shane Cedars-Sinai, Tommy Mai	Rationale: Electronic record keeping systems/software that enable documentation compliance to the	Board staff have considered the comment and recommend a change to this section, although not based solely on this comment. Board staff note that the

		Huntington Health, CSHP	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: <u>(c) Compounding record requirements shall be readily retrievable to comply with USP Chapter 795 and includes the following additional elements:</u>	information may be stored in different locations; however, when requested, the compounding record must be produced to the Board that includes all of the required information in a single document. It is important for the board be able to review all the required information together for individual compounded preparations and not have to guess or wade through unrelated documents that may not have been relied upon. Staff are offering recommended language to clarify.
91	1735.7(c)	Wendy Waldman Torrance Memorial Medical Center	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: <u>(c) Compounding record requirements shall be readily retrievable to comply with USP Chapter 795 and includes the following additional elements:</u>	Board staff have considered the comment and and recommend a change to this section, although not based solely on this comment. Board staff note that the information may be stored in different locations; however, when requested, the compounding record must be produced to the Board that includes all of the required information in a single document. It is important for the board be able to review all the required information together for individual compounded preparations and not have to guess or wade through unrelated documents that may not have been relied upon. Staff are offering recommended language to clarify.
92	1735.7(c)	Walgreens	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	Board staff have considered the comment and recommend a change to this section, although not based solely on this comment. Board staff note that the information may be stored in different locations; however, when requested, the compounding record must be produced to the Board that includes all of the required information in a single document. It is important for the board be able to review all the required information together for individual compounded preparations and not

			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, <u>maintained in a retrievable manner</u> , and includes the following additional elements:	have to guess or wade through unrelated documents that may not have been relied upon. Staff are offering recommended language to clarify.
93	1735.7(c)	Marie Cottman Pacific Compounding	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~~ <u>pharmacist</u> who has direct oversight of compounding, and the pharmacist verifying the final drug preparation.	Board staff have considered the comment and agree that a change to the proposed text is appropriate.
94	1735.7(c)(1)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	Time becomes relevant when BUDs are relatively short (<72 hours). This would be highly uncommon for CNSPs. Recommend that the language be updated to only include the day that the CNSP was compounded.	Board staff do not recommend any changes. Staff note that the USP Chapter 795 establishes either the date or date and time for nonsterile compounding; however, the date AND time are required in Chapter 797. The Board's proposed regulation text ensures consistency between CNSPs and CSPs, standardizing the process for pharmacies.
95	1735.7(c)(1)	John Gray Kaiser Permanente	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	Board staff do not recommend any changes. Staff note that the USP Chapter 795 establishes either the date or date and time for nonsterile compounding; however, the date AND time are required in Chapter 797. The Board's

			chapter 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.	proposed regulation text ensures consistency between CNSPs and CSPs, standardizing the process for pharmacies.
96	1735.7(c)(1)	Paul Lofholm	basis for time documentation for CNSP?	Board staff do not recommend any changes. Staff note that the USP Chapter 795 establishes either the date or date and time for nonsterile compounding; however, the date AND time are required in Chapter 797. The Board's proposed regulation text ensures consistency between CNSPs and CSPs, standardizing the process for pharmacies.
97	1735.7(c)(1)	Philip Smyth Medisca	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.	Board staff do not recommend any changes. Staff note that the USP Chapter 795 establishes either the date or date and time for nonsterile compounding; however, the date AND time are required in the Chapter 797. The Board's proposed regulation text ensures consistency between CNSPs and CSPs, standardizing the process for pharmacies.
98	1735.7(c)(1-4)	Rick Rhoads University Compounding	(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 <u>date or</u> date and time of compounding, <u>if the BUD is listed in hours. The time of preparation is which is the time</u> 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, <u>if immediately packaged into the final dispensing container.</u> Reason: This language is helpful to clarify that the date and/or time of compounding refers to	Board staff are recommending changes to the language in this subdivision but not based solely on this comment. Staff note that the USP Chapter 795 establishes either the date or date and time for nonsterile compounding; however, the date AND time are required in the Chapter 797. The Board's proposed regulation text ensures consistency between CNSPs and CSPs, standardizing the process for pharmacies. Specifically related to the comments to 1735(c)(4) board staff agree that changes to the proposed text is appropriate; however, staff are offering alternative language to address the issue raised by the commenter.

			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.	
99	1735.7(c)(2)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP Also provided at Reg Hearing	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 (I) 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	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments. Staff note that while existing law provides such an exemption, continuation of the current exemption is not appropriate as it hampers the ability of a facility to respond appropriately in the event of a product recall. Staff note that the Chapter requires either the recording of the manufacturers or vendor; however, in separate guidance issued by the FDA, the facility needs to have transparency into the supply chain and awareness of the manufacturer (where the manufacturer and vendor are different.)

			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. <u>(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.</u>	
100	1735.7(c)(2)	Wendy Waldman Torrance Memorial Medical Center	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: <i>(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 (I) shall apply.</i>	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments. Staff note that while existing law provides such an exemption, continuation of the current exemption is not appropriate as it hampers the ability of a facility to respond appropriately in the event of a product recall. Staff note that the Chapter requires either the recording of the manufacturers or vendor; however, in separate guidance issued by the FDA, the facility needs to have transparency into the supply chain and awareness of the manufacturer (where the manufacturer and vendor are different.)

			(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) <u>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.</u>	
101	1735.7(c)(2)	Melanie Horn Sutter Health	Strike language. Duplicated directly from USP 795 CR requirements listed USP 795, since duplicative of USP requirement in Box 3. Compounding Record, bullet 5	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments. Staff note that while existing law provides flexibility to record the manufacturer under limited circumstances, continuation of the current provision is not appropriate as it hampers the ability of a facility to respond appropriately in the event of a product recall. Staff further note that the Board's proposed regulation text is more explicit than the Chapter for the reasons cited elsewhere in this response. Staff note that the Chapter requires either the recording of the manufacturers or

				vendor; however, in separate guidance issued by the FDA, the facility needs to have transparency into the supply chain and awareness of the manufacturer (where the manufacturer and vendor are different.) The FDA has released guidance in this area, including the importance of a compounders knowing your suppliers - - https://www.fda.gov/drugs/human-drug-compounding/fda-compounders-know-your-bulks-and-excipients-suppliers.
102	1735.7(c)(2)	Scott Brunner Alliance for Pharmacy Compounding	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.	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments. Staff note that while existing law provides flexibility to record the manufacturer under limited circumstances, continuation of the current provision is not appropriate as it hampers the ability of a facility to respond appropriately in the event of a product recall. Staff further note that the Board's proposed regulation text is more explicit than the Chapter for the reasons cited elsewhere in this response. Staff note that the Chapter requires either the recording of the manufacturers or vendor; however, in separate guidance issued by the FDA, the facility needs to have transparency into the supply chain and awareness of the manufacturer (where the manufacturer and vendor are different.) The FDA has released guidance in this area, including the importance of a compounders knowing your suppliers - - https://www.fda.gov/drugs/human-drug-compounding/fda-compounders-know-your-bulks-and-excipients-suppliers. Lastly, simply identifying the manufacturer of a component without more does not appear to be requiring the disclosure of a trade secret under Civil Code section 3426.1(d)."
103	1735.7(c)(2)	National Community Pharmacists Association (NCPA)	The word manufacturer should be replaced with supplier. Neither the FDCA nor any FDA implementing regulation—or even a non-binding guidance document—includes a “requirement for the COA” from a supplier to disclose an original manufacturer's identity. The proposed rules point to FDCA to support the	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments. Staff note that while existing law provides flexibility to record the manufacturer under limited circumstances, continuation of the current provision is not appropriate as it hampers the ability of a facility to respond appropriately in the event of a product recall.

		proposed rules and yet the FDCA does not support the proposed rules. The FDCA and its implementing regulations set forth a single requirement for COAs: Compounded drugs must be accompanied by valid COAs for their bulk drug substances to qualify for exceptions to the FDCA. 21 U.S.C. §§ 353a(b)(1)(a)(iii), 353b(a)(2)(D) (both requiring compounded drug products to be "accompanied by valid certificates of analysis for each bulk drug substance"). FDA has not further defined "valid," but there is no reason to believe that "valid" requires identification of the original manufacturer. Indeed, FDA has long accepted the practice of suppliers providing their own COAs, incorporating data from the suppliers' own testing, as well as data from the original manufacturer's quality testing. There are also concerns that the compelled disclosure of original manufacturer or excipient manufacturer information would force revelation of trade secrets. Indeed, for a supplier, the identity of the original manufacturer of API and excipients represents confidential commercial information, and the state cannot compel disclosure of such information. Under the California Public Records Act, Cal. Gov. Code, §§ 6250 et seq., California cannot release certain proprietary information to the public, including corporate records and trade secrets relating to food, drugs, and cosmetics. Cal Gov. Code §§ 6254.15, 6276.44. Notwithstanding that significant swaths of information are available for public disclosure, "corporate proprietary information including trade secrets" is specifically exempt from	Staff further note that the Board's proposed regulation text is more explicit than the Chapter for the reasons cited elsewhere in this response. Staff note that the Chapter requires either the recording of the manufacturers or vendor; however, in separate guidance issued by the FDA, the facility needs to have transparency into the supply chain and awareness of the manufacturer (where the manufacturer and vendor are different.) The FDA has released guidance in this area, including the importance of a compounders knowing your suppliers - - https://www.fda.gov/drugs/human-drug-compounding/fda-compounders-know-your-bulks-and-excipients-suppliers. Lastly, simply identifying the manufacturer of a component without more does not appear to be requiring the disclosure of a trade secret under Civil Code section 3426.1(d)."

			disclosure by the state. Id. at 6254.15. Further, the California Health and Safety Code precludes the state from “reveal[ing] . . . any information acquired . . . concerning any method of process which as a trade secret is entitled to protection.” CA Health & Safety Code § 110165 (2023). The California BOP cannot compel regulated parties to disclose the very information that California law protects from disclosure. There is no question that the federal government—specifically FDA—considers and understands this information to be confidential and thus treats it as such. In Form FDA 483s and in Warning Letters that FDA posts on its website, FDA redacts the identity of the original manufacturer of API for use in compounding under the federal Freedom of Information Act exemption (b)(4) because it is “confidential commercial information.” See, e.g., Downing Labs, LLC, Form FDA 483, Observation 14 (Oct. 9, 2015) (“For example” (b)(4) lot (b)(4) manufactured by (b)(4) as used in Phosphatidylcholine/DCA (b)(4) injectable lot (b)(4) with a BUD of (b)(4).”); Warning Letter to Fagron, Inc. (Aug. 29, 2018) (“You initiated a recall of estriol lots on April 6, 2017, after the API manufacturer, (b)(4). However, after you initiated the recall, (between October 6 and October 23, 2017, your firm released and distributed six quarantined (b)(4) estriol lots to multiple compounding pharmacies. On October 27, 2017, your firm initiated another recall of the previously recalled estriol lots.”)	
104	1735.7(c)(2)	A.J. Day	Commenter expressed concern about the manufacturer requirement of the API as the manufacturer is proprietary trade secret information protected from disclosure.	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments. Staff note that while existing law provides flexibility to record the manufacturer under limited

				circumstances, continuation of the current provision is not appropriate as it hampers the ability of a facility to respond appropriately in the event of a product recall. Staff further note that the Board's proposed regulation text is more explicit than the Chapter for the reasons cited elsewhere in this response. Staff note that the Chapter requires either the recording of the manufacturers or vendor; however, in separate guidance issued by the FDA, the facility needs to have transparency into the supply chain and awareness of the manufacturer (where the manufacturer and vendor are different.) The FDA has released guidance in this area, including the importance of a compounders knowing your suppliers - - https://www.fda.gov/drugs/human-drug-compounding/fda-compounders-know-your-bulks-and-excipients-suppliers. Lastly, simply identifying the manufacturer of a component without more does not appear to be requiring the disclosure of a trade secret under Civil Code section 3426.1(d)."
105	1735.7(c)(4)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	Compounding software programs typically required the metric quantity of a batch prepared, but do not document the qty of each individual unit.	Board staff have reviewed comments and do not recommend changes based solely on this comment. The Board's regulation text is technology neutral. Staff are aware of software that include the ability to identify the quantity and such software/technology is currently used. Staff further note this requirement currently exists in CCR Section 1735.3(a)(2)(l).
106	1735.7(c)(5)	John Gray Kaiser Permanente	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.	Board staff have reviewed the comment and are recommending a change to the proposed text based on the comment received.

			The identity of each person performing the compounding, the person ~~who has exercising~~ <u>direct supervision and control over</u> ~~oversight of~~ compounding, and the pharmacist verifying the final drug preparation.	
107	1735.8	Marie Cottman Pacific Compounding	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.	Board staff have reviewed the comment and amended the regulation text in response to ensure that the dispensing pharmacist is also responsible.

108	1735.8	Paul Lofholm	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	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments. Staff note that the language in the proposed text is based on the language in the Board's current regulation, CCR 1735.2(g).
109	1735.9	Paul Lofholm	The route is inherent on the prescription label	Board staff have reviewed the coment and do not recommend changes to the proposed text. Staff note that the route of administration is not always understood. As an example, a capsule could be taken orally or vaginally. Absent inclusion of the route of administration, in such an instance, the patient may self-administer the medication incorrectly.
110	1735.9	K. Scott Guess	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.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Board staff note there is a legal difference between the "label" and "labeling" The proposed regulation text as drafted provided flexibility.
111	1735.9(a) & (B)	Marie Cottman	COMMENT: These requirements should not be limited to CNPS, but rather applied to all medications dispensed to improve patient	Board staff have reviewed the comment and do not recommend changes to the proposed text. Staff note

		Pacific Compounding	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 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.	that the comments exceed the scope of the proposed regulation.
112	1735.9(c) (Labeled as (b) in comment)	Wendy Waldman Torrance Memorial Medical Center	Rationale: At present, health facilities, defined according to Section 1250 of the Health and Safety Codes, are exempt from requirements regarding patient-centered labels. Recommendation: To align with existing regulations, it is recommended to include exemption	Board staff have reviewed the comment and recommend a change to the proposed regulation text, although not based solely on this comment. Language recommended by staff would establish a more explicit exemption for a CNSP that is administered as specified.

			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. <u>(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.</u>	
113	1735.9(b)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP	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. <u>(i) Exempt from this requirement are health</u>	Board staff have reviewed the comment and recommend a change to the proposed regulation text not based solely on this comment. Language recommended by staff would establish a more explicit exemption for a CNSP that is administered as specified.

			<u>facilities, as defined in Section 1250 of the Health and Safety Code, if the prescriptions are administered by a licensed health care professional.</u>	
114	1735.9(c)	Rheta Silvas Kaweah Health	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 applicable to CNSPs compounded and furnished by the hospital pharmacy for administration to a patient.	Board staff have reviewed the comment and recommend a change to the proposed regulation text not based solely on this comment. Language recommended by staff would establish a more explicit exemption for a CNSP that is administered as specified.
115	1735.10.	Paul Lofholm	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	Board staff have reviewed the comment and do not recommend changes to the comments to the proposed regulation text. Board staff note that container closures vary based on the type of compounded product. Staff note that the Chapter requires consideration of the container-closure system when establishing a BUD.
116	1735.10(b)	Jasmine Parker Pacific Compounding	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.	Board staff have reviewed the comment and do not recommend changes to the proposed text. Staff note that the distinction between USP requirements and the proposed regulation is significant. The Board's regulation text establishes a requirement for the professional to follow the limitations when such documents exist when assigning a BUD. The Chapter requires consideration of these same conditions but does not prohibit establishing a BUD contrary to the conditions identified. The Board's regulation text does prohibit this to ensure that a BUD is not established beyond what the literature allows. This is necessary to ensure product integrity and, hence, patient safety.

117	1735.10(b)	Rheta Silvas Kaweah Health	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.	Board staff has reviewed the comment and do not recommend any changes to the proposed text. Board staff note that the comment appears to be a request of a lesser standard than established in the Boards proposed regulation text AND a lesser standard than established in the USP compounding chapter.
118	1735.10(b)	Marie Cottman Pacific Compounding	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.	Board staff have reviewed the comment and do not recommend changes to the proposed text. Staff note the distinction between USP requirements and the proposed regulation is significant. The Board's regulation text establishes a requirement for the professional to follow the limitations when such documents exist when assigning a BUD. The Chapter requires consideration of these same conditions but does not prohibit establishing a BUD contrary to the conditions identified. The Board's regulation text does prohibit this to ensure that a BUD is not established beyond what the literature allows. This is necessary to ensure product integrity and, hence, patient safety.

			RATIONALE:USP 795 states in Section 10.2 paragraph 2 “When establishing a BUD for a CNSP, compounders <u>must consider</u> 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.	

119	1735.10(b)(1)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	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.	Board staff have reviewed the comment and recommend a change to the proposed regulation text to address the comment.
120	1735.10(b)(2)	Scott Brunner Alliance for Pharmacy Compounding	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.	Board staff have reviewed the comment and do not recommend changes to the proposed text. USP Chapter 795, Section 10.2 specifies that when establishing a BUD for a CNSP compounders MUST consider parameters that may affect quality, including compatibility of the container closure system with the finished preparation (e.g. leachables). The Chapter requires this be done. The Board's proposed regulation text goes beyond just considering the information, but ensuring that the BUD does not go beyond what the parameters reveal to support the BUD. The Cost incurred for this determination (e.g. leachables) are a function of compliance with the Chapter not the Board's regulations. The Board's regulations merely ensure that a pharmacist uses the information it obtains through the USP requirements in establishing a BUD to not exceed the parameters.
121	1735.10(c)	John Gray Kaiser Permanente	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. 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	Board staff have reviewed the comment and recommend changes to the language; however, not solely based on this comment.

			(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.	
122	1735.10(c)	Walgreens	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	Board staff have reviewed the comment and recommend changes to the language; however, not solely based on this comment.

			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.	
123	1735.10(c)	Rick Rhoads University Compounding	(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. 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.	Board staff have reviewed the comment and recommend changes to the language; however, not solely based on this comment. The recommended change provides clarity on the Board's expectation regarding what documentation must be maintained and available when requested.
124	1735.10(c)	Marie Cottman Pacific Compounding	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	Board staff have reviewed the comments and do not recommend changes to the proposed text based solely on these comments. Staff note that in response to other comments received regarding this section staff are recommending changes to the proposed text.

			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.	
125	1735.11	Marci Bencomo Pacifica Compounding	SOPS are identified within USP and including them is not necessary for patient safety.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Staff note that establishing minimum standards for the facility's SOP ensure that pharmacy personnel understand and follow the same procedures that have been established as appropriate for patient safety.
126	1735.11	K. Scott Guess	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	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Staff note that an SOP can be modified in response to issues that may arise including in response to a public health emergency. Staff note that establishing minimum standards for the facility's SOP ensure that pharmacy personnel understand and follow the same procedures

			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	that have been established as appropriate for patient safety.
127	1735.11	Paul Lofholm	1163 is advisable only	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Board staff note that Initial Statement of Reasons documents the basis for inclusion of USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. Business and Professions Code section 4126.8, establishes compliance with pharmacy compounding chapters.
128	1735.11(a)	Walgreens	The use of the phrase "the methods" or "the validated processes" is ambiguous and confusing. Pharmacists should use their professional judgment to determine, 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	Staff note that existing CCR 1751.3 has several of these requirements as current law. Staff note that establishing minimum components for the facility's SOPs ensure that pharmacy personnel understand and follow the same procedures that have been established as appropriate for patient safety. The proposed text does not establish requirements, but rather ensures that the facility has established SOPs in the specified areas, including stating the method chosen by the pharmacist using their professional judgment as to how quality will be checked

			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.~~	
129	1735.11(a)(1)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy 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"	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Board staff note that Initial Statement of Reasons documents the basis for inclusion of USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. Business and Professions Code section 4126.8, establishes compliance with pharmacy compounding chapters
130	1735.11(a)(2)	John Gray Kaiser Permanente	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	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Board staff note that Initial Statement of Reasons documents the basis for inclusion of USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. Business and Professions Code section 4126.8, establishes compliance with pharmacy compounding chapters

			the 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 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. (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.~~ ~~(BA) If applicable, the Pprocedures 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.~~	
131	1735.11(a)(2)(A) & (C)	Marie Cottman Pacific Compounding	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!	Board staff have reviewed the comment and do not recommend changes to the Board text. Staff note that SOPs are intended to ensure consistency. Where overlap of SOPs is identified by a facility, the SOPs can provide cross reference if deemed appropriate or merge into a comprehensive SOP that covers multiple areas.

			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 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.	
132	1735.11(a)(2)(B)	Marie Cottman Pacific Compounding	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>	Board staff have reviewed the comment and recommend a change to the proposed regulation text to address the issue raised to provide clarity that the information is only required where applicable.

133	1735.11(a)(2)(D)	Rheta Silvas Kaweah Health	Recommend: strike or clarify the proposed language so the intent is clear. Rationale – the language is ambiguous.	Board staff have reviewed the comments and do not recommend changes to proposed regulation text. Staff note that establishing minimum standards for the facility's SOP ensure that pharmacy personnel understand and follow the same procedures that have been established as appropriate for patient safety. The SOPs do not establish requirements, but rather ensure that the facility has established SOPs in the specified areas.
134	1735.11(a)(2)(D)	Marie Cottman Pacific Compounding	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.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. Staff note that throughout the proposed article, a pharmacist using professional judgement may determine that an additional SOP may be necessary. When such a determination is made, an SOP must be developed.
135	1735.11(a)(2)(E)	Marie Cottman Pacific Compounding	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	Board staff have reviewed the comment and do not recommend changes to the proposed text. Board staff disagree that the proposed regulation text in the cited paragraph is duplicative.

			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 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 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.	
136	1735.11(a)(2)(E)	Scott Brunner Alliance for Pharmacy Compounding	The statement "validated processes" is unclear and undefined.	Board staff have reviewed the comment and do not recommend changes to the proposed text. Board staff disagree that the term "validated processes" is not clear. The FDA defines "process validation" as establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications. The Board could amend the proposed text to use "process validation" in lieu of "validated processes" if it determines additional clarity is needed.
137	1735.11(a)(2)(E)	Rheta Silvas Kaweah Health	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?	Board staff have reviewed the comment and recommend a change to the proposed text to create an exemption to the requirement of this paragraph if it is not applicable.
138	1735.12	Paul Lofholm	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. CNSP Packaging and Transporting This is really a process validation	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Board staff note that the rationale for the requirements is established in the Initial Statement of Reasons. Board staff that it is the Board's expectation that investigation into a complaint will begin immediately upon receipt.
139	1735.12 should be 1735.12(b)	K. Scott Guess	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	Board staff believes the commenter is referring to section 1735.12(b). Board staff has reviewed the comment and recommended changes to the proposed regulation text to align with the federal definition of "drug experience." Board staff note that the regulation will be establishing a reporting requirement to the Board if a determination is made that a complaint received is a result of or a potential result of a quality problem, as detailed in the Initial Statement of Reasons.

			• Claim of lack of 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.	
140	1735.12(a)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy 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"	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Board staff note that Initial Statement of Reasons documents the basis for inclusion of USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. Business and Professions Code section 4126.8, establishes compliance with pharmacy compounding chapters.
141	1735.12(a)	John Gray Kaiser Permanente	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	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Board staff note that Initial Statement of Reasons documents the basis for inclusion of USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. Business and Professions Code section 4126.8, establishes compliance with pharmacy compounding chapters.

			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 require pharmacies to store drugs at the appropriate temperature, the proposed regulation in 1735.12(a)(2) is unnecessary. (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 <u>facility's quality assurance</u> program shall include ~~the following~~: (1) 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.~~	
142	1735.12(a)(2)	Melanie Horn Sutter Health	Strike language. USP Chapter 795 addresses temperature monitoring documentation in CSP storage areas. Additional standards exist for medication security and this proposed regulation does not provide additional clarity to existing medication standards. Recommend removing additional language.	Board staff have reviewed the comment and do not believe changes to the regulation text are appropriate. Staff note that the proposed regulation text ensure that a facility has a plan to address a temperature issue if such a issue arises.
143	1735.12(a)(2)	Marci Bencomo	Requiring reporting of complaints within 72 hours would result in the Board being	Board staff have reviewed the comment and believe the commenter is referring to CCR Section 1735.12(b). Board staff believes the commenter is referring to section

		Pacifica Compounding	overloaded with complaints and should be limited to Quality complaints.	1735.12(b). Board staff has reviewed the comment and recommend changes to the proposed regulation text to align with the federal definition of "drug experience". Board staff note that the regulation will be establishing a reporting requirement to the Board if a determination is made that a complaint received is a result of or a potential result of a quality problem, as detailed in the Initial Statement of Reasons.
144	1735.12(b)	Lauren Honda Valor Compounding Also Submitted in Reg Hearing	In the interest of maintaining compliance with this proposed 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.	Board staff believes commenter is referring to section 1735.12(b). Board staff has reviewed the comment and recommend changes to the proposed regulation text to align with the federal definition of "drug experience". Board staff note that the regulation will be establishing a reporting requirement to the Board if a determination is made that a complaint received is a result of or a potential result of a quality problem, as detailed in the Initial Statement of Reasons.
145	1735.12(b)	Melanie Horn Sutter Health	Stike language. The requirement in existing law ensures that the Board is notified of a recall meeting certain that would provide notification of the board to learn of quality and safety issues. The current wording does not establish that the adverse drug event is potentially or reasonably attributed to the process of compounding, such that the Board wants to be notified of all events related CNSPs not related to a quality problem to address from the CNSP. This expands to adverse events reported that are attributed to the function of the CNSP, red rash, upset stomach, headache, etc.), which is the definition of an 'adverse drug event.' In contrast, if the regulation is adopted as written, pharmacies must report to the Board any time a patient complains of any minor problem that they attribute to the use of a CNSP regardless determination of a quality problem with the CNSP/process.	Board staff have reviewed the comments related to this issue and are recommending changes to the proposed text to address the comments to extend the time frame to make such a report to the Board to 96 hours. Staff are recommending a change to this paragraph to align with the federal definition of drug event.
146	1735.12(b)	Wendy Waldman	Rationale: A requirement of 72 hours may not provide	Board staff have reviewed the comments related to this issue and are recommending changes to the proposed

		Torrance Memorial Medical Center	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 <u>3 business days</u> ~~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.	text to address the comments to extend the time frame to make such a report to the Board to 96 hours. Staff are recommending a change to this paragraph to align with the federal definition of drug event.
147	1735.12(b)	Marie Cottman Pacific Compounding	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, and I	Board staff have reviewed the comments related to this issue and are recommending changes to the proposed text to address the comments to extend the time frame to make such a report to the Board to 96 hours. Staff are recommending a change to this paragraph to align with the federal definition of drug event.

			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.	
148	1735.12(b)	John Gray Kaiser Permanente	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.'	Board staff have reviewed the comments related to this issue and are recommending changes to the proposed text to address the comments to extend the time frame to make such a report to the Board to 96 hours. Staff are recommending a change to this paragraph to align with the federal definition of 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.	
149	1735.12(b)	CSHP	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 <u>3 business days</u> ~~72 hours of the facility's receipt of a complaint of a potential quality problem~~ <u>after a potential quality problem is identified</u> or the occurrence of an adverse drug event involving a CNSP.	Board staff have reviewed the comments related to this issue and are recommending changes to the proposed text to address the comments to extend the time frame to make such a report to the Board to 96 hours. Staff are recommending a change to this paragraph to align with the federal definition of drug event.
150	1735.12(b)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	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 it is related to the quality of the CNSP. This type of reporting may drown out the times that the board needs to be aware of 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. We suggest the pharmacy must initiate an investigation with 72 hours of receipt of a complaint of a potential quality problem,	Board staff have reviewed the comments related to this issue and are recommending changes to the proposed text to address the comments to extend the time frame to make such a report to the Board to 96 hours. The proposed notification timeframe requested in the comment is not appropriate, given the Board's consumer protection mandate. Staff are recommending a change to this paragraph to align with the federal definition of drug event

			and must notify the Board in writing with 15 days of the receipt of complaint.	
151	1735.12(b)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health	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 <u>3 business days</u> ~~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.	Board staff have reviewed the comments related to this issue and are recommending changes to the proposed text to address the comments to extend the time frame to make such a report to the Board to 96 hours. Staff are recommending a change to this paragraph to align with the federal definition of drug event.
152	1735.12(b)	Keck Medicine of USC	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 <u>3 business days after a potential quality problem is identified</u> ~~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	Board staff has reviewed the comment and recommend changes to the proposed regulation text to align with the federal definition of "drug experience." Board staff are recommending changes to the proposed text to address the comments to extend the time frame to make such a report to the Board to 96 hours.

			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.	
153	1735.12(c)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health	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. 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.	Board staff have reviewed the comments related to this issue and are recommending changes to the proposed text to address the comments to extend the time frame within which the PIC must review a complaint received by the facility.
154	1735.12(c)	Rheta Silvas Kaweah Health	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.	Board staff have reviewed the comment and recommend changes to the proposed changes; however, not solely based on this comment. As recommended by staff, the proposed language would establish a threshold for review in the event the PIC is not available within the time period. Further, the recommended language is making a conforming change to align with the federal definition of "adverse drug experience." With the additional provision for an SOP to address the unavailability of a PIC, a conforming change to proposed section 1735.11(a)(2) is necessary. Staff are offering a recommendation to that section as well.
155	1735.12(c)	Wendy Waldman Torrance Memorial Medical Center	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.	Board staff have reviewed the comments related to this issue and are recommending changes to the proposed text to address the comments to extend the time frame within which the PIC must review a complaint received by the facility.

			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 <u>3 business days</u> ~~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.	
156	1735.12(c) (Labeled as 1735.11(c) in comments)	Marie Cottman Pacific Compounding	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.	Board staff have reviewed the comment and recommend changes to the proposed changes. As recommended by staff, the proposed language would establish a threshold for review in the event the PIC is unavailable within the specified time period and to address the comments to extend the time frame within which the PIC must review a complaint received by the facility. Further, the recommended language is making a conforming change to align with the federal definition of "adverse drug experience." With the additional provision for an SOP to address the unavailability of a PIC, a conforming change to proposed section 1735.11(a)(2) is necessary. Staff are offering a recommendation to that section as well.
157	1735.12(c)	CSHP	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.	Board staff have reviewed the comment and recommend changes to the proposed changes. As recommended by staff, the proposed language would establish a threshold for review in the event the PIC is unavailable within the specified time period and to address the comments to extend the time frame within which the PIC must review a complaint received by the facility. Further, the

			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, <u>or licensed designee</u>, within <u>3 business days</u> ~~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.	recommended language is making a conforming change to align with the federal definition of "adverse drug experience." With the additional provision for an SOP to address the unavailability of a PIC, a conforming change to proposed section 1735.11(a)(2) is necessary. Staff are offering a recommendation to that section as well.
158	1735.13	Marie Cottman Pacific Compounding	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 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	Board staff have considered the comment and do not recommend changes to the proposed regulation text. Staff note that to ensure consistency with the Chapter, the proposed regulation text is requiring appropriate processes for storage, shopping containers, and temperature sensitive CNSPs as defined in the facilities SOPs.

			proposed language and it only confuses the issue.	
159	1735.13	Scott Brunner Alliance for Pharmacy Compounding	The statement "validated processes" is unclear and undefined.	Board staff believe the commenter is related to proposed section 1735.11(a)(1)(E). Board staff disagree that the term "validated processes" is not clear. The FDA defines "process validation" as establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications. The Board could amend the proposed text to use "process validation" if it determines additional clarify is needed.
160	1735.14	Paul Lofholm	Documentation Records strike for at least, 3 years.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. The proposed regulation text is consistent with other provisions of Pharmacy Law and its regulations related to documentation and records requirements, including for example, BPC Section 4081.
161	1735.14(b)	K. Scott Guess	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.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Board staff believe the current law, CCR Section 1735.3(d) and the proposed regulation text are clear.

162	1735.14(b)	John Gray Kaiser Permanente	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. <u>Policies and procedures and SOPs required by USP Chapter 795 and this article</u> ~~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~~ <u>policy and procedure and SOP</u> 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.	Board staff reviewed the comment and made changes to clarify the requirements. USP Chapter 795 Section 14 specifies that documentation must comply with all laws and regulations of the applicable regulation jurisdiction. The Chapter continues that "Records must be legible and store in a manner that prevents their deterioration and/or loss. All required CRs for a particular CNSP (e.g. MFR, CR, and release inspection and testing results) must be readily retrievable for at least two years after preparation or as required by the laws and regulations, whichever is longer." The Board already requires records to be maintained for three years (e.g. 4081, CCR 1735.3 (d)). The USP requirements are clear that the records must be maintained to prevent deterioration and/or loss. The Board language allows for flexibility to maintain the records electronically and specifies that when maintained electronically, an audit trail of changes must be maintained. The Board's proposed regulation text establishing an audit trail meets the requirements of the USP Chapter provision to prevent "loss or deterioration of records." Absent an audit trail, prior versions of a record (e.g., a master formula, etc.) would be lost if maintained in an electronic format without an audit trail. Staff note that a facility can elect to maintain the paper records consistent with the Chapter and not require an electronic audit trail. The Board is trying to establish a means for electronic storage of records that meets the requirements of the USP Chapter to provide flexibility for the business operations.
163	1735.14(b)	Marie Cottman Pacific Compounding	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,..."	Board staff reviewed the comment and made changes to clarify the requirements.

			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 <u>at least 3 years from the date of the revision</u>. Prior versions of each record must be maintained in a readily retrievable format. <u>Each revision must include the changes to the document, identification of the individual who made the change, and the date of each change.</u>	
164	1735.15(b) Should be 1737.14(b)	K. Scott Guess	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	Board staff believes the commenters is referencing section 1737.14(b). Board staff have reviewed the comment and recommend a proposed change to the regulation text to clarify that the requirement applies when an HD is dispensed to the patient or the patient's agent.
165	Article 4.5 Nonsterile Compounding	Mark Johnston CVS Health Also provided at Reg Hearing	Commenter applauds the Board for removing the requirement for routine testing and analysis and adding the requirement for compliance with USP , as it allows for the use of clinical discretion and professional judgment.	The Board agreed with the comment.
166	Non-Sterile	Paul Lofholm	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	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. The comments provided are general and do not provide specific recommended changes to the text. Rather, the comments appear to be

			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.	more commentary. Because compounded drugs are not FDA-approved, FDA does not verify their safety, effectiveness, or quality before they are marketed. Poor compounding practices can result in serious drug quality problems, such as contamination or a drug that contains too much active ingredient. This can lead to serious patient injury and death. The Board relied upon USP as the foundation for the requirements. The Board also note that as included in the Initial Statement of Reasons, many of the requirements included in the proposed regulation text, are requirements in the existing regulations.

#	Section	Commenter	Comment	Board Response
1	1736(a)	John Gray Kaiser Permanente	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 "compounding process" in the definition of the term "compounding personnel."	Board staff have reviewed the comment and offer a recommendation to address the comment reflecting text more in line with the language used in the Chapter.
2	1736(b)	CSHP	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 an 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. 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	Staff believes commenter is referring to 1736.1(b). Staff have considered the comment and note that the language in the proposed text is similar to existing regulation CCR Section 1751.8(e), including the current requirement to document the circumstances causing the immediate need. Staff note that to align with USP, the Board has removed the current one hour start time and will instead allow the four-hour start time provided for in the revised USP Chapter. Further, staff note that the proposed regulation text makes clear that separate documentation is not required, rather, the patient's medical record documenting will comply with the regulation. Staff also note that maintaining complete administration records are required for many regulators, not just the Board. Staff recommend that the Board update Section 1736.17(b) to expand beyond classified area failure to include any equipment failure. SOPs should have redundancy included.

		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.	
3	1736(g)	National Community Pharmacists Association (NCPA),	Refer to 1735(f)	Staff have considered the comment and do not recommend a change based on the comment. Staff note that the comment appears general in nature and does not provide any recommended changes to the section.

		Scott Brunner Alliance for Pharmacy Compounding		
4	1736.1	Paul Lofholm	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.	Staff have considered the change and do not recommend changes to the proposed regulation text. Staff note that referring to nationally recognized sources for drug shortages is necessary to ensure members of the regulated public have clear guidance on authorized sources. The sources specified in the proposed regulation text are consistent with current industry practice. Staff notes further that the proposed regulation text is consistent with the Board's current regulation, CCR Section 1735(d)(3).
5	1736.1(a)	John Gray Kaiser Permanente	"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. For the purposes of this article, sterile compounding occurs, by or under the <u>direct supervision and control</u> of a licensed pharmacist, pursuant to a patient specific prescription, unless otherwise specified in this article.	Staff have reviewed the comment and recommend a change to clarify the language to confirm the Board's expectation that the level of supervision encompasses direct supervision and control.
6	1736.1(b)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	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 use in multiple patients over a 4- hour period. This medication is often needed for infiltration and nerve block. Immediate use CSPs are often prepared from components stored in automated dispensing cabinets in hospitals, for situations which are not considered risking loss of life or intense suffering.	Staff have considered the comment and note that the language in the proposed text is similar to existing regulation CCR Section 1751.8(e), including the current requirement to document the circumstances causing the immediate need. Staff note that to align with USP, the Board has removed the current one hour start time and will instead allow the four-hour start time provided for in the revised USP Chapter. Further, staff note that the proposed regulation text makes clear that separate documentation is not required, rather, the patient's medical record documenting will comply with the regulation. Staff also note that maintaining complete administration records are required for many regulators, not just the Board. Staff recommend that the Board update Section 1736.17(b) to expand

				beyond classified area failure to include any equipment failure. SOPs should have redundancy included.
7	1736.1(b)	John Gray Kaiser Permanente	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. ~~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~~	Staff have considered the comment and note that the language in the proposed text is similar to existing regulation CCR Section 1751.8(e), including the current requirement to document the circumstances causing the immediate need. Staff note that to align with USP, the Board has removed the current one hour start time and will instead allow the four-hour start time provided for in the revised USP Chapter. Further, staff note that the proposed regulation text makes clear that separate documentation is not required, rather, the patient's medical record documenting will comply with the regulation. Staff also note that maintaining complete administration records are required for many regulators, not just the Board. Staff recommend that the Board update Section 1736.17(b) to expand beyond classified area failure to include any equipment failure. SOPs should have redundancy included.

			~~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.~~	
8	1736.1(b)	Tommy Mai Huntington Health	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.~~	Staff have considered the comment and note that the language in the proposed text is similar to existing regulation CCR Section 1751.8(e), including the current requirement to document the circumstances causing the immediate need. Staff note that to align with USP, the Board has removed the current one hour start time and will instead allow the four-hour start time provided for in the revised USP Chapter. Further, staff note that the proposed regulation text makes clear that separate documentation is not required, rather, the patient's medical record documenting will comply with the regulation. Staff also note that maintaining complete administration records are required for many regulators, not just the Board. Staff recommend that the Board update Section 1736.17(b) to expand beyond classified area failure to include any equipment failure. SOPs should have redundancy included.
9	1736.1(b)	Rita Shane Cedars-Sinai	Rationale: In the instance of a patient emergency such as a code blue or a rapid resuscitation event in a hospital,	Staff have considered the comment and note that the language in the proposed text is similar to existing regulation CCR Section 1751.8(e), including the current

		Also provided at Reg Hearing	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 <u>the immediate needs of patients</u> ~~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.~~	requirement to document the circumstances causing the immediate need. Staff note that to align with USP, the Board has removed the current one-hour start time and will instead allow the four-hour start time provided for in the revised USP Chapter. Further, staff note that the proposed regulation text makes clear that separate documentation is not required, rather, the patient's medical record documenting will comply with the regulation. Staff also note that maintaining complete administration records are required for many regulators, not just the Board. Staff recommend that the Board update Section 1736.17(b) to expand beyond classified area failure to include any equipment failure. SOPs should have redundancy included.
10	1736.1(b)	Keck Medicine of USC Also Provided at Reg Hearing	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 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	Staff have considered the comment and note that the language in the proposed text is similar to existing regulation CCR Section 1751.8(e), including the current requirement to document the circumstances causing the immediate need. Staff note that to align with USP, the Board has removed the current one hour start time and will instead allow the four-hour start time provided for in the revised USP Chapter. Further, staff note that the proposed regulation text make clear that separate documentation is not required, rather, the patient's medical record documenting will comply with the regulation. Staff also note that maintaining complete administration records are required for many

			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.	regulators, not just the Board. Staff Recommend that the Board update Section 1736.17(b) to expand to include all equipment failure. SOPs should have redundancy included.
11	1736.1(b)	Philip Smyth Medisca	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	Board staff have reviewed the comment and do not recommend a change to the language. Staff note that should a pharmacist need to compound in such a situation, the current proposed regulation language provides such authority by recognizing the need to avoid situations that would result in extreme pain and suffering to a patient. Immediate use CSP provisions allow for the practice.

			medication is often needed for infiltration and nerve block.	
12	1736.1(b)	Scripps Health	Proposed 1736 1B regarding immediate use can cost the hospital 1.5 million each time an engineering control presents a challenge	This generic statement is not sufficiently specific for the Board to evaluate. Immediate use provisions proposed in the regulation text come from existing regulation language in CCR 1751.8(e). Existing law, however, requires that the administration begin within one hour. Under the proposed regulation text, the administration time is extended to four hours to align with the immediate use provisions in USP Chapter 797 section 1.3. The proposed regulation text provides greater flexibility than current regulations and should result in cost savings. The commenter suggested a cost of \$1.5, those costs, if accurate would be occurred now under the existing immediate use provisions. Board staff understand that at times primary engineering controls (PEC) may fail. Compounding in a PEC is a requirement of the Chapter, not a function of the Board's regulation. The Chapter established provisions for immediate use that allow for compounding outside of a PEC under specified conditions. The Board's proposed (and current) regulations allow for this process as well. As included in the Board's current regulation (CCR 1751.8(e) immediate use is allowed to prevent loss of life or intense suffering. Staff notes that the recommended inclusion of (1) will provide impacted facilities flexibility to continue to take care of patients in the event of an equipment failure for 24 hours while the facility implements its required "corrective action plan" that is required in response to any out-of-range results as established in Chapter 797, Section 5. This is a current flexibility is not allowed with the Board's current requirements but is included to allow for continuity of patient care while the facility implements its required "corrective action plan." Staff understand that there are requirements from other regulators for all hospitals to have emergency plans. The Board would anticipate that equipment failure would be included in such plans in compliance with these other regulatory requirements. Staff are

				recommending changes to the proposed text to clarify that a facility can rely on documentation that already exists in a patient's medical record.
13	1736.1(b)	Melanie Horn Sutter Health Also Provided at Reg Hearing	Sutter Health recognizes the Board intent to maintain the current restrictions for applying the USP 797 immediate use provision by the pharmacy but request revising the immediate use to align with other enforcing regulatory agencies. Revising the patient condition allows pharmacies the ability to serve the needs of patients through owning compounding in immediate use scenarios related to identification of patient harm. Creating a standard that forces immediate use compounding to other professions outside of the Board jurisdiction does not support California consumer protections. Recommend removing documentation from immediate use CSPs to prevent care delay. 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~~	Staff have considered the comment and note that the language in the proposed text is similar to existing regulation CCR Section 1751.8(e), including the current requirement to document the circumstances causing the immediate need. Staff note that to align with USP, the Board has removed the current one hour start time and will instead allow the four-hour start time provided for in the revised USP Chapter. Further, staff note that the proposed regulation text make clear that separate documentation is not required, rather, the patient's medical record documenting will comply with the regulation. Staff also note that maintaining complete administration records are required for many regulators, not just the Board. Staff Recommend that the Board update Section 1736.17(b) to expand to include all equipment failure. SOPs should have redundancy included.
14	1736.1(b)	Wendy Waldman Torrance Memorial Medical Center	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. The current language may lead to substantial	Staff have considered the comment and note that the language in the proposed text is similar to existing regulation CCR Section 1751.8(e), including the current requirement to document the circumstances causing the immediate need. Staff note that to align with USP, the Board has removed the current one-hour start time and will instead allow the four-hour start time provided

			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.~~	for in the revised USP Chapter. Further, staff note that the proposed regulation text makes clear that separate documentation is not required; rather, the patient's medical record documentation will comply with the regulation. Staff also note that maintaining complete administration records are required for many regulators, not just the Board. Staff recommend that the Board update Section 1736.17(b) to expand to include all equipment failure. SOPs should have redundancy included.
15	1736.1(b)	UCSD	There's a lot of documentation that's been proposed and most things are an electronic medical record so as long as it's available to the board in a timely fashion that should be sufficient.	Staff have considered the comment and note that the language in the proposed text is similar to existing regulation CCR Section 1751.8(e), including the current requirement to document the circumstances causing the immediate need. Staff note that to align with USP, the Board has removed the current one-hour start time and will instead allow the four-hour start time provided for in the revised USP Chapter. Further, staff note that the proposed regulation text makes clear that separate documentation is not required; rather, the patient's medical record documentation will comply with the regulation. Staff also note that maintaining complete administration records are required for many regulators, not just the Board.
16	1736.1(b)	UCSF	Comment: • Immediate-use compounding is frequently required	Staff have considered the comment and note that the language in the proposed text is similar to existing

			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. <u>Documentation of administration of CSP shall be recorded in patient's medical record if given.</u> ~~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~~	regulation CCR Section 1751.8(e), including the current requirement to document the circumstances causing the immediate need. Staff note that to align with USP, the Board has removed the current one hour start time and will instead allow the four-hour start time provided for in the revised USP Chapter. Further, staff note that the proposed regulation text make clear that separate documentation is not required, rather, the patient's medical record documenting will comply with the regulation. Staff also note that maintaining complete administration records are required for many regulators, not just the Board.
17	1736.1(b) should be 1735.1(b)	Rheta Silvas Kaweah Health	Recommend: 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	Staff believes the commenter is referring to section 1735.1(b). Staff have considered the comment and recommend a change to the language. Specifically, staff recommend removing 1735.1(b) to avoid the potential overexpansion of the definition of compounding to encompass the strict removal of a dangerous drug from a manufacturer's bottle and placing it in a prescription vial.

			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. Concerns: 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.	
18	1736.1(d)	Rheta Silvas Kaweah Health	Recommend: strike "compounded drug preparation". Rationale: this verbiage is preceded by the abbreviation CSP and is redundant.	Board staff have considered the comment and, in response to the comment, are offering a change to the proposed regulation text to address the comment and to make a conforming change to the language to reiterate the provisions related to patient-specific furnishing.
19	1736.1(e)	Scripps Health	Proposed 1736.1(e) regarding drug shortages will cost the hospital 120,000 to over a million dollar per year	This generic statement is not sufficiently specific for the Board to evaluate. The Board is unclear how the proposed regulation will result in the costs represented by the commenter, as the regulation of drug manufacturers falls under the jurisdiction of the FDA. The Board has also reached this conclusion for several other reasons. First, the proposed text referenced by the commenter is similar to the conditions in existing law, CCR Section 1735.2(d)(3). Further, federal law establishes the provisions for when compounding (FDCA section 503A can occur and provides authority to compound "essentially a copy" only under very limited circumstances. Federal law defines "essentially a copy" in FDCA 503A (b)(2). As included in the FDA's guidance document, "The restrictions on making drugs that are essentially copies ensure that pharmacists and physicians do not compound drug products under the exemptions for patients who could use a commercially available drug product. Such a practice would create significant public health risk because patients would be unnecessarily exposed to drug products that have not been shown to be safe

				and effective and that may have been prepared under substandard manufacturing conditions. FDA has investigated serious adverse events in patients who received contaminated compounded drugs when a comparable approved drug, made in a facility subject to CGMP requirements, was available. Restrictions in section 503A prevent compounders from producing drugs without having to comply with monograph standards, or CGMP requirements." Staff note that as written, the language provides flexibility for a clinician to use their professional judgment when determining if a compound is essentially a copy. https://www.fda.gov/files/drugs/published/Compounded-Drug-Products-That-Are-Essentially-Copies-of-a-Commercially-Available-Drug-Product-Under-Section-503A-of-the-Federal-Food--Drug--and-Cosmetic-Act-Guidance-for-Industry.pdf.
20	1736.1(e)	Melanie Horn Sutter Health	ASHP and FDA drug shortage lists can have a lag between the posted shortage and a disruption in supply. In 2023, the Akorn recall was posted after the State Board notification of the company shut down with multiple unlisted drug shortages already impacting supply. Wholesalers frequently cannot supply critical medications, especially in a pre-shortage situation. California code restrictions in place prevent compounding during these supply disruptions and contribute to heightened risk and safety concerns for patients unable to access medication therapies. Documentation of inability to acquire due to wholesaler not able to supply documentation is a solution recommended. Compounding to meet an immediate need when a commercially available dosage form is not stocked but is not done so in regular or inordinate amounts is a necessary exclusion to provide patient access and continuity of care through compounded preparations.	Response to comment is in line 19

			If not done so based on establishing a routine pattern or in inordinate quantities deemed by the board creating a clear exemption. An example is treating Clostridioides difficile with compounded from sterile vancomycin vial manufactured products to make an oral suspension where a rural or small facility will not routinely order the commercial medication it does not routinely utilize but would be remiss to delay or withhold the compounding treatment to initiate therapy. Recommended new language: (A) the drug product is deemed not commercially available, appearing in an American Society of Health-System Pharmacists (ASHP) or FDA Drug Shortages Database that is in short supply at the time of compounding, ~~and at the time of dispensing,~~ or <u>(B) the drug product is not commercially available due to inability to supply by the manufacturer or wholesaler.</u> <u>(C) the drug product is unavailable to dispense and the CNSP is not compounded regularly or in inordinate amounts.</u> (D) the compounding produces a clinically significant difference for the medical need of an identified individual patient, as determined by the prescribing practitioner. <u>If such determination has not been documented on the prescription by the prescriber, the</u> (ii) the compounding pharmacist, and or (iii) the dispensing pharmacist(s) <u>Shall ensure that the determination is documented on the prescription.</u> (C) Documentation describing the conditions in (1)(A) , (1)(B), (1)(C) and <u>1 (D)</u> is maintained in a readily retrievable format	
21	1736.1(e)	National Community Pharmacists Association	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 the combination of two or more commercially	The proposed regulation text referenced by the commenter is similar to the conditions in existing law, CCR Section 1735.2(d)(3). Further, federal law establishes the provisions for when compounding

		(NCPA), Scott Brunner Alliance for Pharmacy Compounding	available drug products. Recommend that California align with FDA's description used in the 503A copies guidance.	(FDCA section 503A can occur and provides authority to compound "essentially a copy" only under very limited circumstances. Federal law defines "essentially a copy" in FDCA 503A (b)(2). As included in the FDA's guidance document," The restrictions on making drugs that are essentially copies ensure that pharmacists and physicians do not compound drug products under the exemptions for patients who could use a commercially available drug product. Such a practice would create significant public health risk because patients would be unnecessarily exposed to drug products that have not been shown to be safe and effective and that may have been prepared under substandard manufacturing conditions. FDA has investigated serious adverse events in patients who received contaminated compounded drugs when a comparable approved drug, made in a facility subject to CGMP requirements, was available. Restrictions in section 503A prevent compounders from producing drugs without having to comply with monograph standards, or CGMP requirements." Staff note that as written, the language provides flexibility for a clinician to use their professional judgment when determining if a compound is essentially a copy. https://www.fda.gov/files/drugs/published/Compounded-Drug-Products-That-Are-Essentially-Copies-of-a-Commercially-Available-Drug-Product-Under-Section-503A-of-the-Federal-Food--Drug--and-Cosmetic-Act-Guidance-for-Industry.pdf.
22	1736.1(e)	Philip Smyth Medisca	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.	The proposed regulation text referenced by the commenter is similar to the conditions in existing law, CCR Section 1735.2(d)(3). Further, federal law establishes the provisions for when compounding (FDCA section 503A can occur and provides authority to compound "essentially a copy" only under very limited circumstances. Federal law defines "essentially a copy" in FDCA 503A (b)(2). As included in the FDA's guidance document," The restrictions on making drugs that are essentially copies ensure that pharmacists and

				physicians do not compound drug products under the exemptions for patients who could use a commercially available drug product. Such a practice would create significant public health risk because patients would be unnecessarily exposed to drug products that have not been shown to be safe and effective and that may have been prepared under substandard manufacturing conditions. FDA has investigated serious adverse events in patients who received contaminated compounded drugs when a comparable approved drug, made in a facility subject to CGMP requirements, was available. Restrictions in section 503A prevent compounders from producing drugs without having to comply with monograph standards, or CGMP requirements." Staff note that as written, the language provides flexibility for a clinician to use their professional judgment when determining if a compound is essentially a copy.
23	1736.1(e)(1)(A-C)	Philip Smyth Medisca	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.	The proposed regulation text referenced by the commenter is similar to the conditions in existing law, CCR Section 1735.2(d)(3). Further, federal law establishes the provisions for when compounding (FDCA section 503A) can occur and provides authority to compound "essentially a copy" only under very limited circumstances. Federal law defines "essentially a copy" in FDCA 503A (b)(2). As included in the FDA's guidance document, "The restrictions on making drugs that are essentially copies ensure that pharmacists and physicians do not compound drug products under the exemptions for patients who could use a commercially available drug product. Such a practice would create significant public health risk because patients would be unnecessarily exposed to drug products that have not been shown to be safe and effective and that may have been prepared under substandard manufacturing conditions. FDA has investigated serious adverse events in patients who received contaminated compounded drugs when a comparable approved drug, made in a facility subject to CGMP requirements, was available. Restrictions in

				section 503A prevent compounders from producing drugs without having to comply with monograph standards, or CGMP requirements." Staff note that the proposed text provides flexibility for a clinician to use their professional judgment when determining if a compound is essentially a copy. https://www.fda.gov/files/drugs/published/Compounded-Drug-Products-That-Are-Essentially-Copies-of-a-Commercially-Available-Drug-Product-Under-Section-503A-of-the-Federal-Food--Drug--and-Cosmetic-Act-Guidance-for-Industry.pdf.
24	1736.1(e) (1)(A)	Wendy Waldman Torrance Memorial Medical Center	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. (e) In addition to prohibitions established in federal law,	Board staff have reviewed the comments and considered comments from members related to this issue and are recommending changes to the proposed text to address the comments by establishing additional authority for a healthcare facility, licensed pursuant to HSC 1250, to compound essentially a copy of a commercially available product under specified conditions.

			no licensed pharmacy personnel shall compound a CSP that: (1) Is essentially a copy of one or more commercially available drug products, unless: (A) <u>That drug product is not available (cannot be purchased) by the manufacturer or wholesaler,</u> 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...	
25	1736.1(e) (1)(A)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP	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 shortage² and recent manufacturer bankruptcies (i.e. Akorn, Apotex) it is becoming more challenging for Health-Systems to obtain commercially available products. 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	Board staff have reviewed the comments and considered comments from members related to this issue and are recommending changes to the proposed text to address the comments by establishing additional authority for a healthcare facility, licensed pursuant to HSC 1250, to compound essentially a copy of a commercially available product under specified conditions.

			CSP that: (1) Is essentially a copy of one or more commercially available drug products, unless: (A) <u>That drug product is not available (cannot be purchased) by the manufacturer or wholesaler,</u> 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	
26	1736.1(e) (1)(A)	UCSF	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 <u>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</u>	Board staff have reviewed the comments and considered comments from members related to this issue and are recommending changes to the proposed text to address the comments by establishing additional authority for a healthcare facility, licensed pursuant to HSC 1250, to compound essentially a copy of a commercially available product under specified conditions.
27	1736.1(e) (1)(A,B,C)	National Community	There is no accommodation for veterinary compounds, which are regulated under different provisions of	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text

		Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	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.	based on this comment. Pharmacists must remain knowledgeable of current practice standards and legal requirements of the industry while exercising their professional judgment, including any guidance for the industry, including those issued by the FDA related to veterinary patients.
28	1736.1(e)(1)(A)	Marie Cottman Pacific Compounding	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 <u>that are in short supply and the drug status is "currently in shortage"</u> at the time of compounding and at the time of dispensing, or	Board staff have reviewed the comments and considered comments from members related to this issue and are recommending changes to the proposed text to address the comments by establishing additional authority for a healthcare facility, licensed pursuant to HSC 1250, to compound essentially a copy of a commercially available product under specified conditions.
29	1736.1(e)(1)(B)	Marie Cottman Pacific Compounding	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?	Staff note that as written, the language provides flexibility for a clinician to use their professional judgment when determining if a compound is essentially a copy by determining if a change will produce a clinically significant difference. Staff have reviewed the comment and do not recommend changes to the proposed regulation text. Staff note that FDA guidance documents help establish the

			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	standard of practice for compounders. Staff note that pharmacists must remain knowledgeable of current practice standards and legal requirements of the industry while exercising their professional judgment. Staff note that a compounding pharmacist may not have access to the patient's record to make a determination that the compounding product is the appropriate treatment. Staff note that all pharmacists have a professional obligation to patient care, which includes the selection of the drug therapy being provided to their patient.
30	1736.1(e)(1)(B)	Jasmine Parker Pacific Compounding	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	Staff have considered the change and do not recommend changes. Staff note that FDA guidance documents establish the standard of practice for compounders. It is incumbent on licensed professionals to remain current on guidance issued to ensure compliance with established provisions. Staff note that, as written, the language provides flexibility for a clinician to use their professional judgment when determining if a compound is essentially a copy, by considering whether a change will produce a clinically significant difference.
31	1736.1(e)(1)(B)(i-iii)	Rheta Silvas Kaweah Health Melanie Horn Sutter Health	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	Board staff have reviewed the comments and considered feedback from members. Staff are recommending changes to the proposed text to remove the requirements that could have potentially required two pharmacists to make independent determinations.

			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 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. 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	
32	1736.1(e)(2)	Scott Brunner Alliance for Pharmacy Compounding	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 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.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. Pharmacists must remain knowledgeable of current practice standards and legal requirements of the industry while exercising their professional judgment including any guidance for industry, including those issued by the FDA related to veterinary patients.

33	1736.1(e) (2)	National Community Pharmacists Association (NCPA)	Reference to AMDUCA is vague, compounded preparations are not covered under AMDUCA. Pharmacists should determine suitability of ingredients.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. Pharmacists must remain knowledgeable of current practice standards and legal requirements of the industry while exercising their professional judgment, including any guidance for the industry, including those issued by the FDA related to veterinary patients.
34	1736.1(e) (2)	Marie Cottman Pacific Compounding	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~~ <u>animal</u> population, unless allowable under the Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA).	Staff have reviewed the comment and recommend changes to the proposed regulation text to address the comment and provide clarity regarding applicability to veterinary patients.
35	1736.1(e) (3)	Marie Cottman Pacific Compounding	COMMENT: This says that one cannot use bulk-powder for CSP if a manufactured sterile component is appropriate. However, there is no definition of	Board staff have considered the comment and are offering a recommended change to the proposed regulation text. The proposed text offered by staff

			"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.	does not prevent nonsterile to sterile compounding and will ensure that appropriate safeguards are in place to protect patients, including stability testing, which ensures the product is stable throughout the established beyond-use date. Pharmacists must remain knowledgeable of current practice standards and legal requirements of the industry while exercising their professional judgment to determine when it is appropriate or not.
36	1736.1(e)(3)	Rheta Silvas Kaweah Health	COMMENT: There is no definition of "appropriate" that can be applied, this is based on pharmacist judgment. RECOMMENDATION: Remove.	Staff have reviewed the comment and do not recommend changes to the proposed regulation text. Pharmacists must remain knowledgeable of current practice standards and legal requirements of the industry while exercising their professional judgment.
37	1736.1(e)(3)	Rick Rhoads University Compounding Also Provided at Reg Hearing	Strike (e)(3). 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.	Board staff have considered the comment and are offering a recommended change to the proposed regulation text. The proposed text offered by staff does not prevent nonsterile to sterile compounding and will ensure that appropriate safeguards are in place to protect patients, including stability testing which ensures the product is stable throughout the beyond use date.
38	1736.1(e)(3)	Lauren Honda Valor Compounding Also Submitted in Reg Hearing	Commenter disagrees with the proposed law mandating compounding with a conventionally manufactured component when it is available as it fails to account for the nuanced considerations	Board staff have considered the comment and are offering a recommended change to the proposed regulation text. The proposed text offered by staff does not prevent nonsterile to sterile compounding and will ensure that appropriate safeguards are in

			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."	place to protect patients, including stability testing which ensures the product is stable throughout the beyond use date.
39	1736.1(e)(3)	National Community Pharmacists Association (NCPA), Scott Brunner	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 compounding set-up, using a conventionally manufactured	Board staff have considered the comment and are offering a recommended change to the proposed regulation text. The proposed text offered by staff does not prevent nonsterile to sterile compounding and will ensure that appropriate safeguards are in place to protect patients, including stability testing

		Alliance for Pharmacy Compounding	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 ingredients already shortens the BUD of the final product. Does "conventionally manufactured" mean commercially available?	which ensures the product is stable throughout the beyond use date.
40	1736.1(e) (4)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	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?	Staff have reviewed the comment and do not recommend any changes to the proposed regulation text. Staff note that on September 25, 2019, this issue was raised. At that time, counsel advised members that "provided based on her research of 503A subdivision (a) (1), the federal exemption applies to a state licensed pharmacy that exempts the pharmacy for the manufacturer requirements when compounding. Business and Professions Code sections 4127 and 4127.1 specifically reference the compounding has to occur in a sterile compounding pharmacy – a singular pharmacy – and the license is not transferable thereby emphasizing all compounding exempted under the federal law that occur can in a compounding pharmacy has to occur in a single licensed facility. Board counsel added at that time there are no statutory exemptions and would expect all aspects of compounding to occur in the single regulated unit.
41	1736.1(e) (4)	Philip Smyth Medisca	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?	Staff have reviewed the comment and do not recommend any changes to the proposed regulation text. Staff note that on September 25, 2019, this issue was raised. At that time, counsel advised members that "provided based on her research of 503A subdivision (a) (1), the federal exemption applies to a state licensed pharmacy that exempts the pharmacy for the manufacturer requirements when compounding. Business and Professions Code sections 4127 and 4127.1 specifically reference the

				compounding has to occur in a sterile compounding pharmacy – a singular pharmacy – and the license is not transferable thereby emphasizing all compounding exempted under the federal law that occur can in a compounding pharmacy has to occur in a single licensed facility. Board counsel added at that time there are no statutory exemptions and would expect all aspects of compounding to occur in the single regulated unit.
42	1736.1(e) (4)	Mike Pavlovich Westcliff Compounding	Commenter states he employs 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. 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. Commenter states he selected eBeam for terminal	Staff have reviewed the comment and do not recommend any changes to the proposed regulation text. Staff note that on September 25, 2019, this issue was raised. At that time, counsel advised members that "provided based on her research of 503A subdivision (a) (1), the federal exemption applies to a state licensed pharmacy that exempts the pharmacy for the manufacturer requirements when compounding. Business and Professions Code sections 4127 and 4127.1 specifically reference the compounding has to occur in a sterile compounding pharmacy – a singular pharmacy – and the license is not transferable thereby emphasizing all compounding exempted under the federal law that occur can in a compounding pharmacy has to occur in a single licensed facility. Board counsel added at that time there are no statutory exemptions and would expect all aspects of compounding to occur in the single regulated unit.

			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. 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, commenter knows 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. Commenter urges the Board to reconsideration this important regulation and ask that it be struck down entirely as stated.	
43	1736.1(g) -should be 1735.1(h)	Melanie Horn Sutter Health	Harmonize the terminology used in 1735.1(i) and 1736.1(h). Refer to comment above for 1735.1(i) (i) ~~CSPs with~~ Human whole blood or human whole blood derivatives used in CSPs shall be produced in compliance with Health and Safety Code section 1602.5 <u>or supplied as a commercial biologic product licensed as a Fractionated Plasma Products.</u>	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. Staff notes that federal law does not allow for pharmacy compounding of biologic products. Staff note that the FDA has released guidance in this area. Staff note that FDA guidance documents help establish the standard of practice for compounders. It is incumbent on licensed professions to remain current on guidance issued to ensure compliance with established provisions. The guidance document is available at https://www.fda.gov/files/drugs/published/Mixing--

				Diluting--or-Repackaging-Biological-Products-Outside-the-Scope-of-an-Approved-Biologics-License-Application.pdf
44	1736.1(g)	Wendy Waldman Torrance Memorial Medical Center	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. <u>(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.</u>	Staff have reviewed the comment and agree that additional clarification to the language is appropriate to more specifically describe when patient consultation is required. Staff is offering recommended language.
45	1736.1(g)	Mark Johnston CVS Health	Commenter indicates that section 1702.2(c), Duty to Consult, only lists two categories of mandatory counseling and the pending regulations would create a third. Additionally, 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. Commenter states that 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	Staff have reviewed the comment and agree that additional clarification to the language is appropriate to more specifically describe when patient consultation is required. Staff is offering recommended language.

			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. Commenter believes the pending regulations are essentially requiring pharmacists to provide legal advice on proper disposal, for which they are not well educated. Commenter requests the following edit: (g) In addition to the provisions in Section 1707.2, <u>whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral</u> consultation shall be provided to the patient and/or patient's agent concerning proper use, storage, <u>and handling and disposal</u> of the CSP and related supplies furnished.	
46	1736.1(g)	Tommy Mai Huntington Health, CSHP	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 <u>(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.</u>	Staff have reviewed the comment and agree that additional clarification to the language is appropriate to more specifically describe when patient consultation is required. Staff is offering recommended language.

47	1736.1(g)	Rheta Silvas Kaweah Health	Recommend: add this language to 1707.2 or add language to clarify settings in which it is applicable. Rationale: 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.	Staff have reviewed the comment and agree that additional clarification to the language is appropriate to more specifically describe when patient consultation is required. Staff is offering recommended language.
48	1736.1(g)	John Gray Kaiser Permanente	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. <u>When a CSP is furnished to a patient or patient's agent,</u> 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.	Staff have reviewed the comment and agree that additional clarification to the language is appropriate to more specifically describe when patient consultation is required. Staff is offering recommended language.
49	1736.1(g)	Marie Cottman Pacific Compounding	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	Board staff have considered the comment and do not recommend changes based solely on this comment. Staff note that changes to CCR 1707.2 are outside of the scope of the regulation. Should the Board seek to amend CCR 1707.2, it will consider at that time whether consultation should also encompass disposal information on manufactured drug products. Staff are offering language to address other comments received regarding the provisions in this section.

			initiate the rulemaking process to update 1707.2 for additional consultation requirements.	
50	1736.1(h)	Marie Cottman Pacific Compounding	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.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. Staff note that the FDA has released a guidance in this area. Staff note that FDA guidance documents establish the standard of practice for compounders. It is incumbent on licensed professions to remain current on guidance's issued to ensure compliance with provisions established. The guidance document is available at https://www.fda.gov/files/drugs/published/Mixing--Diluting--or-Repackaging-Biological-Products-Outside-the-Scope-of-an-Approved-Biologics-License-Application.pdf
51	1736.1(h)	Tommy Mai Huntington Health, CSHP	Rationale: The current health and safety code section 1602.5 states the following: (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	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. Staff note that the language is to ensure any blood handled from any patient is in compliance with the provision.

			regulation does not apply to CSPs made with human blood/derivative that is manufactured by pharmaceutical companies. (h) CSPs with <u>patient's own</u> whole blood or human whole blood derivatives <u>from the patient</u> shall be produced in compliance with Health and Safety Code section 1602.5.	
52	1736.1(h)	Wendy Waldman Torrance Memorial Medical Center	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 <u>patient's own</u> whole blood or human whole blood derivatives <u>from the patient</u> shall be produced in compliance with Health and Safety Code section 1602.5.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. Staff note that the language is to ensure any blood handled from any patient is in compliance with the provision.
53	1736.2(b)	Wendy Waldman Torrance Memorial Medical Center	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:	Staff have reviewed the comment and do not recommend a change to the proposed regulation text. Staff note that the requirement to document would occur once every three to six months. Further, the documentation ensures that a compounding personnel need only complete a single training and can leverage that training in other compounding

			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.	environments with the same equipment. The unique identifier is necessary to identify where the competency was performed.
54	1736.2(b)	Tommy Mai Huntington Health, CSHP	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.	Staff have reviewed the comment and do not recommend a change to the proposed regulation text. Staff note that the requirement to document would occur once every three to six months. Further, the documentation ensures that a compounding personnel need only complete a single training and can leverage that training in other compounding environments with the same equipment. The unique identifier is necessary to identify where the competency was performed.
55	1736.2(b)	Rheta Silvas Kaweah Health	Recommend: clarify the term "materials" by adding to the sterile compounding definitions (CCR 1736). Rationale: the term "materials" is ambiguous.	Board staff have reviewed the comment and do not recommend changes to the proposed text. Staff note that the language of the regulation must be broad and flexible to allow for facilities to make site specific determinations in operationalizing the requirements.
56	1736.2(d)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP	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:	Board staff have considered the comment and do not recommend changes based solely on this comment. Staff note that an individual that fails any aseptic manipulation for example can compromise the integrity of the product. Staff have significant patient safety concerns with an individual that fails any aspect of the core competencies established in the Chapter be involved in compounding of sterile compounding preparations. Compounding of CSPs is a high-risk function that if not done appropriate can have dire impacts on patients. Regrettable there too many

			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 an action plan <u>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.</u>	instances of patient death and harm attributed to lack of training and staff. Staff note that in adverse event reports it is common that the contributing factor was the training of the staff. Staff are recommending changes to the proposed text to extend the duration of time an individual can continue to provide such supervision and control.
57	1736.2(d)	Rheta Silvas Kaweah Health	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	Board staff have considered the comment and do not recommend changes based solely on this comment. Staff note that an individual that fails any aseptic manipulation for example can compromise the integrity of the product. Staff have significant patient safety concerns with an individual who fails any aspect of the core competencies established in the Chapter be involved in compounding of sterile compounding preparations. Compounding of CSPs is a high-risk function that if not done appropriate can have dire impacts on patients. Regrettably there too many instances of patient deaths and harm attributed to lack of training and staff. Staff note that in adverse event reports it is common that the contributing factor was the training of the staff. Staff are recommending

			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 the failed results are received.	changes to the proposed text to extend the duration of time an individual can continue to provide such supervision and control.
58	1736.2(d)	Narinder Singh Santa Clara Valley Healthcare (SCVH) Also Provided at Reg Hearing	The proposed language is very restrictive and will have significant impacts on smaller hospitals with limited staffing. We recommend allowing compounding personnel to continue with sterile compounding with a limitation of immediate use expiration dating pending results of the aseptic manipulation and competency evaluation	Board staff have considered the comment and recommend changes, although not based solely on this comment. Staff note that an individual that fails any aseptic manipulation for example can compromise the integrity of the product. Staff have significant patient safety concerns with an individual who fails any aspect of the core competencies established in the Chapter be involved in compounding of sterile compounding preparations. Compounding of CSPs is a high-risk function that if not done appropriately can have dire impacts on patients. Regrettably there too many instances of patient deaths and harm attributed to lack of training and staff. Staff note that in adverse event reports it is common that the contributing factor was the training of the staff. Staff are recommending changes to the proposed text to extend the duration of time an individual can continue to provide such supervision and control.
59	1736.2(d)	Muno Bholat Providence	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	Board staff have considered the comment and do not recommend changes based solely on this comment. Staff note that an individual that fails any aseptic manipulation for example can compromise the integrity of the product. Staff have significant patient safety concerns with an individual who fails any aspect of the core competencies established in the Chapter be involved in compounding of sterile compounding preparations. Compounding of CSPs is a high-risk function that if not done appropriate can have dire impacts on patients. Regrettably there too many instances of patient deaths and harm attributed to lack of training and staff. Staff note that in adverse event reports it is common that the contributing factor was the training of the staff. Staff are recommending changes to the proposed text to extend the duration

		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 <u>have no more than 14 days after a failure to successfully pass</u> ~~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. <u>If training and competency are not passed after the 14 days,</u> ~~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~~	of time an individual can continue to provide such supervision and control.

			~~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.~~	
60	1736.2(d)	Melanie Horn Sutter Health	Failure of the aseptic technique competency evaluation can include contamination by the designated competency evaluator, an environmental testing failure and/or 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: Establish requirement for facility's SOP for an investigation and corrective action plan that specifies compounding personnel failing any aspect of aseptic manipulation requirements specific to ongoing training and competency evaluation. (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 <u>have a documented investigation of failure and remediation that demonstrates 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.</u> 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 business days after a failure of any aspect while applicable aseptic manipulation ongoing training and competency evaluation results are pending	Board staff have considered the comment and do not recommend changes based solely on this comment. Staff note that an individual who fails any aseptic manipulation for example can compromise the integrity of the product. Staff have significant patient safety concerns with an individual who fails any aspect of the core competencies established in the Chapter be involved in compounding of sterile compounding preparations. Compounding of CSPs is a high-risk function that if not done appropriate can have dire impacts on patients. Regrettably there too many instances of patient death and harm attributed to lack of training and staff. Staff note that in adverse event reports it is common that the contributing factor was the training of the staff. Staff are recommending changes to the proposed text to extend the duration of time an individual can continue to provide such supervision and control.
61	1736.2(d)	Wendy Waldman Torrance Memorial	Rationale: Several factors may contribute to the failure of staff in aseptic technique training and competency evaluation, such as environmental testing failure and	Board staff have considered the comment and do not recommend changes based solely on this comment. Staff note that an individual that fails any aseptic manipulation for example can compromise the

		Medical Center	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.	integrity of the product. Staff have significant patient safety concerns with an individual that fails any aspect of the core competencies established in the Chapter be involved in compounding of sterile compounding preparations. Compounding of CSPs is a high-risk function that if not done appropriate can have dire impacts on patients. Regrettable there too many instances of patient death and harm attributed to lack of training and staff. Staff note that in adverse event reports it is common that the contributing factor was the training of the staff. Staff note that in adverse event reports it is common that the contributing factor was the training of the staff. Staff are recommending changes to the proposed text to extend the duration of time an individual can continue to provide such supervision and control.
62	1736.2(d)	John Gray Kaiser Permanente	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 personnel" from the first sentence. There might be situations in which a compounding personnel	Board staff have considered the comment and do not recommend changes based solely on this comment. Staff note that an individual that fails any aseptic manipulation for example can compromise the integrity of the product. Staff have significant patient safety concerns with an individual that fails any aspect of the core competencies established in the Chapter

			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. 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 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 <u>compounding</u> 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~~ <u>21</u> days after a failure of any aspect while applicable aseptic manipulation ongoing training and competency evaluation results are pending.	be involved in compounding of sterile compounding preparations. Compounding of CSPs is a high-risk function that if not done appropriate can have dire impacts on patients. Regrettable there too many instances of patient death and harm attributed to lack of training and staff. Staff note that in adverse event reports it is common that the contributing factor was the training of the staff. Staff note that in adverse event reports it is common that the contributing factor was the training of the staff. Staff are recommending changes to the proposed text to extend the duration of time an individual can continue to provide such supervision and control.
63	1736.2(d)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	The person with only direct oversight who fails will need more than 14 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 extended to 21 days. Similar to the comment in nonsterile compounding, removing people from performing all compounding due to a	Board staff have considered the comment and do not recommend changes based solely on this comment. Staff note that an individual that fails any aseptic manipulation for example can compromise the integrity of the product. Staff have significant patient safety concerns with an individual that fails any aspect of the core competencies established in the Chapter be involved in compounding of sterile compounding preparations. Compounding of CSPs is a high-risk function that if not done appropriate can have dire

			failure in any training area is not appropriate. A more nuanced approach should be used. If a person fails in their use of an autoclave 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 completely removed from all compounding of CSPs.	impacts on patients. Regrettable there too many instances of patient death and harm attributed to lack of training and staff. Staff note that in adverse event reports it is common that the contributing factor was the training of the staff. Staff note that in adverse event reports it is common that the contributing factor was the training of the staff. Staff are recommending changes to the proposed text to extend the duration of time an individual can continue to provide such supervision and control.
64	1736.2(e)	Rheta Silvas Kaweah Health	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.	Board staff have considered the comment and do not recommend changes to the proposed text. Staff note that documentation requirements are established in proposed section 1736.20.
65	1736.2 and 1736.3	Sam Kim USC	Personnel training requirements lack any evidence that this training is necessary. The cost to provide training would be substantial.	This generic statement is not sufficiently specific for the Board to evaluate. Training is so critical to sterile compounding USP 797 has an entire section, Section 2, dedicated to personnel training and evaluation. The Chapter details out the core competencies of training that must be completed at least every 12 months. Any costs incurred for these trainings is a function of compliance with the Chapter, not the Board's proposed regulation. The Board's proposed regulations do require training in four additional areas not specified in the chapter - - quality assurance and quality control; container closure and equipment selection; component selection and handling; and sterilization techniques (only when applicable). As noted in the ISOR, these additional components ensure that personnel are adequately training in all aspects of compounding including for example quality assurance which ensure an individual has knowledge to perform a root cause analysis if an issue arises with product quality or a medication error, or an understanding of a particular component selection when making a compounded preparation that could occur in a number of circumstances, including for example under extreme pressure such as for immediate use. Staff note

				that current regulations, CCR 1751.6 requiring training in these areas - - 1751.8(e)(1)(J) container, equipment, and closure system selection; 1751.8(e)(1)(D) quality assurance procedures, 1751.8(e)(I) sterilization technique for compounding. These costs would already be incurred so the staff is unclear how this would be a new cost. Staff note that Section 9.3 of the Chapter requires an SOP on component selection. An SOP without completing training on the provisions undermines the value of the SOP. Section 18 of Chapter 797 requires compliance with the training and assessment requirements. The need for proper training is highlighted in a number of areas, including in the USP 797 Commentary document which include "Personnel are the biggest source of contamination, and this frequency of personnel monitoring helps ensure continued, consistent, and proper performance." Elsewhere in the commentary, in response to another comment the USP includes, "The (training) standards are based on a combination of available evidence, expertise of the Compounding Expert Committee, and input from stakeholders, and take into consideration stability and sterility data, the compounding environment, and the financial impact on compounders and patients. Personnel are the main source of contaminants, and a frequency of every 6 months for the garbing competency for compounders helps assure continued proper hand hygiene and garbing procedures. The text was changed to allow designated person(s) and personnel who oversee compounding personnel to perform the competency every 12 months."
66	1736.3	Paul Lofholm	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?	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff believe the comment is related to proposed text in CCR 1736.3(c). Staff note that the language provides flexibility to allow for SOPs to allow for the practice in a safe manner and how it is monitored. Staff note that garbing needs to occur outside of compounding

				space to decrease the risk of the introduction of contaminants.
67	1736.3	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	Refer to 1735.3(a) above	Staff reviewed the comment and do not recommend changes to the language. The USP Expert committee identified the risk and as such included provisions in the Chapter. The Board believes a brightline rule is necessary ensure the environment is not compromised. Staff note that as an example, an individual with an active respiratory illness can release airborne pathogens into the compounding environment thus compromising the environment.
68	1736.3(a)	Marie Cottman Pacific Compounding	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~~ <u>should use their judgement to prevent</u> personnel with potentially contaminating conditions to enter the designated compounding area.	Staff reviewed the comment and do not recommend changes to the language. The USP Expert committee identified the risk and as such included provisions in the Chapter. The Board believes a brightline rule is necessary to ensure the environment is not compromised. Staff note that as an example, an individual with an active respiratory illness can release airborne pathogens into the compounding environment, thus compromising the environment.
69	1736.3(b)	Narinder Singh Santa Clara Valley Healthcare (SCVH)	Covering the non-removeable piercings with PPE eliminated the risk of contamination of CSP. Add the following language to this section. "The personnel may be allowed to enter the compounding area if the non-removable piercings is covered with PPE."	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. Staff believe that the provisions in CCR 1736.3(e) relating to provisions for granting an accommodation are sufficient to address this issue.
70	1736.3(c)	Rheta Silvas Kaweah Health	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 Chapter <797> section 3.2 in the	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. Staff note that the current proposed regulation text provides for flexibility in where gloving can occur by stating that the facilities SOPs may define specific processes.

			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".	
71	1736.3(c)	Sam Kim USC	Donning and Doffing in the anti room is a should in USP; however, a shall with the regulations and there is not evidence that this impacts contamination or environmental growth.	Board staff have considered the comment and do not recommend any changes to the proposed regulation text. Board staff disagree with the commenter. The Chapter notes the need for it, but is providing flexibility through its discretionary language. The Board's proposed regulation language establishes a minimum threshold but allows flexibility for a facility to develop an SOP where it chooses not to meet the minimum threshold. Both the Chapter and the Board's proposed regulations provide flexibility for the facility to determine how best to handle donning and doffing. Staff note that in 2015 USP 797 Pharmaceutical Compounding briefing the language prohibited donning and doffing from occurring at the same time in an anteroom or SCA. As part of the USP commentary, a change was made to provide flexibility because not all facility designs are the same. The Board's proposed regulation text provides flexibility through the option of facility SOPs. Further, staff notes that FDA includes as an example of insanitary conditions applicable to the production of Sterile drugs as "putting on gowning apparel in a way that may cause the gowning apparel to become contaminated."
72	1736.4(a)	Rheta Silvas Kaweah Health	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	Board staff have reviewed the comment and do not recommend changes to the proposed text. Staff note that compounding personnel washing their hands after using the restroom does not meet the standards for hand hygiene before compounding. As an example,

			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.	the compounding leaving the restroom would then be touching a door knob to open the door, creating the potential to contaminate their hands.
73	1736.4(c)	Wendy Waldman Torrance Memorial Medical Center	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).	Staff note that CCR 1751.4(k) currently requires that the sterile compounding area in the pharmacy shall have a comfortable and well-lit working environment, which typically includes a room temperature of 20 degrees Celsius or cooler to maintain comfortable conditions. Board staff are unclear how the continuation of existing regulation requirements would result in a change in HVAC systems. Furthermore, USP Chapter 797, Section 4.2, discusses facility design and environmental controls, noting that, in addition to minimizing airborne contamination, sterile compounding facilities must be designed and controlled to provide a well-lit and comfortable working environment. The Chapter provides that the cleanroom suite should be maintained at a temperature of 20 degrees or cooler and a relative humidity of 60% to below to minimize the risk of microbial proliferation. The Board's current regulation and its proposed language provide flexibility by providing the temperature must typically meet the requirements. This allows for some minor fluctuations while addressing the necessity established in the Chapter. The Chapter also provides that the temperature and humidity in the cleanroom suite must be controlled through an HVAC system. The Chapter thus establishes the requirements for the temperature and humidity control. Staff also note provisions in California Code of Regulations, Title 24 and other legal provisions also establish temperature requires for which licenses must comply.
74	1736.4(c)	Rita Shane Cedars-Sinai, Tommy Mai Huntington	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	Staff note that CCR 1751.4(k) currently requires the sterile compounding area in the pharmacy to have a comfortable and well-lit working environment, which typically includes a room temperature of 20 degrees

		Health, CSHP Also submitted at Reg Hearing	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 or 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).	Celsius or cooler to maintain comfortable conditions. Board staff are unclear how the continuation of existing regulation requirements would result in a change in HVAC systems. Further, USP Chapter 797, Section 4.2 discusses facility design and environmental controls and notes that in addition to minimizing airborne contamination, sterile compounding facilities must be designed and controlled to provide a well-lighted and comfortable working environment. The Chapter stipulates that the cleanroom suite should be maintained at a temperature of 20 degrees or cooler and a relative humidity of 60% or lower to minimize the risk of microbial proliferation. The Board's current regulation and its proposed language provides flexibility by providing the temperature must typically meet the requirements. This allows for some minor fluctuations, while addressing the necessity established in the Chapter. The Chapter also provides that the temperature and humidity in the cleanroom suite must be controlled through an HVAC system. The Chapter thus establishes the requirements for the temperature and humidity control. Staff also note provisions in California Code of Regulations, Title 24 and other legal provisions also establish temperature requires for which licenses must comply.
75	1736.4(c)	John Gray Kaiser Permanente	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.	Staff note that CCR 1751.4(k) currently requires the sterile compounding area in the pharmacy to have a comfortable and well-lit working environment, which typically includes a room temperature of 20 degrees Celsius or cooler to maintain comfortable conditions. Board staff are unclear how the continuation of existing regulation requirements would result in a change in HVAC systems. Further, USP Chapter 797, Section 4.2 discusses facility design and environmental controls and notes that in addition to minimizing airborne contamination, sterile compounding facilities must be designed and controlled to provide a well-lighted and comfortable working environment. The Chapter provides that the cleanroom suite should be maintained at a temperature of 20 degrees or cooler

				and a relative humidity of 60% to below to minimize the risk of microbial proliferation. The Board's current regulation and its proposed language provide flexibility by providing the temperature must typically meet the requirements. This allows for some minor fluctuations while addressing the necessity established in the Chapter. The Chapter also provides that the temperature and humidity in the cleanroom suite must be controlled through an HVAC system. The Chapter thus establishes the requirements for temperature and humidity control. Staff also note provisions in the California Code of Regulations, Title 24, and other legal provisions that also establish temperature requirements for which licenses must comply.
76	1736.4(c)	Marie Cottman Pacific Compounding	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~~ <u>should</u> 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.	Staff note that CCR 1751.4(k) currently requires the sterile compounding area in the pharmacy to have a comfortable and well-lit working environment, which typically includes a room temperature of 20 degrees Celsius or cooler to maintain comfortable conditions. Board staff are unclear how the continuation of existing regulation requirements would result in a change in HVAC systems. Furthermore, USP Chapter 797, Section 4.2, discusses facility design and environmental controls, noting that, in addition to minimizing airborne contamination, sterile compounding facilities must be designed and controlled to provide a well-lit and comfortable working environment. The Chapter provides that the cleanroom suite should be maintained at a temperature of 20 degrees or cooler and a relative humidity of 60% to below to minimize the risk of microbial proliferation. The Board's current regulation and its proposed language provide flexibility by providing the temperature must typically meet the requirements. This allows for some minor fluctuations while addressing the necessity established in the Chapter. The Chapter also provides that the temperature and humidity in the cleanroom suite must be controlled through an HVAC system. The Chapter

				thus establishes the requirements for temperature and humidity control.
77	1736.4(c) (1)	Melanie Horn Sutter Health	USP 797 Chapter, states “the cleanroom suite should be maintained at a temperature of 20° or cooler.” The term “designated compounding area(s)” definition encompasses SCA and Cleanroom suites to maintain a temperature lower than 20 C. SCA areas are often contiguous with general pharmacy areas and controlled room temperature medication storage requirements of USP Chapter 650 between 20°–25° C. These SCAs typically are present in smaller, critical access hospitals that do not have dedicated HVAC systems and a typical temperature at or below 20° Celsius lend to discomfort of the general work area and drug storage. When a SCA temperature is maintained at 70 F and 21.1 C this would require no CSP to be compounded as the facility with either a SCA or a Cleanroom suite would be ineligible to compound ANY CSP as directed in 1736.4(f). Additionally, the Board language proposal relevant to temperature standards in ACEAs for allergenic extract compounding could be harmonized since the allergenic compounding maintains the same compounding PPE requirements. Recommend removing CCR. 1736.4 subsection (c) and default to USP 797 standard. If added oversight for temperature required, recommend the Board of Pharmacy to add language to align with temperature monitoring harmonized with ACEA in allergenic extract compounding. (c)(1) <u>The cleanroom suite</u> ~~Designated compounding area(s)~~ shall typically be maintained at a temperature of 20° Celsius or cooler.	Staff note that CCR 1751.4(k) currently requires the sterile compounding area in the pharmacy to have a comfortable and well-lit working environment, which typically includes a room temperature of 20 degrees Celsius or cooler to maintain comfortable conditions. Further, USP Chapter 797, Section 4.2 discussed facility design and environmental controls and notes that in addition to minimizing airborne contamination, sterile compounding facilities must be designed and controlled to provide a well-lighted and comfortable working environment. The Chapter provides that the cleanroom suite should be maintained at a temperature of 20 degrees Celsius or cooler and a relative humidity of 60% to below to minimize the risk of microbial proliferation. The Board proposed language provides flexibility by providing the temperature must typically meet the requirements. This allows for some minor fluctuations while addressing the necessity established in the Chapter. The Chapter also provides that the temperature and humidity in the cleanroom suite must be controlled through an HVAC system. The Chapter thus establishes the parameters for the temperature and humidity control. Critical access hospitals that do not have a dedicated HVAC system would be in violation of the Chapter.
78	1736.4(e)	Marie Cottman Pacific Compounding	COMMENT: Passive airflow connections between classified areas is required based on the physics of airflow and HVAC system operation.	Board staff have reviewed and comment and recommend a change to the language to address the comment. As noted in the Chapter, due to the interdependence of the various rooms or areas that

			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 <u>passive air exchange vents of appropriate design.</u>	make up a sterile compounding facility, it is essential to carefully design and control the dynamic interactions permitted between areas and rooms. Staff note that passive air vents are uncontrolled.
79	1736.4(f)	John Gray Kaiser Permanente	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. No CSP shall be compounded if the compounding environment fails to meet criteria specified in law or the facility's SOPs. <u>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.</u>	Board staff have reviewed the proposed comment and do not recommend a change to the proposed text. Board staff note that the proposed language is consistent with existing law, CCR section 1751.4(a). SOPs should have redundancy included should a failure occur.

80	1736.4(f)	Marie Cottman Pacific Compounding	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.	Board staff have reviewed the proposed comment and do not recommend a change to the proposed text. Board staff note that the proposed language is consistent with existing law, CCR section 1751.4(a). Staff also note that the language provides flexibility through the use of an SOPs. SOPs should have redundancy included should a failure occur.
81	1736.4(f)	Narinder Singh Santa Clara Valley Healthcare (SCVH)	When an environment fails to meet criteria specified in the law or the facility's SOPs, the BUD of the CSP should change. Not allowing any compounding will negatively impact patient care. We recommend the following language: "Only CSP with BUD of Segregated Compounding Area (SCA) or Immediate Use shall be compounded if the compounding environment fails to meet criteria specified in law or the facility's SOPs."	Board staff have reviewed the proposed comment and do not recommend a change to the proposed text. Board staff note that the proposed language is consistent with existing law, CCR section 1751.4(a). Staff also note that the language provides flexibility through the use of SOPs. SOPs should include redundancy in case of a failure. Staff also refer commenter to proposed changes in CCR 1736.1 being recommended by staff related to immediate use provisions.
82	1736.4(f)	Rheta Silvas Kaweah Health	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	Board staff have reviewed the proposed comment and do not recommend a change to the proposed text. Board staff note that the proposed language is consistent with existing law, CCR section 1751.4(a). Staff also note that the language provides flexibility through the use of SOPs. SOPs should include redundancy in case of a failure.

			continuation of compounding operations without jeopardizing the health and safety of patients. Ceasing compounding in some cases would be counter to consumer protection.	
83	1736.4(f)	Tommy Mai Huntington Health, CSHP	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.	Board staff have reviewed the proposed comment and do not recommend a change to the proposed text. Board staff note that the proposed language is consistent with existing law, CCR section 1751.4(a). Staff also note that the language provides flexibility through the use of SOPs. SOPs should include redundancy in case of a failure.
84	1736.5(a) and (b)	Narinder Singh Santa Clara Valley Healthcare (SCVH)	Recommending removing CETA requirement for certification as updated USP 797 chapter doesn't require.	Board staff have reviewed the comment and do not recommend any change to the proposed language. Staff note that the proposed language is similar to existing provisions in CCR 1751.4(d). The proposed text updates the reference to the current CETA guidelines, which were revised in 2022.
85	1736.5(a)	John Gray Kaiser Permanente	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. 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 <u>the most recent version of the CETA Certification Guide</u>	Board staff have reviewed the comment and do not recommend changes to the proposed regulations. Staff note that the proposed language suggested by the commenter may not meet the clarity standards of the Administrative Procedures Act because it would incorporate a changing standard.

			for Sterile Compounding Facilities (CAG003, Revised 2022), which is hereby incorporated by reference.	
86	1736.6(a)	John Gray Kaiser Permanente	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. ~~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.~~	Board staff have reviewed the comment and considered the feedback from members. Staff are recommending removal of the subdivision.
87	1736.6(a)	Marie Cottman Pacific Compounding	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.	Board staff have reviewed the comment and considered the feedback from members. Staff are recommending removal of the subdivision.

			RECOMMENDATION: Remove. Allow 797 to stand as is.	
88	1736.6(a)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	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?	Board staff have reviewed the comment and considered the feedback from members. Staff are recommending removal of the subdivision.
89	1736.6(a)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP	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 <u>exceeds action level</u> to trend for growth of microorganisms. Investigation must be consistent with the deviation and must include evaluation of trends.	Board staff have reviewed the comment and considered the feedback from members. Staff are recommending removal of the subdivision.
90	1736.6(a)	Walgreens	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 <u>completed and if growth has been observed it shall</u> identified to at least the genus level, regardless of the CFU count ~~to trend for growth of microorganisms~~. Investigation must be consistent	Board staff have reviewed the comment and considered the feedback from members. Staff are recommending removal of the subdivision.

			with the deviation and must include evaluation of trends.	
91	1736.6(a)	UCSF	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.	Board staff have reviewed the comment and considered the feedback from members. Staff are recommending removal of the subdivision.
92	1736.6(a)	Narinder Singh Santa Clara Valley Healthcare (SCVH)	Identifying genus levels "regardless of CFU counts" is burdensome and adds no value to the safety of CSP. Recommend that genus level identification only occur if CFU count exceeds actionable level per USP 797. "At a minimum of every 6 months, air and surface sampling results shall be identified to at least the genus level, if CFU count exceeds actionable level per USP 797. Investigation must be consistent with the deviation and must include evaluation of trends."	Board staff have reviewed the comment and considered the feedback from members. Staff are recommending removal of the subdivision.
93	1736.6(b)	Marie Cottman Pacific Compounding	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	Board staff have reviewed the comment and recommend a change to the proposed text to reflect the current revision date of 2020. Board staff do not believe additional changes to the language are appropriate. As indicated in the Initial Statement of

			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~~ <u>should</u> 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.	Reasons, a standard is necessary to ensure consistent and repeatable testing at facilities.
94	1736.4(f)	Wendy Waldman Torrance Memorial Medical Center	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.	Board staff have reviewed the proposed comment and do not recommend a change to the proposed text. Board staff note that the proposed language is consistent with existing law, CCR section 1751.4(a). Staff also note that the language provides flexibility through the use of an SOP.
95	1736.6(a)	Melanie Horn Sutter Health	The USP 797 standard identifies on a genus level for above threshold CFUs only. The tracking and trending genus level below action levels has no identified impact on risk to CSPs and patients. Consider if genus level sought, that requirement be based on repeated and consecutive growth to trend, regardless of CFU count for investigation of the source at sample	Board staff have reviewed the comment and do not recommend changes to the proposed text based on the comment. Board staff note that air sampling is extremely important in ensuring safe CSPs. Staff highlights that an issue with the HVAC for example could create a contaminated compounding environment, which would not be identified without air

			locations in classified areas. Random every 6 months genus level identification of low-level growth will not establish actionable trends. Alternative wording: Investigation of air and surface sampling results that exceed action levels must be consistent with the deviation and must include evaluation of trends. 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.	sampling. Further, staff note that air sampling is a requirement of the Chapter and accepted the recommend text would contrary to the Chapter.
96	1736.6(a)	Wendy Waldman Torrance Memorial Medical Center	Rationale: 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.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text not based on this comment. As indicated in the ASHP release "Pharmacy Environmental Monitoring (EM) Implementation Toolkit- "A hallmark of a strong EM program is the measurement of progress in order to continuously program compounding conditions, and effectively correct excursions." This document further provides metrics to consider during tracking efforts and descriptions of the benefits of the trending. Staff note that the ASHP document recommends monitoring monthly; however, the Board's proposed regulation text only requires trending every six months. Further, as noted in USP Chapter 1161, "Particulate counts as well as microbial counts within controlled environments vary with the sampling locations and the activities being conducted during sampling. Monitoring the environment for nonviable particulates and microorganisms is an important control function because they both are important in achieving product compendial requirements for Foreign and Particulate Matter and Sterility in Injections and Implanted Drug Products." Also included in Chapter 1161, "Environmental microbial monitoring and analysis of data by qualified personnel can assist in ensuring that

				a suitable state of control is maintained." The Chapter further provides, "Since the advent of comprehensive environmental monitoring programs, their applications in capturing adverse trends or drifts has been emphasized."
97	1736.6(a)	Mark Johnston CVS Health Also provided at Reg Hearing	Commenter indicates that 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). Commenter states according to USP 797, based upon scientific expert review, ISO 7 and 8 areas are expected to have a CFU count > 1CFU. Commenter requests the following edit: (a) At a minimum of every 6 months, air and surface sampling <u>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.</u> Investigation must be consistent with the deviation and must include evaluation of trends.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. Board staff note that it is necessary to determine at least to the genus level, regardless of the CFU count, to trend for the growth of microorganisms. CFU fungus tend (e.g. aspergillus) to be more harmful than a CFU of environmental bacteria (e.g. bacillus). Absent a determination to at least the genus level, compounding personnel would be unable to determine if action steps such as a change in cleaning practices or products. Board staff have reviewed the comment and do not recommend a change to the proposed regulation text not based on this comment. As indicated in the ASHP release "Pharmacy Environmental Monitoring (EM) Implementation Toolkit- "A hallmark of a strong EM program is the measurement of progress in order to continuously program compounding conditions, and effectively correct excursions." This document further provides metrics to consider during tracking efforts and descriptions of the benefits of the trending. Staff note that the ASHP document recommends monitoring monthly; however, the Board's proposed regulation text only requires trending every six months. Further, as noted in USP Chapter 1161, "Particulate counts as well as microbial counts within controlled environments vary with the sampling locations and the activities being conducted during sampling. Monitoring the environment for nonviable particulates and microorganisms is an important control function because they both are important in achieving product compendial requirements for Foreign and Particulate Matter and Sterility in Injections and Implanted Drug Products." Also included in Chapter 1161, "Environmental microbial monitoring and analysis of

				data by qualified personnel can assist in ensuring that a suitable state of control is maintained." The Chapter further provides, "Since the advent of comprehensive environmental monitoring programs, their applications in capturing adverse trends or drifts has been emphasized."
98	1736.6(a-b) should be 1737.6(a-b)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	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.	Board staff have reviewed the comment and believe the commenter is referring to CCR 1737.6(a-b) related to hazardous compounding staff. Staff note that the requirements in hazardous compounding in article 4.7 does not establish a requirement as suggested by the commenter.
99	1736.7(a)	Melanie Horn Sutter Health	USP 797 states, "The frequency, method(s), and location(s) of cleaning, disinfecting, and applying sporicidal disinfectants must be established in written SOPs, in accordance with the manufacturer's instructions and must be followed by all cleaning personnel. The manufacturer's directions or published data for the minimum contact time must be followed for each of the cleaning, disinfecting, and sporicidal disinfectants used." Recommend removing duplicate requirements. ~~Any cleaning, disinfecting, and sporicidal disinfectants used by the facility to meet the requirements in this article shall be used in accordance with manufacturers' specifications.~~	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments. Staff note that the Board's regulatory text requires a licensee to follow a manufacturer's instructions. The USP Chapter only requires the SOPs to address the issue. The Board's language is more direct and specific.
100	1736.7(b)	Melanie Horn Sutter Health	Request Board to consider that storage directly along the back wall of an ISO-5 LAFW has no impact on PEC. Consider revision to opening or 1 meter from the DCA of a PEC.	Board staff have considered the comment and do not recommend a change to the proposed regulation text. Board staff note that the proposed regulation text establishes a 1-meter perimeter around the PEC, which appears to be what the commenter is also suggesting.
101	1736.7(c)	Melanie Horn Sutter Health	Cleaning Logs include each occurrence with identity of individual and detail the cleaning agent(s) and when used. The Board proposed language places additional burden of added documentation of listing multiple cleaning agents used every day. Each	Staff believe that documentation of the cleaning process as described in the proposed language is appropriate and consistent with the actions necessary to maintain and clean the compounding environment. Staff note that operationalizing the requirements could

			occurrence to document a fixed rotation of cleaning agents adds burden that does not introduce added compliance to performing a thorough and detailed cleaning task. The facility's documentation of each occurrence of the cleaning and sanitizing of the compounding area shall include <u>the product name(s) of the cleaning and sanitizing agents used. The documentation for each cleaning occurrence shall identify 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.</u>	be quite simple, including a prepared log that already has the items listed. Staff performing the cleaning could then document the date, time, and place a check box or other indication next to the products used.
102	1736.8	Marie Cottman Pacific Compounding	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.	Board staff have reviewed the comment and do not recommend a change to the proposed language. Board staff note that 1736.8 requires the compounding personnel to comply with the SOPs that are required to be developed in CCR 1736.17(d)
103	1736.9	Paul Lofholm	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?	Board staff have reviewed the comment and believe the comment is related to 1736.9(d). Board staff do not recommend a change to the proposed text based on the comment. Staff note that provisions in 503A require all API to be manufactured by a drug establishment registered with the FDA. Board staff note that federal law establishes the requirements for APIs, and FDA issued guidance provides further clarification. Staff note that FDA guidance documents establish the standard of practice for compounders. It is incumbent on licensed professionals to remain current on guidance issued to ensure compliance with established provisions.
104	1736.9(b)	Melanie Horn Sutter Health	Recommend aligning to match USP 825 California proposed section 1738.6 (e), "(e) Incubators must be calibrated and operated in accordance with the	Board staff have reviewed the comment and are offering recommended language to ensure

		Also Provided at Reg Hearing	manufacturer's specifications. Temperatures must be monitored either manually or by a continuous recording device during incubation, and the results must be reviewed and documented as described in the facility's SOPs." Incubators require regular cleaning and maintenance per manufacturer specifications, but are not maintained in a controlled environment to establish a required interval of every 30 days. ~~Incubators used by the facility shall be cleaned, maintained, must be calibrated, and operated in accordance with manufacturers' specifications. For incubators without specific manufacturers' specifications, cleaning shall take place at least every 30 days and temperature calibration shall take place at least every 12 months. Temperatures must be monitored either manually or by a continuous recording device during incubation, and the results must be reviewed and documented as described in the facility's SOPs.~~	consistency between article 4.6 and article 4.8 related to the use of incubators.
105	1736.9(b)	John Gray Kaiser Permanente	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. (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. <u>(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.</u>	Board staff have reviewed the comment and do not recommend changes to the proposed regulation language. Board staff note that the Board's text ensures the monitoring device is functioning as specified by the manufacturer at least every 12 months.

106	1736.9(c)	Rheta Silvas Kaweah Health	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.	Board staff have reviewed the comment and do not recommend changes to the proposed regulatory text. Board staff believe the commenter may be conflating the use of a component versus the indication of a prescription.
107	1736.9(d)	Rick Rhoads University Compounding Also provided at Reg Hearing	(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, <u>unless the manufacturer name and address are retrieved from the supplier and documented on the COA.</u> 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.	Board staff have reviewed the comment and recommend a change to the proposed text to clarify that the proposed regulation text only applies to APIs, not excipient components. Pharmacists must remain knowledgeable of current practice standards and legal requirements of the industry while exercising their professional judgment. Staff note that included in guidance provided by the FDA, improper repackaging or lack of supply change transparency regarding API or excipients can cause serious vulnerabilities in the supply chain and may lead to patient safety issues. Source: FDA to Compounders: Know Your Bulks and Excipients Suppliers.
108	1736.9(d)	Jasmine Parker Pacific Compounding	COMMENT: There is no definition of what constitutes "suitable for use in sterile pharmaceuticals" RECOMMENDATION:(d) All AP/ and excipient components used to compound a CSP shall be manufactured by an FDA-registered facility, be accompanied by a Certificate of Analysis (GOA), and suitable for use in sterile pharmaceuticals. A GOA that includes the compendia/ name, the grade of the material, and the applicable compendia/ designations	Pharmacists must remain knowledgeable of current practice standards and legal requirements of the industry while exercising their professional judgment. Staff note that included in guidance provided by the FDA, improper repackaging or lack of supply change transparency regarding API or excipients can cause serious vulnerabilities in the supply chain and may lead to patient safety issues. Source: FDA to Compounders: Know Your Bulks and Excipients Suppliers.

			on the GOA, must be received and evaluated prior to use, unless components are commercially available drug products. When the GOA is received from a supplier, it must provide the name and address of the manufacturer. AP/ and excipient components provided with a GOA without this data shall not be used in a CSP	
109	1736.9(d)	Philip Smyth Medisca	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.	Board staff have reviewed the comment and recommend a change to the proposed text to clarify that the proposed regulation text only applies to APIs, not excipient components. Pharmacists must remain knowledgeable of current practice standards and legal requirements of the industry while exercising their professional judgment. Staff note that included in guidance provided by the FDA, improper repackaging or lack of supply change transparency regarding API or excipients can cause serious vulnerabilities in the supply chain and may lead to patient safety issues. Source: FDA to Compounders: Know Your Bulks and Excipients Suppliers.
110	1736.9(d)	Lauren Honda Valor Compounding Also Submitted in Reg Hearing	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	Pharmacists must remain knowledgeable of current practice standards and legal requirements of the industry while exercising their professional judgment. Staff note that included in guidance provided by the FDA, improper repackaging or lack of supply change transparency regarding API or excipients can cause serious vulnerabilities in the supply chain and may lead to patient safety issues. Source: FDA to Compounders: Know Your Bulks and Excipients Suppliers. Board staff are recommending a change to allow flexibility for the PIC or designated person to include the manufacturer's name and address on the COA provided by the supplier. Staff also note that the USP Chapter requires reasonable means to establish the identity, strength, purity, and quality of the ingredients

			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.	obtained from a supplier, which includes 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. The Chapter further states: "All APIs and other components used must be evaluated for suitability for use in sterile drug preparation. Components labeled with "not for pharmaceutical use", "not for injectable use", "not for human use" or an equivalent statement must not be used to compound for these purposes."
111	1736.9(d)	A.J. Day	Requires all excipient components to be manufactured by an FDA registered facility however the FDA does not require registration for excipient manufacturers and therefore those manufacturers generally do not register.	Board staff have reviewed the comment and recommend a change to the proposed text to clarify that the proposed regulation text only applies to APIs, not excipient components. Pharmacists must remain knowledgeable of current practice standards and legal requirements of the industry while exercising their professional judgment. Staff note that included in guidance provided by the FDA, improper repackaging or lack of supply chain transparency regarding API or excipients can cause serious vulnerabilities in the supply chain and may lead to patient safety issues. Source: FDA to Compounders: Know Your Bulks and Excipients Suppliers. Board staff are recommending a change to allow flexibility for the PIC or designated person to include the manufacturer name and address on the COA provided by the supplier. Staff also note that the USP Chapter requires reasonable means to establish the identity, strength, purity, and quality of the ingredients obtained from a supplier, which includes 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. The Chapter further states: "All APIs and other components used must be evaluated for suitability for use in sterile drug preparation. Components labeled with "not for pharmaceutical use", "not for injectable use", "not for human use" or

				an equivalent statement must not be used to compound for these purposes."
112	1736.9(d)	Scott Brunner Alliance for Pharmacy Compounding	Most excipient components are sold by FDA-registered 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.	Board staff have reviewed the comment and recommend a change to the proposed text to clarify that the proposed regulation text only applies to APIs, not excipient components. Pharmacists must remain knowledgeable of current practice standards and legal requirements of the industry while exercising their professional judgment. Staff note that the FDA has released compounding alerts and guidance related to this issue. Staff note that as stated in FDA guidance, improper repackaging or lack of supply chain transparency regarding API or excipients can cause serious vulnerabilities in the supply chain and may lead to patient safety issues. Source: FDA to Compounders: Know Your Bulks and Excipients Suppliers. Staff further note that section 503A(b)(1)(A)(ii) of the FDCA requires that APIs used in compounding be manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)) of the FDCA. To confirm compliance with this specific federal requirement, knowledge of the manufacturer is required. Further, USP Chapter 797 includes guidance related to the components used in CSPs. The Chapter requires that compounding personnel use reasonable means to establish the identity, strength, purity and quality of the ingredients obtained from a supplier, which includes evaluation of a COA supplied by the manufacturer and/or verification by testing a sample to determine conformance with the COA or other specifications. The Chapter further states: "All APIs and other components used must be evaluated for suitability for use in sterile drug preparation. Components labeled with "not for pharmaceutical use", "not for injectable use", "not for human use" or an equivalent statement must not be used to compound for these purposes." Lastly, simply identifying the manufacturer of a component without more does not appear to be requiring the disclosure of a trade secret under Civil Code section 3426.1(d)

113	1736.9(d)	Marie Cottman Pacific Compounding	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.	Pharmacists must remain knowledgeable of current practice standards and legal requirements of the industry while exercising their professional judgment. Staff note that the FDA has released compounding alerts and guidance related to this issue. Further, the USP Chapter also includes guidance related to the components used in CSPs. The Chapter also states: "All APIs and other components used must be evaluated for suitability for use in sterile drug preparation. Components labeled with "not for pharmaceutical use", "not for injectable use", "not for human use" or an equivalent statement must not be used to compound for these purposes."
114	1736.9(d)	National Community Pharmacists Association (NCPA)	Refer to 1735.7(c)(2) above	Board staff have reviewed the comment and recommend a change to the proposed text to clarify that the proposed regulation text only applies to APIs, not excipient components. Pharmacists must remain knowledgeable of current practice standards and legal requirements of the industry while exercising their professional judgment. Staff note that the FDA has released compounding alerts and guidance related to this issue. Staff note that as stated in FDA guidance, improper repackaging or lack of supply chain transparency regarding API or excipients can cause serious vulnerabilities in the supply chain and may lead to patient safety issues. Source: FDA to Compounders:

				Know Your Bulks and Excipients Suppliers. Staff further note that section 503A(b)(1)(A)(ii) of the FDCA requires that APIs used in compounding be manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)) of the FDCA. To confirm compliance with this specific federal requirement, knowledge of the manufacturer is required. Further, USP Chapter 797 includes guidance related to the components used in CSPs. The Chapter requires that compounding personnel use reasonable means to establish the identity, strength, purity, and quality of the ingredients obtained from a supplier, which includes evaluation of a COA supplied by the manufacturer and/or verification by testing a sample to determine conformance with the COA or other specifications. The Chapter further states: "All APIs and other components used must be evaluated for suitability for use in sterile drug preparation. Components labeled with "not for pharmaceutical use", "not for injectable use", "not for human use" or an equivalent statement must not be used to compound for these purposes." Lastly, simply identifying the manufacturer of a component without more does not appear to require the disclosure of a trade secret under Civil Code section 3426.1(d)
115	1736.9(e)	Marie Cottman Pacific Compounding	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 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.	In response to this and other comments, Board staff are recommending a change to the proposed text to, subject to specified conditions, allow for the compounding of a bulk drug substance that currently appears in 503A Category 1 on FDA's website. Staff note that the "recommendation" appears to be consistent with the language in the proposed text.

			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.” 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.	
116	1736.9(e)	Scott Brunner Alliance for Pharmacy Compounding Also provided at Reg Hearing	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 CSP will harm California patients who require these medications, and who cannot get them otherwise.	Board staff have reviewed the comment. The proposed regulation text is not intended to create barriers to effective treatments, rather was intended to provide flexibility as practices evolve and research supports emerging treatments. However, in response to public comment, staff are recommending a proposed change to noticed text. The recommended text if approved would more directly allow for the compounding of a bulk drug substance that is included in the published 503A Category 1 bulk substance list under specified conditions. Staff remind all commenters that the FDA evaluates research studies to determine the safety and efficacy of drugs and establish the appropriate and approved use of medications including compounded preparations. The Board defers to the FDA judgment and notes that the FDA releases information, guidance documents, evaluation of research, etc., and that such FDA information establishes a standard of practice of which Board licensees must remain mindful when evaluating prescriptions and exercising clinical judgment,

				including the proposed provisions related to bulk drug substances. Pharmacists must remain knowledgeable of current practice standards and legal requirements of the industry while exercising their professional judgment. Staff note that the FDA has released compounding alerts and guidance related to this issue. Further, the USP Chapter also includes guidance related to the components used in CSPs. Staff note that included in guidance provided by the FDA, improper repackaging or lack of supply change transparency regarding API or excipients can cause serious vulnerabilities in the supply chain and may lead to patient safety issues. Source: FDA to Compounders: Know Your Bulks and Excipients Suppliers. Board staff are recommending a change to allow flexibility for the PIC or designated person to include the manufacturer's name and address on the COA provided by the supplier. The Chapter further states: "All APIs and other components used must be evaluated for suitability for use in sterile drug preparation. Components labeled with "not for pharmaceutical use", "not for injectable use", "not for human use" or an equivalent statement must not be used to compound for these purposes."
117	1736.9(e)	National Community Pharmacists Association (NCPA)	21 CFR 216 only includes items on the Final FDA bulks list, and not anything on the interim bulks list (category 1 items). FDA has enacted the interim policy to avoid disruptions to patient care while they finalize the 503A bulks list. Removal of the ability to use these agents in a CSP will harm California patients who require these medications. We respectfully request this provision be stricken from the proposed rules until an analysis is made available which assess the health and safety impact of removing patient access to impacted medications.	Board staff have reviewed the comment. The proposed regulation text is not intended to create barriers to effective treatments, rather was intended to provide flexibility as practices evolve and research supports emerging treatments. However, in response to public comment, staff are recommending a proposed change to noticed text. The recommended text if approved would more directly allow for the compounding of a bulk drug substance that is included in the published 503A Category 1 bulk substance list under specified conditions. Staff remind all commenters that the FDA evaluates research studies to determine the safety and efficacy of drugs and establish the appropriate and approved use of medications including compounded preparations. The Board defers to the FDA judgment and notes that the

				FDA releases information, guidance documents, evaluation of research, etc., and that such FDA information establishes a standard of practice of which Board licensees must remain mindful when evaluating prescriptions and exercising clinical judgment, including the proposed provisions related to bulk drug substances. Pharmacists must remain knowledgeable of current practice standards and legal requirements of the industry while exercising their professional judgment. Staff note that the FDA has released compounding alerts and guidance related to this issue. Further, the USP Chapter also includes guidance related to the components used in CSPs. Staff note that included in guidance provided by the FDA, improper repackaging or lack of supply change transparency regarding API or excipients can cause serious vulnerabilities in the supply chain and may lead to patient safety issues. Source: FDA to Compounders: Know Your Bulks and Excipients Suppliers. Board staff are recommending a change to allow flexibility for the PIC or designated person to include the manufacturer's name and address on the COA provided by the supplier. The Chapter further states: "All APIs and other components used must be evaluated for suitability for use in sterile drug preparation. Components labeled with "not for pharmaceutical use", "not for injectable use", "not for human use" or an equivalent statement must not be used to compound for these purposes."
118	1736.9(e)	Philip Smyth Medisca	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.	Board staff have reviewed the comment. The proposed regulation text is not intended to create barriers to effective treatments, rather was intended to provide flexibility as practices evolve and research supports emerging treatments. However, in response to public comment, staff are recommending a proposed change to noticed text. The recommended text if approved would more directly allow for the compounding of a bulk drug substance that is included in the published 503A Category 1 bulk substance list under specified conditions. Staff remind

				all commenters that the FDA evaluates research studies to determine the safety and efficacy of drugs and establish the appropriate and approved use of medications including compounded preparations. The Board defers to the FDA judgment and notes that the FDA releases information, guidance documents, evaluation of research, etc. and that such FDA information establishes a standard of practice for which Board licensees must remain mindful of when evaluating prescriptions and exercising clinical judgment including the proposed provisions related to bulk drug substances. Pharmacists must remain knowledgeable of current practice standards and legal requirements of the industry while exercising their professional judgment. Staff note that the FDA has released compounding alerts and guidance related to this issue. Further the USP Chapter also includes guidance related to the components used in CSPs. Staff note that included in guidance provided by the FDA, improper repackaging or lack of supply change transparency regarding API or excipients can cause serious vulnerabilities in the supply chain and may lead to patient safety issues. Source: FDA to Compounders: Know Your Bulks and Excipients Suppliers. Board staff are recommending a change to allow flexibility for the PIC or designated person to include the manufacturer name an address on the COA provided by the supplier. The Chapter further states: "All APIs and other components used must be evaluated for suitability for use in sterile drug preparation. Components labeled with "not for pharmaceutical use", "not for injectable use", "not for human use" or an equivalent statement must not be used to compound for these purposes."
119	1736.10	Paul Lofholm	Sterilization and Depyrogenation reference to 1228 is advisory, basically sterilization processes must be validated and meet SOP for sterilization	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Staff note that compliance with Chapter 1228 is necessary to ensure that sterile products are free from harmful pyrogens.

120	1736.10	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	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 numbered below 1000, a monograph, or these General Notices"	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Staff note that the comment appears it is general in nature and does not provide recommendations for response.
121	1736.10(e)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	This would prevent the use of e- beam or gamma-irradiation sterilization methods, which are performed off-site at validated facilities.	Staff have reviewed the comment and do not recommend any changes to the proposed regulation text. Staff note that on September 25, 2019, this issue was raised. At that time, counsel advised members that "provided based on her research of 503A subdivision (a) (1), the federal exemption applies to a state-licensed pharmacy that exempts the pharmacy for the manufacturer requirements when compounding. Business and Professions Code sections 4127 and 4127.1 specifically reference that compounding has to occur in a sterile compounding pharmacy – a singular pharmacy – and the license is not transferable, thereby emphasizing that all compounding exempted under the federal law that occur can in a compounding pharmacy has to occur in a single licensed facility. Board counsel added at that time that there are no statutory exemptions and would expect all aspects of compounding to occur in the single regulated unit.
122	1736.10(e)	Philip Smyth Medisca	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.	Staff have reviewed the comment and do not recommend any changes to the proposed regulation text. Staff note that on September 25, 2019, this issue was raised. At that time, counsel advised members that "provided based on her research of 503A subdivision (a) (1), the federal exemption applies to a state-licensed pharmacy that exempts the pharmacy for the manufacturer requirements when compounding. Business and Professions Code sections 4127 and 4127.1 specifically reference that compounding has to occur in a sterile compounding pharmacy – a singular pharmacy – and the license is

				not transferable, thereby emphasizing that all compounding exempted under the federal law that occur can in a compounding pharmacy has to occur in a single licensed facility. Board counsel added at that time that there are no statutory exemptions and would expect all aspects of compounding to occur in the single regulated unit.
123	1736.10(e)	Mike Pavlovich Westcliff Compounding	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.	Staff have reviewed the comment and do not recommend any changes to the proposed regulation text. Staff note that on September 25, 2019, this issue was raised. At that time, counsel advised members that "provided based on her research of 503A subdivision (a) (1), the federal exemption applies to a state licensed pharmacy that exempts the pharmacy for the manufacturer requirements when compounding. Business and Professions Code sections 4127 and 4127.1 specifically reference the compounding has to occur in a sterile compounding pharmacy – a singular pharmacy – and the license is not transferable thereby emphasizing all compounding exempted under the federal law that occur can in a compounding pharmacy has to occur in a single licensed facility. Board counsel added at that time there are no statutory exemptions and would expect all aspects of compounding to occur in the single regulated unit.
124	1736.11(a) (1)	Walgreens	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 concerns by the compounding pharmacists, requests can be made to receive a copy of the materials supporting the extended BUD.	Board staff have considered the comment. Board staff note that the information may be stored in different locations and in various means (e.g., paper, electronic form, etc); however, when requested, the compounding record must be produced to the Board that includes the required information in a single document. Staff are offering a proposed change to the language to clarify.

			Recommended language: (1) If a source is referenced to support the assigned beyond-use date (BUD), each source referenced shall be <u>available upon request prior to compounding</u> ~~readily retrievable at the time of compounding~~ and shall be retrievable maintained for three years from the date each CNSP is dispensed.	
125	1736.11(c)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP	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: (c) <u>Compounding record requirements shall be readily retrievable to comply with USP Chapter 797</u> and includes the following additional elements:	Board staff have considered the comment. Board staff note that the information may be stored in different locations and in various means (e.g., paper, electronic form, etc); however, when requested, the compounding record must be produced to the Board that includes the required information in a single document. Staff are offering a proposed change to the language to clarify.
126	1736.11(c)	Walgreens	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:	Board staff have considered the comment. Board staff note that the information may be stored in different locations and in various means (e.g., paper, electronic form, etc); however, when requested, the compounding record must be produced to the Board that includes the required information in a single document. Staff are offering a proposed change to the language to clarify.

127	1736.11(c)	Rheta Silvas Kaweah Health	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.	Board staff have considered the comment. Board staff note that the information may be stored in different locations and in various means (e.g., paper, electronic form, etc); however, when requested, the compounding record must be produced to the Board that includes the required information in a single document. Staff are offering a proposed change to the language to clarify.
128	1736.11(c)	Melanie Horn Sutter Health	USP 797 states, "If an ACD, workflow management system, or other similar equipment is used, the required information in the CR may be stored electronically as long as it is retrievable and contains the required information." Harmonize the CR requirement for USP 795 & USP 797 for clarity and support automated workflow solutions with forcing functions to capture and detail the required information readily. The current electronic health record and most other safety IV workflow technologies have some limitations in their ability to produce a single document, but all information is readily obtained and held within the management system. Mandating a single "document" requires transitioning from electronic automated capture to collating elements that the software does not keep within a single document but is within a single electronic record. (c) A compounding record (CR) shall be ~~a single document, readily retrievable and contain the required information.~~ <u>The document shall</u> to satisfy the requirements of USP Chapter 797, and ~~also contain~~ the following:	Board staff have considered the comment. Board staff note that the information may be stored in different locations and in various means (e.g., paper, electronic form, etc); however, when requested, the compounding record must be produced to the Board that includes the required information in a single document. Staff are offering a proposed change to the language to clarify.
129	1736.11(c)	Wendy Waldman Torrance Memorial Medical Center	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	Board staff have considered the comment. Board staff note that the information may be stored in different locations and in various means (e.g., paper, electronic form, etc); however, when requested, the compounding record must be produced to the Board that includes the required information in a single

			document. Recommendation: Recommend the Board consider modify the language to: (c) <u>Compounding record requirements shall be readily retrievable to comply with USP Chapter 797 and includes the following additional elements:</u>	document. Staff are offering a proposed change to the language to clarify.
130	1736.11(c) (1)	Rick Rhoads University Compounding	(1) The date, <u>or date</u> and time of preparation, <u>if the BUD is listed in hours</u> . 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.	Board staff have reviewed the comment and do not recommend a change to the proposed language. Board staff note that the Chapter requires the compounding record to include the date and time. Further, the Chapter provides that the BUD is determined from the date and time that the preparation of the CSP is initiated. Given the specificity in the Chapter, staff believe (c)(1) could be deleted from the proposed text if the Board believes such action is appropriate.
131	1736.11(c) (3)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP Also provided at Reg Hearing	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	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments. Staff note that while existing law provides such an exemption, continuation of the current exemption is not appropriate as it hampers the ability of a facility to respond appropriately in the event of a product recall. Staff note that the Chapter requires either the recording of the manufacturers or vendor; however, in separate guidance issued by the FDA, the facility needs to have transparency in the supply chain and awareness of the manufacturer (where the manufacturer and vendor are different). Staff note that the Chapter provides a limited exemption for CSPs prepared for a single patient for sterile-to-sterile compounding only.

			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. <u>(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.</u>	
132	1736.11(c)(3)	Wendy Waldman Torrance Memorial Medical Center	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. 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. <u>(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.</u>	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments. Staff note that while existing law provides such an exemption, continuation of the current exemption is not appropriate as it hampers the ability of a facility to respond appropriately in the event of a product recall. Staff note that the Chapter requires either the recording of the manufacturers or vendor; however, in separate guidance issued by the FDA, the facility needs to have transparency into the supply chain and awareness of the manufacturer (where the manufacturer and vendor are different.) Staff note that the Chapter provides a limited exemption for CSPs prepared for a single patient for sterile-to-sterile compounding only.

133	1736.11(c) (5)	Tommy Mai Huntington Health, CSHP	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.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. Staff note that where the compounding personnel is a pharmacist, there would be no requirement to document a separate pharmacist providing direct oversight, as there is no requirement for a pharmacist to compound under the direct oversight of another pharmacist. Similarly, where a pharmacist is performing the compounding, there is no requirement for another pharmacist to perform the final verification of the drug preparation.
134	1736.11(c) (5)	Wendy Waldman Torrance Memorial Medical Center	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.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. Staff note that where the compounding personnel is a pharmacist, there would be no requirement to document a separate pharmacist providing direct oversight, as there is no requirement for a pharmacist to compound under the direct oversight of another pharmacist. Similarly, where a pharmacist is performing the compounding, there is no requirement for another pharmacist to perform final verification of the drug preparation.
135	1736.11(c) (5)	John Gray Kaiser Permanente	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.	Staff have reviewed the comment and recommend a change to clarify the language to confirm the Board's expectation that the level of supervisions encompasses direct supervision and control.

			The identity of each person performing the compounding, the person ~~that has exercising~~ <u>supervision and control over oversight of</u> compounding, and the pharmacist verifying the final drug preparation.	
136	1736.11(c) (6)	Marie Cottman Pacific Compounding	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	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that not all compounding pharmacies use an outside vendor to perform endotoxin testing. In such instances where this is performed by the pharmacy, documentation of the endotoxin levels calculations are necessary. For a pharmacy that outsources the endotoxin testing, the levels calculations would not be applicable.
137	1736.12(b)	Melanie Horn Sutter Health	Per USP 797, sterility testing and thus validation of method suitability is required to be completed in certain cases for category 2 or 3 CSPs. Modify to indicate that this requirement needs to be met only when applicable to the CSP in question. <u>If applicable, A</u> 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	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Staff note that the language applies only if the facility is using an alternate method for sterility testing.

			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.	
138	1736.12(b)	John Gray Kaiser Permanente	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.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Staff note they believe the commenter is referencing Section 1736.12(c). Staff note that the proposed regulations require testing for endotoxins for all nonsterile to sterile testing. Such testing is necessary to ensure that the end product does not contain excessive bacterial endotoxins, which, if present, place patients at risk.
139	1736.12(b)	Scott Brunner Alliance for Pharmacy Compounding	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.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Staff note that the language applies only if the facility is using an alternate method for sterility testing.
140	1736.12(c)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	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 components and are not sterility tested only have a 4-day BUD. Typical endotoxin testing would not be available before the end of the BUD.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Staff note that this is currently required in CCR 1751.7(e)(1) for batch testing. Staff note that endotoxin testing can be performed in-house and completed within four hours. Staff note that the proposed regulations are limited to injectable CSPs made from nonsterile components. Staff note that harm has occurred to patients where nonsterile to sterile compounding from a single preparation, including decreased blood pressure, shortness of breath, hospitalization, etc.
141	1736.13(a)	Melanie Horn Sutter Health	The USP 797 requires that prescription "labeling" include instructions for administration. The labeling versus label is recommended as the requirement based on complexities of including specific administration instructions for sterile compounds directly onto the label.	Board staff have reviewed the comment and recommend a change to the proposed language to address the comment, in part. Staff note that the route of administration is different than the instructions for administration. Staff further note that the instructions for administration (which the commenter is proposing to delete) is existing language in CCR 1751.2(b).

			When CSPs are dispensed directly to patients the administration instructions readily available in the USP 797 labeling allows for more accurate and inclusive administration detail. Healthcare facilities labels have significant concern regarding ability to fit the detailed administration procedures. Administration instructions, titrations and medication details often require the additional support of the electronic health record (EHR) system due to complexity and required modification of administration detail. Labels produced cannot be replaced or updated for all corresponding changes to administration instructions. Consider revising a label requirement to reference where to refer to instructions for administration location. 503b provided CSPs from California licensed pharmacies cannot be labeled and furnished with specific instructions for administration beyond "See order" or "refer to electronic health record". CCR 1735.4(3) referenced "admixed IV solutions" has been revised to "an admixed CSP". Since CSPs are all admixed, recommend eliminating the duplicative terminology by removing "admixed." The scope of the revised terminology is recommended for revision to clearly define the scope of the requirement is for CSPs administered by infusion requiring rates and durations. The broad scope of the required dosage forms sterile CSPs include body cavity irrigations, gravity instilled CSPs, inhaled medications for bronchial inhalation, eye drops, and intrathecal which would be imposed arbitrary or misleading mandatory durations for the CSP to be administered. (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~~ For CSPs administered by	

			infusion, the rate of infusion, or range of rates of infusion as prescribed, or the duration for the entire CSP to be administered.	
142	1736.13(a)	Wendy Waldman Torrance Memorial Medical Center	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 <u>these can also be readily retrievable from the EHR:</u> (1) Route of intended administration; (2) The solution utilized, if applicable; (3) Instructions for administration; (A) For an admixed CSP <u>that are to be infused</u>, the rate of infusion, or range of rates of infusion as prescribed, or the duration for the entire CSP to be administered.	Board staff have reviewed the comment and recommend a change to the proposed language to address the comment, in part. There is nothing in the proposed regulation text that would prohibit the information from also being available in an EHR.
143	1736.13(a)	Tommy Mai Huntington Health, CSHP	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 <u>these can also be readily retrievable from the EHR:</u> (1) Route of intended administration; (2) The solution utilized, if applicable; (3) Instructions for administration; (A) For an admixed CSP <u>that are to be infused</u>, the rate of infusion, or range of rates of infusion as prescribed, or the duration for the entire CSP to be administered.	Board staff have reviewed the comment and recommend a change to the proposed language to address the comment, in part. There is nothing in the proposed regulation text that would prohibit the information from also being available in an EHR.
144	1736.13(a)	Rita Shane Cedars-Sinai Also provided at Reg Hearing	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	Board staff have reviewed the comment and recommend a change to the proposed language to address the comment, in part. There is nothing in the proposed regulation text that would prohibit the information from also being available in an EHR. Staff note that the route of administration is different than

			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 <u>these can also be readily retrievable from the EHR:</u> (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.~~	the instructions for administration. Staff note that not all health care facilities have EHRs that are linked to infusion pump systems.
145	1736.13(a)(2)	Scott Brunner Alliance for Pharmacy Compounding	Clarify what this means.	Board staff have reviewed the comment and are recommending a change to the proposed text to clarify the requirement if the CSP is administered by infusion.
146	1736.13(a)(2)	Marie Cottman Pacific Compounding	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	Board staff have reviewed the comment and recommend a change to the proposed text to address the comment. Staff believe that the label only needs to include the solution if the compounded CSP is administered through infusion.

			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~~ <u>should</u> include all of the following: (1) Route of intended administration;(2) The solution utilized, if applicable;	
147	1736.13(a)(3)(A)	Keck Medicine of USC	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 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 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	Board staff have reviewed the comment and recommend a change to the proposed language to address the comment, in part. There is nothing in the proposed regulation text that would prohibit the information from also being available in an EHR. Staff note that the route of administration is different than the instructions for administration. Staff note that not all health care facilities have EHRs that are linked to infusion pump systems.

			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 <u>(unless the infusion rate is specified in a shared electronic medical record system)</u>, or the duration for the entire CSP to be administered."	
148	1736.13(a)(4)	Jasmine Parker Pacific Compounding	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).	Board staff have reviewed the comment and do not recommend changes to the proposed regulations. Staff note that this requirement is existing language in CCR section 1735.4(a)(1).
149	1736.14(a)(1-3)	Jasmine Parker Pacific Compounding	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.	Board staff have reviewed the comment and do not recommend changes to the proposed text. Staff note the distinction between USP requirements and the proposed regulation is merely that the BUD shall not extend beyond the literature. The Board's regulation text establishes a requirement for the professional to follow the limitations when documents in assigning a BUD as opposed to only considering the information as required in USP. Staff notes that the USP compounding already requires reliance upon studies.
150	1736.14(a)(2)	Rheta Silvas Kaweah Health	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), <u>where such information is available; and.</u> Rationale – a BUD limit based on the criteria included in	Board staff have reviewed the comment and do not recommend changes to the proposed text. Staff note the distinction between USP requirements and the proposed regulation is merely that the BUD shall not extend beyond the literature. The Board's regulation text establishes a requirement for the professional to follow the limitations when documents in assigning a BUD as opposed to only considering the information as

			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.	required in USP. Staff notes that the USP compounding already requires reliance upon studies.
151	1736.13(a) (4)	Marie Cottman Pacific Compounding	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 (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).~~	Board staff have reviewed the comment and do not recommend changes to the proposed regulations. Staff note that this requirement is existing language in CCR section 1735.4(a)(1).
152	1736.13(b)	Marie Cottman Pacific Compounding	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)	Board staff have reviewed the comment and recommend a change to the proposed regulation text not based solely on this comment. Language recommended by staff would establish a more explicit exemption for a CSP that is administered as specified.

			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.	
153	1736.13(b)	Tommy Mai Huntington Health, CSHP	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. <u>(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.</u>	Staff have reviewed the comment and agree that additional clarification to the language is appropriate to more specifically describe when patient consultation is required. Staff is offering recommended language to address the comment.
154	1736.13(b)	Wendy Waldman Torrance Memorial	Rationale: Currently, a health facility, as defined in Section 1250 of the Health and Safety Codes, are exempt from patient centered label requirements.	Staff have reviewed the comment and agree that additional clarification to the language is appropriate to more specifically describe when patient

		Medical Center	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. <u>(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.</u>	consultation is required. Staff is offering recommended language to address the comment.
155	1736.14 not correct section	Marie Cottman Pacific 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"? RECOMMENDATION: Remove regulation.	Board staff have reviewed the comment and do not recommend a change in the proposed regulation text. Staff note that the Chapter requires the information to be available in USP 1163. Staff does not believe there is any redundancy in the proposed regulation text and the referenced USP Chapter 1163.
156	1736.14(a)(1)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	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.	Board staff have considered the comment and recommend a change to the proposed language as it is consistent with appropriate compounding practices.
157	1736.14(c)	Scott Brunner Alliance for Pharmacy Compounding	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	Board staff have reviewed the comment and do not recommend a change to the proposed language. Staff note that existing law, CCR 1751.7(e)(1) , generally establishes a similar requirement. Staff note

			testing creates a situation where patients could be denied a medication if testing cannot be performed fast enough to prevent suffering or patient harm.	that the sterility testing is required in the Chapter as part of the establishment of a BUD for the compounded preparation
158	1736.14(c)	National Community Pharmacists Association (NCPA)	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. In some situations patients will experience harm or suffering from delays in treatment. Hospitals cannot receive all endotoxin and sterility results before furnishing CSPs to patients in all situations.	Board staff have reviewed the comment and do not recommend a change to the proposed language. Staff note that existing law, CCR 1751.7(e)(1) , generally establishes a similar requirement. Staff note that the sterility testing is required in the Chapter as part of the establishment of a BUD for the compounded preparation
159	1736.14(c)	John Gray Kaiser Permanente	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.	Board staff have reviewed the comment and recommend a change in the proposed text to clarify the requirement. Staff note that testing is not required in all situations. Rather, testing is required to be consistent with USP requirements and for nonsterile to sterile compounding. Board current regulations and the proposed text require test results be received and reviewed by furnishing the CSP.
160	1736.14(c)	Marie Cottman Pacific Compounding	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.	Board staff have reviewed the comment and recommend a change in the proposed text to clarify the requirement. Staff note that testing is not required in all situation. Rather, testing is required to be consistent with USP requirements and for nonsterile to sterile compounding. Board current regulations and the proposed text require test results be received and reviewed by furnishing the CSP.

161	1736.14(c)	Philip Smyth Medisca	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.	Board staff have reviewed the comment and recommend a change in the proposed text to clarify the requirement. Staff note that testing is not required in all situations. Rather, testing is required to be consistent with USP requirements and for nonsterile to sterile compounding. Board current regulations and the proposed text require test results be received and reviewed by furnishing the CSP.
162	1736.14(c)	Melanie Horn Sutter Health	Per USP 797, endotoxin testing, and sterility testing are required to be completed in certain cases for category 2 or 3 CSPs. Modify to indicate that this requirement needs to be met only when applicable to the CSP in question <u>If applicable</u>, 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.	Board staff have reviewed the comment and recommend a change in the proposed text to clarify the requirement. Staff note that testing is not required in all situations. Rather, testing is required to be consistent with USP requirements and for nonsterile to sterile compounding. Board current regulations and the proposed text require test results be received and reviewed by furnishing the CSP.
163	1736.14(c)	Wendy Waldman Torrance Memorial Medical Center	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 <u>(when applicable)</u> for BUD determination is performed and has received and reviewed the results.	Board staff have reviewed the comment and recommend a change in the proposed text to clarify the requirement. Staff note that testing is not required in all situations. Rather, testing is required to be consistent with USP requirements and for nonsterile to sterile compounding. Board current regulations and the proposed text require test results be received and reviewed by furnishing the CSP.
164	1736.14(c)	Rita Shane Cedars-Sinai, Tommy Mai Huntington	Rationale: Per USP 797, endotoxin testing, and sterility testing are required to be completed in certain cases for category 2 or 3 CSPs.	Board staff have reviewed the comment and recommend a change in the proposed text to clarify the requirement. Staff note that testing is not required in all situations. Rather, testing is required to be consistent with USP requirements and for nonsterile to

		Health, CSHP	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 (<u>when applicable</u>) for BUD determination is performed and has received and reviewed the results.	sterile compounding. Board current regulations and the proposed text require test results be received and reviewed by furnishing the CSP.
165	1736.14(c)	UCSF	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 <u>applicable</u> sterility and endotoxin testing for BUD determination is performed <u>per USP</u> 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.	Board staff have reviewed the comment and recommend a change in the proposed text to clarify the requirement. Staff note that testing is not required in all situations. Rather, testing is required to be consistent with USP requirements and for nonsterile to sterile compounding. Board current regulations and the proposed text require test results be received and reviewed by furnishing the CSP.
166	1736.16(a)	Marie Cottman Pacific Compounding	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	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that the USP Chapter provides a definition of compounded stock solution.

			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.	
167	1736.17	Scripps Health	Transferring and documentation of items in the ante room and PEC will cause pharmacies to double staffing to take care of this rule alone, which will cost 200 to 1,000 to over a million dollars per year.	This generic statement is not sufficiently specific for the Board to evaluate. Board staff are unclear on the scope of the comment. The referenced section relates to the requirement to develop Standard Operating Procedures on their chosen workflow. Should the comment be referring to 1736.17(d), Board staff note that the proposed regulation text requires the facility to develop a policy, providing flexibility to the facility to determine how to operationalize their SOP. Absent additional information to support the claim, Board staff are unclear how the development of the SOP could result in a doubling of staff and a cost of over \$1,000,000 per year. Chapter 797, Section 8, establishes the requirements for introducing items into the secondary engineering control and primary engineering control. The Board is not establishing any requirements above what the Chapter provides. It may be helpful for the commenter to describe how the development of an SOP could result in over a \$1,000,000/annually and a doubling of staff. Of note, staff believe that in the prior version of Chapter 797, there was already a requirement to have a process in place, similar to what the Board's proposed regulation text is requiring.
168	1736.17(a)	John Gray Kaiser Permanente	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.	Board staff have reviewed the comment and recommend changes to the proposed regulation text related to infection materials. Further, Board staff note that Initial Statement of Reasons documents the basis for inclusion of USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. Business and

			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. (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 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;~~	Professions Code section 4126.8, establishes compliance with pharmacy compounding chapters.
169	1736.17(a) (1)-(2)	Melanie Horn Sutter Health	The USP 797 chapter provides relevant quality assurance requirements, listing required Compounding SOPs and 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 duplicative versus prescriptive as a standard. 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 overall quality assurance and quality control standards outlined in the regulation and within the USP 797 chapter. 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.	Board staff have reviewed the comment and recommend changes to the proposed regulation text related to infection materials. Further, Board staff note that Initial Statement of Reasons documents the basis for inclusion of USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. Business and Professions Code section 4126.8, establishes compliance with pharmacy compounding chapters.

			(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;~~	
170	1736.17(a) (2)(C)	Melanie Horn Sutter Health	Automated workflow systems utilizes barcode scanning and often additional image capture to validate accurate ingredient components before allowing technicians to proceed with compounding without requiring pharmacist advance determination. Recommend revising the statute language to support automated workflows with technology and the pharmacist ability to determine and approve during the duration of the process can be captured, even after compounding has begun. The methods a pharmacist will use to determine and approve the ingredients and the compounding process for each preparation ~~before compounding begins;~~	Board staff have reviewed the comments and do not recommend a change to the proposed text. Staff note that this is consistent with the board's current regulation requirements in the SOP, CCR 1751.3(a)(22). The Board understands automation typically require some sort of confirmation step before compounding begins. These methods could be documented in the SOPs.
171	1736.17(a) (2)(C)	Wendy Waldman Torrance Memorial Medical Center	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;	Board staff have reviewed the comments and do not recommend a change to the proposed text. Staff note that this is consistent with the board's current regulation requirements in the SOP, CCR 1751.3(a)(22). Further, staff note that not all technology solutions are the same. The Board understands that automation typically requires some sort of confirmation step before compounding begins. These methods could be documented in the SOPs.

			<u>(i) A sterile compounding workflow system may be utilized for verification of correct components used for preparing a CSP.</u>	
172	1736.17(a) (2)(c)	Tommy Mai Huntington Health	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; <u>(i) A sterile compounding workflow system may be utilized for verification of correct components used for preparing a CSP.</u>	Board staff have reviewed the comments and do not recommend a change to the proposed text. Staff note that this is consistent with the board's current regulation requirements in the SOP, CCR 1751.3(a)(22). Further, staff note that not all technology solutions are the same. The Board understands that automation typically requires some sort of confirmation step before compounding begins. These methods could be documented in the SOPs.
173	1736.17(a) (2)(D)	Rheta Silvas Kaweah Health	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.	Board staff have reviewed the comments and do not recommend changes to the proposed regulation text. Staff note that establishing minimum standards for the facility's SOP ensures that pharmacy personnel understand and follow the same procedures that have been established as appropriate for patient safety. The SOPs do not establish requirements but rather ensure that the facility has established SOPs in the specified areas.
174	1736.17(d)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health	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.	Board staff have reviewed the comments and do not recommend a change to the proposed text. Staff note that this is consistent with the board's current regulation requirements in the SOP, CCR 1751.3(a)(22). Further, staff note that not all technology solutions are the same. The Board understands that automation typically requires some sort of confirmation step before compounding begins. These methods could be documented in the SOPs.

			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.~~	
175	1736.17(d)	Narinder Singh Santa Clara Valley Healthcare (SCVH)	Recommending language to change category of cleaning agents instead of what the product is	Board staff have reviewed the comment and do not recommend a change. Staff note that the SOP must be specific to ensure consistency among all staff performing the task.
176	1736.17(d)	Wendy Waldman Torrance Memorial Medical Center	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.~~	Board staff have reviewed the comments and do not recommend a change to the proposed text. Staff note that this is consistent with the board's current regulation requirements in the SOP, CCR 1751.3(a)(22). Further, staff note that not all technology solutions are the same. The Board understands that automation typically requires some sort of confirmation step before compounding begins. These methods could be documented in the SOPs.
177	1736.17(d)	CSHP	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	Board staff have reviewed the comments and do not recommend a change to the proposed text. Staff note that this is consistent with the board's current regulation requirements in the SOP, CCR 1751.3(a)(22). Further, staff note that not all technology solutions are the same. The Board understands automation typically require some sort of confirmation step before compounding begins. These methods could be documented in the SOPs.

			practice, this requirement could be interpreted that the 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.~~	
178	1736.17(g)	Scott Brunner Alliance for Pharmacy Compounding	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)?	Board staff have reviewed the comment and do not recommend any changes to the proposed regulations. Staff note that "validated processes" is not used in article 4.6.
179	1736.18(a)	Melanie Horn Sutter Health	In the Initial Statement of Reasons, the Board references pharmacies are required to meet the requirements of USP Chapter 1163 "per BPC 4126.8." 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]." The USP 797 chapter provides relevant quality assurance requirements, including referencing USP chapter 1163; therefore, including a requirement for pharmacies to meet all	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Board staff note that Initial Statement of Reasons documents the basis for inclusion of USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. Business and Professions Code section 4126.8, establishes compliance with pharmacy compounding chapters. Furthermore, staff note that in the event of a temperature excursion, the facility has a plan in place to address the issue.

			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." 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 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. (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 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.~~	
180	1736.18(a)	John Gray Kaiser Permanente	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	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Board staff note that Initial Statement of Reasons documents the basis for inclusion of USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. Business and Professions Code section 4126.8, establishes compliance with pharmacy compounding

			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 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. (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 <u>facility's quality assurance</u> 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. ~~(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.~~	chapters. Furthermore, staff note that in the event of a temperature excursion, the facility has a plan in place to address the issue.
181	1736.18(a)(1)	Marie Cottman Pacific Compounding	COMMENT: Recalls are not scheduled events. RATIONALE: Recalls are not scheduled actions. Remove "scheduled" and simply have "a written	Board staff have reviewed the language and recommend a change to the proposed text based on the comment received to clarify the language as suggested by the commenter.

			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.	
182	1736.18(b)	Rheta Silvas Kaweah Health	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.	Board staff has reviewed the comment and recommends changes to the proposed regulation text to align with the federal definition of "drug experience." Board staff note that the regulation will establish a reporting requirement to the Board if a determination is made that a complaint received is a result of or a potential result of a quality problem, as detailed in the Initial Statement of Reasons.
183	1736.18(b)	Marie Cottman Pacific Compounding	COMMENT: Redundant of other regulations. RATIONALE: Redundant. No need for a regulation that states you must comply with another regulation? RECOMMENDATION: Remove regulation.	Board staff has reviewed the comment and recommends changes to the proposed regulation text to align with the federal definition of "drug experience." Board staff note that the regulation will establish a reporting requirement to the Board if a determination is made that a complaint received is a result of or a potential result of a quality problem, as detailed in the Initial Statement of Reasons.
184	1736.18(c)	CSHP	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, <u>or licensed designee</u>, within <u>3 business days</u> ~~72 hours~~ of receipt of the complaint or	Board staff have reviewed the comment and do not recommend a change to the language based on the comment related to 72 hours; however, Board staff do recommend a change to the language to clarify that in the event the PIC is not available, another designated person must complete the review.

			occurrence. Such review shall be documented and dated as defined in the SOPs.	
185	1736.18(c)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	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 CSP whether or not it is related to the quality of the CSP. This type of reporting may drown out the times that the board needs to be aware of a CSP 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. We advise that the pharmacy must initiate an investigation with 72 hours of receipt of a complaint of a potential quality problem, and must notify the Board in writing with 15 days of the receipt of complaint.	Board staff have reviewed the comment and do not recommend a change to the language based on the comment related to 72 hours; however, Board staff do recommend a change to the language to clarify that in the event the PIC is not available, another designated person must complete the review.
186	1736.18(c)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health	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 <u>3 business days</u> ~~72 hours~~ of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs.	Board staff have reviewed the comment and do not recommend a change to the language based on the comment related to 72 hours; however, Board staff do recommend a change to the language to clarify that in the event the PIC is not available, another designated person must complete the review.
187	1736.18(c)	Keck Medicine of USC	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.	Board staff have reviewed the comment and do not recommend a change to the language based on the comment related to 72 hours; however, Board staff do recommend a change to the language to clarify that

			Recommendation 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 <u>designated pharmacist within 3 business days</u> of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs."	in the event the PIC is not available, another designated person must complete the review.
188	1736.18(c)	Rheta Silvas Kaweah Health	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.	Board staff has reviewed the comment and recommend changes to the proposed regulation text to align with the federal definition of "drug experience".
189	1736.18(c)	Wendy Waldman Torrance Memorial Medical Center	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 <u>3 business days</u> ~~72 hours~~ of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs.	Board staff have reviewed the comment and do not recommend a change to the language based on the comment related to 72 hours; however, Board staff do recommend a change to the language to clarify that in the event the PIC is not available, another designated person must complete the review.
190	1736.19	Marie Cottman Pacific Compounding	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	Board staff have reviewed the comment and believe the change to the proposed language as proposed by the commenter is appropriate. Staff are offering recommended language.

			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.	
191	1736.20(b)	John Gray Kaiser Permanente	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. <u>Policies and procedures and SOPs required by this article</u> ~~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~~ <u>policy and procedure and SOP</u> must be maintained in a readily retrievable format and include the changes to the document, identification of	Board staff have reviewed the comments related to this issue and are recommending changes to the proposed text to clarify the requirement.

			individual who made the change, and the date of each change.	
192	1736.21	Marie Cottman Pacific 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 allergen compounding.	Board staff have reviewed the comment and recommend changes to the proposed language to clearly indicate that the provisions of this section apply to the compounding of allergenic extracts.
193	1736.21 (a)	Marie Cottman Pacific Compounding	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 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	Board staff have reviewed the comment and do not recommend changes to the proposed text based solely on this comment. Board staff are offering recommended changes to the text as recommended by other comments received related to this section.

			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.	
194	1736.21(a)	Wendy Waldman Torrance Memorial Medical Center	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 <u>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.</u>	Board staff have reviewed the comment and do not recommend changes to the proposed text based solely on this comment. Board staff are offering recommended changes to the text consistent with comments received related to this section.
195	1736.21(a)	Melanie Horn Sutter Health	The new USP 797 chapter requires that allergenic extracts be compounded in either a 1) ISO Class 5	Board staff have reviewed the comment and do not recommend changes to the proposed text based

			Primary Engineering Control chamber (PEC), or (2) in a dedicated Allergenic Extracts Compounding Area (AECA). Allergenic extracts are sterile liquids manufactured from natural substances and diluted using sterile preservatives that inhibit microbial growth for extended periods. The requirement to raise the standard for pharmacies by restricting compounding to a dedicated PEC for allergenic extracts would lead to inability for pharmacists to oversee this compounding. These additional requirements impose a significant variance to operational and financial burden for a pharmacy versus physician office compounding not regulated by the board in an AECA. There is no evidence that natural substances sterilized within vial dosage forms when extracted with sterile needles and supplies pose any risk to other nonallergenic extract CSPs. (a) Any allergenic extract compounding shall take place in a <u>dedicated Allergenic Extracts Compounding Area</u> ~~dedicated~~ PEC. No other CSP may be made in this PEC <u>at the same time allergenic extract compounding is occurring. Work surface of the PEC must be cleaned disinfected immediately after compounding.</u>	solely on this comment. Board staff are offering recommended changes to the text consistent with comments received related to this section.
196	1736.21 (a)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP	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	Board staff have reviewed the comment and do not recommend changes to the proposed text based solely on this comment. Board staff are offering recommended changes to the text consistent with comments received related to this section.

			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 <u>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.</u>	
197	1736.21 (a)	UCSF	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 <u>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.</u>	Board staff have reviewed the comment and do not recommend changes to the proposed text based solely on this comment. Board staff are offering recommended changes to the text consistent with comments received related to this section.
198	1736.21 (a)	Jasmine Parker Pacific Compounding	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.	Board staff have reviewed the comment and do not recommend changes to the proposed text based solely on this comment. Board staff are offering recommended changes to the text as recommended by other comments received related to this section.
199	1736.21 (b)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP	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	Board staff have reviewed the comment and are recommending changes to the paragraph necessary to conform to the changes made in paragraph (a) of this section.

			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.	
200	1736.21 (a)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding Also provided at Reg Hearing	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.	Board staff have reviewed the comment and do not recommend changes to the proposed text based solely on this comment. Board staff are offering recommended changes to the text consistent with comments received related to this section.
201	1736.21 (b)	Marie Cottman Pacific Compounding	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.	Board staff have reviewed the comment and are recommending changes to the paragraph necessary to conform to the changes made in paragraph (a) of this section.
202	1736.21 (b)	National Community Pharmacists Association (NCPA),	Allergenic extracts are in a category 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	Board staff have reviewed the comment and are recommending changes to the paragraph necessary to conform to the changes made in paragraph (a) of this section.

		Scott Brunner Alliance for Pharmacy Compounding	onerous than FDA's approach to compounding these preparations as discussed in their Biologics guidance document.	
203	1736.21 (b)	Melanie Horn Sutter Health	Strike Language. Allergen extract compounding conditions are listed in USP 797 as exempt from the category 1 or 2 dating since they contain significant preservative and pose a limited infection risk in published literature to causing patient harm when kept for durations allowed with USP 797 up to 1 year as listed in allergenic extract package insert dating. Recommend remove the requirement and to align with USP 797.	Board staff have reviewed the comment and are recommending changes to the paragraph necessary to conform to the changes made in paragraph (a) of this section.
204	1736.21 (c)	Marie Cottman Pacific Compounding	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.	Board staff have reviewed the comment and believe a change to the proposed text is appropriate to provide clarity in the regulation as recommended by the commenter.
205	Sterile Compounding	Ryan Cassata, Fire Fighters + 15	Forever toxins cause cancer in fire fighters. Commenter states that the Board's regulations are making sterile compounding illegal. Sterile Compounding of IV and Nebulized glutathione is needed medication to remove forever toxins from fire fighters and prevent cancer. Glutathione is necessary for treatment of autoimmune disease treatment.	Board staff note that the comment appears to be limited to specific provisions related to CSP bulk ingredients. Staff note that the proposed regulation text as initially noticed, if enacted, would allow for compounding using a bulk drug substance in an emergency use situation for a patient-specific compound if authorized by a public health official. (CCR 1736.9(e)). This language as drafted could specifically allow for compounding of glutathione especially in cases of wildfires and other declared disasters, with the authorization of a public health official. The proposed regulation text is not intended to create barriers to effective treatments, rather was intended to provide flexibility as practices evolve and research supports emerging treatments. However, in response to public comment, staff are recommending

				a proposed change to noticed text. The recommended text if approved would more directly allow for the compounding of a bulk drug substance that is included in the published 503A Category 1 bulk substance list under specified conditions. This additional provision is in recognition that treatment may be required beyond a declared disaster, e.g, a wild fire. Staff remind all commenters that the FDA evaluates research studies to determine the safety and efficacy of drugs and establish the appropriate and approved use of medications including bulk substances. The Board defers to the FDA judgment and notes that the FDA releases information, guidance documents, evaluation of research, etc and that such FDA information establishes a standard of practice of which Board licensees must remain mindful when evaluating prescriptions and exercising clinical judgment including the proposed provisions related to bulk drug substances.
206	Article 4.6 Sterile Compounding	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, A. Haas,	Commenters 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. Commenters believe the regulation of physician in-office compounding should remain under the purview of the state medical board, however, indicate that it is essential that policymakers work collaboratively to ensure timely access to safe and effective medications for patients. 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. 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	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. Staff note its jurisdiction are individuals and businesses within its practice act. Board staff read the comment as suggesting that the Board's proposed regulations would apply to a physician, in this instance an orthopaedic surgeon. It may be appropriate for the commenter to confer with their licensing board to determine in the practice described if the scenario described their comment is allowable.

		California Society of Plastic Surgeons Also Provided Oral Comments on Topic	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.	
207	Article 4.6 Sterile Compounding	Melanie Horn Sutter Health	Sutter Health generally supports the regulation of compounding; however, believes that the proposed regulations holds the practice of pharmacy to a higher standard than other licensed professions and therefore, pharmacists and pharmacy personnel are being asked to do more.	The Board appreciates the support of the board's regulation. Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. The Board relied upon USP as the foundation for the requirements. The Board also note that as included in the Initial Statement of Reasons, many of the requirements included in the proposed regulation text, are requirements in the existing regulations.
208	Article 4.6 Sterile Compounding	Jerome Potozkin, Daneil A. Di Cesare, Bill Resh, Tanya Kormeili, Jennifer Chen, Plus 21 Others Also Provided Oral Comments on Topic	Commenters 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. Commenters believe the regulation of physician in-office compounding should remain under the purview of the state medical board, however, indicate that it is essential that policymakers work collaboratively to ensure timely access to safe and effective medications for patients.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. Staff note its jurisdiction are individuals and businesses within its practice act. Board staff read the comment as suggesting that the Board's proposed regulations would apply to a physician, in this instance an orthopaedic surgeon. It may be appropriate for the commenter to confer with their licensing board to determine in the practice described if the scenario described their comment is allowable.
209	Article 4.6 Sterile Compounding	CA Orthopaedic Association Also Provided Oral Comments on Topic	As an orthopaedic surgeon, our commitment to patient care and safety is paramount. One crucial aspect of our practice involves the administration of medication 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	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. Staff note its jurisdiction are individuals and businesses within its practice act. Board staff read the comment as suggesting that the Board's proposed regulations would apply to a physician, in this instance an orthopaedic surgeon. It may be appropriate for the commenter to confer with

			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 coadministration of a local anesthetic can also give useful diagnostic information about the anatomic course 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 erected 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 their medications in his or her	their licensing board to determine in the practice described if the scenario described their comment is allowable.

			office. Please consider proposed regulations which would hinder this ability	
210	Article 4.6 Sterile Compound ing	CA Naturopathic Doctor Association (CNDA) Also provided at Reg Hearing	CNDA is requesting that the Board postpone any decisions made with regard to this issue and refer the matter to the Joint Sunset Review to allow for a full discussion of the legislature allowing for a better understanding of the impacts of this proposed rulemaking. The proposed products for regulation, methylcobalamin (vitamin B12) and glutathione are essential for patient care, specifically patients suffering from chronic health ailments. Naturopathic doctors (NDs) use compounding pharmacies routinely to provide safe and effective care for complex patients (e.g. patients with allergies to additives in pills). The California Board of Pharmacy has been taking action to limit access to some of these legal medications for Californians, in spite of the fact that they are able to be compounded in other states. Some examples are injectable methylcobalamin and glutathione for inhalation. Injectable methylcobalamin has been shown to be effective in helping people with ALS (Lou Gehrig's Disease), a terminal condition for which there are few helpful treatments. Inhaled glutathione has been shown to be helpful in patients with cystic fibrosis (a very serious genetic condition that affects the lungs). We want to make sure that legislators are aware of these issues as the California State Board of Pharmacy heads into its next sunset review. Proposed state restrictions that supersede the current requirements by federal law will remove products that serve to improve the daily quality of health, productivity, and longevity of patients relying on these specific compounded medications. Rather than improve safety, which has not been shown to be a known issue, it will be a deterrent to quality healthcare. Please consider this statement as an opportunity to voice our concerns and request postponement of this issue to the Board's sunset review.	Board staff note that the comments appear to be limited to specific provisions related to CSP bulk ingredients in proposed text CCR Section 1736.9. Board staff note that staff are recommending a proposed change to noticed text in part based on this comment that could address the specific products mentioned. The regulation text is not intended to create barriers to effective treatments as practices evolve. Staff note that the FDA evaluates research studies to determine the safety and efficacy of drugs and establish the appropriate and approved use of medications including compounded preparations. The Board defers to the FDA judgment and notes that the FDA releases information, guidance documents, evaluation of research, etc and notes that such FDA information establishes a standard of practice for which Board licensees must remain mindful of when evaluating prescriptions and exercising clinical judgment. The Board also notes that pursuant to the provisions of BPC 4127(c) the Board must consider changes made to USP within 90 days.

#	Section	Commenter	Comment	Board Response
1	Article 4.7 Hazardous Drugs	Occupational Safety and Health Standards Board (OSHSB)	As compounded drugs can pose a safety risk to works, individuals handling hazardous drug must be aware of the safety and health risks. OSHSB requests that a Note be added to article 4.7 to alert licensees of the Cal/OSHA regulations within Title 8. OSHSB provided the following language: Note: To ensure proper worker protections, additional safety and health requirements are included in title 8 of the California Code of Regulations.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. Board staff note that the Initial Statement Reasons reminds stakeholders about the obligation to comply with other legal requirements, including those established in the California Code of Regulations, Title 8. Staff note that some changes to the proposed regulation text are being offered to remove provisions that strictly address employee protections, e.g. provisions related to wipe sampling.
2	1737	Scripps Health	For Hazardous drug compounding, commenters indicate the following costs will be incurred: wipe sampling will be \$6,000 per biological safety cabinet per year, sterile gloves \$40,000 per biological safety cabinet per year gloves for patients \$188,000 per year sterile disposable preparation mats 52,000 per biological safety cabinet per year Commenter states USP is adequate to protect public health.	Board staff have reviewed the comment and are recommending a change to the proposed regulation text. Staff are unclear where the suggested costs related to wipe sampling provisions would stem from. Staff note that the facility's SOP will define how and when wipe sampling will be performed. Any cost established would be a function of the facility's SOP. i.e. IF the facility's SOPs established a requirement for wipe sampling in the BSC, THEN a cost would be incurred. However, IF the SOP does not require wipe sampling in the BSC, the facility would not include those costs. Staff note that the type of glove required for BSCs are established in the Chapter, not the Board's regulation. The Board notes that its regulation text could require more frequent changing of gloves to prevent cross contamination but is recommending removal of the requirement to change gloves every 30 minutes. The Initial Statement of Reasons and Economic Impact Statement include this fiscal impact. The board did acknowledge this potential cost impact to the initial regulation text and anticipates that this further recommended change will result in additional cost savings. (Note: an online search reveals that the cost of a pair of gloves is about \$.14/pair). Staff note that in response to this and other comments related to the use of preparation mats, staff is offering changes to make

				the use of mats discretionary. As recommended, where the mats are used, the requirement to change the mats will still exist. (Note: an online search shows that a sterile preparation mat is about \$1.08/mat and a nonsterile preparation mat is about \$0.74/mat)
3	1737	Marie Cottman Pacific Compounding	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.	Board staff have reviewed the comment and do not recommend any changes to the proposed text. As noted in the initial statement of reasons, compliance with the other articles is necessary as USP Chapter 800 does not include all end-to-end aspects of hazard drug compounding.
4	1737.1	John Gray Kaiser Permanente	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. <u>When an HD is furnished to a patient or patient's agent,</u> 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.	Staff have reviewed the comment and agree that additional clarification to the language is appropriate to more specifically describe when patient consultation is required. Staff is offering recommended language.
4	1737.1	Marie Cottman Pacific Compounding	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.	Board staff have considered the comment and do not recommend changes based solely on this comment. Staff note that changes to CCR 1707.2 are outside of the scope of the regulation. Should the Board seek to amend CCR 1707.2, at that time, the Board will consider if consultation should also encompass disposal information on manufactured drug products.

			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.	
6	1737.1	CSHP	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: <u>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.</u>	Staff have reviewed the comment and agree that additional clarification to the language is appropriate to describe when patient consultation is required more specifically. Staff is offering recommended language.
7	1737.1	Melanie Horn Sutter Health	When a CSP is furnished to a patient or patient's agent, 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.	Staff have reviewed the comment and agree that additional clarification to the language is appropriate to more specifically describe when patient consultation is required. Staff is offering recommended language

			<u>When a CSP is furnished to a patient or patient's agent, 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.</u>	
8	1737.1	Wendy Waldman Torrance Memorial Medical Center	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: <u>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.</u>	Staff have reviewed the comment and agree that additional clarification to the language is appropriate to more specifically describe when patient consultation is required. Staff is offering recommended language
9	1737.1	Mark Johnston CVS Health	Commenter indicates that section 1702.2(c), Duty to Consult, only lists two categories of mandatory counseling and the pending regulations would create a third. Additionally, 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. Commenter states that 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	Staff have reviewed the comment and are not recommending a change to the proposed language based solely on this comment. Staff is offering recommended language to this section to more specifically describe when patient consultation is required.

			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. Commenter believes the pending regulations are essentially requiring pharmacists to provide legal advice on proper disposal, for which they are not well educated. Commenter requests the following edit: 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, <u>whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral</u> consultation shall be provided to the patient and/or patient's agent concerning handling ~~and disposal~~ of an HD or related supplies furnished.	
10	1737.1	UCSF	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 <u>unless the CSP is being administered by a healthcare professional.</u>	Staff have reviewed the comment and agree that additional clarification to the language is appropriate to more specifically describe when patient consultation is required. Staff is offering recommended language.

11	1737.1	Tommy Mai Huntington Health	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: <u>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.</u>	Staff have reviewed the comment and agree that additional clarification to the language is appropriate to more specifically describe when patient consultation is required. Staff is offering recommended language
12	1737.2(a) & (b)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP	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	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. Board staff note that the PIC is responsible for compliance with all provisions of Pharmacy Law, which would include the proposed regulations. Where an entity elects to also select a designated person, the responsibility for compliance with Pharmacy Law must continue to reside with the PIC.

			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~~ <u>or</u> the pharmacist-in-charge, or professional director of a clinic, or designated representative-in-charge, as applicable.	
13	1737.2(a)	Walgreens	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.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. Board staff note that the PIC is responsible for compliance with all provisions of Pharmacy Law, which would include the proposed regulations. Where an entity elects to also select a designated person, the responsibility for compliance with Pharmacy Law must continue to reside with the PIC.
14	1737.2(b)	Walgreens	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	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. Board staff note that the PIC is responsible for compliance with all provisions of Pharmacy Law,

			scenarios where there are not two individuals at a pharmacy who 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.	which would include the proposed regulations. Where an entity elects to also select a designated person, the responsibility for compliance with Pharmacy Law must continue to reside with the PIC.
15	1737.2(a) and (b)	Mark Johnston CVS Health Also provided at Reg Hearing	Commenter 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. 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. Additionally, commenter states CVS uses corporate level policies and the "designated person" is a corporate person and not approved by the PIC. Commenter requests the following amendment: (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~~ <u>may</u> 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, <u>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.</u> 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	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. Board staff note that the PIC is responsible for compliance with all provisions of Pharmacy Law, which would include the proposed regulations. Where an entity elects to also select a designated person, the responsibility for compliance with Pharmacy Law must continue to reside with the PIC. The PIC must approve a designated person.

			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.	
16	1737.2(a) and (b)	Wendy Waldman Torrance Memorial Medical Center	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 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.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. Board staff note that the PIC is responsible for compliance with all provisions of Pharmacy Law which would include the proposed regulations. Where an entity elects to also select a designated person, the responsibility for compliance with Pharmacy Law must continue to reside with the PIC.

17	1737.3	Marie Cottman Pacific Compounding	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 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. 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. 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	Board staff have reviewed the comment and do not recommend any changes to the language based on the comment. Staff note that as included in the Initial Statement of Reasons, the proposed regulation text ensures that all compounding personnel are aware of the types of HD exposures that may occur as referenced in the Chapter and that documentation occurs. An understanding of the types of HD exposures ensure employees understand how to avoid potential cross-contamination.

			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.	
18	1737.5(c)	Wendy Waldman Torrance Memorial Medical Center	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. <u>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].</u> <u>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.</u>	Board staff have reviewed the comment and recommend changes to the proposed language, although not based solely on this comment. Staff note that California Code of Regulations, Title 24, prohibits a passthrough between classified and unclassified spaces in the HD environment. Board staff are offering recommended changes to the proposed text to align with building code requirements. Further, staff are recommending changes to establish a delayed implementation for installation of interlocking doors to allow two years to come into compliance. Title 24, 1224.19.3.3.2.8 Pass-throughs "If a pass-through is used between the buffer and anteroom, both doors should not be capable of being open at the same time, and the doors should be interlocking. A pass-through is not permitted between the hazardous drug buffer room and any unclassified area.""
19	1737.5(c)	Melanie Horn Sutter Health	USP 800 establishes that the unclassified C-SCA configuration to compound hazardous drugs. A C-SCA area is a C-SEC. The proposed standard restricts a pass through between and C-SCA which is unclassified into an unclassified space. A pass through that is gasketed and interlocking with	Board staff have reviewed the comment and recommend changes to the proposed language, although not based solely on this comment. Staff note that California Code of Regulations, Title 24, prohibits a passthrough between classified and unclassified spaces in the HD environment. Board staff are offering recommended changes to the

			HEPA purge type provides greater protection to facilitate reduced contamination of final CSPs from the C-SEC than frequent opening and closing of sliding doors to pass final CSPs in both a C-SCA and a classified cleanroom C-SEC. Board reasoning states "minor transfers [of gasses or vapors] may still occur and can impact the sterility of the area," but fails to scope that without a pass through the personnel must either enter the larger hands-free sliding doors and perform frequent donning and doffing of HD PPE to facilitate final CSP transfer for patient doses which significantly increases transfer risks of vapors, HD residue and particulate. Recommend removing this restriction and allowing the safe use of pass throughs to facilitate final HD CSPs to move efficiently and safely to and from the HD room in proper transport packaging. If deemed appropriate, please exclude C-SCA. 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.~~	proposed text to align with building code requirements. Further, staff are recommending changes to establish a delayed implementation for installation of interlocking doors to allow two years to come into compliance. Title 24, 1224.19.3.3.2.8 Pass-throughs "If a pass-through is used between the buffer and anteroom, both doors should not be capable of being open at the same time, and the doors should be interlocking. A pass-through is not permitted between the hazardous drug buffer room and any unclassified area.""
20	1737.5(c)	Mark Johnston CVS Health Also provided at Reg Hearing	Commenter indicates 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 that trigger additional requirements to perform disinfection procedures. Commenter requests the following edit: (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.~~	Board staff have reviewed the comment and recommend changes to the proposed language, although not based solely on this comment. Staff note that California Code of Regulations, Title 24, prohibits a passthrough between classified and unclassified spaces in the HD environment. Board staff are offering recommended changes to the proposed text to align with building code requirements. Further, staff are recommending changes to establish a delayed implementation for installation of interlocking doors to allow two years to come into compliance. Title 24, 1224.19.3.3.2.8 Pass-throughs "If a pass-through is used between the buffer and anteroom, both doors should not be capable of being open at the same

				time, and the doors should be interlocking. A pass-through is not permitted between the hazardous drug buffer room and any unclassified area.'"
21	1737.5(c)	Muno Bholat Providence	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	Board staff have reviewed the comment and recommend changes to the proposed language, although not based solely on this comment. Staff note that California Code of Regulations, Title 24, prohibits a passthrough between classified and unclassified spaces in the HD environment. Board staff are offering recommended changes to the proposed text to align with building code requirements. Further, staff are recommending changes to establish a delayed implementation for installation of interlocking doors to allow two years to come into compliance. Title 24, 1224.19.3.3.2.8 Pass-throughs "If a pass-through is used between the buffer and anteroom, both doors should not be capable of being open at the same time, and the doors should be interlocking. A pass-through is not permitted between the hazardous drug buffer room and any unclassified 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.	
22	1737.5(c)	Keck Medicine of USC Also Provided at Reg Hearing	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 <u>constructed after [insert date].</u>"	Board staff acknowledge, that in the HD environment, removal of the use of a passthrough, changes to workflows may be necessary to achieve compliance and as such, Board staff are recommending a in implementation. Staff note that under California Code of Regulations, Title 24 hospitals will be required to meet this requirement under specified conditions. Where a hospital elects not to meet the requirements in paragraph c, the HD will move through the anteroom, which could result in an increase in staffing cost. The transporting of a completed HD via a pass-through versus walking it through an HD room may result in additional costs; however this could be addressed through changes in workflow to manage these costs. Prohibiting the use of the pass-through is necessary to preserve the compounding environment within the HD space. Board staff are offering recommended changes to the proposed text to align with building code requirements. Title 24, 1224.19.3.3.2.8 Pass-throughs "If a pass-through is used between the buffer and anteroom, both doors should not be capable of being open at the same time, and the doors should be interlocking. A pass-though is not permitted between the hazardous drug buffer room and any unclassified area."" The commenter indicates that prohibition on the presence of a pass-thought between an c-sec and an unclassified space is not a requirement of USP 797 or USP 800, which is true. Staff note that it IS a requirement of Title 24, CCR 1224.19.3.3.2.8 for HD environments.
23	1737.5(c)	UCSF	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	Board staff have reviewed the comment and recommend changes to the proposed language, although not based solely on this comment. Staff note that California Code of Regulations, Title 24, prohibits a passthrough between classified and

			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.~~ <u>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.</u>	unclassified spaces in the HD environment. Board staff are offering recommended changes to the proposed text to align with building code requirements. Further, staff are recommending changes to establish a delayed implementation for installation of interlocking doors to allow two years to come into compliance. Title 24, 1224.19.3.3.2.8 Pass-throughs "If a pass-through is used between the buffer and anteroom, both doors should not be capable of being open at the same time, and the doors should be interlocking. A pass-through is not permitted between the hazardous drug buffer room and any unclassified area."
24	1737.5(c)	Tommy Mai Huntington Health, CSHP	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.~~ <u>A passthrough may be allowed if installed before [OAL insert effective date].</u> <u>An existing secondary engineering control that has a</u>	Board staff have reviewed the comment and recommend changes to the proposed language, although not based solely on this comment. Staff note that California Code of Regulations, Title 24, prohibits a passthrough between classified and unclassified spaces in the HD environment. Board staff are offering recommended changes to the proposed text to align with building code requirements. Further, staff are recommending changes to establish a delayed implementation for installation of interlocking doors to allow two years to come into compliance. Title 24, 1224.19.3.3.2.8 Pass-throughs "If a pass-through is used between the buffer and anteroom, both doors should not be capable of being open at the same time, and the doors should be interlocking. A pass-through is not permitted between the hazardous drug buffer room and any unclassified area."

			<u>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.</u>	
25	1737.5(c)	Rheta Silvas Kaweah Health	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.	Board staff have reviewed the comment and recommend changes to the proposed language, although not based solely on this comment. Staff note that California Code of Regulations, Title 24, prohibits a passthrough between classified and unclassified spaces in the HD environment. Board staff are offering recommended changes to the proposed text to align with building code requirements. Further, staff are recommending changes to establish a delayed implementation for installation of interlocking doors to allow two years to come into compliance. Title 24, 1224.19.3.3.2.8 Pass-throughs "If a pass-through is used between the buffer and anteroom, both doors should not be capable of being open at the same time, and the doors should be interlocking. A pass-through is not permitted between the hazardous drug buffer room and any unclassified area."
26	1737.5(c)	Rick Rhoads University Compounding	(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~~ <u>an ISO classified C-SEC for sterile</u>	Board staff have reviewed the comment and recommend a change to the proposed language to clarify that the language is related to HD CSPs. Staff note that the recommended being offered by staff

			<u>compounding</u> 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.	address the recommendations offered by this commenter.
27	1737.5(c)	John Gray Kaiser Permanente	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 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. 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.~~	Board staff have reviewed the comment and recommend changes to the proposed language, although not based solely on this comment. Staff note that California Code of Regulations, Title 24, prohibits a passthrough between classified and unclassified spaces in the HD environment. Board staff are offering recommended changes to the proposed text to align with building code requirements. Further, staff are recommending changes to establish a delayed implementation for installation of interlocking doors to allow two years to come into compliance. Title 24, 1224.19.3.3.2.8 Pass-throughs "If a pass-through is used between the buffer and anteroom, both doors should not be capable of being open at the same time, and the doors should be interlocking. A pass-through is not permitted between the hazardous drug buffer room and any unclassified area."
28	1737.5(c)	Marie Cottman Pacific Compounding	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	Board staff have reviewed the comment and recommend changes to the proposed language, although not based solely on this comment. Staff note that California Code of Regulations, Title 24, prohibits a passthrough between classified and unclassified spaces in the HD environment. Board staff are offering recommended changes to the proposed text to align with building code requirements. Further, staff are recommending changes to establish a delayed implementation for installation of interlocking doors to allow two years to

			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 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-through. Specific standard operating procedures (SOPs) shall be written to address the maintenance of the ISO 7 classification.~~	come into compliance. Title 24, 1224.19.3.3.2.8 Pass-throughs "If a pass-through is used between the buffer and anteroom, both doors should not be capable of being open at the same time, and the doors should be interlocking. A pass-through is not permitted between the hazardous drug buffer room and any unclassified area."
29	1737.5(c)	UCSD	There's no publish or agreed upon list of volatile HDs some guidance on this would be helpful. A pass through is not allowed between the SEC into an unclassified space this will have a wide ranging impact on many pharmacies and cause a large economic impact including another round of complete compounding room redesign most pharmacies have already undergone extensive remodels just to comply with USP 797 and now this would require a whole new set of potential remodels and some pharmacies may have to shut down or change their operations. In the next section there's a requirement for a very expensive hepa Purge pass through which also creates complexity in cost and redesign uh we already do extensive Environmental Testing that shows any pattern of growth so these new changes.	Board staff have reviewed the comment and recommend changes to the proposed language, although not based solely on this comment. Staff note that California Code of Regulations, Title 24, prohibits a passthrough between classified and unclassified spaces in the HD environment. Board staff are offering recommended changes to the proposed text to align with building code requirements. Further, staff are recommending changes to establish a delayed implementation for installation of interlocking doors to allow two years to come into compliance. Title 24, 1224.19.3.3.2.8 Pass-throughs "If a pass-through is used between the buffer and anteroom, both doors should not be capable of being open at the same time, and the doors should be interlocking. A pass-through is not permitted between the hazardous drug buffer room and any unclassified area."

30	1737.5(d)	Rick Rhoads University Compounding	~~(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.	Board staff have reviewed the comment and recommend changes to the proposed language, although not based solely on this comment. Staff note that California Code of Regulations, Title 24, prohibits a passthrough between classified and unclassified spaces in the HD environment. Board staff are offering recommended changes to the proposed text to align with building code requirements. Further, staff are recommending changes to establish a delayed implementation for installation of interlocking doors to allow two years to come into compliance. Title 24, 1224.19.3.3.2.8 Pass-throughs "If a pass-through is used between the buffer and anteroom, both doors should not be capable of being open at the same time, and the doors should be interlocking. A pass-through is not permitted between the hazardous drug buffer room and any unclassified area."
31	1737.5(e)	Walgreens	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.~~	Board staff have reviewed the language and do not recommend a change to the proposed text based on the comment. Staff note that CCR 1751.4(g) already includes reference to the CETA guidelines; however, the proposed regulation text updates to the current version of the guidelines. Board staff have recommended a slight change to the proposed regulation to conform with the CETA guidelines referenced.
32	1737.5(e)	Marie Cottman Pacific Compounding	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://efaidnbmninnibpcapjpcglclefindmkaj/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.	Board staff have reviewed the comment and do not recommend changes to the proposed text based solely on this comment. Staff are recommending proposed changes to this paragraph. Staff note that the requirements should not be limited to sterile compounding and pressure differentials are required by the Chapter for CNSP hazardous preparations.

			RECOMMENDATION: Clarify that 1735.5 is for sterile areas only. (e) <u>Sterile</u> 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 <u>in the sterile areas</u>.	
33	1737.6	John Gray Kaiser Permanente	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.	Board staff have reviewed the comment and recommended changes to the proposed language to address the comment received. Staff note that the Board is only requiring an SOP to describe environmental wipe sampling. Staff note that the SOP needs to provide site-specific information as the SOP will define what is necessary. As an example, an SOP related to environmental wipe sampling would most likely be different for a hospital versus an oncology infusion pharmacy that specializes in compounding chemotherapy agents. The environmental wipe sampling provides the facility with an understanding of exposure risks in the various environments. The facility's SOPs will determine the spaces, frequency, etc. to assess for potential cross-contamination.

34	1737.6(a)	Marie Cottman Pacific Compounding	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 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	Board staff have reviewed the comment and recommended changes to the proposed language to address the comment received. Staff note that the Board is only requiring an SOP to describe environmental wipe sampling. Staff note that the SOP needs to provide site specific information as the SOP will define what is necessary. As an example, an SOP related to environmental wipe sampling would most likely be different for a hospital versus an oncology infusion pharmacy that specialized in compounding chemotherapy agents. The environmental wipe sampling provides the facility with an understanding of exposure risks in the various environments. The facilities SOPs will determine the spaces, frequency, etc.

			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.	
35	1737.6(a)	UCSD	Please provide more specific requirements on a minimum standard frequency and evidence based guidance.	Board staff have reviewed the comment and recommended changes to the proposed language to address the comment received. Staff note that the Board is only requiring an SOP to describe environmental wipe sampling. Staff note that the SOP needs to provide site specific information as the SOP will define what is necessary. As an example, an SOP related to environmental wipe sample would most likely be different for a hospital versus an oncology infusion pharmacy that specialized in compounding chemotherapy agents. The environmental wipe sampling provides the facility with an understanding

				of exposure risks in the various environments. The facilities SOPs will determine the spaces, frequency, etc.
36	1737.6(a)	Sam Kim USC	There is no evidence or guidance provided for licensees to follow as there is no standard for acceptable limits for hazardous drug contamination. What is an acceptable level if they do test? There are no certifying agencies for wipe sample kits to use. USP has it as a should and not a requirement.	Board staff have reviewed the comment and recommended changes to the proposed language to address the comment received. Staff note that the Board is only requiring an SOP to describe environmental wipe sampling. Staff note that the SOP needs to provide site specific information as the SOP will define what is necessary. As an example, an SOP related to environmental wipe sample would most likely be different for a hospital versus an oncology infusion pharmacy that specialized in compounding chemotherapy agents. The environmental wipe sampling provides the facility with an understanding of exposure risks in the various environments. The facilities SOPs will determine the spaces, frequency, etc.
37	1737.6(a)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP Also submitted at Reg Hearing	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~~ <u>should</u> address environmental wipe sampling for HD	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Staff note that the Board is only requiring an SOP to describe environmental wipe sampling. Staff note that the SOP needs to provide site-specific information as the SOP will define what is necessary. As an example, an SOP related to an environmental wipe sample would most likely be different for a hospital versus an oncology infusion pharmacy that specializes in compounding chemotherapy agents. The environmental wipe sampling provides the facility with an understanding of exposure risks in the various environments. The facility's SOPs will determine the spaces, frequency, etc.

			surface residue, its frequency, areas of testing, levels of measurable contamination, and actions when those levels are exceeded.	
38	1737.6(a)	Wendy Waldman Torrance Memorial Medical Center	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~~ <u>should</u> address environmental wipe sampling for HD surface residue, its frequency, areas of testing, levels of measurable contamination, and actions when those levels are exceeded	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Staff note that the Board is only requiring an SOP to describe environmental wipe sampling. Staff note that the SOP needs to provide site-specific information as the SOP will define what is necessary. As an example, an SOP related to an environmental wipe sample would most likely be different for a hospital versus an oncology infusion pharmacy that specializes in compounding chemotherapy agents. The environmental wipe sampling provides the facility with an understanding of exposure risks in the various environments. The facility's SOPs will determine the spaces, frequency, etc.
39	1737.6(a) & (b)	Keck Medicine of USC Also Provided at Reg Hearing	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.	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Staff note that the Board is only requiring an SOP to describe environmental wipe sampling. Staff note that the SOP needs to provide site-specific information as the SOP will define what is necessary. As an example, an SOP related to an environmental wipe sample

			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, "there 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	would most likely be different for a hospital versus an oncology infusion pharmacy that specializes in compounding chemotherapy agents. The environmental wipe sampling provides the facility with an understanding of exposure risks in the various environments. The facility's SOPs will determine the spaces, frequency, etc.

			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.	
40	1737.6(a) & (b)	Walgreens	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 OSHA standards are followed must always be required. Recommended language: (a) The SOPs of a premises where HDs are handled ~~shall~~ <u>may</u> 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~~ <u>measurable</u> level of	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Staff note that the Board is only requiring an SOP to describe environmental wipe sampling. Staff note that the SOP needs to provide site-specific information as the SOP will define what is necessary. As an example, an SOP related to an environmental wipe sample would most likely be different for a hospital versus an oncology infusion pharmacy that specializes in compounding chemotherapy agents. The environmental wipe sampling provides the facility with an understanding of exposure risks in the various environments. The facility's SOPs will determine the spaces, frequency, etc.

			contamination is found, at a minimum the following shall occur as described in the SOPs:	
41	1737.6(a-b)	Philip Smyth Medisca	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.	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Staff note that the Board is only requiring an SOP to describe environmental wipe sampling. Staff note that the SOP needs to provide site-specific information as the SOP will define what is necessary. As an example, an SOP related to environmental wipe sampling would most likely be different for a hospital versus an oncology infusion pharmacy that specializes in compounding chemotherapy agents. The environmental wipe sampling provides the facility with an understanding of exposure risks in the various environments. The facility's SOPs will determine the spaces, frequency, etc.
42	1737.7(b) & (c)	Narinder Singh Santa Clara Valley Healthcare (SCVH)	This requirement is above and beyond the USP 800. There is no added value of this requirement but adds burden to the end user which can lead to errors. Please remove (b) & (c) as USP 800 doesn't require.	Board staff have reviewed the comment and recommend changes to the proposed regulation language. Staff note that the type of gloves to be used and a minimum threshold for changing gloves is established in the Chapter. Staff note that the proposed changes to the text will remove the requirement to change gloves every 30 minutes.
43	1737.7(b) & (c)	Walgreens	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 <u>API</u> preparation.	Board staff have reviewed the comment and do not recommend a change to the proposed language. The language as drafted provides flexibility to the compounding personnel to only change the gloves between different HD preparations. This is necessary to prevent cross-contamination between different active ingredients.
44	1737.7(c)	Melanie Horn Sutter Health Also Provided at Reg Hearing	The Board has proposed in 1735 USP 795 language to allow for outer gloves used for HD compounding "shall be wiped between each different HD preparation." to reduce cross contamination.	Board staff have reviewed the comment and recommend changes to the proposed regulation language. Staff note that the type of gloves to be used and a minimum threshold for changing gloves is

			Changing gloves more frequently for cross contamination of HD residue levies a significant operational burden on the licensed technicians compounding HDs and the organization as a requirement. This standard has not been in place or utilized prior to this proposal no evidence has demonstrated that current HD handling practices which require routine wiping and changing of outer gloves at least every 30 minutes offers additional safety protections. The standard also is not the only mitigated protection for workers from residues during HD compounding procedures and should be assessed collectively with those additional protections to allow a decontamination process. This operational requirement requires an HD technician to change gloves up to 30 times in an average volume facility with regular HD compounding during an 8-hour shift. This restricts ability to provide patient care with no evidence of benefit. (c) Outer gloves used for HD compounding shall be <u>wiped to decontaminate</u> or changed between each different HD preparation.	established in the Chapter. Staff note that proposed changes to the text will remove the requirement to change gloves every 30 minutes. Staff is unaware of any research that supports wiping gloves as a means to decontaminate. Staff notes that the Chapter specifies the types of gloves to be used.
45	1737.7(c)	Tommy Mai Huntington Health	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.	Board staff have reviewed the comment and do not recommend a change to the proposed text. As the cited research demonstrates, while the CSTD does REDUCE the risk of contamination, it does not eliminate it.

			Recommendations: Revise the proposed language to: (c) Outer gloves used for HD compounding shall be changed between each different HD preparation <u>if a closed system transfer device (CSTD) is not used.</u>	
46	1737.7(c)	Marie Cottman Pacific Compounding	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 <u>non-sterile</u> and sterile HD gloving practices. (c) Outer gloves used for nonsterile HD compounding shall be changed between each different HD preparation. <u>Outer gloves used for sterile HD compounding shall be changed in compliance with 1737.7 (b).</u>	Board staff have reviewed the comment and do not recommend a change to the proposed text based solely on this comment. As the cited research demonstrates, while the CSTD does REDUCE the risk of contamination, it does not eliminate it. Board staff note that the proposed regulation text only require use of sterile gloves when the compounding involved sterile preparations.
47	1737.7(c)	Rita Shane Cedars-Sinai	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	Board staff have reviewed the comment and recommend changes to the proposed regulation language. Staff note that the type of gloves to be used and a minimum threshold for changing gloves is established in the Chapter. Staff note that the proposed changes to the text will remove the requirement to change gloves every 30 minutes.

			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	
48	1737.7(c)	Jasmine Parker Pacific Compounding	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).	Board staff have reviewed the comment and recommend a change to the proposed text. As the cited research demonstrates, while the CSTD does REDUCE the risk of contamination, it does not eliminate it. It is necessary to change outer gloves to avoid cross-contamination.
49	1737.7(c)	Wendy Waldman Torrance Memorial Medical Center	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 <u>if a closed system transfer device (CSTD) is not used</u>.	Board staff have reviewed the comment and do not recommend a change to the proposed text based solely on this comment. As the cited research demonstrates, while the CSTD does REDUCE the risk of contamination, it does not eliminate it. Staff note that the proposed changes to the text will remove the requirement to change gloves every 30 minutes.

50	1737.7(c)	CSHP	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~~ <u>on a frequency determined by SOPs</u> 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 <u>if a closed system transfer device (CSTD) is not used</u>.	Board staff have reviewed the comment and do not recommend a change to the proposed text based solely on this comment. As the cited research demonstrates, while the CSTD does REDUCE the risk of contamination, it does not eliminate it. Staff note that the proposed changes to the text will remove the requirement to change gloves every 30 minutes.

51	1737.7(c)	John Gray Kaiser Permanente Also Provided at Reg Hearing	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.	Board staff have reviewed the comment and do not recommend a change to the proposed text based solely on this comment. As the cited research demonstrates, while the CSTD does REDUCE the risk of contamination, it does not eliminate it. Staff note that the proposed changes to the text will remove the requirement to change gloves every 30 minutes. ASHP guidance notes that many studies show that areas where HDs are handled have significant surface contamination and promotes that the outer gloves be removed before labeling or removing the preparation from the C-PEC.
52	1737.7 (d)	National Community Pharmacists Association (NCPA)	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	Board staff have reviewed the comment and agree that additional clarification of the proposed regulation language is appropriate; however, it is not based solely on this comment.

			pressure buffer room. These facilities with a negative pressure anteroom also have a positive pressure gowning room..	
53	1737.7(d)	Walgreens	To reduce confusion in this proposed rule, we ask the board to update the language as suggested. Recommended language: (d) <u>PPE removal process shall be done in a manner removed</u> 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.	Board staff have reviewed the comment and agree that additional clarification of the proposed regulation language is appropriate.
54	1737.7(d)	Jasmine Parker Pacific Compounding	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.	Board staff have reviewed the comment and do not recommend a change based solely on the comment. Staff note that typically the outer layer of PPE, which is potentially contaminated PPE, is removed in the negative pressure environment.
55	1737.7(d)	Marie Cottman Pacific Compounding	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.	Board staff have reviewed the comment and do not recommend a change to the proposed text based solely on the comment. Staff note that the Chapter does not draw a distinction between HD CNSPs and CSP. Staff believe the proposed regulation text offered by the commenter would be contrary to the Chapter requirements. Staff are recommending changes to the proposed text to provide further clarification of the requirement.

			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) <u>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.</u> (d)(2) <u>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.</u> (d)(3) <u>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.</u>	
56	1737.7(d)	Scott Brunner Alliance for Pharmacy Compounding	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.	Board staff have reviewed the comment and do not recommend a change based solely on the comment. Staff note that typically the outer layer of PPE, which is potentially contaminated PPE, is removed in the negative pressure environment.
57	1737.7(d)	Rheta Silvas Kaweah Health	Recommend: include the word "outer" before the second instance of the word PPE. Rationale: If PPE is doffed before leaving the C-SEC,	Board staff have reviewed the comment and do not recommend a change based solely on the comment. Staff note that typically the outer layer of PPE, which is

			personnel would then be on the clean side of the ante-room wearing no garb.	potentially contaminated PPE, is removed in the negative pressure environment.
58	1737.8	Melanie Horn Sutter Health	In the Initial Statement of Reasons, states "in addition to the requirements of Title 8, California 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." The Board's assessment does not account for state (8 CCR 5194) and federal (29 CFR 1910.1200) hazard communication program requirements already in place at healthcare facilities. The USP 800 Chapter is written in to provide multi-disciplinary approach to the design and implementation of the hazard communication program. Recommend removing this requirement from current language.	Board staff have reviewed the comment and do not recommend a change to the proposed language. Staff are offering recommended language to provide clarification on the Board's expectations. Staff note that compliance with California Code of Regulations, Title 8 will be required.
59	1737.8	John Gray Kaiser Permanente	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 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	Board staff have reviewed the comment and do not recommend a change to the proposed language. Staff are offering recommended language to provide clarification on the Board's expectations. Staff note that compliance with California Code of Regulations, Title 8 will be required.

			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.	
60	1737.9 (b)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	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.	Board staff have reviewed the comment and recommend a change to the proposed language to allow for a 14-day period for the supervising pharmacist to continue while undergoing a new competency assessment.
61	1737.9(b)	Marie Cottman Pacific Compounding	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. 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 delay access to compounded medications to the patients of California. This proposed regulation may also force Pharmacy owners (who are willing to stay in the compounding business) to hire additional staff, for the	Board staff have reviewed the comment and recommend a change to the proposed language to allow for a 14-day period for the supervising pharmacist to continue while undergoing a new competency assessment.

			"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.	
62	1737.10.	Melanie Horn Sutter Health	Apply language to reference licensed supplier, distributors or wholesaler requirement since the receipt of HD APIs and antineoplastic HDs is out of the licensed pharmacy receiving control. To consider removing the entire section or clarify if receipt outside is handled (i.e. treated as a spill) or wording to allow pharmacies how to manage receipt of HD drugs such as current spill SOPs . All HD APIs and antineoplastic HDs shall be ~~shipped and~~ received from the supplier contained in segregated impervious plastic and labeled "Hazardous Drugs" on the outside of the delivery container. If not, the receiving procedure must follow the SOPs to manage a hazardous spill.	Board staff have reviewed the comment and recommend a change to the proposed regulation to clarify that the requirement applies to the distributor, not the receiving pharmacy.
63	1737.10.	Wendy Waldman Torrance	Rationale: Health-systems typically do not have control over how hazardous drug active pharmaceutical ingredients (HD	Board staff have reviewed the comment and recommend a change to the proposed regulation to

		Memorial Medical Center	APIs) and antineoplastic hazardous drugs (HDs) are shipped, as this process is directly managed by the distributing companies. Recommendations: Consider removing the entire section.	clarify that the requirement applies to the distributor, not the receiving pharmacy.
64	1737.10.	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP	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.	Board staff have reviewed the comment and recommend a change to the proposed regulation to clarify that the requirement applies to the distributor, not the receiving pharmacy.
65	1737.10.	Keck Medicine of USC	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. <u>When the pharmacy ships HD APIs and antineoplastic HDs to another pharmacy or location, the HD APIs and HDs shall be shipped in</u> segregated impervious plastic and labeled "Hazardous Drugs" on the outside of the delivery container."	Board staff have reviewed the comment and recommend a change to the proposed regulation to clarify that the requirement applies to the distributor, not the receiving pharmacy.
66	1737.10.	UCSF	Comment: This section appears to imply that all HD (reproductive, non-antineoplastic hazardous drugs)	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff

			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 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 <u>1737.10. Receiving, Shipping and Handling</u> <u>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.</u>	note that the Chapter refers to this section as "Receiving" similar to the proposed regulation text.
67	1737.10.	Walgreens	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.~~	Board staff have reviewed the comment and recommend a change to the proposed regulation to clarify that the requirement applies to the distributor, not the receiving pharmacy.
68	1737.10.	Marie Cottman Pacific Compounding	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...	Board staff have reviewed the comment and recommend a change to the proposed regulation to clarify that the requirement applies to the distributor, not the receiving pharmacy.

			RECOMMENDATION: modify this proposed regulation: 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" <u>or "Chemotherapy"</u> the outside of the delivery container. <u>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.</u>	
69	1737.10.	John Gray Kaiser Permanente	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 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). Recommend striking the section.	Board staff have reviewed the comment and recommend a change to the proposed regulation to clarify that the requirement applies to the distributor, not the receiving pharmacy.
70	1737.11(a)	Marie Cottman Pacific Compounding	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.	Board staff have reviewed the comment and recommend a change to the proposed regulation text not based solely on this comment. Language recommended by staff would establish a more explicit exemption for a HD that is administered as specified.
71	1737.11(a)	Tommy Mai Huntington Health, CSHP	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	Board staff have reviewed the comment and recommend a change to the proposed regulation text not based solely on this comment. Language recommended by staff would establish a more explicit exemption for a HD that is administered as specified.

			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 <u>(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.</u>	
72	1737.11(a)	Rheta Silvas Kaweah Health	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.	Board staff have reviewed the comment and recommend a change to the proposed regulation text not based solely on this comment. Language recommended by staff would establish a more explicit exemption for a HD that is administered as specified.
73	1737.11(a)	Wendy Waldman Torrance Memorial Medical Center	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):	Board staff have reviewed the comment and recommend a change to the proposed regulation text not based solely on this comment. Language recommended by staff would establish a more explicit exemption for a HD that is administered as specified.

			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 <u>(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.</u>	
74	1737.11(b)	Marie Cottman Pacific Compounding	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.	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that the language in the proposed regulation is different than the language cited by the commenter.
75	1737.11(b)	Walgreens	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 <u>packaged and</u> transported from the facility in an impervious plastic container and labeled as HD on the outside of the container.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation. Staff note that the Chapter appears to address the packaging requirements sufficiently.
76	1737.13	Walgreens	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	Board staff have reviewed the comment and recommend a change to the proposed text to address the comment as well as other comments received regarding this paragraph. As proposed to

			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~~ <u>may</u> 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.	be amended by staff, the proposed text would clarify that, when a mat is used. it must be changed after each different HD preparation is compounded. This is necessary to prevent cross-contamination. Further, staff note that the proposed text to address the comment as well as other comments received regarding this paragraph including concerns and cost implications of using preparation mats.
77	1737.13	Rheta Silvas Kaweah Health	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.	Board staff have reviewed the comment and recommend a change to the proposed text to address the comment as well as other comments received regarding this paragraph. As proposed to be amended by staff, the proposed text would clarify that, when a mat is used. it must be changed after each different HD preparation is compounded. This is necessary to prevent cross-contamination. Further, staff note that the proposed text to address the comment as well as other comments received regarding this paragraph including concerns and cost implications of using preparation mats.

78	1737.13	John Gray Kaiser Permanente Also Provided at Reg Hearing	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 of 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 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	Board staff have reviewed the comment and recommend a change to the proposed text to address the comment as well as other comments received regarding this paragraph. As proposed to be amended by staff, the proposed text would clarify that, when a mat is used, it must be changed after each different HD preparation is compounded. This is necessary to prevent cross-contamination. Further, staff note that the proposed text to address the comment as well as other comments received regarding this paragraph including concerns and cost implications of using preparation mats.

			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.	
79	1737.13(a)	Marie Cottman Pacific Compounding	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 static 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."	Board staff have reviewed the comment and do not recommend a change to the proposed text based solely on the comment. A pharmacist using professional judgement can determine if a spill as occurred. Staff note that if a facility chooses to do so, it can further define "spill" in the facility's SOPs.
80	1737.13(a)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP Also provided at Reg Hearing	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 to 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~~ <u>should</u> 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~~	Board staff have reviewed the comment and recommend a change to the proposed text to address the comment as well as other comments received regarding this paragraph. As proposed to be amended by staff, the proposed text would clarify that, when a mat is used, it must be changed after each different HD preparation is compounded. This is necessary to prevent cross-contamination. Further, staff note that the proposed text to address the comment as well as other comments received regarding this paragraph including concerns and cost implications of using preparation mats.

			<u>between different HD</u> , and at the end of daily compounding activity.	
81	1737.13(a)	Melanie Horn Sutter Health	USP 800 language states that a 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 halts HD compounding in the event of a shortage of this item. Sterile mats are extremely costly to replace between each HD prep and do not facilitate routine sanitization of the DCA nor a process of performing DDCCD between each HD prep. The mats within the PEC while closed should not be a requirement to perform sterile HD compounding with the other USP 800 required protections in place. This as a standard introduces significant and costly waste without identified benefit to mandate usage. Mats may be used in the event of a spill of for other purposes but must not be mandated to provide compounding inside a BSC. Recommendations: Revise language to be consistent with USP 800 requirements but require if/when a mat is used it is sterile and replaced routinely. (a) A disposable preparation mat shall be placed on the work surface of the C-PEC when compounding sterile 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~~, regularly during use, and at the end of daily compounding activity.	Board staff have reviewed the comment and recommend a change to the proposed text to address the comment as well as other comments received regarding this paragraph. As proposed to be amended by staff, the proposed text would clarify that, when a mat is used, it must be changed after each different HD preparation is compounded. This is necessary to prevent cross-contamination. Further, staff note that the proposed text to address the comment as well as other comments received regarding this paragraph including concerns and cost implications of using preparation mats.
82	1737.13(a)	Wendy Waldman Torrance Memorial Medical Center	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.	Board staff have reviewed the comment and recommend a change to the proposed text to address the comment as well as other comments received regarding this paragraph. As proposed to be amended by staff, the proposed text would clarify that, when a mat is used, it must be changed after

			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~~<u>should</u> 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~~, <u>during decontamination between different HD</u>, and at the end of daily compounding activity.	each different HD preparation is compounded. This is necessary to prevent cross-contamination. Further, staff note that the proposed text to address the comment as well as other comments received regarding this paragraph including concerns and cost implications of using preparation mats.
83	1737.13(a)	Keck Medicine of USC	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, 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	Board staff have reviewed the comment and recommend a change to the proposed text to address the comment as well as other comments received regarding this paragraph. As proposed to be amended by staff, the proposed text would clarify that, when a mat is used, it must be changed after each different HD preparation is compounded. This is necessary to prevent cross-contamination. Further, staff note that the proposed text to address the comment as well as other comments received regarding this paragraph including concerns and cost implications of using preparation mats.

			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 may be placed on the work surface of the C-PEC when compounding HD preparations. Where the compounding is a sterile preparation and a preparation mat is used, the mat shall be sterile. If used, the preparation mat shall be changed immediately if a spill occurs, after each HD drug, and at the end of daily compounding activity.”	
84	1737.13(a)	Rick Rhoads University Compounding Also provided at Reg Hearing	(a) A disposable preparation mat shall be placed on the work surface of the C-PEC when compounding <u>antineoplastic</u> HD preparations. <u>For non-antineoplastic HD preparations, an assessment of risk may be performed for alternative work practices.</u> 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	Board staff have reviewed the comment and recommend a change to the proposed text to address the comment as well as other comments received regarding this paragraph. As proposed to be amended by staff, the proposed text would clarify that, when a mat is used, it must be changed after each different HD preparation is compounded. This is necessary to prevent cross-contamination. Further, staff note that the proposed text to address the comment as well as other comments received

			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>).	regarding this paragraph including concerns and cost implications of using preparation mats.
85	1737.13(a)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	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."	Board staff have reviewed the comment and recommend a change to the proposed text to address the comment as well as other comments received regarding this paragraph. As proposed to be amended by staff, the proposed text would clarify that, when a mat is used, it must be changed after each different HD preparation is compounded. This is necessary to prevent cross-contamination. Further, staff note that the proposed text to address the comment as well as other comments received regarding this paragraph including concerns and cost implications of using preparation mats. Board staff is not aware of a cleanable mat that can be used inside a hood that meets the requirements of the Chapter.
86	1737.13(b)	Marie Cottman Pacific Compounding	COMMENT: A variety of products may take significant time to reconstitute (15 to 30 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.	Board staff have reviewed the comment and do not recommend a change to the proposed text. Board staff note that the proposed regulation text as noticed provides flexibility to allow for multiple units of the same HD preparation to be prepared at one time.
87	1737.13(b)	Jasmine Parker Pacific Compounding	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 hinders the ability of a facility to service multiple orders at once. RECOMMENDATION:	Board staff have reviewed the comment and do not recommend a change to the proposed text. Board staff note that the proposed regulation text as noticed provides flexibility to allow for multiple units of the same HD preparation to be prepared at one time.

			(b) Only one HD preparation may be handled in a C-PEC at one time.	
88	1737.14(a)	Walgreens	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?	Board staff have reviewed the comment and recommend a change to the proposed text to address the comment. Staff Board note that the CDC's NIOSH has references available in this area that may assist in the development of an SOP where the facility determines such an approach is appropriate. References: Managing Hazardous Drug Exposures: Information for Healthcare Settings: https://www.cdc.gov/niosh/docs/2023-130/2023-130.pdf?id=10.26616/NIOSH PUB2023130 . Board staff are recommending a change to the proposed text in CCR Section 1737.14(a) based on other comments received.
89	1737.14(a) (1)	Marie Cottman Pacific Compounding	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;	Board staff have reviewed the comment and recommend a change to the proposed text, although not based solely on this comment. Staff Board note that the CDC's NIOSH has references available in this area that may assist in the development of an SOP where the facility determines such an approach is appropriate. References: Managing Hazardous Drug Exposures: Information for Healthcare Settings: https://www.cdc.gov/niosh/docs/2023-130/2023-130.pdf?id=10.26616/NIOSH PUB2023130 . Board staff are recommending a change to the proposed text in CCR Section 1737.14(a) based on other comments received.
90	1737.14(a) (2)	Marie Cottman Pacific Compounding	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	Board staff have reviewed the comment and recommend a change to the proposed text to address the comment.

			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.	
91	1737.14(a)(2)	National Community Pharmacists Association (NCPA)	Not all lines can be primed in the pharmacy. Medications hung as a secondary that are already primed may mess up the entire setup of the lines.	Board staff have reviewed the comment and recommend a change to the proposed text, although not based solely on this comment.
92	1737.14(a)(2)	Jasmine Parker Pacific Compounding	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.	Board staff have reviewed the comment and recommend a change to the proposed text to address the comment.
93	1737.14(b)	Tommy Mai Huntington Health, CSHP	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. <u>(i) Exempt from this requirement are health facilities, as</u>	Board staff have reviewed the comment and recommend a proposed change to the regulation text to clarify that the requirement applies when an HD is dispensed to the patient or patient's agent.

			<u>defined in Section 1250 of the Health and Safety Code, if the prescriptions are administered by a licensed health care professional.</u>	
94	1737.14(b)	Walgreens	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, <u>the dispensing pharmacy must ensure</u> 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.~~	Board staff have reviewed the comment and recommend a proposed change to the regulation text to clarify that the requirement applies when an HD is dispensed to the patient or patient's agent.
95	1737.14(b)	Lauren Honda Valor Compounding Also Submitted in Reg Hearing	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.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text based on the comment. Staff note that a pharmacist, using professional judgment, should determine the number of gloves required for use by the patient or patient's agent. Based on separate comments received related to the proposed text in CCR Section 1737.14(b), staff are recommending changes to the proposed text.
96	1737.14(b)	Wendy Waldman Torrance Memorial Medical Center	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	Board staff have reviewed the comment and recommend a proposed change to the regulation text to clarify that the requirement applies when an HD is dispensed to the patient or patient's agent.

			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. <u>(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.</u>	
97	1737.14(b)	Melanie Horn Sutter Health	To avoid confusion about the cases in which gloves must be provided to the patient or patient's agent, 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.	Board staff have reviewed the comment and recommend a proposed change to the regulation text to clarify that the requirement applies when an HD is dispensed to the patient or patient's agent.
98	1737.14(b)	Jasmine Parker Pacific Compounding	COMMENT: If not furnishing the drug directly to the patient (ex. Going to a facility or other provider to administer), 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.	Board staff have reviewed the comment and recommend a proposed change to the regulation text to clarify that the requirement applies when an HD is dispensed to the patient or patient's agent.
99	1737.14(b)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	Who bears liability if the patient refuses to pay for the gloves? Who bears liability if the patient does not use the gloves that shall be made available for purchase?	Board staff have review the comment and do not recommend a change to the proposed text based on the comment. The comments appear broad in nature and ask questions beyond the scope of the proposed regulation. Board staff note that staff are recommending changes to the proposed text in response to other comments received about this section.
100	1737.14(b)	John Gray Kaiser Permanente	When furnishing an antineoplastic HD <u>to the patient or patient's agent</u> , 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.	Board staff have reviewed the comment and recommend a proposed change to the regulation text to clarify that the requirement applies when an HD is dispensed to the patient or patient's agent.

			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.	
101	1737.14(b)	Marie Cottman Pacific Compounding	COMMENT: Not every dispense situation requires provision of gloves. Changing the 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>	Board staff have reviewed the comment and recommend a proposed change to the regulation text to clarify that the requirement applies when an HD is dispensed to the patient or patient's agent.
102	1737.15(b)	Marie Cottman Pacific Compounding	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	Board staff have reviewed the comment and recommend a change to the proposed text in response to the comment. Staff note that the Chapter specifies that the appropriate solution is not delivered by a spray bottle to avoid spreading HD residue.

			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.	
103	1737.15(b)	Jasmine Parker Pacific Compounding	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 wet the wipe by pouring. 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.	Board staff have reviewed the comment and recommend a change to the proposed text not based solely on this comment. Staff note that the Chapter specifies that the appropriate solution is not delivered by a spray bottle to avoid spreading HD residue.
104	1737.15(c)	Walgreens	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.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text based on this comment. Staff note that based on other comments received, staff recommend that the proposed regulation text in CCR 1737.15(c) be removed. Staff remind the commenter that BPC 4113 provide that the pharmacist-in-charge is responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to to the practice of pharmacy, including the requirements established in these regulations.

105	1737.15(c)	Marie Cottman Pacific Compounding	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.	Board staff have reviewed the comment and based on the comment received, believe the proposed regulation text in CCR 1737.15(c) should be removed from the proposed regulation text.
106	1737.16	Marie Cottman Pacific Compounding	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	Board staff have reviewed the comment and recommend a change to the proposed text that ensures an entities SOP outlines how a qualified person will be available at all times.

			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 <u>to clean up an HD spill</u> will be always available while HDs are handled.	
107	1737.16	Walgreens	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: <u>Unless all pharmacy staff are trained in HD spill control</u>, 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.	Board staff have reviewed the comment and recommend a change to the proposed text that ensures an entities SOP outlines how a qualified person will be available at all times.
108	1737.16	Melanie Horn Sutter Health	As required by USP 800, personnel are trained to handle HD, which includes cleaning up an HD spill, prior to handling HD. The proposed language implies all spills are manageable by trained personnel; however, SOPS outline overall spill management including the determination of need to have spill response beyond internal individuals such as a major spill incident. Recommend modification to align with requirements of spill control plan. ~~The premises shall maintain a list of properly trained and qualified personnel able to clean up an HD spill. An SOP shall outline spill management plan and procedures and qualifications for spill management. such a qualified person to clean up an HD spill will be always available while HDs are handled.~~	Board staff have reviewed the comment and recommend a change to the proposed text that ensures an entity's SOP outlines how a qualified person will be available at all times.

109	1737.16	Wendy Waldman Torrance Memorial Medical Center	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 <u>to clean up an HD spill</u> will be always available while HDs are handled.	Board staff have reviewed the comment and recommend a change to the proposed text that ensures an entities SOP outlines how a qualified person will be available at all times.
110	1737.16	Mark Johnston CVS Health Also provided at Reg Hearing	Commenter believes that maintaining employee lists, which may be subject to frequent change, is an example of a burden that APhA, ASHP, and NABP has asked the Board 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.~~	Board staff have reviewed the comment and recommend a change to the proposed text that ensures an entities SOP outlines how a qualified person will be available at all times.
111	1737.16	John Gray Kaiser Permanente	The <u>premises designated person</u> 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	Board staff have reviewed the comment and recommend a change to the proposed text that ensures an entities SOP outlines how a qualified person will be available at all times.

			regulation by changing the term "premises" to "designated person".	
112	1737.17(a)	John Gray Kaiser Permanente	The <u>designated person</u> for ~~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".	Staff have reviewed the comment and recommend a change to the proposed language not based solely on this comment to align the proposed regulation text with the language used in the Chapter.
113	1737.17(b) (3)	Mark Johnston CVS Health	Commenter states 1737.17(b)(3) requires the SOP to address "designation of HD areas"; however, USP 800 does not require separate areas when only dispensing manufactured dosage forms. Commenter requests the following edit: (3) Designation of HD areas <u>or separate counting trays/spatulas</u>	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that such a change would be contrary to the Chapter. Staff note that the SOPs are necessary for anyone handling HDs to avoid cross-contamination and ensure the appropriate environmental conditions.
114	1737.17(b) (5)	Mark Johnston CVS Health	Commenter states 1737.17(5) also requires the SOP to address "storage", but again, USP 800 does not require special storage for manufacturer's bottles. Commenter requests the following edit: (5) Storage <u>for HD removed from manufacturer's packaging</u>	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that such a change would be contrary to the Chapter. Staff note that the SOPs are necessary for anyone handling HDs to avoid cross-contamination and ensure the appropriate environmental conditions.
115	Hazardous	Paul Lofholm	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. Commenter also commented on the need for the Board to consider allowing irradiation for sterility methods and that USP Chapters above 1000 are guidelines and not requirements.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Referenced chapters include both required actions and recommended actions. Where a required action as established in the reference USP Chapter is applicable, compliance is necessary; however, where the provisions within a USP referenced Chapter is only recommended (e.g., "should") compliance is permissive unless otherwise specified in the Board's regulation text or other provisions of the law.
116	Hazardous	Rick Rhoads University Compounding Also provided at Reg Hearing	Reference chapters are guidelines and difficult to enforce.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Referenced chapters include both required actions and recommended actions. Where a required action as established in the reference USP Chapter is

				applicable, compliance is necessary; however, where the provisions within a USP referenced Chapter is only recommended (e.g., "should") compliance is not mandated unless otherwise specified in the Board's regulation text or other provisions of the law.
117	Article 4.7 Hazardous Drugs	Mark Johnston CVS Health Also provided at Reg Hearing	Commenter states that 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. Commenter requests that the following edit be made to each section in Article 4.7: In addition to the standards in USP Chapter 800, Hazardous Drugs – ~~Handling~~ Compounding in Healthcare Setting shall meet the following requirements of this article.	The Board reviewed the comment are made changes to the article in each of the subsections to limit the scope of the article to generally apply to facilities that compound HDs or facilities that perform "other manipulations" as included in Table 1 of the USP Chapter 800 of antineoplastic HDs.

#	Section	Commenter	Comment	Board Response
1	1738.4(c)	Tommy Mai Huntington Health, CSHP	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.	Staff have reviewed the comment and do not recommend a change to the proposed regulation text. Staff note that the requirement to document would occur once every three to six months as training occurs. The PEC unique identifier is necessary to identify where the competency was performed. Further, the documentation ensures that a compounding personnel need only complete a single training and can leverage that training in other compounding environments with the same equipment.
2	1738.4(c)	Wendy Waldman Torrance Memorial Medical Center	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	Staff have reviewed the comment and do not recommend a change to the proposed regulation text. Staff note that the requirement to document would occur once every three to six months as training occurs. The PEC unique identifier is necessary to identify where the competency was performed. Further, the documentation ensures that a compounding personnel need only complete a single training and can leverage that training in other compounding environments with the same equipment.

			procedures, type of equipment, and materials used in aseptic compounding.	
3	1738.5(b)	Paul Mahan Siemens Medical	The draft regulation should harmonize with <825> in that temperature and humidity monitoring should take place in the area containing a hot-cell.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation. Board staff note that the proposed regulation text is consistent with existing law CCR 1751.4(k). Staff noted that the proper choice of placement of an SRPA in the preparation of sterile products. Staff also notes provisions in the California Code of Regulations Title 24 and other legal provisions that also establish temperature requirements for which licensees must comply. Staff note that Title 24 provisions are more restrictive related to temperatures.
4	1738.5(d)	Wendy Waldman Torrance Memorial Medical Center	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) <u>Radiopharmaceutical</u> compounding shall not take place in the SRPA.	Board staff have reviewed the comment and do not recommend a change in the proposed text. The Board notes that the article applies to radiopharmaceuticals.
5	1738.5(d)	Rita Shane Cedars- Sinai, Tommy Mai Huntington Health, CSHP	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	Board staff have reviewed the comment and do not recommend a change in the proposed text. The Board notes that the article applies to radiopharmaceuticals.

			(d) <u>Radiopharmaceutical</u> compounding shall not take place in the SRPA.	
6	1738.5(j)	Melanie Horn Sutter Health	Request clarification on the purpose of dynamic airflow smoke pattern test for the classified spaces outside of the ISO-5 PEC every 6 months. In addition, recommend the BOP be consistent with USP 825 recommendations and remove this proposed subsection. This does not align with CETA standards for frequency of SEC smoke pattern testing.	Board staff have reviewed the comment. Board staff recommend removal of the paragraph as the requirement for smoke studies are established in the Chapter.
7	1738.5(j)	Wendy Waldman Torrance Memorial Medical Center	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.	Board staff have reviewed the comment. Board staff recommend removal of the paragraph as the requirement for smoke studies are established in the Chapter.
8	1738.5(j)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP	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.	Board staff have reviewed the comment. Board staff recommend removal of the paragraph as the requirement for smoke studies are established in the Chapter.

9	1738.6(b)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP	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 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 <u>exceeds action level</u> to trend for growth of microorganisms. Trends of microorganism growth must be identified and evaluated.	Board have reviewed the comment and considered the feedback from members. Staff are recommending removal of the subdivision.
10	1738.6(b)	Melanie Horn Sutter Health	USP 825 recommends identifying sampling results on a genus level for actionable CFUs (CFUs exceeding action levels). The proposed BOP language is not consistent with USP 825 and requires identification every CFU count at least to the genus level regardless of if they exceeded the CFU action levels which is a considerable burden that is not the requested standard for USP 797 1736. Recommend harmonizing requirement to 1736 if revised and not USP 825 standard. CETA. CETA Application Guide CAG-003:2022 Certification of Sterile Compounding Facilities for USP Compliance. Accessed May 20th, 2024. 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 <u>exceeds action level</u> to trend for growth of microorganisms. Trends of microorganism growth must be identified and evaluated.	Board have reviewed the comment and considered the feedback from members. Staff are recommending removal of the subdivision.

11	1738.6(b)	Wendy Waldman Torrance Memorial Medical Center	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~~ <u>when the colony forming units (CFU) count exceeds action level</u> to trend for growth of microorganisms. Trends of microorganism growth must be identified and evaluated.	Board have revied the comment and considered the feedback from members. Staff are recommending removal of the subdivision.
12	1738.10(c)	Wendy Waldman Torrance Memorial Medical Center	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.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. The proposed regulation text establishes the areas that must be covered in a facility's SOPs and staff notes that deviations are necessary at times to meet a patient's need. The facility's SOPs will define the circumstances under which a deviation may be necessitated.
13	1738.10(c)	Rita Shane Cedars-Sinai, Tommy Mai	Rationale: The proposed language is inconsistent with USP 825 recommendations, will require health-systems to incorporate patient need which may not be pertinent	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. The proposed regulation text establishes the areas that must be covered in a facilities SOPs and staff notes that

		Huntington Health, CSHP	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.	deviations are necessary at times to meet a patient's need. The facility's SOPs will define the circumstances under which a deviation may be necessitated.
14	1738.14(b)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP	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~~ <u>3 business days</u> 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.	Board staff have reviewed the comment and recommended a change to the proposed regulation text; however, it is not solely based on this comment.
15	1738.14(b)	Paul Mahan Siemens Medical	Proposed text: 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. Comment: 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)	Board staff have reviewed the comment and recommend a change to the proposed regulation text, however not solely based on this comment.
16	1738.14(b)	Melanie Horn Sutter Health	Radiopharmaceuticals can be obtained from manufacturers in ready to inject forms (while limited) the scope of this statement does not clarify the Board scope regarding complaints of a manufactured product.	Board staff have reviewed the comment and recommend a change to the proposed regulation text, however not solely based on this comment. The proposed change offered by staff incorporates the definition used in federal law to ensure clarity in the proposed regulation text.

			The notification obligation addressed by the processing nuclear pharmacy and extended to 3 business days.	
17	1738.14(b)	Wendy Waldman Torrance Memorial Medical Center	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~~ <u>3 business days</u> 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.	Board staff have reviewed the comment and recommend a change to the proposed regulation text, however not solely based on this comment.
18	1738.14(c)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP	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 <u>3 business days</u> ~~72 hours~~ of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs.	Board staff have reviewed the comment and recommend a change to the proposed regulation text, however not solely based on this comment.
19	1738.14(c)	Wendy Waldman Torrance Memorial Medical Center	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	Board staff have reviewed the comment and recommend a change to the proposed regulation text, however not solely based on this comment.

			~~3 business days~~ 72 hours of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs.	

#	Section	Commenter	Comment	Board Response
1	General	Marie Cottman Pacific Compounding (Hearing Comment)	Commenter states that the regulations lack evidence and recommends that the Board not move forward with the regulation and rescind the existing regulations.	Board staff have reviewed the comment and do not recommend changes to the proposed text based on this comment. The comments provided are general and do not provide specific recommended changes to the text. Board staff note that the proposed regulation focus on requirements necessary for public protection as included in the Initial Statement of Reason. The Board relied upon USP as the foundation for the requirements.
2	General	Unknown Commenter at Reg Hearing	Imposing restrictions for access to care to citizens is "absurd" and the requirements should be tabled to allow access to compounded medication.	Board staff have reviewed the comment and do not recommend changes to the proposed text based on this comment. The comments provided are general and do not provide specific recommended changes to the text. Board staff note that the proposed regulation focus on requirements necessary for public protection as included in the Initial Statement of Reason. The Board relied upon USP as the foundation for the requirements. The regulation text is not intended to create barriers to effective treatments as practices evolve. Staff note that the FDA evaluates research studies to determine the safety and efficacy of drugs and establish the appropriate and approved use of medications, including compounded preparations. The Board defers to the FDA judgment and notes that the FDA releases information, guidance documents, evaluation of research, etc, and notes that such FDA information establishes a standard of practice of which Board licensees must remain mindful when evaluating prescriptions and exercising clinical judgment. The Board also notes that pursuant to the provisions of BPC 4127(c) the Board must consider changes made to USP within 90 days.
3	General	UCSD (Hearing Comment)	The regulations create a double standard between pharmacy licensees and medical licensees. The regulations must be developed with evidence based guidelines.	Board staff have reviewed the comment and do not recommend changes to the proposed text based on this comment. Staff note its jurisdiction are individuals and businesses within its practice act. Board staff read the comment as suggesting that the Board's proposed regulations would apply to a physician. It may be appropriate for the commenter to confer with those licensing boards to determine compounding requirements.

4	General	Erik Clausen (Hearing Comment)	Commenter states that he sold his compounding pharmacy because of the USP requirements. The Board needs to do more to consider the impact of the regulations.	Board staff have reviewed the comment and do not recommend changes based on this comment. Board staff note that the proposed regulation focus on requirements necessary for public protection as included in the Initial Statement of Reason. The Board relied upon USP as the foundation for the requirements consistent with the requirements in Business and Professions Code section 4126.8 and provisions of Section 503A. The regulation of compounding practices have evolved significantly over the past 20 years in federal and state law and USP standards. Many of the requirements put forth in the proposed regulations are existing requirements that have been renumbered to align with the new structure of the compounding regulation text.
5	General	Dieter Steinmetz Coast Compounding	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. 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 general safety and efficiency of retail compounding pharmacy operations.	Board staff have reviewed the comment and do not recommend changes based on this comment. Staff note that the comment is outside of the scope of the regulation. Staff note that the Licensing Committee is evaluating the current pharmacist-to-pharmacy technician ratio. The commenter may wish to participate or follow those efforts.
6	General	Rheta Silvas Kaweah Health	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.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. Staff note that each article is titled to indicate the scope of each article, e.g., CNSP, CSP, etc.

7	General	Paul Lofholm	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 General its ingredients Quality essentially means what's on the label is what is in the preparation [plus or minus 10%]	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. The comments provided are general and do not provide specific recommended changes to the text. Staff note that elsewhere in this document, responses are applicable to the general comments made.
8	General	California Veterinary Medical Association (Hearing Comment)	Vets are struggling to procure compounded medications because compounding pharmacies are afraid to compound due to possible Board enforcement. CVMA would like a meeting with the Board to discuss in future detail.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. Staff note that the proposed regulation text includes language reflecting requests from the CVMA and that public comment provided during the regulation hearing acknowledged the Board's actions to address concerns raised by CVMA.
9	General	CA Pharmacists Association	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	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. Board staff note that some of the comment is general in nature and does not offer changes for the Board to considered. Many of the areas raised by the commenter are not related to the issue of compounding and may already be under review and consideration by the Board. Further, the Board is not familiar with the CHART group. Board staff not that the proposed regulation focus on requirements necessary for public protection as included in the Initial Statement of Reasons. The Board relied upon USP as the foundation for the requirements.

			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.	
10	General	Rita Shane Cedars-Sinai (Hearing Comment)	Commenter encourages the Board to look at the regulations and reduce some of the requirements which add steps and impact patient care. Commenter indicates they do not trust 503B facilities and do not wish to use them for compounded products.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. Board staff note that the proposed regulation focus on requirements necessary for public protection as included in the Initial Statement of Reasons. The Board relied upon USP as the foundation for the requirements. The Board also further notes that as included in the Initial Statement of Reasons, many of the requirements included in the proposed regulation text, are requirements in the existing regulations.
11	General	CA Hospital Association Also provided at Reg Hearing	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	Board staff have reviewed the comment and do not recommend changes based on this comment. Board staff note that the comments are general in nature and do not provide specific recommendations to modify sections of the proposed text for the Board's consideration. Board staff note that the proposed regulation focus on requirements necessary for public protection as included in the Initial Statement of Reasons. The Board relied upon

		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.	USP as the foundation for the requirements. Board staff also note that as included in the Initial Statement of Reasons, many of the requirements included in the proposed regulation text, are requirements in the existing regulations. Legal provisions, both federal and state law, require compliance with USP, e.g., BPC Section 4342 provides the Board with the authority to institute any action or actions as may be provided by that that are necessary to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the USP. Section 503A of the FDC Act includes as one of the conditions to compound under the federal exemption that the licensed pharmacy comply with the standards including the United States Pharmacopoeia chapter on compounding. Staff further note the regulation of compounding practices have evolved significantly over the past 20 years in federal and state law and USP standards. Consistent with the requirement established in BPC 4127.1, the Board through this process has reviewed revisions to USP and determined amendments that are necessary. It is not appropriate nor relevant to associate costs to comply with the USP Chapters in this rulemaking. The Initial Statement of Reasons generally describes the costs identified that are associated with the regulations itself. As an example, USP Chapter 800 requires the use of a specific type of glove. The costs for the gloves are necessary to comply with USP 800, federal law, Pharmacy Law to name a few. However, as the Board's proposed regulations could require impacted individuals to change their HD gloves more frequently than the USP, the Board highlighted the anticipated cost that could be incurred by a facility.

			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.	
12	General	John Gray Kaiser Permanente Also Provided at Reg Hearing	The board has not provide any empirical evidence such as peer-review Journal articles, meta analyses to support the proposed compounding regulations in the initial statement of reasons. During the board's February 2023 enforcement committee meeting, the board presented photographs showing dirty and disorganized pharmacies as evidence that the USP plus approach to regulating compounding is necessary to protect the Health and Welfare of California residents and Kaiser disagrees. Kaiser requests an effective date of 1 year from the date of OAL approval.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. Board staff note that the USP Chapters have been in effect since November 1, 2023. The Board further note that as included in the Initial Statement of Reasons, many of the requirements included in the proposed regulation text, are requirements in the existing regulations. Where a new requirement is established, board staff believe a delayed implementation is not necessary unless the text otherwise establishes a delay. Staff further note that it anticipates the Board will suggest that following implementation of the adopted text, staff focus on education of new requirements (those that are not currently required under existing law) as a means to facilitate compliance unless the practice places patients at risk.
13	General	Scripps Health (Hearing Comment)	The regulations will increase the cost of caring for patients both directly and indirectly it will prevent access to Medical Services increase weight times for very sick patients and encourages an evidence based approach to the regulations. The commenter states that the regs adds standards, are duplicative, and are resource intensive.	Board staff have reviewed the comment and do not recommend changes based on this comment. Board staff note that the comments are general in nature and do not provide specific recommendations to modify sections of the proposed text for the Board's consideration. Board staff note that the proposed regulation focus on requirements necessary for public protection as included in the Initial Statement of Reasons. The Board relied upon USP as the foundation for the requirements. The Board further note that as included in the Initial Statement of Reasons, many of the requirements included in the proposed regulation text, are requirements in the existing regulations. Legal provisions, both federal and state law, require compliance with USP, e.g., BPC Section 4342

				provides the Board with the authority to institute any action or actions as may be provided by that that are necessary to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the USP. Section 503A of the FDC Act includes as one of the conditions to compound under the federal exemption that the licensed pharmacy comply with the standards, including the United States Pharmacopoeia chapter on compounding. Staff further note the regulation of compounding practices have evolved significantly over the past 20 years in federal and state law and USP standards. Consistent with the requirement established in BPC 4127.1, the Board through this process has reviewed revisions to USP and determined amendments that are necessary. It is not appropriate nor relevant to associate costs to comply with the USP Chapters in this rulemaking. The Initial Statement of Reasons generally describes the costs identified that are associated with the regulations itself. As an example, USP Chapter 800 requires the use of a specific type of glove. The costs for the gloves are necessary to comply with USP 800, federal law, Pharmacy Law to name a few. However, as the Board's proposed regulations could require impacted individuals to change their HD gloves more frequently than the USP, the Board highlighted the anticipated cost that could be incurred by a facility.
14	General	Walgreens	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 practiced and generally 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	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. The comments provided are general and do not provide specific recommended changes to the text. Rather, the comments appear to be more commentary. Because compounded drugs are not FDA-approved, FDA does not verify their safety, effectiveness, or quality before they are marketed. Poor compounding practices can result in serious drug quality problems, such as contamination or a drug that contains too much active ingredient. This can lead to serious patient injury and death. The Board has provided education through presentations during public meetings

			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	on the general requirements in federal law (Section 503A of the FDC Act) and the requirements of several USP Chapters to aid licensees in gaining an understanding of such requirements. These presentations are available on the Board's website. The commenter's use of the phrase "simple compounding" is not limited by the proposed regulation. Nonsterile compounding that is limited in nature does not require special licensure or equipment under the Board's proposed regulations.
15	General	Marci Bencomo Pacifica Compounding (Hearing Comment)	The proposed regulations do not appear to aid patient safety as they are redundant or overly restricted. Pharmacy and Pharmacy staff would suffer because they would need to spend time learning the requirements.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. The comments provided are general and do not provide specific recommended changes to the text. Rather, the comments appear to be more commentary. Because compounded drugs are not FDA-approved, FDA does not verify their safety, effectiveness, or quality before they are marketed. Poor compounding practices can result in serious drug quality problems, such as contamination or a drug that contains too much active ingredient. This can lead to serious patient injury and death.

				Board staff note that the proposed regulation focus on requirements necessary for public protection as included in the Initial Statement of Reasons. The Board relied upon USP as the foundation for the requirements. The Board also further notes that as included in the Initial Statement of Reasons, many of the requirements included in the proposed regulation text, are requirements in the existing regulations. Legal provisions, both federal and state law, require compliance with USP, e.g., BPC Section 4342 provides the Board with the authority to institute any action or actions as may be provided by that that are necessary to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the USP. Section 503A of the FDC Act includes as one of the conditions to compound under the federal exemption that the licensed pharmacy comply with the standards including the United States Pharmacopoeia chapter on compounding. Staff further note the regulation of compounding practices have evolved significantly over the past 20 years in federal and state law and USP standards. Consistent with the requirement established in BPC 4127.1, the Board through this process has reviewed revisions to USP and determined amendments that are necessary.
16	Notice	Philip Smyth Medisca, Scott Brunner Alliance for Pharmacy Compounding Also provided at Reg Hearing	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.	Board staff have reviewed the comment and do not recommend changes based on this comment. Board staff note that the comments are general in nature and do not provide specific recommendations to modify sections of the proposed text for the Board's consideration. Board staff note that the proposed regulation focus on requirements necessary for public protection as included in the Initial Statement of Reasons. The Board relied upon USP as the foundation for the requirements. The Board also further notes that as included in the Initial Statement of Reasons, many of the requirements included in the proposed regulation text, are requirements in the existing regulations. Legal provisions, both federal and state law, require compliance with USP, e.g., BPC Section 4342 provides the Board with the authority to institute any action

				or actions as may be provided by that that are necessary to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the USP. Section 503A of the FDC Act includes as one of the conditions to compound under the federal exemption that the licensed pharmacy comply with the standards including the United States Pharmacopoeia chapter on compounding. Staff further note the regulation of compounding practices have evolved significantly over the past 20 years in federal and state law and USP standards. Consistent with the requirement established in BPC 4127.1, the Board through this process has reviewed revisions to USP and determined amendments that are necessary. It is not appropriate nor relevant to associate costs to comply with the USP Chapters in this rulemaking. The Initial Statement of Reasons generally describes the costs identified that are associated with the regulations. As an example, USP Chapter 800 requires the use of a specific type of glove. The costs for the gloves are necessary to comply with USP 800, federal law, Pharmacy Law to name a few. However, as the Board's proposed regulations could require impacted individuals to change their HD gloves more frequently than the USP, the Board highlighted the anticipated cost that could be incurred by a facility.

#	Section	Commenter	Comment	Board Response
1	1735(a)	Alliance for PHY Compounding	As written, this definition assumes that all FDA-approved drugs have a diluent, resultant strength, and storage me. This will not always be the case.	Board staff have reviewed the comment and do not recommend a substantive change to the proposed text. Board staff note that this language was amended following the 45-day comment period.
2	1735(b)	Stanford Health Care	Comment: Can the pharmacist-in-charge assign themselves to be the designated person? For smaller pharmacies with a limited number of employees, it may be difficult to identify someone interested and willing to take on the responsibilities of the designated person. Recommendation: Revise language to allow the pharmacist-in-charge the option to assign themselves to be the designated person.	Board staff have reviewed the comment. While Board staff believe the language would allow for the PIC to also serve as the designated person, the comment submitted indicates that is not clearly the case. As such, Board staff recommend a change to the proposed text to provide clarity to the proposed regulation text. 1735 (b) Designated person(s) means one or more individuals assigned by the pharmacist-in-charge to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of the compounded nonsterile preparations ("CNSP") for the purposes of this article). Nothing in this definition allows for a designated person to exceed the scope of their issued license. When the designated person is not a pharmacist, the Pharmacist-in-Charge (PIC) must review all practices related to the operations of the facility that require the professional judgment of a pharmacist. Nothing in this definition shall prohibit the PIC from also serving as the designated person.
2	1735(c)	Alliance for PHY Compounding	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. Recommendation: Accept section 1735.4(b) identification of water types.	Board staff have reviewed the comment and do not recommend a substantive change to the proposed text. Staff note that USP 795 6.1.2 speaks to the quality of water that must be used for compounding nonsterile drug preparations when formulations indicate the inclusion of water. The Board's proposed text is consistent with the Chapter and provides clarity to the Chapter by providing examples of the acceptable types of water that may be used for reconstitution.

				Board staff recommend the following technical changes to reflect the language of the Chapter. <u>1735 (c) "Diluent" means a liquid with no pharmacological activity used in reconstitution, such as ~~P~~urified ~~w~~Water or ~~S~~terile ~~w~~Water.</u>
3	1735(d)	Outsourcing Facilities Association	This definition creates incoherence and confusion in conjunction with proposed § 1735.1(f), as explained in § A, <i>infra</i>. (See comment for specific reasons)  OFA Public Comment Proposed	Board staff have reviewed the comment. Board staff appreciate the comments submitted by the commenter and highlighting the potential conflict. Staff note that the Board does not have regulatory authority over the prescribing practitioner. Staff note that the practice of pharmacy includes pharmacists verifying that a prescribed medication is clinically appropriate for a patient irrespective of whether it is a compounded medication. Staff recommend the following change to the language to remove the potential confusion and concern that the Board is attempting to regulate the prescriber. <u>1735 (d) "Essentially a copy" of a commercially available drug product means a preparation that includes the same active ingredient(s) (API) 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 products for that patient a clinically significant difference, as ~~determined verified and documented~~ by the ~~pharmacist prescribing practitioner~~, between that compounded preparation and the comparable commercially available drug product.</u>
4	1735(d)	Alliance for PHY Compounding Wedgewood Pharmacy	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	Board staff have considered the comment and do not recommend a change to the proposed text. Staff note that as written, the language provides flexibility for a pharmacist to use their professional judgment when determining if a compound is essentially a copy. Should the Board amend the language to include the recommended text, the

			the FDA approach. We continue to recommend that California aligns its definition of “essentially a copy” with the FDA’s for clarity and ease of compliance.	Board would be limiting this flexibility and a clinician’s professional judgment. Staff note that it appears the commenter is referring to a draft definition provided in an FDA guidance document (as opposed to the language contained within FDCA 503a). The federal statutory definition, similar to the Board’s proposed regulation, requires that the compound must produce a significant difference in the patient. The Board’s proposed text is clarifying federal law to ensure the significant difference is clinical in nature. Such an approach provides flexibility for a pharmacist to use clinical judgment.
5	1735(e)	Torrance Memorial	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)).	Board staff have reviewed the comment and believe the commenter is referring to 1735(d). Board staff have considered the comment and do not recommend a change to the proposed text. Staff note that as written, the language provides flexibility for a pharmacist to use their professional judgment when determining if a compound is essentially a copy. Should the Board amend the language to include the recommended language, the Board would be limiting this flexibility and a clinician’s professional judgment.
6	1735.1	Assoc of NorCal Oncologists and Medical Oncology Assoc. California Rheumatology Alliance CalDerm	We are concerned that the proposed regulations will require a pharmacist to be present during these types of activities, which would be an onerous burden on community sites of care, particularly those in rural settings. ANCO and MOASC are concerned that these proposed regulations, if adopted, would result in cancer patients being forced to obtain their chemotherapy at a hospital or infusion center, which would place new burdens on patients who are already fighting for their lives. 1735.1. In addition to the standards in USP Chapter 795 and, Food Drug Cosmetic Act (FDCA) section 503a (21 U.S.C. §353a) the compounding of a CNSP shall meet the following requirements of this article. This article shall not apply to	Board staff have reviewed the comment and do not recommend a change to the proposed text based on the comment. Staff note the Board only has jurisdiction over individuals and businesses within its practice act. Board staff read the comment as suggesting that the Board’s proposed regulations would apply to a physician. Business and Professions Code section 4170(c) makes clear that the Medical Board of California is specifically charged with the enforcement of Pharmacy Law (Chapter 9, Division 2 of the Business and Profession Code) with respect to its licensees.

		CA Medical Association	compounding by or under the direct supervision of a licensed physician and surgeon.	It may be appropriate for the commenter to confer with their licensing board to discuss their concerns. Board staff note that the Medical Board of California has previously provided a written response to individuals inquiring about the applicability of the Board of Pharmacy's regulations to individuals and practices that operate under the jurisdiction of the Medical Board of California. Below is the information provided from the Medical Board - - Dear Ms. Sodergren: I understand that some concerns have been raised by stakeholders about the applicability of the Board of Pharmacy's pending compounding regulations to licensees of the Medical Board of California (MBC). Existing statute (see Business and Professions Code (BPC) section 2220.5) makes it clear that only the MBC can discipline its physician licensees. Whenever a physician is engaging in compounding (or any other action that their medical license authorizes them to perform) they must always do so consistent with the standard of care. For the purposes of MBC's enforcement program, the standard of care is established by expert testimony in the context of the facts and circumstances of a specific case. It is certainly possible that whatever regulations that are implemented by the Board of Pharmacy may influence the standard of care for physicians who are compounding, especially since some of the proposed regulations reflect what is already required for physician compounding under federal law, including, but not limited to, Section 503A of the Federal Food, Drug, and Cosmetic Act (BPC section 2225(b) allows MBC to investigate violations of federal law related to the practice of medicine). Feel free to share this message with others as you see fit who might also be concerned about the

				applicability of their pending regulations to the physician community. Please contact me if you have any further questions. Sincerely, Reji Varghese A copy of this communication is provided in attachment 6.
7	1735.1(b)	Alliance for PHY 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." 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 expiration 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.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Board staff note that the Initial Statement of Reasons documents the basis for inclusion of USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. Business and Professions Code section 4126.8, establishes compliance with pharmacy compounding chapters. Staff further notes, USP has stated, "Although it is possible for FDA or another government authority in the U.S. or elsewhere to require the use a USP General Chapter numbered 1000 to 1999, the authority in question would need to make this requirement expressly applicable under law, regulation, or another appropriate vehicle that prescribes enforceable requirements."
	1735.1(d)	Wedgewood Pharmacy	"Reasonable quantity" needs to be defined clearly to avoid ambiguity, provide clear compliance standards, and make clear what enforcement will entail. It is unfair to place the burden of determining a "reasonable quantity" on the pharmacist when it is a) an unclear standard and b) the pharmacist doesn't know the prescriber's patient base nor their needs. Recommendations: Change terminology "veterinary office" to "veterinary practice". Mobile veterinarians practice in the field, not an office. Eliminate the words "Reasonable quantity". Clauses 1 and 2 of this provision and the phrase "estimated by the prescriber" establish clear criteria for the amount of office stock drugs that can be ordered and sold. The prescriber is	Board staff have conferred with its expert in veterinary practice who has confirmed the term "veterinary office" is appropriate. The expert further commented about the need for some limitations on the volume of compounding to be reasonable, noting that the FDA has publicly expressed concerns regarding 'large-scale drug manufacturing under the guise of pharmacy compounding.' The practicing veterinarian, in selecting a California licensed pharmacy to supply drugs to their patients, has no way to determine if the compounded drugs are being made in accordance with state and federal regulations. The egregious violations of the Animal Medicinal Drug Use Clarification Act of 1994

			in the best position to determine based on their practice the amount of drugs that are appropriate. A pharmacy has no reasonable basis to determine what a particular practice may need particularly when the practice is permitted to both administer drugs in office and dispense.	(AMDUCA) along with multiple violations of pharmacy law, is not only potentially injurious to the animal patients, but also places the veterinarian at risk of liability for use of these drugs. As the commenter notes, reasonable quantity is further clarified in paragraphs (1) and (2). Board staff don't recommend a change in response to the comment; however, staff believe that given that the proposed change is in nonsterile compounding, staff believe an extended day supply may be possible. <u>~~(d) (2) for furnishing of not more than 7-day supply, or up to no more than 14 days for antibiotics, for an individual patient, as fairly estimated by the prescriber, and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing for an individual patient.~~</u>
8	1735.1(e)	Alliance for PHY Compounding	Prior version cited 21CFR353a. Replacing the citation with "federal law" is vague and could apply to any federal law. We still assert that referencing specific regulations instead of the general "federal law" provides clarity and specificity to which laws this applies.	Board staff have reviewed the comment and do not recommend a change. Staff note that it is incumbent on the pharmacist to maintain an understanding of all relevant laws. The Board notes that the practice of compounding is a complex area of practice for which pharmacists must possess a strong understanding of all relevant laws. The Board's inclusion of a single code reference as suggested by the commenter may inadvertently suggest to a pharmacist that is the only relevant section of the law to be considered. In such an instance, the Board's regulation would be potentially misleading, as the pharmacist must consider all relevant sections of the law applicable to the compounding being performed.
9	1735.1(e) (1)	Wedgewood Pharmacy	Recommendation: Edit 1735.1 (e) to align with the language that is more appropriate in 1736.1 (e)	Board staff have reviewed the comment and believe the commenter is suggesting that the Board consider its comments from 1735.1(e) to similarly apply to 1736.1(e)(2). With this understanding, staff note that the suggestion to incorporate GFI #256

				was reviewed by staff and a Board's expert on veterinary compounding. Staff recommend the following to respond to the comment. <u>1735(e)(2) Is made with any component not suitable for use in a CNSP for the intended veterinary population, unless allowable under the Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA). When a veterinarian acting within a valid veterinarian-client-patient relationship (VCPR), determines there is no medically appropriate human or animal drug that is FDA-approved, conditionally approved, or indexed to treat the animal a pharmacy may use a bulk drug substance to compound an animal drug. This compound shall be in compliance with the Center for Veterinary Medicine Guidance for Industry #256-- Compounding Animal Drugs from Bulk Drug Substances issued August 2022.</u>
10	1735.1(e)(1)	Alliance for PHY Compounding	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. 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. The final compounding regulations should reference GFI #256 where it applies to animal drug compounders. APC recommends aligning with what is required in the FDA's Essential Copy Guidance document, which does require	Board staff have reviewed the comment and believe the commenter may be referring to separate issues within a single comment. In this response staff will respond to the portion of the comment that appears to be related to the provisions in (e)(1), essentially a copy. Board staff have considered the comment and do not recommend a change to the proposed text. Staff note that as written, the language provides flexibility for a pharmacist to use their professional judgment when determining if a compound is essentially a copy. Should the Board amend the language to include the recommended language, the Board would be limiting this flexibility and a pharmacist's professional judgment. Further, Board

			documentation when a pharmacist dispenses a medication for which a change is made so it is not a copy of an FDA-approved product. The prescriber makes the determination that the compound is required, and the Board should not intend to question the prescriber's judgement. We also recommend that California provide examples of appropriate documentation to allow for all inspectors to apply the rule consistently. The Board's own definition of "essentially a copy" is as determined by the prescribing practitioner, not the pharmacist. Likewise, the pharmacist is not the one that makes the determination that the medication is required, but does document the determination on the prescription.	staff note that the commenter appears to suggest that a pharmacist does not have an obligation to exercise clinical judgment when compounding or dispensing a medication. The Board believes it is important to underscore that pharmacists must exercise clinical judgment in all aspects of practice and not simple defer their judgment to another individual. This is obligation is memorialized throughout Pharmacy Law, including notably BPC Section 4306.5.
11	1735.1(e) (1)(A)	CSHP Cedars-Sinai Torrance Memorial Wedgewood Pharmacy Kaweah Health	The ASHP and FDA drug shortage lists do not always reflect 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. 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. This proposed regulation has the potential to dramatically impact public health by disabling health system pharmacies in their efforts to provide life-saving medications to acutely ill patients during the scenarios above. (e)(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, <u>or in a health care facility licensed pursuant to Health and Safety Code Section 1250 where the drug product cannot be obtained from the manufacturer or wholesaler and documentation is maintained, or</u> (B) The pharmacist determines and documents that the <u>preparation</u> produces a clinically significant	Board staff have reviewed the comment and appreciate that the commenter has raised this issue. Staff note that the Board agreed with the policy raised in this comment related to sterile compounding. Board staff agree that a similar accommodation is appropriate for nonsterile compounding, specifically for inpatients of a hospital and suggests the following modification. <u>1735.1(e)(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 in a health care facility licensed pursuant to Health and Safety Code Section 1250 where the drug product cannot be obtained from the manufacturer or wholesaler and documentation is maintained, or</u>

			difference based on the medical need of an identified individual patient	
12	1735.1(e)(2)	Dan Baxter CA Veterinary Medical Assoc Alliance for PHY Compounding Wedgewood Pharmacy	Is made with any component not suitable for use in a CNSP for the intended ~~veterinary~~ <u>animal</u> population, unless allowable under the Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA) <u>and, if applicable, the Federal Food and Drug Administration Guidance for Industry #256 (GFI 256).</u>" Commenter requests the inclusion of the reference to the Federal Drug Administration's Guidance for Industry #256 (GFI 256), in addition to the current reference to the Animal Medicinal Drug Use Clarification Act (AMDUCA). While AMDUCA is relevant to the provisions at issue, it alone does not provide the level of detail and specific guidance needed for licensees to understand what is allowable in compounding compounded nonsterile preparations and compounded sterile preparations. AMDUCA amended the Federal Food, Drug, and Cosmetic Act to legalize extralabel drug use (ELDU) under a valid veterinarian-client-patient relationship (VCPR), and to specify conditions and requirements for use, record keeping, and labeling according to FDA regulations. In August of 2022, the FDA developed and published GFI 256, which serves as an inclusive list of active pharmaceutical ingredients permissible for use in compounding medications for animal patients. FDA has generally exercised enforcement discretion with regard to animal drug compounding from bulk drug substances under certain circumstances. Namely, the FDA recognizes that many vital animal drugs are unavailable in FDA-approved form and that veterinarians must be able to treat animals with needed medications, despite the pharmaceutical industry's inability or unwillingness to bring them to market. GFI 256 is intended to provide clarity to veterinarians and pharmacists about the FDA's current thinking on compounding from APIs. The guidance identifies the FDA's enforcement priorities regarding animal drugs compounded from bulk drugs substances and describes the circumstances under which the FDA does not intend at this time to take enforcement action for violations of the Food, Drug and	Board staff have reviewed the comment and believe the commenter may be referring to separate issues within a single comment. In this response staff will respond to the portion of the comment that appears to be related to the provisions in (e)(2) specifically related the GFI #256. Staff note that the suggestion to incorporate GFI #256 was reviewed by staff and an external expert on veterinary compounding. The expert reported that inclusion of the GFI #256 is ill-advised. Staff recommend the following change in response to the comment. <u>(e)(2) Is made with any component not suitable for use in a CNSP for the intended veterinary population, unless allowable under the Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA). ~~When a veterinarian acting within a valid veterinarian-client-patient relationship (VCPR), determines there is no medically appropriate human or animal drug that is FDA-approved, conditionally approved, or indexed to treat the animal a pharmacy may use a bulk drug substance to compound an animal drug. This compound shall be in compliance with the Center for Veterinary Medicine Guidance for Industry #256 – Compounding Animal Drugs from Bulk Drug Substances issued August 2022.~~</u> The Board believes it is important to underscore that pharmacists must exercise clinical judgment in all aspects of practice including veterinary compounding. This obligation is memorialized throughout Pharmacy Law, including notably BPC Section 4306.5.

			Cosmetic Act with respect to the compounding of animal drugs from bulk drug substances.	
13	1735.1(e)(1) and (e)(2)	Alliance for PHY Compounding	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. 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. The final compounding regulations should reference GFI #256 where it applies to animal drug compounders. 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? As written, this eliminates the compounding 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. APC recommends aligning with what is required in the FDA's Essential Copy Guidance document, which does require documentation when a pharmacist dispenses a medication for which a change is made so it is not a copy of an FDA-approved product. The prescriber makes the determination that the compound is required, and the Board should not intend to question the prescriber's judgement. We also recommend that California provide examples of appropriate documentation to allow for all inspectors to	Board staff have reviewed the comment and believe the commenter may be referring to separate issues within a single comment. In this response staff will respond to the portion of the comment that appears to be related to the provisions in (e)(2), specifically related to GFI #256. As stated previously, board staff recommend the following change. <u>1735.1(e)(2) Is made with any component not suitable for use in a CNSP for the intended veterinary population, unless allowable under the Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA). ~~When a veterinarian acting within a valid veterinarian-client-patient relationship (VCPR), determines there is no medically appropriate human or animal drug that is FDA-approved, conditionally approved, or indexed to treat the animal a pharmacy may use a bulk drug substance to compound an animal drug. This compound shall be in compliance with the Center for Veterinary Medicine Guidance for Industry #256.- Compounding Animal Drugs from Bulk Drug Substances issued August 2022.~~</u> The Board believes it is important to underscore that pharmacists must exercise clinical judgment in all aspects of practice including veterinary compounding. This obligation is memorialized throughout Pharmacy Law, including notably BPC Section 4306.5.

			apply the rule consistently. The Board's own definition of "essentially a copy" is as determined by the prescribing practitioner, not the pharmacist. Likewise, the pharmacist is not the one that makes the determination that the medication is required, but does document the determination on the prescription.	
14	1735.1(e)(1)(B)	Kaweah Health	<u>Recommend</u> : strike (B)(iii) to be consistent with proposed language in 1736.1(e)(1)(B) unless there is a compelling reason the language for CNSPs in this section needs to vary. If staff do not agree with the above recommendation, the staff recommended modified changes should be clarified to improve readability and at minimum a renumbering is required. There is a B(iii) without a B(i) or B(ii).	Board staff have reviewed the comment and note that the language referenced in the comment was already identified for removal in the prior comment period.
15	1735.1(f)	Outsourcing Facilities Association	The proposed amendment should not be adopted, for the reasons stated in §§ A–D, <i>infra</i>. (see comment for specific reasons)  OFA Public Comment Proposed	Board staff have reviewed the comment. [Note while the comment referenced 1735.1(f), Board staff believe the comment is related to 1735.1(e).] Board staff note that the suggested conflict is proposed to be resolved through an update to the definition section, referenced, above to proposed section 1735 (d). Conforming change is also necessary in 1735.1(e)(1)(B) as follows: <u>1735.1(e)(1)(B) The pharmacist ~~determines verifies~~ and documents that the compounding produces a clinically significant difference for the medical need of an identified individual patient, as determined by:</u>
16	1735.1(f)	Keck / USC	This requirement exceeds current FDA guidance for the industry and will impose an unjustified burden on health-system pharmacies, creating gaps in patient care and negatively affecting clinical outcomes. The FDA guidance uses the term "should" when discussing compounding in 503A facilities. By prohibiting this practice, the BOP would impose a burden on inpatient hospital pharmacy licensees and negatively impact patient outcomes when a drug is unavailable within the institution, yet there is an urgent clinical need. Additionally, determining that the compounded product produces a clinically significant difference for the medical need of a patient will be challenging and subjective. Maintaining retrievable	Board staff note that the commenter referenced the wrong section. [Note while the comment referenced 1735.1(f), Board staff believe the comment is related to 1735.1(e).] In response to this and other comments received Board staff recommend a change to the proposed regulation text. The language recommended is the following: <u>1735.1(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</u>

			justification documentation each time a medication is compounded will burden operations and may impact timely patient care. Furthermore, USP 795 allows for any CNSP compounding when the master formulation record (MFR) is available. To allow for continuity of care, change the language to “In addition to prohibitions and requirements for compounding established in federal law, <u>no CNSP should</u> be prepared that”.	<u>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 in a health care facility licensed pursuant to Health and Safety Code Section 1250 where the drug product cannot be obtained from the manufacturer or wholesaler and documentation is maintained, or</u>
17	1735.1(f)(1)(A)	Walgreens	Understandably, the Board would like to impose strict and clear guardrails for compounding to inspect and enforce when commercially available products are on the market. However, the language will cause issues for patients and limit their ability to access compounded medications, especially in times of need. 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 and the board should weigh the pros and cons of trusting manufacturers to appropriately report shortages of their medications. Walgreens suggests the board allow the compounding of a copy or essentially a copy of a commercial product so long as there is a clinically significant, therapeutic reason, such as a documented allergy or product shortage. (A) the drug product appears in an American Society of Health- System Pharmacists (ASHP) or FDA Drug Shortages Database ~~that~~ <u>or</u> are in short supply at the time of compounding ~~and at the time of dispensing,~~ or	Board staff have reviewed the comment and believe the commenter is referring to the new proposed 1736(e)(1)(A). Board staff have reviewed the comment and do not recommend a change in the proposed text. Staff note that the use of a compounded drug (which can create higher risks to patients) when an FDA manufactured product is available. Further staff notes that the FDA has stated that “A drug ‘appears on the drug shortage list in effect under section 506A’ if the drug is ‘currently in shortage’ status (and not in “resolved status) in the FDA’s drug shortage database. The FDA notes: “Commercially available drugs are available on the market, and they are generally subject to FD&C Act requirements relating to approval, labeling, and CGMP requirements, and the copies restriction applies to all such drugs because section 503A is not intended to provide a means for compounders to produce compounded drugs exempt from the Act’s requirements that are essentially copies of commercially available drug products.”
18	1735.1(i)	CVS Health	If the Board is to consider flavoring as compounding, CVS Health requests an exemption to labeling. We also believe that the compounding cleaning and record keeping requirements are excessive for flavoring. While we prefer that flavoring is exempted from compounding, we understand the Board to not be amenable. Thus, in order for CVS Health to consider flavoring prescriptions in California, we request	Board staff have reviewed the comment and appreciate the commenter providing recommendations to help facilitate the compounding with a flavoring agent. Board staff recommend the addition a subdivision specifically related to flavoring agents and an addition to 1735.1(i) related to compounding by combining a

		the following, which is mainly derived from the Missouri Board of Pharmacy's 2020 Pharmacy Practice Guide: <i>(i) Using sound professional judgment, a pharmacist may authorize the flavoring of a prescription unless the prescriber expressly prohibits flavoring upon issuing the prescription.</i>	flavoring agent with an FDA approved drug in an oral liquid solution. The recommended text is provided below. ~~(i) 1735.1(i) A facility that limits compounding to combining a flavoring agent with a prescribed FDA approved drug in an oral liquid dosage form at the request of a prescriber, patient or patient's agent shall be exempt from the requirements established in subdivision (f) and Sections 1735.2 – 1735.13~~ ~~1735.15. Flavoring Agents.~~ ~~(a) In addition to the standards in USP Chapter 795 and Food Drug Cosmetic Act (FDCA) section 503a (21 U.S.C. §353a) a facility that limits its compounding as described in Section 1735.1(i) shall establish the following SOPs:~~ ~~1. Provisions of accommodations as described in Personnel Preparation, Section 3.1 of USP Chapter 795~~ ~~2. Provisions for cleaning and sanitizing designated compounding area when in use.~~ ~~3. Provisions to ensure documentation is available and maintained confirming the quality of the medication is not impacted by the adding of the flavoring agent.~~ ~~4. Provisions for maintaining the elements of the compounding record to ensure information is readily retrievable upon request.~~ ~~5. Provisions to ensure the prescription label includes information that a flavoring agent was added.~~ ~~6. Provisions to ensure documentation is available to support the establishment of a BUD.~~

				~~(b) A pharmacist may compound by combining a flavoring agent with a prescribed FDA approved drug in an oral liquid dosage form at the request of the patient or patient's agent without consultation with the prescriber or the prescriber's authorized agent. A pharmacist performing such compounding must document the compounding on the prescription record.~~
19	1735.2(c)	Alliance for PHY Compounding	Having people who 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 compounding entirely. If they fail compounding of capsules, it does not generally mean they could not continue to compound suspensions provided that they had passed the training for that dosage 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.	Board staff have considered the comment and do not recommend changes to the proposed regulation text based solely on this comment. The Board amended this section following the 45-day comment period to focus on the core competencies established in the USP Chapter. This will permit the supervising pharmacist to continue to oversee compounding for the specified time.
20	1735.3(a)	Stanford Health Care Alliance for PHY Compounding	Comment: This language does not align with the BOP's requirement for sterile compounding. The BOP's proposed section 1736.3 does not require a supervising pharmacist to evaluate all sterile compounding personnel for specific contaminating conditions before entering the compounding area. This requirement may not be feasible for a high-volume pharmacy (e.g., a large hospital pharmacy) with numerous employees who may be asked to compound at any given time. Additionally, supervisors have raised concerns that this may require them to ask staff personal questions about their health conditions, which may be seen as inappropriate. Remove language to be consistent with USP 795, where it is the responsibility of the compounding person to report contaminating conditions to the designated person(s); or 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	Board staff have reviewed the comment and do not recommend a change to the proposed text based on this comment. Commenter is suggesting that the Board remove the current flexibility provided in the proposed text and instead prohibit any such personnel. Board staff believe the current approach providing flexibility to the worksite for nonsterile compounding is appropriate and consistent with the USP 795 Chapter.

			them to compounding. Requiring the pharmacist to inspect their team prior to compounding for all the listed items will create HR-related challenges and is not realistic. Revise the language to read: "If the supervising pharmacist observes personnel experiencing any of the conditions mentioned above and determines that such personnel pose a risk to CNSPs or the environment, the supervising pharmacist shall prohibit the individual from entering the compounding area."	
21	1735.4(b)	John Gray Kaiser Walgreens	~~Purified water, distilled water, or reverse osmosis water, or higher quality water shall be used for rinsing equipment and utensils.~~ The Board has still not provided any empirical evidence of untoward effects associated with the water used to rinse equipment and utensils used for non-sterile compounding. Instead of providing actual evidence to substantiate the purported risk, the Board has added additional unreferenced, unsubstantiated risks to its Modified Initial Statement of Reasons. Because the Board has no concrete evidence to support the need for this regulation and because USP Chapter 795 adequately addresses the recommended use of purified, distilled, or reverse osmosis water for rinsing equipment and utensils, we continue to recommend that this requirement be deleted. If the Board chooses not to delete this requirement, then we encourage the Board to provide a definition of the term "higher quality water."	Board staff have reviewed the comment and do not recommend any change to the proposed regulation text. Staff note that USP identifies various grades of water including in Section 4.3 of the Chapter for rinsing; however, the permissive language of the Chapter is not appropriate given the patient safety concerns described below. Staff notes that the quality of water is of significance for patient safety as contaminated water will contaminate the equipment used for CNSP. It is relevant to note that the Chapter requires the use of specific water in the preparation of the CNSP. Allowing for the use of tap water then for example, undermines the patient protection of the higher quality water used in the CNSP. As an example, tap water may be contaminated with fungus, bacteria, and other elements that could contaminate the equipment used in the preparation of CNSPs. It is important to note that this section of the proposed regulation text speaks to rinsing (as opposed to cleaning).
22	1735.4(c)	Alliance for PHY Compounding	APC Recommendation: California regulations could reference FDA's Insanitary Conditions guidance for clarity.	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that a pharmacist may determine that additional standards established in the FDA's Insanitary Conditions Guidance can be incorporated into the facility's SOPs.

23	1735.5 (a)	Walgreens	Commenter believes this is unnecessary and overly burdensome language that does not improve patient safety. This language could be interpreted to require pharmacies to list the specific brand or manufacturer of commonly used cleaning and sanitizing products Requiring pharmacy teams to follow USP guidelines and instructions for cleaning is sufficient to ensure patient safety. <u>Recommended:</u> (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.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. Staff note that it is regrettably a common occurrence for a pharmacy to be unable to provide inspector staff with the name of cleaning and sanitizing agents used. Failure to maintain documentation of the products used prevents the facility and the Board from verifying compliance with SOPs established.
24	1735.5(c)	CVS Health	If the Board is to consider flavoring as compounding, CVS Health requests an exemption to labeling. We also believe that the compounding cleaning and record keeping requirements are excessive for flavoring. While we prefer that flavoring is exempted from compounding, we understand the Board to not be amenable. Thus, in order for CVS Health to consider flavoring prescriptions in California, we request the following, which is mainly derived from the Missouri Board of Pharmacy's 2020 Pharmacy Practice Guide: <i>(c) When flavoring a prescription, this section is satisfied when cleaning and sanitizing measuring devices only.</i>	Board staff have reviewed the comment and thank the commenter for offering recommendations to facilitate compliance with compounding with flavoring agents. Board staff recommend the addition a subdivision specifically related to flavoring agents and an addition to 1735.1 (i) related to compounding by combining a flavoring agent with an FDA approved drug in an oral liquid solution. Further staff recommend adding next section 1735.15 Flavoring Agents. The draft text is provided in response to the comment from CVS related to 1735.1 (i).
25	1735.6(a)	Stanford Health Care	Comment: Manufacturer specifications are not always available for all compounding equipment (e.g., mortar and pestle). Recommendation: Revise language to read: "Any equipment used to compound a CNRP shall be used in accordance with the manufacturer's specification or, in the absence of such specifications, in accordance with professional standards for use."	Board staff have reviewed the comment. While staff believe the language is sufficiently clear, submission of the comment indicates otherwise. Board staff believe additional clarification of the language may be appropriate to provide that a manufacturer's specifications for use must be followed when provided by the manufacturer. Staff note that where a manufacturer has provided specifications for use, such specifications MUST be followed. 1735.6.(a) In addition to the standards set forth in USP Chapter 795, the following requirements apply

				to nonsterile compounding. (a) Any equipment used to compound a CNSP shall be used in accordance with the manufacturer's specifications, <u>where established by the manufacturer.</u>
26	1735.7(a)(1)	Walgreens	We ask the board to clarify and specify the requirement for readily retrievable at the time of compounding. Does the board intend for this information to be immediately available to the compounding pharmacist or just available and retrievable if requested by the pharmacist or board? If the board's intent is for the pharmacist to have the source referenced for the master formulation record in hand at the time of compounding, this would further limit locations that could provide compounding services. USP monographs are widely referenced for beyond- use date assignments; however, access to these monographs is limited and cost prohibitive for many pharmacies. Often, if requested by the compounding pharmacist, a copy of the materials supporting the extended BUD will and can be provided but are not sent to the pharmacist for review, unless requested. Recommended language: (1) If a source is referenced to support the assigned beyond-use date (BUD), each source referenced shall be <u>available upon request prior to compounding</u> ~~readily retrievable at the time of compounding and shall be retrievable maintained~~ for three years from the date each CNSP is dispensed.	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff notes that the term "readily retrievable" is used throughout Pharmacy Law and its regulations. Board staff suggest that if the Board wishes to define this term, it should be separate from this discussion as it would impact several other areas of Pharmacy Law.
27	1735.7(c)(1)	John Gray Kaiser Stanford Health Care Alliance for PHY Compounding CVS Health	Commenters request the elimination of "and time" or clarification with respect to what "time" is referring to. Possible additional language is: "(1) The date and time of compounding, which is the time when compounding the CNSP <u>began, and is the time from which the assigned BUD is determined.</u>"	Board staff have reviewed the comments and believe a change to the proposed language as suggested is appropriate. Board staff believe deletion of (c)(1) is appropriate. 1735.7(c)(1) The date and time of compounding, which is the time when compounding the CNSP started, and which determines when the assigned BUD starts.
28	1735.7(c)(2)	UC San Diego	Current language in CCR 1735.3 below has a provision for CSPs compounded in health facilities to prevent delays in	Board staff have reviewed the comment and do not recommend a change to proposed text. Staff note

		CSHP Cedars-Sinai Torrance Memorial UC Health	care to acutely ill patient, i.e. infections, cancer, critical care, etc. To prevent delays in care to acutely ill patients, recommend striking (c)(2) or add an exemption for health care facilities licensed under section 1250 of the Health and Safety Code.	that upon inspections, inspectors note that health systems maintain this information within its electronic system. The noticed proposed text in the 30-day comment period specifically provides that a facility is not required to maintain the information in a single document. If information is required by the Board, the information must be retrieved from the electronic system and provided to the Board as a single document.
29	1735.7(c)(2)	Alliance for PHY Compounding	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. Per the Civil Code, "Trade secret" means information, including a formula, pattern, compilation, program, device, method, technique or process that (1) derives independent economic value, actual or potential, from being generally known to the public or to other persons who can obtain economic value from its disclosure or use, and (2) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy. Some pharmacy vendors maintain that the manufacturers they source API from is a trade secret and disclosure would cause economic injury.	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments. Staff note that while existing law provides flexibility to record the manufacturer under limited circumstances, continuation of the current provision is not appropriate as it hampers the ability of a facility to respond appropriately in the event of a product recall. Staff further note that the Board's proposed regulation text is more explicit than the Chapter for the reasons cited elsewhere in this response. Staff note that the Chapter requires either the recording of the manufacturer or vendor; however, in separate guidance issued by the FDA, the facility needs to have transparency into the supply chain and awareness of the manufacturer (where the manufacturer and vendor are different.) The FDA has released guidance in this area, including the importance of a compounders knowing your suppliers - - https://www.fda.gov/drugs/human-drug-compounding/fda-compounders-know-your-bulks-and-excipientssuppliers . Lastly, simply identifying the manufacturer of a component without more does not appear to be requiring the disclosure of a trade secret under Civil Code section 3426.1(d).
30	1735.7(c)(4)	Alliance for PHY Compounding	Compounding software programs typically require the metric quantity of a batch prepared, but do not document the quantity of each individual unit.	Board staff have reviewed the comment and do not recommend a change to the proposed text. Board have reviewed the USP Chapter referenced and

			Proposed modified text was edited to “the total quantity, or amount compounded, which shall include the number of units made and the volume or weight of each unit, where applicable.” Recommend aligning with USP Chapter <905>, <i>Uniformity of Dosage Units</i> , for ease of compliance.	note that the intent of the referenced chapter is to ensure the consistency of dosage units, each unit in a batch should have a drug substance content within a narrow range around the label claim. Dosage units are defined as dosage forms containing a single dose or a part of a dose of drug substance in each unit. The Board's proposed regulation text in this subdivision is related to documentation for a compounding record.
31	1735.7(c)(5)	Stanford Health Care	Comment: <i>The pharmacist who has direct supervision and control of compounding is often the pharmacist verifying the final drug preparation.</i> Recommendation: <i>Revise language to read:</i> “(5) The identity of personnel performing the compounding, the pharmacist verifying the final drug preparation, as well as the pharmacist who has direct supervision and control of compounding <u>if different from the pharmacist verifying the final drug preparation.</u>”	Board staff have reviewed the comment. While staff believe the language is sufficiently clear, submission of the comment suggests otherwise. Board staff believe the additional language submitted by the commenter may provided additional clarity to the regulated public. 1735.7(c)(5) The identity of personnel ~~each person~~ performing the compounding, ~~pharmacist the person~~ who has direct ~~oversight~~ <u>supervision and control</u> of compounding, and the pharmacist verifying the final drug preparation, if different. (Note: with the recommended deletion of 1735.7(c)(1) above, this paragraph will be renumbered to 1735.7(c)(4).)
32	1735.7(d)	CVS Health	If the Board is to consider flavoring as compounding, CVS Health requests an exemption to labeling. We also believe that the compounding cleaning and record keeping requirements are excessive for flavoring. While we prefer that flavoring is exempted from compounding, we understand the Board to not be amenable. Thus, in order for CVS Health to consider flavoring prescriptions in California, we request the following, which is mainly derived from the Missouri Board of Pharmacy's 2020 Pharmacy Practice Guide: <i>(d) When flavoring a prescription, this section is satisfied by only notating the act of flavoring in the pharmacy's prescription record, including in a logbook or in the prescription record.</i>	Board staff have reviewed the comment and thank the commenter for offering recommendations to facilitate compliance with compounding with flavoring agents. Board staff recommend the addition a subdivision specifically related to flavoring agents and an addition to 1735.1(i) related to compounding by combining a flavoring agent with an FDA approved drug in an oral liquid solution. Further staff recommend adding next section 1735.15 Flavoring Agents. The draft text is provided in response to the comment from CVS related to 1735.1(i).

33	1735.9(d)	CVS Health	If the Board is to consider flavoring as compounding, CVS Health requests an exemption to labeling. We also believe that the compounding cleaning and record keeping requirements are excessive for flavoring. While we prefer that flavoring is exempted from compounding, we understand the Board to not be amenable. Thus, in order for CVS Health to consider flavoring prescriptions in California, we request the following, which is mainly derived from the Missouri Board of Pharmacy's 2020 Pharmacy Practice Guide: <i>(d) When flavoring a prescription, this section is satisfied by indicating that the product was flavored on the patient's container.</i>	Board staff have reviewed the comment and thank the commenter for offering recommendations to facilitate compliance with compounding with a flavoring agents. Board staff recommend the addition a subdivision specifically related to flavoring agents and an addition to 1735.1(i) related to compounding by combining a flavoring agent with an FDA approved drug in an oral liquid solution. Further staff recommend adding next section 1735.15 Flavoring Agents. The draft text is provided in response to the comment from CVS related to 1735.1(i).
34	1735.10 (a)	Stanford Health Care	Comment: Electronic health record (EHR) systems use the 24- hour format for time entries. Recommendation: Revise language to include 24-hour time format (e.g., 23:59).	Board staff have reviewed the comment. While staff believe the language is sufficient clear, submission of the comment indicates clarification may be necessary. Board staff believe modification to the language can provided additional clarity to the regulated public. 1735.10. Establishing Beyond-Use Dates. In addition to the standards set forth in USP Chapter 795, the following requirements apply to nonsterile compounding. (a) Beyond-use dates (BUDs) assigned with only a date shall expire at 11:59 p.m. ~~or 23:59~~ on that date.
35	1735.10 (c)(1)	CVS Health	CVS Health is supportive of prescription flavoring within our pharmacies and supportive of the overwhelming majority of states who do not consider flavoring as compounding. We believe that the increased potential for adherence to medication regimens and thus increased public safety for California residents (particularly children) is evident and any perceived risk to public safety has not been substantiated with data or evidence.	Board staff have reviewed the comment and believe that the intent of the comment was to express the commenter's support of flavoring. Staff note that the commenter did not appear to offer any recommended changes specifically to this section of the proposed text.
36	1735.10 (b)(1)	Alliance for PHY Compounding	Components such as pH adjusters should be excluded from impacting the BUD of the formula on. 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	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that USP Chapter 795 does not establish provisions such as those referenced by the commenter. Board staff agree with the USP Expert

			have a 1-day BUD. Recommend aligning with USP's approach to exclude pH adjusters from the determination of the BUD.	Committee that this is not necessary. Staff note that this comment would be relevant in the compounding of a sterile preparation.
37	1735.10 (b)(2)	Alliance for PHY Compounding	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. There are several USP chapters that apply to leachables and extractables. They apply to manufacturers making packaging materials and do not apply to pharmacies. USP 795 10.2 does indicate that a pharmacy should consider leachables, but does not indicate that the pharmacy itself must conduct leachable studies.	Board staff have reviewed the comment and do not recommend changes to the proposed text. USP Chapter 795, Section 10.2 specifies that when establishing a BUD for a CNSP, compounders MUST consider parameters that may affect quality, including compatibility of the container closure system with the finished preparation (e.g. leachables). The Chapter requires this be done. The comment appears to suggest that the pharmacy itself must conduct the leachable studies. The Board's proposed regulation text does not require the pharmacy to conduct the test, rather it requires the pharmacist to ensure that the BUD does not go beyond what the parameters reveal to support the BUD, which could be done by review of a test conducted outside of the pharmacy. Any cost incurred for this determination (e.g. leachables) are a function of compliance with the Chapter, not the Board's regulations. The Board's regulations merely ensure that a pharmacist uses the information it obtains through the USP requirements in establishing a BUD to not exceed the parameters.
38	1735.11 (a)(1)	Alliance for PHY Compounding Wedgewood Pharmacy	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." Recommendation: USP Chapters above 1000 are for informational purposes only. They contain no mandatory tests, assays, or other requirements applicable to any article, regardless of citation in a general chapter below 1000 , a monograph or these General Notices. The Board's assertion that it is just listing out all the tests required on API (and other	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Board staff note that the Initial Statement of Reasons documents the basis for inclusion of USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. Business and Professions Code section 4126.8, establishes compliance with pharmacy compounding chapters. Staff further notes, USP has stated, "Although it is possible for FDA or another government authority in the U.S. or elsewhere to require the use a USP General Chapter numbered 1000 to 1999, the

			requirements in Chapters above 1000) is untrue. Per USP, these tests are not required, even if they are cited in chapters below 1000. We recommend removing all requirements for pharmacies outlined in the proposed regulations that reference USP chapters above 1000.	authority in question would need to make this requirement expressly applicable under law, regulation, or another appropriate vehicle that prescribes enforceable requirements."
39	1735.11 (a)(2)(E)	Alliance for PHY Compounding	The statement "validated processes" is unclear and undefined. APC recommends changing the wording to "process validation" as it has a specified definition and is not up for interpretation.	Board staff have reviewed the comment do not recommend a change to the proposed text. Staff note that it does not believe that full "process validation," is necessary. "Process validation" is a costly and extensive process defined as the collection and evaluation of data, from the process design stage through commercial production, which establishes scientific evidence that a process is capable of consistently delivering quality product. The FDA guidance describes process validation activities in three stages; 1) Stage 1 – Process Design, 2) Stage 2 – Process Qualification, 3) Continued Process Verification.
40	1735.12 (a)	Alliance for PHY 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." Recommendation: USP Chapters above 1000 are for informational purposes only. They contain no mandatory tests, assays, or other requirements applicable to any article, regardless of citation in a general chapter below 1000 , a monograph or these General Notices. The Board's assertion that it is just listing out all the tests required on API (and other requirements in Chapters above 1000) is untrue. Per USP, these tests are not required, even if they are cited in chapters below 1000. We recommend removing all requirements for pharmacies outlined in the proposed regulations that reference USP chapters above 1000.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Board staff note that the Initial Statement of Reasons documents the basis for inclusion of USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. Business and Professions Code section 4126.8, establishes compliance with pharmacy compounding chapters. Staff further notes, USP has stated, "Although it is possible for FDA or another government authority in the U.S. or elsewhere to require the use a USP General Chapter numbered 1000 to 1999, the authority in question would need to make this requirement expressly applicable under law, regulation, or another appropriate vehicle that prescribes enforceable requirements."

41	1735.12 (a)(2)	John Gray Kaiser	~~(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.~~ 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 Modified 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." 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 require pharmacies to store drugs at the appropriate temperature, the proposed regulation in 1735.12(a)(2) is unnecessary.	Board staff have reviewed the comment. Board staff thank the commenter for underscoring the applicability of CCR 1714(b) that extends to all drug storage areas within a hospital. With that common understanding, Board staff believe that the recommended change by the commenter to delete proposed text 1735.12(a)(2) is appropriate. 1735.12. ~~(a) (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.~~
42	1735.12 (b)	John Gray Kaiser CSHP Alliance for PHY Compounding	~~The Board shall be notified in writing within 72-96 hours of the facility's receipt of a complaint of a potential quality problem or the occurrence of an adverse drug experience as defined in 21 CFR 310.305(b) drug event involving a CNSP.~~ The modified regulation text references the definition of the term "adverse drug experience" provided in federal regulations pertaining to drug manufacturers and distributors. The referenced definition of the term adverse drug experience is too broad and would explicitly include untoward effects resulting from "intentional overdoses, drug abuse, and failures of expected pharmacological action." 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 requirement in existing law ensures that the Board is notified of serious quality and safety issues while reducing the administrative burden associated with reporting events that	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that BPC 4126.9 requires reporting to the Board only in the event of a recall. The proposed regulation text requires notification specifically regarding a complaint of a potential quality problem or an unexpected ADE. Nothing in the proposed regulation text is intended to require reporting of an expected outcome stemming from the intended use of a compounded preparation for a specific outcome, such as, a patient dying after taking an aid-in-dying drug.

			are in no way related to the quality of products compounded by the pharmacy (e.g., intentional overdose). One could argue that, as written, the proposed regulation would require a pharmacy to report cases in which it becomes aware that an individual died after ingesting an aid- in-dying drug under the California End of Life Option Act.¹⁴ Given these factors, we recommend deleting this requirement from the proposed regulation. If the Board believes that this additional requirement to report adverse drug events to the Board be maintained in the regulation, then we encourage the Board to modify the regulation to align the requirement with Business and Professions Code section 4127.1(f). If the language is not stricken, amend to read: (b) The Board shall be notified in writing within 96 hours of the facility's receipt of a complaint of a potential quality problem or and the occurrence of a serious and unexpected adverse drug experience as defined in 21 CFR 310.305(b) involving a CNSP.	
43	1735.12 (c)	Cedars-Sinai Torrance Memorial	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 <u>3 business days</u> ~~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.	Board staff have reviewed the comment and do not recommend a change in the proposed staff. Staff are concerned that a "business day" varies greatly depending on the practice site and differing operating hours.
44	1735.13	Alliance for PHY Compounding	The statement "validated processes" is unclear and undefined. APC recommends changing the wording to "process validation" as it has a specified definition and is not up for interpretation.	Board staff have reviewed the comment do not recommend a change to the proposed text. Staff note that it does not believe that full "process validation," is necessary. "Process validation" is a costly and extensive process defined as the collection and evaluation of data, from the process design stage through commercial production, which establishes scientific evidence that a process is capable of consistently delivering quality product.

				The FDA guidance describes process validation activities in three stages; 1) Stage 1 – Process Design, 2) Stage 2 – Process Qualification, 3) Continued Process Verification.

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1	1736(c)	Stanford Health Care	Comment: Can the pharmacist-in-charge assign themselves to be the designated person? For smaller pharmacies with a limited number of employees, it may be difficult to identify someone interested and willing to take on the responsibilities of the designated person. Recommendation: Revise language to allow the pharmacist-in-charge the option to assign themselves to be the designated person.	Board staff have reviewed the comment. While Board staff believe the language would allow for the PIC to also serve as the designated person, the comment submitted indicates that may not be the case. As such, Board staff recommend a change to the proposed text to provide clarity to the proposed regulation text. 1736(c) Designated person(s) means one or more individuals assigned by the pharmacist-in-charge to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of the compounded nonsterile preparations ("CNSP") for the purposes of this article). Nothing in this definition allows for a designated person to exceed the scope of their issued license. When the designated person is not a pharmacist, the Pharmacist-in-Charge (PIC) must review all practices related to the operations of the facility that require the professional judgment of a pharmacist. Nothing in this definition shall prohibit the PIC from also serving as the designated person.
2	1736(e)	Alliance for PHY Compounding	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. APC recommends aligning with what is required in the FDA's Essential Copy Guidance document, which does require documentation when a pharmacist dispenses a medication for which a change is made so it is not a copy of an FDA approved product. The prescriber makes the determination that the compound is required, and the Board should not intend to question the prescriber's judgement. We also recommend that California provides examples of appropriate documentation to allow for all inspectors to apply the rule consistently. The Board's own	Board staff have considered the comment and do not recommend a change to the proposed text. Staff note that as written, the language provides flexibility for a clinician to use their professional judgment when determining if a compound is essentially a copy. Should the Board amend the language to include the recommended text, the Board would be limiting this flexibility and a clinician's professional judgment. Staff note that it appears the commenter is referring to a draft definition provided in an FDA guidance document (as opposed to the language contained within FDCA 503a). The legal federal definition, similar to the Board's proposed regulation, requires that the compound must produce a significant

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			definition of "essentially a copy" is as determined by the prescribing practitioner, not the pharmacist. Likewise, the pharmacist is not the one that makes the determination that the medication is required, but does document the determination on the prescription.	difference in the patient. The Board's proposed text is clarifying federal law to ensure the significant difference is clinical in nature. Such an approach provides flexibility for a pharmacist to use clinical judgment.
3	1736.1	Assoc of NorCal Oncologists and Medical Oncology Assoc. California Rheumatology Alliance CA Medical Association CalDerm	We are concerned that the proposed regulations will require a pharmacist to be present during these types of activities, which would be an onerous burden on community sites of care, particularly those in rural settings. ANCO and MOASC are concerned that these proposed regulations, if adopted, would result in cancer patients being forced to obtain their chemotherapy at a hospital or infusion center, which would place new burdens on patients who are already fighting for their lives. 1736.1: In addition to the standards set forth in USP Chapter 797 and Food Drug Cosmetic Act (FDCA) section 503a (21 U.S.C. §353a) the following requirements apply throughout this article. This article shall not apply to compounding by or under the direct supervision of a licensed physician and surgeon.	Board staff have reviewed the comment and do not recommend a change to the proposed text based on the comment. Staff note the Board's jurisdiction are individuals and businesses within its practice act. Board staff read the comment as suggesting that the Board's proposed regulations would apply to a physician. Business and Professions Code section 4170(c) makes provides clear statutory reference that the Medical Board of California is specifically charged with the enforcement of Pharmacy Law (Chapter 9, Division 2) with respect to its licensees. Further, Business and Professions section 4111 generally establishes prohibitions on individuals that can own a pharmacy. Specifically, 4111(a)(1) prohibits a person or persons authorized to prescribe or write a prescription from owning a pharmacy. It may be appropriate for the commenter to confer with their licensing board to determine in the practice described if the scenario described their comment is allowable. Board staff note that the Medical Board of California has previously provided a written response to individuals inquiring about the applicability of the Board of Pharmacy's regulations to individuals and practices that operate under the jurisdiction of the Medical Board of California. Below is the information provided from the Medical Board - - Dear Ms. Sodergren: I understand that some concerns have been raised by stakeholders about the applicability of the Board

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				of Pharmacy's pending compounding regulations to licensees of the Medical Board of California (MBC). Existing statute (see Business and Professions Code (BPC) section 2220.5) makes it clear that only the MBC can discipline its physician licensees. Whenever a physician is engaging in compounding (or any other action that their medical license authorizes them to perform) they must always do so consistent with the standard of care. For the purposes of MBC's enforcement program, the standard of care is established by expert testimony in the context of the facts and circumstances of a specific case. It is certainly possible that whatever regulations that are implemented by the Board of Pharmacy may influence the standard of care for physicians who are compounding, especially since some of the proposed regulations reflect what is already required for physician compounding under federal law, including, but not limited to, Section 503A of the Federal Food, Drug, and Cosmetic Act (BPC section 2225(b) allows MBC to investigate violations of federal law related to the practice of medicine). Feel free to share this message with others as you see fit who might also be concerned about the applicability of their pending regulations to the physician community. Please contact me if you have any further questions. Sincerely, Reji Varghese
4	1736.1(b)	John Gray Kaiser Keck/USC	~~(b) (1) Except as allowed in paragraph (2), 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. If not already documented in the patient's medical record, documentation for each such CSP shall also include identification of the CSP, the compounded~~	Staff have considered the comment and note that the language in the proposed text is similar to existing regulation CCR Section 1751.8(e), including the current requirement to document the circumstances causing the immediate need. Staff note that to align with USP BUD provisions, the Board has removed the current one hour start time and will instead allow the four-hour start time provided for in the revised USP Chapter.

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			~~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.~~ ~~(2) If the sterile compounding equipment or environment fail(s) to meet any required specification, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering of an identifiable patient. This provision may only be used for 24 hours after such failure(s). All such failures must be documented in accordance with facility's SOP and shall be reported to the BOP within 72 hours.~~ While we acknowledge that this proposed regulation is similar to the existing requirements for immediate use compounding in 16 CCR 1751.8(e), we continue to assert that neither the current regulation nor the proposed regulation are necessary. First, the USP 797 Chapter provides sufficient guidance on the preparation of immediate use CSPs. More importantly, continuing to enforce these requirements will incentivize organizations to shift compounding to non-pharmacy personnel in situations in which immediate use compounding is necessary, Kaiser encourages the Board to delete this proposed regulation and enforce the USP standards for immediate use compounding.	Staff note that the Board's regulations focus on patient safety in all compounding environments. Investigations have revealed that some entities have defaulted to immediate use provisions for all compounded preparations. Staff believe that there are times when, for patient safety, the use of immediate use compounding is appropriate; however, such occurrences should not be a standard practice.
5	1736.1(b)(1)	Bobgo1970@gmail.com	Only allows immediate use compounding if "failure to administer such CSP could result in loss of life or intense suffering of an identifiable patient." and in the case of equipment/environment failure. The USP797 has no such requirement. Please remove this requirement.	Staff have considered the comment and note that the language in the proposed text is similar to existing regulation CCR Section 1751.8(e), including the current requirement to document the circumstances causing the immediate need. Staff note that to align with USP BUD provisions, the Board has removed the current one hour start time and will instead allow the four-hour start time provided for in the revised USP Chapter. Staff note that the Board's regulations focus on patient safety in all compounding environments.

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				Investigations have revealed that some entities have defaulted to immediate use provisions for all compounded preparations. Staff believe that there are times when, for patient safety, the use of immediate use compounding is appropriate; however, such occurrences should not be a standard practice.
6	1736.1(b)(2)	UC San Diego CSHP Cedars-Sinai Torrance Memorial UC Health Alliance for PHY Compounding Kaweah Health	Requiring health-system pharmacies to remedy equipment failures within 24 hours may not be feasible due to a variety of reasons why there could have been equipment failures. Often times, it may take more than 24 hours to remedy. To use outside facility or vendor to provide compounding preparations would still pose a safety risk as they may not be following the health-systems processes and procedures. Given the concerns about potential audits, institutions may hesitate to report issues to the Board of Pharmacy. We urge the Board to embrace a 'Just Culture' framework, which emphasizes accountability and learning over punitive measures. To remove the requirement for immediate use compounding under this provision to be used for 24 hours after such failure(s), and requiring such failures must be documented in accordance with facility's SOP and shall be reported to the BOP within 72 hours. Or (2) If the sterile compounding equipment or environment fail(s) to meet any required specification, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering of an identifiable patient. This provision may only be used for 24 hours 7 business days after such failure(s). All such failures must be documented in accordance with facility's SOP and shall be available for inspection. reported to the BOP within 72 hours.	Board staff have reviewed the comment and recommend a change to the proposed text. Board staff note that the proposed text currently would provide a pharmacy (or hospital pharmacy) 24-hours to implement their action plan in the event of an equipment failure. (Note: Existing regulations do not include such an allowance.) The intent of the proposed regulation text provides the opportunity to implement a facility's backup plan (as opposed to developing and implementing a backup plan at the time failure). After further consideration of the comment, staff are recommending additional amendment to clarify the provision and extend the allotted time for immediate use compounding to 48-hours. <u>1736.1(b)(2) If the sterile compounding equipment or environment fail(s) to meet any required specification, ~~after attempts to remediate pursuant to the facility's SOPs are unsuccessful,~~ an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering of an identifiable patient. This provision may only be used for ~~24 48~~ hours after such failure(s). All such failures must be documented in accordance with facility's SOP and shall be reported to the BOP within 72 hours.</u>

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7	1736.1(d)	WedgeWood Pharmacy	Change terminology "veterinary office" to "veterinary practice". Mobile veterinarians practice in the field, not an office. Eliminate the words "Reasonable quantity". Clauses 1 and 2 of this provision and the phrase "estimated by the prescriber" establish clear criteria for the amount of office stock drugs that can be ordered and sold. The prescriber is in the best position to determine based on their practice the amount of drugs that are appropriate. A pharmacy has no reasonable basis to determine what a particular practice may need particularly when the practice is permitted to both administer drugs in office and dispense. Align sterile and non-sterile to the 7-day supply standard. Current language in 1736.1 (d)(2) lists 120 hours.	Board staff have conferred with a veterinary expert who indicated that the Board's reference to "veterinary office" is appropriate and consistent with language used in the VMB regulations and GFI #256. Further staff have reviewed the comment related to the day supply included in the proposed text. Staff recommend that the Board extend the provision to the 7-day supply as requested. The following language could be used: <u>1736.1(d)(2) for furnishing of not more than a ~~120-hour~~ 7-day supply for an individual patient, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing;</u>
8	1736.1(d)(2)	Donald Cottman	As written, it limits the provision of compounds for a vet to furnish to "an individual patient... and documented...prior to furnishing." The furnishing to the office for an individual patient prevents the office from having products available for immediate furnishing, when needed. The "for an individual patient" requirement requires the office to provide a name, then the pharmacy can send it to the office, who could then furnish it to the patient. This is the same as the pharmacy dispensing it themselves to an individual patient. Pharmacy law already allows a pharmacy to send a patient's prescription to the office for the office to then furnish to the patient. This regulation, if that is the intent, would be redundant of existing regulation.	Board staff have reviewed the comment and do not recommend any change to the proposed text based on the comment. Staff note that provisions for office use relate only to veterinary office provisions as specified.
9	1736.1(e)(1)	Alliance for PHY Compounding WedgeWood Pharmacy	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.	Board staff have reviewed the comment and do not recommend a change to the proposed text based on the comment received. Board staff note that the provisions related to veterinary compounding are provided in 1736.1(e)(2).

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			The final compounding regulations should reference GFI #256 where it applies to animal drug compounders.	Staff note a recommendation to include reference to the GFI in section 1736.1(e)(2). (See below)
10	1736.1(e)(2)	Alliance for PHY Compounding Wedgewood Pharmacy	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 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. The phrase "not suitable for use in the intended veterinary population" is ambiguous and unnecessary. If a drug or excipient is toxic to a specific animal population, professional judgment and existing pharmacy practice standards already preclude its use. The reference to AMDUCA in this context is also problematic. AMDUCA permits the off-label use of FDA-approved human and animal drugs in veterinary patients but does not address compounding or bulk drug substances. The law neither explicitly allows nor prohibits compounding from bulk drug substances, and its inclusion in the regulation creates unnecessary confusion. FDA's Guidance for Industry 256 allows for the use of bulk drug substances in compounded animal medications when there is a clinical rationale, but this guidance is not a law or regulation restricting such practices. Recommend removing the reference to AMDUCA or revising the regulation to explicitly protect the ability to compound using bulk drug substances.	Staff note that the suggestion to incorporate GFI #256 was reviewed by staff and an external expert. Board staff are recommending the following change to the proposed regulation text to incorporate reference to GFI #256. <u>1736.1(e)(2) Is made with any component not suitable for use in a CNSP for the intended veterinary population, unless allowable under the Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA). When a veterinarian acting within a valid veterinarian-client-patient relationship (VCPR), determines there is no medically appropriate human or animal drug that is FDA-approved, conditionally approved, or indexed to treat the animal a pharmacy may use a bulk drug substance to compound an animal drug. This compounding shall be done in compliance with the Center for Veterinary Medicine Guidance for Industry #256 – Compounding Animal Drugs from Bulk Drug Substances issued August 2022.</u>
11	1736.1(e)(3)	Alliance for PHY Compounding	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 compounding set-up, using a conventionally 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	Board staff have reviewed the comment and recommend a change to the proposed regulation text to provide flexibility for a pharmacist to use their clinical judgment to determine which USP Category the CSP must be prepared under. A pharmacist, using their professional clinical judgment will be responsible for determining the USP category.

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			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 nonsterile ingredients already shortens the BUD of the final product. Does "conventionally manufactured" mean commercially available? APC recommends allowing for compounding with non-sterile starting ingredients outside of full Category 3 requirements or shortages when it makes more sense for the product to be compounded with API rather than finished form injectable products.	The below text could be used. 1736.1(e)(3) Is made with a non-sterile component for which a conventionally manufactured sterile component is available ~~and appropriate for the intended CSP, unless the CSP master formula supports such use and is appropriate for the intended CSP. is compounded in full compliance with USP 797 Category 3 requirements, or the conventionally manufactured sterile component appears in an American Society of Health-System Pharmacists (ASHP) or FDA Drug Shortages Database.~~
12	1736.1(e)(3)	Donald Cottman	This regulation will completely exclude licensed pharmacies, typically smaller ones, from the ability to provide compounding in an environment that have been accepted as a standard of practice, have been implemented in compliance with those standards, and have established patient populations dependent on access to their services. To suddenly have these pharmacies and their compounds be excluded from serving patients is a grave injustice to pharmacy owners, California prescribers, and California patients. Additionally, to state that a non-sterile to sterile preparation can be made as a category 2 if it is in shortage, but not at other times is illogical with respect to protecting the public. If it is not safe for a licensed pharmacy to prepare a particular non-sterile to sterile product in a Category 2 environment on a routine basis, why is it suddenly acceptable for the public to get it from them during a shortage? The Board should decide that it is either appropriate, or not appropriate, for non-sterile to sterile compounding to be performed under USP Category 2 conditions. Commenter cannot understate the extreme hardship this regulation would impose on licensed pharmacies to the detriment it represents to California patient access to medications.	Board staff have reviewed the comment and recommend a change to the proposed regulation text to provide flexibility for a pharmacist to use their clinical judgment to determine which USP Category the CSP must be prepared under. A pharmacist, using their professional clinical judgment will be responsible for determining the USP category. The below text could be used. 1736.1(e)(3) Is made with a non-sterile component for which a conventionally manufactured sterile component is available ~~and appropriate for the intended CSP, unless the CSP master formula supports such use and is appropriate for the intended CSP. is compounded in full compliance with USP 797 Category 3 requirements, or the conventionally manufactured sterile component appears in an American Society of Health-System Pharmacists (ASHP) or FDA Drug Shortages Database.~~

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13	1736.1 (e) (4)	Alliance for PHY Compounding Wedgewood Pharmacy	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? Recommendation: E-beam sterilization is an FDA approved process. It is recognized and accepted by international standards organizations, and should be allowed.	Staff have reviewed the comment and do not recommend any changes to the proposed regulation text. Staff note that on September 25, 2019, this issue was raised. At that time, counsel advised members that "based on her research of 503A subdivision (a) (1), the federal exemption applies to a state licensed pharmacy that exempts the pharmacy from the manufacturer requirements when compounding. Business and Professions Code sections 4127 and 4127.1 specifically reference the compounding has to occur in a sterile compounding pharmacy – a singular pharmacy – and the license is not transferable thereby emphasizing all compounding exempted under the federal law that can occur in a compounding pharmacy has to occur in a single licensed facility." Board counsel added at that time there are no statutory exemptions and would expect all aspects of compounding to occur in the single regulated unit.
14	1736.1 (h)	UC San Diego CSHP UC Health	The current health and safety code section 1602.5 states the following: 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.) 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.	Board staff have reviewed the comment. While Board staff believe the language is clear, submission of the comment suggests otherwise. Board staff are offering language that could further clarify the Board's policy. <u>1736.1(h) CSPs with human whole blood or human whole blood derivatives shall be produced in compliance with Health and Safety Code section 1602.5. This shall not apply to the compounding of an FDA- approved human whole blood or human whole blood derivative product.</u>

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			(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.	
15	1736.2(b)	Stanford Health Care	Comment: It is unclear whether "aseptic qualifications" include hand hygiene and garbing competencies (observational competency and gloved fingertip and thumb sampling) or if it pertains to aseptic technique competencies only. Recommendation: To avoid confusion, be more specific with what sterile compounding competencies are transferrable <u>between pharmacy locations or define "aseptic qualifications."</u>	Board staff have reviewed the comment and agree with the commenter that clarification of the language may be appropriate. <u>1736.2(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. ~~Garbing and hand hygiene competencies and Aseptic qualifications manipulation competencies~~ from one premises may be used for another premises if all of the following conditions are met:</u> <u>(1) The Standard Operating Procedures (SOPs) required by section 1736.17 related to compounding are identical.</u> <u>(2) The Secondary Engineering Control (SEC) facility designs are sufficiently similar to accommodate the use of the same SOPs.</u> <u>(3) The PECs are of the same type and sufficiently similar to accommodate the use of the same SOPs describing use and cleaning.</u>
16	1736.2(b)	CSHP	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. Recommend the Board consider removing the requirement of "PEC unique identifier". Proposed Revision: Initial and ongoing aseptic manipulation training and competency documentation shall include the Primary	Staff have reviewed the comment. Staff note that the requirement to document would occur once every three to six months. Staff note that the unique identifier is necessary to identify where the competency was performed. Staff note that maintaining the PEC unique identifier provides the facility with the location of the equipment and is consistent with the standard of practice. The

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			Engineering Control (PEC) type and PEC unique identifier used during the evaluation.	language provides flexibility for each facility to determine the PEC unique identifier, e.g. hood 2.
17	1736.2(d)	UC San Diego Cedars-Sinai Torrance Memorial UC Health	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: (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 <u>may continue to provide only direct oversight including performing in-process checks, final verification, and dispensing of CSPs for no more than 30 days after a failure of any aspect while applicable aseptic manipulation ongoing training and competency evaluation results are pending.</u> Recommended revisions are underlined in italics for emphasis. While there is no modified text to provide public comment on in this section, public comment was submitted for the proposed changes to the current language with acknowledgment of review by staff but no recommended changes to the proposed text, noting that the current proposed text provides for flexibility in where gloving can occur by stating that the facilities SOPs may	Board staff have considered the comment and do not recommend changes based on this comment. Staff note that an individual that fails any aseptic manipulation for example can compromise the integrity of the product. Staff note that with the recent changes in the proposed regulation text that was released for the 30-day comment period, provisions were already extended to allow an individual that has failed aspects of aseptic manipulation to continue oversight of compounding for 30-days. This time period was established to allow for retraining and sufficient time to process the results of the retesting. Staff have significant patient safety concerns going beyond the 30-day timeframe for any individual that fails any aspect of the core competencies established in the Chapter to be involved in compounding of sterile compounding preparations. Compounding of CSPs is a high-risk function that if not done appropriately can have dire impacts on patients. Staff note that in adverse event reports it is common that a contributing factor was the training of the staff. Staff highlight that a person with direct oversight over personnel, who fail any aspect competency assessment may continue to provide such oversight for 30 days. Staff note that the comment related to donning and doffing is responded to below in the proposed responses to comments related to 1736.3(c).

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			define specific processes. Respectfully disagree with staff response, the proposed text as it reads provides flexibility specific to <u>simultaneous donning and doffing</u> in the anteroom. Please reconsider. <u>Rationale:</u> Current language as proposed is in conflict with USP 797 in regards to donning of sterile gloves. See section 3.2 Hand Hygiene (last sentence above Box 4).	
18	1736.3(a)	Donald Cottman	There is no definition of "potentially contaminating condition" and there is a "shall not allow" requirement. Without a definition, it cannot be determined if compliance has been achieved.	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that "potentially contaminating condition" is the term used in the chapter. A pharmacist, using their professional clinical judgment will be responsible to determine if such a condition exists as specified in the language.
19	1736.3(c)	Kaweah Health	<u>Recommend:</u> Revise language to read " <u>With the exception of sterile gloves</u> , garb shall be donned in an anteroom or immediately outside the segregated compounding area (SCA). <u>Sterile gloves must be donned in a classified room or SCA.</u> 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.	Board staff have reviewed the comment and agree with the commenter and that the proposed text should be clarified to avoid confusion. Below is text that could be used. <u>1736.3(c) With the exception of sterile gloves, garb shall be donned in an anteroom or immediately outside the segregated compounding area (SCA). Sterile gloves must be donned in a classified room or 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.</u>
20	1736.3(d) and (e)	Donald Cottman	What is being affected by this regulation is the prevention of passive-air movement, typically though low in doors, from an ante-room and uncontrolled room air. This requirement would require the ante-room be sealed off from the room air so only the HVAC system would push air into the room (through HEPA filters) and remove air from the room through return ducting. This is contrary to basic design principles of HVAC systems. HVAC systems REQUIRE the ability to have air flow out of the area to accommodate normal variations between	Board staff have reviewed the comment and believe the comments are related to 1736.4 (e). Board staff agree with the commenter that the proposed text requires modification. Board staff believe the subsection can be removed. Staff note that the Chapter addresses many of the different forms of penetration. ~~1736.4(e) Except as provided in subsection (d), dynamic interactions between areas and rooms~~

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			the air flowing in from supply and the air leaving by returns. Due to the fluid-dynamics of air flow, these are NEVER in perfect balance and need passive points of overflow. In addition, the point of overpressuring a room's supply relative to its return is so that when the door is opened, the positive pressure pushes air out of the room. The industry standard design, and long standing history of success, and the basic physics of HVAC design REQUIRE passive airflow connections between the cleanroom and the surrounding room air.	~~with classified air and unclassified air shall be controlled through a heating, ventilation, and air condition (HVAC) system.~~
21	1736.4(c)	John Gray Kaiser Stanford Health Care CSHP Cedars-Sinai Torrance Memorial	Because the proposed regulation is not clear, we suggest that this section of regulation be deleted and that the Board simply enforce the USP standard for the temperature of the compounding suite. USP defines room temperature storage as a temperature range of 20°C to 25°C.	Board staff have reviewed the comment and do not recommend any change to the proposed regulation text. Staff note that CCR 1751.4(k) currently requires that the sterile compounding area in the pharmacy shall have a comfortable and well lighted working environment, which typically includes a room temperature of 20 degrees Celsius or cooler to maintain comfortable conditions. Further, USP Chapter 797, Section 4.2 discusses facility design and environmental controls and notes that in addition to minimizing airborne contamination, sterile compounding facilities must be designed and controlled to provide a well-lighted and comfortable working environment. The Chapter provides that the cleanroom suite should be maintained at a temperature of 20 degrees or cooler and a relative humidity of 60% or below to minimize the risk of microbial proliferation. The Board's current regulation and its proposed language provides flexibility by providing the temperature must typically meet the requirements. This allows for some minor fluctuations, while addressing the necessity established in the Chapter.
22	1736.4(f)	Torrance Memorial	In smaller rural hospitals, this proposed law in combination with CCR 1736.1 Introduction and Scope. Subsection (b) would lead to severe consequences for	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that compounding facilities must have

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			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. Recommend the Board of Pharmacy to consider removing the requirement of CCR. 1736.4 subsection (f) and defer to USP 797.	back-up plans in their SOPs so that in the event of a failure in the compounding environment, to ensure provisions for patient care can continue. This flexibility is established in another section of the proposed regulations allowing for transition to immediate use provisions while implementing the back-up plan. However, staff appreciate the reference to the unique challenges of rural hospitals and believe that a change to 1736.1(b)(3) is appropriate to allow a longer duration of time for immediate use provisions for critical access hospitals. The following text could be used. Additional changes in 1736.1(b)(2) are recommended based on additional comments referenced elsewhere in this document. ~~1736.1(b)(3) If a critical access hospital, as defined in the Social Security Act 42 U.S.C. 1395i-4 section (c)(2)(B), experiences a sterile compounding equipment or environment failure to meet any required specification, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering of an identifiable patient. This provision may only be used for 120 hours after such failure(s). All such failures shall be documented in accordance with facility's SOP and shall be reported to the Board within 72 hours.~~
23	1736.5(b)	Donald Cottman	The pharmacy cannot control the output of reports from vendors, so having a "shall be recorded on the report" is overly restrictive. It is reasonable to instruct that the PIC shall document what standard the vendor used in preparing the report.	Board staff have reviewed the comment do not recommend changes to the proposed text. Board staff note that a facility, if concerned about this requirement, can make this a condition of the contract with the vendor. Inspector staff have provided education to various vendors performing certifications to underscore the legal requirement to include this information in the report.
24	1736.6(a)	Kaweah Health	<u>Recommend</u> : modify the language to include the current versioning and application guide title. Allow the	Board staff have reviewed the comment and recommend a change to the proposed text. Staff

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			public an opportunity to comment after having had an opportunity to review the specific version of the application guide the regulated public will be expected to comply with. <u>Rationale:</u> Proposed language presented for public comment during the 45-day comment period April 19th, 2024 to June 3, 2024 and the modified changes to the proposed language presented for public comment during the 30-day comment period November 8, 2024 to December 9, 2024 did not include the correct versioning or title of CAG-009. CAG-009 version 2020 document is not available for the regulated public to review to determine if compliance can be achieved. The most current version is 2023, the title of the current application guide is Viable Environmental Monitoring for Sterile Compounding Facilities.	have confirmed that CAG 009 was most recently revised September 2020. As the proposed regulation text references the incorrect title and wrong month, staff are recommending a change to accurately reflect the title and revision date. <u>1736.6(a) Environmental sampling shall be done in compliance with Controlled Environment Testing Association's Certification Application Guide USP Viable Environmental ~~Monitoring for Sterile Compounding Facilities Sampling & Gowning Evaluation~~ (CAG-009, Revised ~~September 2022~~ 2020), which is hereby incorporated by reference.</u>
25	1736.8	Donald Cottman	Having a regulation stating that you must comply with another regulation is redundant. Delete.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. Board staff believe the cross-reference to the other regulation serves as an important reminder that SOPs are specifically required for introducing items into an SEC or PEC.
26	1736.9(d)	Alliance for PHY Compounding	Most excipient components are sold by FDA-registered 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. Per the Civil Code, "Trade secret" means information, including a formula, pattern, compilation, program, device, method, technique or process that (1) derives independent economic value, actual or potential, from	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments. Staff note that both the USP and the FDA have released information to assist pharmacists in determining what is suitable for use in sterile pharmaceuticals when the pharmacist is using professional judgment in making the decision. The FDA has at times released information about contacting the manufacturer of the API to determine its intended use. Pharmacists should similarly consider taking such action. Staff note that the Chapter requires either the recording of the manufacturer or vendor; however, in separate guidance issued by the FDA, it notes

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			being generally known to the public or to other persons who can obtain economic value from its disclosure or use, and (2) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy. Some pharmacy vendors maintain that the manufacturers they source API from is a trade secret and disclosure would cause economic injury.	that a facility needs to have transparency into the supply chain and awareness of the manufacturer (where the manufacturer and vendor are different.) The FDA has released guidance in this area, including the importance of a compounders knowing your suppliers -- https://www.fda.gov/drugs/human-drug-compounding/fda-compounders-know-your-bulks-and-excipientssuppliers . Lastly, simply identifying the manufacturer of a component does not appear to be requiring the disclosure of a trade secret under Civil Code section 3426.1(d)."
27	1736.9(d)	Donald Cottman	FDA registered wholesalers consider source manufacturer information proprietary and will not provide it directly to pharmacies. Language that would allow a PIC to have an agreement with wholesalers that they are willing to provide, under NDA, this information directly to the BOP upon request, would accomplish the same effect and be agreeable to wholesalers.	Board staff have considered the comment and do not recommend a change to the proposed text. As stated elsewhere in this document, the FDA has released information on this topic.
28	1736.9(e)	Alliance for PHY Compounding	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 CSP will harm California patients who require these medications, and who cannot get them otherwise. Items in FDA's Interim Bulks List 1 are allowed to be used in compounded drug products by the FDA and every other state. They should not have requirements that are different than any other API. Pharmacies must use a grade of API that is appropriate for sterile compounding. Stability studies are not required for other API compounded under Category 1 or 2, and will limit patient access to specialized therapies like inhaled glutathione. There is no point in endotoxin testing API and then also requiring endotoxin testing of the CSP.	Board staff have reviewed the comment and believe the comment is in relation to 1736.17(a)(2)(e). Board staff do not recommend a change to the proposed regulation text based on the comment. Staff believe that the commenter may be misunderstanding some of the language in the proposed regulation. The Board's proposed text will explicitly allow for compounding of certain bulk drug substance under specified conditions. In staff's view the commenter is not correctly characterizing the FDA's Interim Bulks List. The Board strongly encourages all individuals interested in FDA's Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act to read this guidance document in its totality to gain a full understanding of the provisions.

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				The Board has been clear about its intentions to create a legal pathway in California to compound using bulk ingredients on the FDA's Category 1 list. Board staff believes that the language of the proposed text aligns the enforcement discretion articulated by the FDA and also meets the provisions of the USP 797 Chapter through the requirement to develop SOPs that establish provisions for additional testing and evaluation. The FDA has released information that explicitly states there is value in testing. The Board received a presentation that included information about an FDA warning specifically related to glutathione that demonstrated, through subsequent testing of the involved API, that endotoxins of the API caused harm to patients. Testing the API before the use of the API provides a pharmacist with information necessary to use their clinical judgment to determine if the API is in fact appropriate for use in the CSP to be compounded. Endotoxin testing of the API will enable the pharmacist to determine if the API is grossly contaminated and therefore rendered either safe or unsafe through the filtration process.
29	1736.9(e)(1)	Donald Cottman	There is no definition of what a "public health official" nor "emergency use situation". This allows that person to approve for use in compounding a drug without a monograph, nor having been FDA approved drug, not on on the bulks list... which means this allows a public health official can approve the compounding of an unapproved drug, for a specific patient, upon their definition of an emergency use situation. This does not seem to be in the public's best interest.	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Board staff note that while the regulation itself does not include a definition of "public health official," this term is commonly understood. Board staff further notes that although very rare, there was a prior instance where a child required a compound that was ordered by a public health official to prevent the death of the child. Inclusion of the language will provide assurances to a pharmacist facing such a scenario to provide the compounded medication should such a condition arise in the future.

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30	1736.10	Alliance for PHY Compounding	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 numbered below 1000, a monograph, or these <i>General Notices</i>." Recommendation: USP Chapters above 1000 are for informational purposes only. They contain no mandatory tests, assays, or other requirements applicable to any article, regardless of citation in a general chapter below 1000, a monograph or these <i>General Notices</i>. The Board's assertion that it is just listing out all the tests required on API (and other requirements in Chapters above 1000) is untrue. Per USP, these tests are not required, even if they are cited in chapters below 1000. We recommend removing all requirements for pharmacies outlined in the proposed regulations that reference USP chapters above 1000.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Board staff note that the Initial Statement of Reasons documents the basis for inclusion of USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. Business and Professions Code section 4126.8, establishes compliance with pharmacy compounding chapters. Staff further notes, USP provides, "Although it is possible for FDA or another government authority in the U.S. or elsewhere to require the use a USP General Chapter numbered 1000 to 1999, the authority in question would need to make this requirement expressly applicable under law, regulation, or another appropriate vehicle that prescribes enforceable requirements."
31	1736.10(e)	Alliance for PHY Compounding	This would prevent the use of e-beam or gamma-irradiation sterilization methods, which are performed off-site at validated facilities. E-beam sterilization is an FDA approved process. It is recognized and accepted by international standards organizations, and should be allowed.	Staff have reviewed the comment and do not recommend any changes to the proposed regulation text. Staff note that on September 25, 2019, this issue was raised. At that time, counsel advised members that "provided based on her research of 503A subdivision (a) (1), the federal exemption applies to a state licensed pharmacy that exempts the pharmacy for the manufacturer requirements when compounding. Business and Professions Code sections 4127 and 4127.1 specifically reference the compounding has to occur in a sterile compounding pharmacy – a singular pharmacy – and the license is not transferable thereby emphasizing all compounding exempted under the federal law that occur can in a compounding pharmacy has to occur in a single licensed facility." Board counsel added at that time there are no statutory exemptions and would expect all aspects of compounding to occur in the single regulated unit.

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32	1736.11(c) (2)	UC San Diego CSHP Cedars-Sinai Torrance Memorial UC Health	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. Add back the language above: 1736.11 Master Formulation and Compounding Records, subsection (c)(3) The manufacturer, lot number, and expiration date shall be recorded for each component for CSPs. <i>(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.</i>	Board staff have reviewed the comment and do not recommend a change to proposed text. Staff note that current regulations provide an exemption to the compounding record requirement. Staff do not believe that the exemption is still appropriate. Staff note that inspections reveal that health systems and other facilities generally maintain this information within its electronic system or other documentation. Recalls can occur requiring action at the patient level. Maintenance of this information is essential to identify impacted patients. Collection of this information also allows facilities to maintain documentation of compliance with manufacturer approved labeling provisions. The recent proposed changes in the 30-day comment period provided further clarification that the information required in this subsection does not need to be maintained in a single document. Such an approach is providing flexibility in how a pharmacy maintains this information.
33	1736.11(c) (4)	Stanford Health Care	Comment: The pharmacist who has direct supervision and control of compounding is often the pharmacist verifying the final drug preparation. Recommendation: Revise language to read: (4) The identity of personnel performing the compounding, the pharmacist verifying the final drug preparation, as well as the pharmacist who has direct supervision and control of compounding, <u>if different from the pharmacist verifying the final drug preparation.</u>	Board staff have reviewed the comment. While staff believe the language is sufficiently clear, submission of the comment indicates otherwise. Board staff believe the additional language submitted by the commenter may provide additional clarity to the regulated public. 1736.11(c)(4) The identity of ~~each personnel person~~ performing the compounding, ~~pharmacist that~~ who has direct ~~oversight~~ supervision and control of compounding, and the pharmacist verifying the final drug preparation, <u>if different.</u>

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34	1736.12(b)	Alliance for PHY Compounding	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. Recommendation: USP Chapters above 1000 are for informational purposes only. They contain no mandatory tests, assays, or other requirements applicable to any article, regardless of citation in a general chapter below 1000, a monograph or these General Notices. The Board's assertion that it is just listing out all the tests required on API (and other requirements in Chapters above 1000) is untrue. Per USP, these tests are not required, even if they are cited in chapters below 1000. We recommend removing all requirements for pharmacies outlined in the proposed regulations that reference USP chapters above 1000.	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that USP 797 Chapter references USP Chapter 1223 where it discusses alternative testing methods. The Board is not requiring a pharmacist to perform the testing required in USP Chapter 1223; however, the Board is explicitly stating that where an alternative method for sterility testing is used, a pharmacist must ensure the test used was compliant with Chapter 797 requirements. Staff further notes, USP provides, "Although it is possible for FDA or another government authority in the U.S. or elsewhere to require the use a USP General Chapter numbered 1000 to 1999, the authority in question would need to make this requirement expressly applicable under law, regulation, or another appropriate vehicle that prescribes enforceable requirements."
35	1736.12(c)	Alliance for PHY Compounding	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 components and are not sterility tested only have a 4- day BUD. Typical endotoxin testing would not be available before the end of the BUD. Recommend aligning with USP standards for endotoxin testing.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Staff note that current regulation CCR 1751.7(e)(1) contains these requirements for batch-testing and is essential for patient safety. Staff note that endotoxin testing can be performed in house and completed within four hours. Further, the provisions of the proposed regulations are limited to injectable CSPs made from nonsterile components.
36	1736.13(a)	Cedars-Sinai Torrance Memorial	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	Board staff have reviewed the comment and recommend a change to the proposed text based on the comment. 1736.13(a)(s)(A)

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			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. Recommend updating the regulation to: A CSP label shall include all of the following and <i>these can also be readily retrievable from the EHR</i>: (1) Route of intended administration; (2) The solution utilized, if applicable; (3) <i>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.</i> ~~(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~~	(A) For an admixed CSPs administered by infusion, the rate of infusion, or range of rates of infusion as prescribed, or the duration for the entire CSP to be administered. ~~A health care facility licensed pursuant to Health and Safety Code Section 1250 may reference the patient's chart in lieu of rate of infusion when a patient's condition requires a variable rate.~~
37	1736.13(a)(3)(A)	Keck/USC	Displaying "rate of infusion, or range of rates of infusion" is not feasible to accomplish in many contemporary electronic medical record (EMR) systems. Most of labels for titratable medications display the rate as "As Directed", and the order details are specified in the EMR. 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 revising as follows: A) For an admixed CSP, the <u>rate of infusion, or range of rates of infusion as directed (unless the infusion rate is specified in a shared electronic medical record system)</u>, or the duration for the entire CSP to be administered.	Board staff have reviewed the comment and recommend a change to the proposed text based on the comment. 1736.13(a)(3)(A) (A) For an admixed CSPs administered by infusion, the rate of infusion, or range of rates of infusion as prescribed, or the duration for the entire CSP to be administered. ~~A healthcare facility licensed pursuant to 1250 may reference the patient's chart in lieu of rate of infusion when a patient's condition requires a variable rate.~~

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38	1736.14(a)(1)	Alliance for PHY Compounding	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.	Board staff have reviewed the comment. Staff note that while the issue addressed in the comment appears to be covered in the proposed text 1736.14(a)(1)(A), it appears that given the comment additional clarification to the language is necessary, staff believe amendment to the text may be appropriate by moving the language in 1736.14(a)(1)(A) to 1736.14(a)(3) <u>1736.14 Establishing Beyond-Use Dates.</u> <u>In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.</u> <u>(a) A CSP's beyond-use date (BUD) shall not exceed:</u> <u>(1) The chemical and physical stability data of the active pharmaceutical ingredient(s) and any added substances in the preparation; ~~(A) Nothing in this section shall prohibit the allowances in USP 797 section 14.3 for pH-altering solutions.~~</u> (2) The compatibility of the container-closure system with the finished preparation (e.g., possible leaching, interactions, and storage conditions); and <u>(3) The shortest remaining expiration date or BUD of any of the starting components. ~~Nothing in this section shall prohibit the allowances in USP 797 section 14.3 for pH-altering solutions.~~</u>
39	1736.14(b)	Stanford Health Care	Comment: Electronic health record (EHR) systems use the 24- hour format for time entries. Recommendation: Revise language to include 24-hour time format (e.g., 23:59).	Board staff have reviewed the comment. While staff believe the language is sufficient clear, submission of the comment indicates clarification may be necessary. Board staff believe modification to the language can provided additional clarity to the regulated public. 1736.14. (b) Beyond-use dates (BUDs) assigned with only a date shall expire at 11:59 p.m. ~~or 23:59~~ on that date.

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40	1736.14(c)	Alliance for PHY Compounding	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. Recommend aligning with USP, allowing release before receipt of sterility and endotoxin results as long as the pharmacy has a program in place in the event they need to perform a recall.	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that the language of the proposed text is consistent with current provisions in CCR 1751.7(e). Board staff note that the proposed regulation text allows for alternative forms of testing that provide results within 72 hours. The suggestion from the commenter would be contrary to requirements of Chapter 797 which states, "sterility testing performed and passed" for Category 2 when establishing a longer BUD. Staff further note that consistent with the Chapter's provisions, a shorter BUD can be established without sterility testing.
41	1736.17(a)(1)	Wedgewood Pharmacy	This has been mentioned in previous comment sections, USP Chapters above 1000 are for reference only and not intended to be a regulatory requirement.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Board staff note that the Initial Statement of Reasons documents the basis for inclusion of USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. Business and Professions Code section 4126.8, establishes compliance with pharmacy compounding chapters. Staff further notes, USP states that, "Although it is possible for FDA or another government authority in the U.S. or elsewhere to require the use a USP General Chapter numbered 1000 to 1999, the authority in question would need to make this requirement expressly applicable under law, regulation, or another appropriate vehicle that prescribes enforceable requirements."
42	1736.17(a)(2)(C)	Cedars-Sinai Torrance Memorial	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	Board staff have reviewed this comment and recommend a change to the proposed text. The proposed regulation text requires a method to determine and approve ingredients, which could include the use of a workflow system consistent with legal requirements.

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			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>(i) A sterile compounding workflow system may be utilized for verification of correct components used for preparing a CSP.</i>	1736.17(a)(2)(C) <u>(C) The methods ~~a pharmacist will~~ used to determine and approve the ingredients and the compounding process for each preparation before compounding begins; and</u>
43	1736.17(a)(2)(E)	Medisca	Medisca would like to highlight that there exist in the marketplace today bulk drug substances listed under 503A Category 1 (inclusive of dietary supplements) that have been manufactured in compliance with cGMP for Finished Pharmaceuticals (21 C.F.R. Part 210-211). Medisca requests that the Board amend the regulations to allow pharmacies to compound sterile preparations using such bulk drug substances without the additional requirements listed in 1736.17(a)(2)(E) if the supplier and/or manufacturer can provide evidence of compliance with 1736.17(a)(2)(E) and cGMP. Pharmacies should not have to repeat testing at the ingredient level where a supplier and/or manufacturer has provided evidence of cGMP compliance along with available data demonstrating successful testing for the defined ingredient specifications, as listed in the ingredient-specific Certificate of Analysis. If a supplier, like Medisca, can ensure the quality and safety of 503A Category 1 bulk drug substances with evidence of compliance with cGMPs for finished pharmaceuticals, the regulations should allow for their use in compounded sterile preparations.	Board staff have reviewed the comment and do not agree with the requested change. Staff note that while an API manufacturer may be an FDA registered facility, there is no ability for a compounder to confirm that the ingredient was produced under cGMPs. Staff note, however, that an SOP written to comply with this section could state, for example, that the facility relies upon the COA produced by the manufacturer, repackager, or wholesaler to documents compliance with the required specified standards. Should the Board believe additional clarity is necessary the following language could be used: <u>(E) The methods by which the pharmacist compounding or supervising the compounding pursuant to 1736.9(f) related to use of a bulk drug substance published in the 503A Category 1 bulk substances list, will ensure each lot of the bulk drug substance is representatively sampled per USP 1097 (bulk powder sampling procedures), tested, and found to be in compliance with at least:</u> <u>(i) USP Chapter 1, Injections and Implanted Drug Products (Parenterals) – Product Quality Tests</u> <u>(ii) USP Chapters 232 and 233 related to Elemental Impurities</u> <u>(iii) USP Chapter 467 – Residual Solvents.</u>

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				<u>(iv) USP Chapter 85 – Bacterial Endotoxins and</u> <u>(v) any other USP Chapters deemed appropriate</u> <u>based on the clinical judgment of the pharmacist</u> <u>developing the SOPs.</u> ~~(F) Nothing in paragraph (E) requires the facility to~~ ~~perform this testing when such testing is performed~~ ~~by the manufacturer, repackager or wholesaler and~~ ~~appropriate documentation provided.~~
44	1736.17(a) (2)(E)	Donald Cottman	It is unclear if "...the pharmacist... will ensure each lot... is representative samples...tested and found to be in compliance" requires that the pharmacist obtain samples and perform the tests or if having documentation from the FDA licensed wholesaler that testing was performed.	Board staff have reviewed the comment and do not agree with the requested change. Staff note that an SOP written to comply with this section could state, for example, that the facility relies upon the COA produced by the manufacturer, repackager, or wholesaler to documents compliance with the required specified standards. Should the Board believe additional clarity is necessary staff believe the following language could be used: <u>(E) The methods by which the pharmacist</u> <u>compounding or supervising the compounding</u> <u>pursuant to 1736.9(f) related to use of a bulk drug</u> <u>substance published in the 503A Category 1 bulk</u> <u>substances list, will ensure each lot of the bulk drug</u> <u>substance is representatively sampled per USP 1097</u> <u>(bulk powder sampling procedures), tested, and</u> <u>found to be in compliance with at least:</u> <u>(i) USP Chapter 1, Injections and Implanted Drug</u> <u>Products (Parenterals) – Product Quality Tests</u> <u>(ii) USP Chapters 232 and 233 related to Elemental</u> <u>Impurities</u> <u>(iii) USP Chapter 467 – Residual Solvents.</u> <u>(iv) USP Chapter 85 – Bacterial Endotoxins and</u> <u>(v) any other USP Chapters deemed appropriate</u> <u>based on the clinical judgment of the pharmacist</u> <u>developing the SOPs.</u>

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				~~(F) Nothing in paragraph (E) requires the facility to perform this testing when such testing is performed by the manufacture, repackager or wholesaler and appropriate documentation provided.~~
45	1736.17(a)(2)(F)	Donald Cottman	There is no definition of "potential quality problem" to determine if compliance has been achieved.	Board staff have reviewed the comment and believe the commenter is referring to 1736.17(f). Staff do not recommend a change to the proposed regulation text based on the comment. Staff note that USP Chapter 797 refers to CSP quality and quality problems throughout the Chapter. Staff also note that the proposed regulation text in CCR Section 1736(g) defines "quality." As a licensed health care professional, pharmacist must exercise professional judgment to make a determination based on the complaints received is indicative of a potential quality problem.
46	1736.17(d)	CSHP Cedars-Sinai Torrance Memorial	In many health-system pharmacies there are many items entering the sterile compounding spaces including into the SEC and PEC. The proposed language as it is written, could be interpreted to suggest that the SOP must state that how each item introduced from the unclassified space be cleaned and the contact time be timed and then this time be documented. 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 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	Board staff have reviewed the comment recommend a change to the proposed text to provide clarity. Board staff note that the proposed regulation text establishes the parameters for development and use of an SOP. The proposed regulation text does not establish the SOP requirements themselves. Development of the SOP must be developed by responsible individuals including the PIC and other designated staff. The SOPs themselves will determine how a facility will document compliance with its SOPs. As an example the "method to ensure" could be determined in the SOP as being done through random auditing. The proposed regulation text is intended to provide the facility flexibility in operationalizing the requirement through the development of the SOP. <u>(d) The SOPs shall specify the process and products to be used on any equipment and other items</u>

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			manufacturer recommended dwell times as part of sterile compounding practice and wish to point out the potential for misinterpretation during enforcement inspections. Recommendation (BOLD): (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 the method to ensure dwell time is achieved will be monitored and documented.~~	<u>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 contact dwell time required, and ~~how the method to ensure dwell time is achieved will be monitored and documented.~~</u>
47	1736.18(a)	John Gray Kaiser	(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 written procedure for scheduled action, such as a recall, in the event any compounded drug preparation is discovered to be outside the expected standards for integrity, quality, or labeled strength. We anticipate that hospitals and other health care facilities are the most likely entities to be impacted by the requirement for a facility's quality assurance program to include a written procedure for responding to out-of-range temperature variations within medication storage areas when a furnished drug may be returned for furnishing to another patient. In some cases, the procedure for managing this kind of temperature excursion might be jointly managed by several departments within the facility. We suggest amending the proposed regulation to clarify that a facility-wide procedure would meet this requirement.	Board staff have review the comment. While staff believe the current language is sufficiently clear, submission of the comment indicates otherwise. Board staff believe the additional language submitted by the commenter may provide additional clarity to the regulated public. 1736.18 Quality Assurance and Quality Control. In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding. 1738.18(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:
48	1736.18(c)	CSHP Cedars-Sinai Torrance Memorial	The way the regulation is written, suggests that the review must be completed within 72 hours since it states that "such review shall be documented and dated as defined in the SOPs." The proposed language requirement for a documentation and dating of the review together with the preceding sentence's	Board staff have reviewed the comment and do not recommend a change in the proposed text. Staff are concerned that the term "business day" could vary greatly based on the practice site and differing operating hours.

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		Alliance for PHY Compounding	requirement for review within 72 hours from the receipt of the complaint could be seen as requiring the review to be completed within the 72 hours timeframe. A requirement of 72 hours may not provide sufficient time for pharmacies to thoroughly investigate and determine root causes. It is reasonable to expect that a review after a complaint be started within three business days. Investigation could take longer than this due to many factors involved in such an investigation that needs to be looked at. Many of these may not be available or apparent within this timeframe. Recommendation (BOLD): We recommend that the intent of this proposed regulation be clarified with the following proposed language: (c) In addition to subsection (b), all complaints made to the facility related to a potential quality problem with a CSP and all adverse drug experiences events shall be reviewed by the pharmacist-in-charge and shall start within three (3) business days within 72 hours of receipt of the complaint or occurrence of the adverse drug experience. Such review shall be documented and dated as defined in the SOPs.	
49	1736.21(c)	CSHP Cedars-Sinai	If this proposed testing requirement would become regulation, it would create an immediate and permanent inability for pharmacies to be able to compound allergenic extracts for patients. What the proposed rule would require in practice, is that every stock solution for every patient be sent in to a laboratory for testing according to the requirements. It would create a waiting time for the results and add enormous cost to pharmacies, health plans and patients. It would further place enormous pressure on the supply chain of these products that would in effect stop the provision of these products to patients' access to these treatments. There is not enough staff and there are not enough laboratories or laboratory supplies in existence to perform these tests on the stock solutions for each and every patient being treated in the state of California.	Board staff have reviewed the comment and recommend a change to the text. Board staff thank the commenter for highlighting this issue. As part of its research into the comment, Board staff reviewed the USP 797 Commentary related to compounding allergenic extracts. Review of the USP commentary provides the following: Comment Summary #634: The commenter recommended allowing allergenic extract vials to be multiple-dose and still allow a 1-year BUD limit. Response: Comment not incorporated. Multiple-dose vials have increased risk of contamination. Compounding allergenic extracts is per individual patient prescription set only. The Compounding

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			Since this regulation would only apply to pharmacies, they may very likely decide to stop providing this service. This severe economic impact was not stated in the initial statement of reasons. As an alternative to this required testing, an alternate strategy could be followed by compounding stock solutions from scratch for each patient visit. This will have equally impactful consequences as explained in the next bullet point. ~~(c) Any compounded stock allergy 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.~~	Expert Committee has received feedback from stakeholders that small variations for allergenic extract prescription sets can lead to anaphylaxis and the smallest amount possible needs to be made all at once to avoid variations. Given this, Board staff believe it is appropriate to delete the provisions as suggested by the commenter. Staff note that significant education will be required as it believes that many pharmacies currently compound allergenic stock solutions. This is not allowed under the provisions of the USP Compounding Chapter. ~~(c) Any compounded stock allergy 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.~~

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1	1737	Cal/OSHA	Cal/OSHA is concerned that the proposed regulations partially duplicate but are less protective than certain Cal/OSHA regulations for employee health and safety. These parallel standards may in turn create confusion for the regulated community, which may comply with the less stringent and less protective regulation. Additionally, as drafted, the regulation may interfere with a statutory requirement under labor code 144.8 for Cal/OSHA to develop a regulation for the safe handling of anti-neoplastic drugs. Cal/OSHA recommends the addition of a note reading: Additional safety and health requirements are included in the California Code of Regulations, Title 8 and enforced by the Division of Occupational Safety and Health.	Board staff have reviewed the comment and believe that a reminder to licensees of the additional requirements under the purview of Cal/OSHA may be appropriate. Board staff recommend the inclusion of the requested language at the beginning of Article 4.7 1737. Handling of Hazardous Drugs. This article applies to the handling compounding of Hazardous Drugs (HDs) or performing "other manipulations" included in Table 1 of the Chapter of antineoplastic HDs, of Hazardous drugs established by United States Pharmacopeia (USP) General Chapter 800 (USP Chapter 800), titled Hazardous Drugs – Handling in Healthcare Setting. 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).~~ 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. ~~(b). Additional safety and health requirements are included in the California Code of Regulations, Title 8 and enforced by the Division of Occupations Safety and Health.~~
2	1737.1	Assoc of NorCal Oncologists and Medical Oncology Assoc.	We are concerned that the proposed regulations will require a pharmacist to be present during these types of activities, which would be an onerous burden on community sites of care, particularly those in rural settings. ANCO and MOASC are concerned that these proposed regulations, if adopted, would result in cancer patients being forced to obtain their chemotherapy at a hospital or infusion center, which	<i>Board staff have reviewed the comment and do not recommend a change to the proposed text based on the comment.</i> Staff note the Board only has jurisdiction over individuals and businesses within its practice act. Board staff read the comment as suggesting that the Board's proposed regulations would apply to a

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		California Rheumatology Alliance	would place new burdens on patients who are already fighting for their lives.	physician. Business and Professions Code section 4170(c) makes clear that the Medical Board of California is specifically charged with the enforcement of Pharmacy Law (Chapter 9, Division 2 of the Business and Professions Code) with respect to its licensees.
		CA Medical Association	§ 1737.1: In addition to the requirements in USP Chapter 800 and Food Drug Cosmetic Act (FDCA) section 503a (21 U.S.C. §353a) the following requirements apply to the compounding of Hazardous Drugs. This article shall not apply to compounding by or under the direct supervision of a licensed physician and surgeon.	It may be appropriate for the commenter to confer with their licensing board to discuss their concerns. Board staff note that the Medical Board of California has previously provided a written response to individuals inquiring about the applicability of the Board of Pharmacy's regulations to individuals and practices that operate under the jurisdiction of the Medical Board of California. Below is the information provided from the Medical Board - -
		CalDerm		Dear Ms. Sodergren: <i>I understand that some concerns have been raised by stakeholders about the applicability of the Board of Pharmacy's pending compounding regulations to licensees of the Medical Board of California (MBC). Existing statute (see Business and Professions Code (BPC) section 2220.5) makes it clear that only the MBC can discipline its physician licensees.</i> <i>Whenever a physician is engaging in compounding (or any other action that their medical license authorizes them to perform) they must always do so consistent with the standard of care. For the purposes of MBC's enforcement program, the standard of care is established by expert testimony in the context of the facts and circumstances of a specific case.</i> <i>It is certainly possible that whatever regulations that are implemented by the Board of Pharmacy may influence the standard of care for physicians</i>

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				who are compounding, especially since some of the proposed regulations reflect what is already required for physician compounding under federal law, including, but not limited to, Section 503A of the Federal Food, Drug, and Cosmetic Act (BPC section 2225(b) allows MBC to investigate violations of federal law related to the practice of medicine). Feel free to share this message with others as you see fit who might also be concerned about the applicability of their pending regulations to the physician community. Please contact me if you have any further questions. Sincerely, Reji Varghese
3	1737.2(a)	Stanford Health Care	Comment: For a large health system pharmacy department, it is common for multiple people to assume the responsibilities of the designated person. Additionally, proposed sections 1735 and 1736 define the designated person(s) as "one or more individuals." The USP <800> FAQ further supports this by clarifying that the designated person may be more than one person. Recommendation: Revise language to allow the designated person for hazardous drug handling to be "one or more individuals."	The Board staff have reviewed the comment and recommend a change to the proposed regulation text based on the comment and other comments received related to this section. Recommended language is below: <u>1737.2(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), ~~or the~~ professional director of a clinic, or ~~the~~ designated representative-in-charge, as applicable. Approval shall be documented at least every 12 months.</u> <u>(1) In a pharmacy. The designated person(s) 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(s) shall not exceed the scope of their issued license. When ~~a the~~</u>

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				<u>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.</u>
4	1737.2(a)	CSHP	It must be noted that the PIC is responsible for compliance but need not to be doing all the work associated with following these laws. PIC's must be able to delegate operational and administrative matters according to their professional discretion. Pharmacists are practicing professionals, and this is associated with making many important patient care and operational decisions. (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) or designee, 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. And this 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 or designee, professional director of a clinic, or designated representative in charge, as applicable.~~	Board staff have reviewed the comment. Board staff have concerns with the proposed change offered by the commenter, but note that a separate commenter has offered a recommendation that preserves the policy goal of the Board while balancing what the Board understands may be, at least in part, the concerns of the commenter. Board staff recommend the following change. Staff note that a designated person is not required to be a pharmacist. <u>1737.2(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), ~~or the~~ professional director of a clinic, or ~~the~~ designated representative-in-charge, as applicable. Approval shall be documented at least every 12 months.</u> <u>(1) In a pharmacy. If the designated person(s) 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(s) shall not exceed the scope of their issued license. When ~~a 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.</u>

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5	1737.2(a) and (b)	Cedars-Sinai Torrance Memorial	Often times, the designated person may be the pharmacist-in-charge. 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(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. CCR 1737.2(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.	Board staff have reviewed the comment and do not recommend a change based on the comment. Staff note that a designated person is not required to be a pharmacist. Staff are recommending changes to the proposed text to clarify the requirement. <u>1737.2(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), ~~or the~~ professional director of a clinic, or ~~the~~ designated representative-in-charge, as applicable. Approval shall be documented at least every 12 months.</u> <u>(1) In a pharmacy. The designated person(s) 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(s) shall not exceed the scope of their issued license. When ~~a 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.</u>
6	1737.2(b)	Cedars-Sinai Torrance Memorial	Often times, the designated person may be the pharmacist-in-charge. 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(b): If an assessment of risk approach is taken as authorized in USP Chapter 800, it shall be approved	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that a designated person is not required to be a pharmacist. Staff are recommending changes to the proposed text to clarify the requirement.

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7	1737.5(c)	John Gray Kaiser UC San Diego CSHP Torrance Memorial Kaweah Health	by the designated person ~~and or~~ the pharmacist-in-charge, ~~or~~ professional director of a clinic, or designated representative-in-charge, as applicable. ~~Where a pass through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking. Effective [OAL insert six months following the effective date] a pass-through is not allowed between the hazardous drug buffer room C-SEC into an unclassified space.~~ We appreciate the Board's reference to the restriction on pass-throughs from a hazardous buffer room to unclassified space in the California Building Code. Because existing state regulations already address this restriction, we encourage the Board to delete this provision from the proposed regulations. While we recognize that the Board cannot change the requirement in the Building Code, we continue to believe that a restriction on pass-throughs from a hazardous buffer room to unclassified space is misguided. Undoubtedly, increased human traffic in and out of the buffer room presents the greatest risk of microbial contamination and migration of Hazardous Drug (HD) residues. A properly configured pass-through that is used appropriately is a commonsense tool to mitigate these risks.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text based on the comment received. Staff note that California Code of Regulations, Title 24, prohibits a passthrough between classified and unclassified spaces in the HD environment. The proposed text provides a delay in implementation to allow for the facility to develop the process to operationalize the requirements.
8	1737.5(c)	Keck/USC UC Health	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 approval of this requirement will place extreme hardship on existing facilities that were compliant with applicable codes at the time of construction. Cleanroom designs were approved, and compounding pharmacies were licensed by the CA board and CDPH. Given extremely high cost of cleanroom re-design, construction and modifications, this requirement may lead to pharmacy closures, negatively affecting patient access to care.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text based on the comment received. Staff note that California Code of Regulations, Title 24, Section 122.149 prohibits a passthrough between classified and unclassified spaces in the HD environment. The proposed text provides a delay in implementation to allow for the facility to develop the process to operationalize the requirements.

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			Per USP 800, “ Although not a recommended facility design, if the negative-pressure HD buffer room is entered though the positive-pressure non-HD buffer room, the following is also required: ... A method to transport HDs, HD CSPs, and HD waste into and out of the negative pressure buffer room <u>to minimize the spread of HD contamination.</u> This may be accomplished by use of a pass-through chamber between the negative-pressure buffer area and adjacent space. 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.” Recommendation: The BOP is asked to reconsider requiring this standard not specified in USP 800, or otherwise providing for a process to allow the presence in existing construction (e.g., grandfathering). For example: “(c) A pass-through is not allowed between the C-SEC into an unclassified space in cleanrooms <u>if constructed after [insert date].</u>” “Where an existing pass-through is already installed between the C-SEC into an unclassified space, the <u>doors must be gasketed and interlocking and the pass-through must be included in the facility's certification</u>”	
9	1737.5(d)	Unknown	“Where an existing pass-through is already installed between the C-SEC into an unclassified space, the <u>doors must be gasketed and interlocking and the pass-through must be included in the facility's certification</u>”	The Board staff have reviewed the comment that appears to be related to CCR 1737.5(c) and do not recommend a change to the proposed regulation text based on the comment received. Staff note that California Code of Regulations, Title 24, Section 122.149 prohibits a passthrough between classified and unclassified spaces in the HD environment. The proposed text provides a delay in implementation to allow for the facility to develop the process to operationalize the requirements.

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10	1737.5(e)	Walgreens	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 compounding hazardous materials. We request this language is removed to prevent further confusion and ensure alignment with USP guidelines.	Board staff have reviewed the comment and believe the commenter is referring to 1737.5 (f) and appreciate the commenter highlighting the issue. Based on the comment received staff believe a change to the proposed text is appropriate. ~~(e) Where sterile hazardous compounding is performed, 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.~~
11	1737.6(a)	Cedars-Sinai Torrance Memorial Donald Cottman Wedgewood Pharmacy	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. Additionally, requiring additional sampling will add an undue burden to test without any concrete actionable limits. 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 <i>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.</i>	Board staff have reviewed the comment recommend a change to the proposed text to provide clarity on the intent of the language. Staff note that the proposed regulation text does not require a facility to perform environmental wipe sampling with any specified frequency. Rather, the proposed text requires the facility to develop SOPs that include provisions for wipe sampling. It is incumbent upon the PIC (or their designated person) to use their professional judgment to determine when or if wipe sampling occurs and under what conditions. <u>1737.6.</u> <u>In addition to the standards in USP Chapter 800, the following requirements apply to a facility where compounding of HDs is performed.</u> ~~Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article.~~ ~~The premises shall consider environmental wipe sampling and SOPs of a premises where HDs are handled shall address describe provisions for~~

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				~~environmental wipe sampling for HD surface residue, its frequency, and areas of testing, levels of measurable contamination, and actions when these levels are exceeded. Nothing in this section is intended to require the use of environmental wipe sampling.~~
12	1737.6(a) and (b)	Keck/USC Alliance for PHY Compounding	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. Per USP 800, <i>"there are currently no certifying agencies for vendors of wipe sample kits."</i> Recommendation: The Board's proposed requirement to establish an environmental wipe sampling cannot be justified given several significant concerns and barriers listed above. <u>We recommend the Board considers removing the proposed additional requirements and follow the standards outlined in USP 800 as it related to this section.</u>	Board staff have reviewed the comment. It appears the commenter may be referring a prior version of the proposed regulation text. Staff note that the proposed regulation text does not require a facility to perform environmental wipe sampling with any specified frequency. Rather, the proposed text requires the facility to develop SOPs that include provisions for wipe sampling. It is incumbent upon the PIC (or their designated person) to use their professional judgment to determine when or if wipe sampling occurs and under what conditions. ~~1737.6. The premises shall consider environmental wipe sampling and SOPs of a premises where HDs are handled shall address describes provisions for environmental wipe sampling for HD surface residue, its frequency, and areas of testing, levels of measurable contamination, and actions when these levels are exceeded. Nothing in this section is intended to require the use of environmental wipe sampling.~~
13	1737.7(b) & (c)	Walgreens	Walgreens requests clarity on what defines "different" in subsection (c). 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.	Board staff have reviewed the comment and appreciate the commenter seeking clarification of the language. Board staff believe the following language is appropriate to further clarify "between each different HD preparation." (c) <u>Outer gloves used for HD compounding shall be changed between each different HD preparation, unless preparing multiple HD</u>

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				~~preparations of the same drug or preparing multiple HD preparations for a single patient.~~
14	1737.7(c)	John Gray Kaiser Stanford Health Care UC San Diego CSHP Walgreens	Commenters request that the requirement for changing outer gloves be removed as it will result in significant increases in costs and generation of HD waste. Additionally, there is likely minimal benefit if a pharmacy is using CSTDs for HD compounding. Remove language to be consistent with USP 800 or revise language to require changing outer HD gloves, between each different HD preparation, if compounding is performed without a CSTD. Or gloves should only be changed between each different HD API preparation and if there is a gap between the compounding of those products.	The Board staff have reviewed the comment and do not recommend a change to the proposed regulation text based on the comment received. As the cited research demonstrates, while the CSTD does REDUCE the risk of contamination, it does not eliminate it. The Board appreciates the use of the technology as an important safety measure and notes the following from USP. USP Commentary provides, "CSTD provide adjunct control during compounding; however, additional controls are needed to prevent HD contamination, especially during the movement of ingredients and materials into and out of the C-PEC."
15	1737.7(c)	Cedars-Sinai Torrance Memorial UC Health	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%). Double-gloving is primarily designed to offer extra protection against hazardous drug compounds, with the outer glove serving as a first line of defense. If the outer glove is repeatedly removed or exposed to rough conditions, it may wear down, possibly increasing the risk of puncturing or compromising the inner glove. This could lead to reduced protection, especially when handling hazardous drug compound. Frequent removal and disposal of outer glove changes creates significant waste. Recommendations: <i>Revise the proposed language to:</i> (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.	Board staff have reviewed the comment and do not recommend a change to the proposed text. As the studies provided reveal, the use of a CSTD may reduce the risk of contamination but does not eliminate the risk. The Board appreciates the use of the technology as an important safety measure and notes the following from USP. USP Commentary provides, "CSTD provide adjunct control during compounding; however, additional controls are needed to prevent HD contamination, especially during the movement of ingredients and materials into and out of the C-PEC."

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16	1737.7(c)	Donald Cottman	Given the vast efforts made to prevent contaminating events, such as using closed-system-transfer-devices, the occurrence of any actual contamination is extremely low. Requiring a compounder to change gloves between different HD preparations defies logic. If a compounder is handling product A and there is a suspicion, or assumption, of exposure precluding them from handling product B, what is the logic that is ok to handle product A-2? Would not item A-2 be just as contaminated as product B? Should not avoiding contamination of product A-2 be of the same priority as preventing contamination of product B? If we reject the presumption that gloves are inherently contaminated by engaging in compounding, then having regulations that require them to be changed between HD drugs is arbitrary and nonsensical. This regulation should be deleted, or restated to say changing of gloves should be done when contamination is suspected.	Board staff have reviewed the comment and disagree with the commenter suggesting that compounders should assume that gloves are not contaminated. Board staff note that the Chapter states, "Consider all PPE worn when handling HDs to be contaminated with, at minimum, trace quantities of HDs. PPE must be placed in an appropriate waste container and further disposed of per local, state, and federal regulations. PPE worn during compounding should be disposed of in the proper waste container before leaving the C-SEC. Chemotherapy gloves and sleeve covers (if used) worn during compounding must be carefully removed and discarded immediately into a waste container approved for trace contaminated waste inside the C-PEC or contained in a sealable bag for discarding outside the C-PEC."
17	1737.7(d)	Donald Cottman	The C-SEC if the physical space the PEC is located, also known as the buffer room. This is under positive pressure from the ante-room, which has HEPA filtered air feeding into it, so that only HEPA filtered air is pushed into the buffer room. As written, this requires PPE be removed inside the buffer room, leaving a person standing inside the buffer room, with exposed skin and clothing. This creates a profound risk of contamination of the C-SEC buffer room by having un-gowned personnel in that space. This defies all logic for clean-room particle reduction practices. The assumption being proposed is that the PPE worn by the staff is inherently contaminated by the simple act of compounding HD drugs, regardless of all	Board staff have reviewed the comment and disagree with the commenter. Board staff note that the Chapter states, "Consider all PPE worn when handling HDs to be contaminated with, at minimum, trace quantities of HDs. PPE must be placed in an appropriate waste container and further disposed of per local, state, and federal regulations. PPE worn during compounding should be disposed of in the proper waste container before leaving the C-SEC. Chemotherapy gloves and sleeve covers (if used) worn during compounding must be carefully removed and discarded immediately into a waste container approved for trace contaminated waste inside the

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			containment efforts being employed, such as biologic safety cabinets and closed system transfer devices. In this assumption scenario, it is logical that garb should be removed in a negative pressure environment that is externally vented, which would require doffing PPE in the C-SEC buffer room. This is because the ante-room, by definition and design, is a positive pressure room with HEPA filtered air exiting into both uncontrolled space, as well as the C-SEC buffer room. Any contamination in the ante-room would be ejected into the uncontrolled space, so doffing in this space would create a risk to those outside of the ante room. However, if we make the assertion that the simple act of compounding does not contaminate a worker's PPE, given the precautions used during the process that include the PEC, CSTDs, regular cleaning of gloves, and attention to potential contamination events, then the risk of HD contaminated PPE is extremely low. In contrast, the risk of introducing microbial contamination to the C-SEC buffer room is plainly obvious if workers are removing their PPE inside the buffer room. This is a flaw in current USP <800> regulations regarding the removal of PPE in sterile HD compounding. Having an un-gowned person past the line of demarcation in the ante-room, standing un-gowned in the buffer room, is substandard practice for cleanroom protocols. This regulation should be rewritten to state PPE <u>should not</u> be removed in the C-SEC, but rather doffed in the ante-room.	C-PEC or contained in a sealable bag for discarding outside the C-PEC." Board staff note that the Board's proposed regulation text is consistent with the provisions of the Chapter while establishing a provision for the facility to operationalize the requirements through the development of its SOPs.

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18	1737.9	CVS	While USP 800 does not require competency training for Table 1 manipulations, the Board's staff has determined that a portion of the Table 1 manipulations necessitate competency training, such as "withdrawing or diluting injectable HDs from parenteral containers", "expelling air or HDs from syringes", "weighing or mixing components", "constituting or reconstituting powdered or lyophilized HDs" and "crushing or splitting tablets or opening capsules". However, as written if a pharmacy partakes in any listing within Table 1, competency training must be performed. CVS Health believes that competency training for "pouring oral or topical liquids from one container to another", disposing of gloves and cleaning counting trays is overly burdensome and that safe procedures can easily be achieved via less rigorous requirements, such as through computer-based training and SOPs. CVS Health requests that the training of both the person assigned to provide training and the personnel responsible for "other manipulations of antineoplastic HDs" be determined according to professional judgment and documented within required SOPs. <i>In addition to the standards in USP Chapter 800, the following requirements apply to a facility where the compounding of HDs is performed or <u>when a facility's SOPs require training to perform certain</u> ~~one~~ <u>where</u> "other manipulations" included in Table 1 of the Chapter of antineoplastic HDs is performed.</i> <i>1. Any person assigned to provide training the training specified in this Article 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 1737.17. Documentation must be maintained</i>	Board staff have reviewed the comment and believe that additional clarification in appropriate on the specific "other manipulations" to more clearly effectuate the Board's policy in this area. 1737.9. Personnel Training. In addition to the standards in USP Chapter 800, <u>the following requirements apply to a facility where compounding of HDs is performed or ~~one~~ where "other manipulations" included in Table 1 of the Chapter of where crushing or splitting tablets or opening capsules of</u> of antineoplastic HDs is performed. ~~Hazardous Drugs Handling in Healthcare Setting shall meet the following requirements of this article.~~ Note: Additional conforming changes are necessary throughout the article to reflect this change from " 'other manipulations' include in Table 1 of the Chapter" to "crushing or splitting tablets or opening capsules" (or similar) and are reflected in the recommended proposed modified text throughout the article.

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			demonstrating compliance with training requirements, and for compounding demonstrated competency must be maintained. 2. All personnel responsible for compounding HDs or "other manipulations of antineoplastic HDs" for which facility SOPs require demonstrated competency who fail any aspect of ongoing evaluation and training in compounding HDs or other manipulations of antineoplastic HDs shall not compound HDs or perform other manipulations until after successfully passing reevaluations in the deficient area(s), as detailed in the facility's SOPs. Any failure in competency shall comply with the provisions of 1735.2(c) or 1736.2(d), as applicable.	
19	1737.13(a)	Donald Cottman	The requirement that the mat be changed "after each different HD preparation" defies logic. If product A is prepared and regulation requires that the mat must be changed before making product B, then there is a presumption that there is contamination on the mat. But what is the logic that it is ok to prepare product A-2 on that contaminated mat? If there is contamination on the mat, then spreading contamination from A-1 to A-2 should not be allowed. To be consistent with logic, the regulation should be that the mat must be changed after <u>every</u> HD preparation. However, if it is recognized that changing a mat after every HD preparation would result in an unreasonable use of sterile mats, given that 20 mats could be used by one compounder in one compounding session, then one must reject the presumption that a mat is contaminated simply by the process of being used in HD compounding. If we reject the presumption of contamination simply by the act of compounding, then it should not matter if a mat is used for the same	Board staff have reviewed the comment and believe that a mat can continue to be used under if the HD preparations are for a single patient or if the HD preparations are using the same HD ingredient. <u>1737.13 (a) If a disposable preparation mat is used for compounding a CSP it must be sterile and it must be changed immediately if a spill occurs, after each different HD preparation unless multiple preparations of the same drug or single patient is occurring, and at the end of the daily compounding activity, shall be placed on the work surface of the C-PEG 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.</u>

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			HD drug or a different HD drug, since there is no contamination present. This regulation should be limited to stating that the mat should be changed immediately if a spill occurs.	
20	1737.13(b)	Stanford Health Care	There are other effective strategies to prevent drug mix-up and cross-contamination besides limiting one HD preparation in a C-PEC at a time. These include clearly defined segregation between different HD preparations (e.g., dividers, bins, barriers), compounding multiple HD preparations of the same drug, and compounding different HD preparations for the same patient. Front-line staff have commented that there are HD drugs that take a long time to dissolve and not being able to continue compounding other medications would negatively affect patient care. This is especially true for our locations with only one or a limited number of hoods. Revise language to allow exceptions for more than one HD preparation in a C-PEC at a time under the following circumstances 3. Implemented methods that create clearly defined segregation between different HD preparations. 4. Multiple HD preparations of the same drug are being compounded. 5. Multiple HD preparations for the same patient are being compounded.	Board staff have reviewed the comment and recommend changes to the proposed text based on the comment received. Staff note that adverse drug events have been received where two vials were being compounded at the same time. In this instance, a patient received an HD compounded for another patient. In addition, staff remain concerned about the potential risk for cross contamination. Board staff believe the following change to the language provides additional flexibility while preserving patient protections. 1737.13(b) Only one HD preparation may be handled in a C-PEC at one time, <u>unless the multiple HD preparations are of the same drug or are multiple HD preparations for a single patient.</u>
21	1737.13(b)	Donald Cottman	This regulation suggests that having two HDs prepared in a C-PEC at the same time is due to the risk of cross contamination, and not microbial contamination, as there is no limitation to performing non-hazardous sterile compounding on more than one drug. If there is a presumption that the presence of HD Drug 1 contaminates the HD compounding space such that	Board staff have reviewed the comment and recommend changes to the proposed text based on the comment received. Staff note that adverse drug events have been received where two vials were being compounded at the same time. In this instance, a patient received an HD compounded for another patient. In addition, staff remain

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			one cannot have HD Drug 2 in the same space, then regulations should require the complete cleaning and decontamination of the compounding space between each compound. This is not the case, so clearly the BOP and USP<800> do not assert that the simple act of compounding an HD drug contaminates the compounding space. If the compounding space is not contaminated by HD drug, and it is accepted practice that when using good aseptic techniques one may prepare multiple sterile compounds at the same time, in the same space, there is no logic to this restrictive regulation. This regulation should be deleted.	concerned about the potential risk for cross contamination. Board staff believe the following change to the language provides additional flexibility while preserving patient protections. (b) Only one HD preparation may be handled in a C-PEC at one time, <u>unless the multiple HD preparations are of the same drug or are multiple HD preparations for a single patient.</u>
22	1737.14(a)	CSHP	It is not clear if the interpretation of "plastic container" requires a rigid plastic container and/or if a zip-lock bag type is allowable. It is not clear if said single use zip-lock bag must be decontaminated, generally if it is a single use bag decontamination is not needed. Absent clarifying language, the proposed language could be misinterpreted and appears to require that all HD's be placed and furnished in a rigid plastic container when compounding is complete. It is recommended that the proposed language be changed to the following: (a) When furnishing a compounded antineoplastic HD for administration, the facility shall: (1) <u>Double bag or</u> place the HD in a decontaminated plastic container with an HD label on the outside of the <u>bag or</u> container; and (2) For an infused antineoplastic HD, attach and prime tubing and attach a CSTD when appropriate.	Board staff have reviewed the comment and do not recommend a change based on the comment. A facility can determine the number and type of plastic container(s) they wish to use. There is nothing in the proposed regulation text that would prevent double bagging. While reviewing the comment however, staff noted that the provisions is 1737.14(a)(1) would be better placed 1737.11, with the addition of 1737.11(c). <u>1737.11(c) When furnishing a compounded antineoplastic HD for administration within a facility licensed pursuant to Health and Safety Code section 1250, the HD shall be placed in a plastic container and labeled as a hazardous drug on the outside of the container or with a label that is visible through the outside container.</u>
23	1737.14(b)	UC San Diego Torrance Memorial	In health facilities where antineoplastic HD are dispensed and administered by licensed health care professionals who are trained to handle HDs. Supplies	Board staff have reviewed the comment and believe the requested change is consistent with the Board's policy.

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		UC Health	such as ASTM D-6978 grade gloves, and HD disposal bins are readily available. Recommend adding exemption language to the current proposed language for HSC 1250 (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.)	~~1737.14(b) When furnishing dispensing on a compounded antineoplastic HD to a patient or patient's agent, the pharmacy shall offer the patient or patient's agent a sufficient supply of ASTM D-6978 standard gloves, that meet the ASTM D-6978 standard, and shall be provided them upon request to the patient or the patient's agent, to allow for appropriate administration, handling, and disposal of the HD. drugs by the patient or the patient's agent shall be provided. A compounded antineoplastic HD preparation that is administered to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code.~~
24	1737.14(b)	Walgreens Alliance for PHY Compounding	Walgreens believes that mandating the supply of gloves for antineoplastic HD compounded products is overreaching; however, feels that the dispensing pharmacy and the administering facility should ensure that the appropriate gloves are available for administration. Often the patient or patient's agent, such as a nurse, already has the appropriate supplies to administer the product and providing the gloves without the patient or patient's agent requesting them may be wasteful and contribute to excessive and unnecessary HD refuse and waste. Proposed language: (b) When furnishing dispensing a compounded antineoplastic HD to a patient or patient's agent the dispensing pharmacy must ensure a sufficient supply of ASTM D6978 gloves that meet the ASTM D-6978 standard is available and shall be provided upon request to allow for appropriate to allow for appropriate administration, handling, and disposal of HD drugs by the patient or the patient's agent shall be provided.	Board staff have reviewed the comment and believe the requested change is consistent with the Board's policy. Board staff note that the language provided below also incorporates the exemption requested in the prior comment. ~~(1737.14(b) When furnishing dispensing on a compounded antineoplastic HD to a patient or patient's agent, the pharmacy shall offer the patient or patient's agent a sufficient supply of ASTM D-6978 standard gloves, that meet the ASTM D-6978 standard, and shall be provided them upon request to the patient or the patient's agent, to allow for appropriate administration, handling, and disposal of the HD. drugs by the patient or the patient's agent shall be provided. A compounded antineoplastic HD preparation that is administered to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code.~~
25	1737.14(b)	Wedgewood Pharmacy	Recommendation: Change "shall be provided" to "shall be made available for purchase".	Board staff have reviewed the comment and as indicated in the response to the prior comment,

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				recommend a change to the proposed text that would in part address this comment. <u>1737.14(b) When furnishing dispensing on a compounded antineoplastic HD to a patient or patient's agent, the pharmacy shall offer the patient or patient's agent a sufficient supply of ASTM D-6978 standard gloves, that meet the ASTM D-6978 standard, and shall be provided them upon request to the patient or the patient's agent, to allow for appropriate administration, handling, and disposal of the HD. drugs by the patient or the patient's agent shall be provided. A compounded antineoplastic HD preparation that is administered to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code.</u>
26	1737.15	Donald Cottman	There is no definition of the word "deactivation" and the regulation includes a "shall" preventing clarity on when compliance has been achieved. In every publication, from the FDA, to the EPA, to USP, there is the use of the word "deactivation" with no clarity on what it means. Even the FDA says "use of a registered oxidizing agent" where the EPA has no list of products that are registered as deactivating agent. Also, the word has no scientific meaning. An antineoplastic agent that is "deactivated" means what? That doesn't treat cancer anymore? There is published literature showing that antineoplastic drugs, when subject to "deactivating" procedures, like heating in hydrogen peroxide solution for hours, will change their chemical structure so they are no longer the same chemical. But it turns out those new structures were more carcinogenic than the original compound.	Board staff have reviewed the comment and do not recommend any change to the proposed text. Staff note that the proposed text aligns with the language used within the Chapter. Further, staff note that "deactivation" is defined in the Chapter. Board staff note that in reviewing this comment and the Chapter, it was identified that the Board's proposed regulation title in Section 1737.15 does not fully mirror the USP Chapter. As such staff recommend retitling this section to the following: <u>1737.15. Deactivation, Decontamination, Deactivating, Decontaminating, Cleaning, and Disinfecting.</u>

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			California should not participate in adding into its regulatory language the vague and undefined word "deactivate". It can still accomplish the intent of this section of the regulation section by removing the word.	
27	1737.15(a)	Kaiser	Deactivating, decontaminating, cleaning, disinfecting, and sporicidal agents shall be used in accordance with manufacturers' specifications or specifications established in published scientific studies and shall be surface compatible. There are agents that have been shown to be effective in deactivating, decontaminating, cleaning, disinfecting, and/or killing bacterial and fungal spores but for which a manufacturer does not provide instructions for such a use. We encourage the Board to amend the regulation to provide organizations the flexibility to choose an agent that has been shown to be effective in published studies in accomplishing one or more of these required activities.	Board staff have reviewed the comment. Staff recommend a change to the proposed text that will provide flexibility in the use of a specified agent, but in a more limited fashion, based upon a manufacturer's scientific studies that would support such use. 1737.15. (a) Deactivating, decontaminating, cleaning, disinfecting, and sporicidal agents shall be used in accordance with manufacturers' specifications, <u>or subsequent manufacturer approved studies</u>, and shall be surface compatible.
28	1737.17	CVS	While USP 800 does not require competency training for Table 1 manipulations, the Board's staff has determined that a portion of the Table 1 manipulations necessitate competency training, such as "withdrawing or diluting injectable HDs from parenteral containers", "expelling air or HDs from syringes", "weighing or mixing components", "constituting or reconstituting powdered or lyophilized HDs" and "crushing or splitting tablets or opening capsules". However, as written if a pharmacy partakes in any listing within Table 1, competency training must be performed. CVS Health believes that competency training for "pouring oral or topical liquids from one container to another", disposing of gloves and cleaning counting trays is overly burdensome and that safe procedures can easily be achieved via less rigorous	Board staff have reviewed the comment and believe that additional change to the proposed text is appropriate to align with the Board's policy. Board staff recommend the following change to 1737.17(b). <u>1737.15 (b) A facility where compounding HDs is performed or one where crushing or splitting tablets or opening capsules of "other manipulations" antineoplastic HDs is performed shall have ~~The SOPs for compounding or handling HDs shall~~ that include at least the following:</u> Note: Additional conforming changes are necessary throughout the article to reflect this change from " 'other manipulations' include in Table 1 of the Chapter" to "crushing or splitting

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			requirements, such as through computer-based training and SOPs. CVS Health requests that the training of both the person assigned to provide training and the personnel responsible for "other manipulations of antineoplastic HDs" be determined according to professional judgment and documented within required SOPs. <i>(17) Training, including demonstrated competency if compounding.</i>	tablets or opening capsules" (or similar) and are reflected in the recommended proposed modified text throughout the article.
29	1737.17(a) and (b)	Wedgeood Pharmacy	Subpoint (a) is confusingly worded as written and should be further cleaned up to clarify the intent of the subpoint. Subpoint (b) seems to be saying almost the same thing as subpoint (a), but without clarifying (a) it is hard to tell. Recommendation: Either clarify language in subpoint (a) or consider consolidating subpoints (a) and (b) if intent is the same.	Board staff have reviewed the comment and believe a change to the proposed text in 1737.17(a) is appropriate to reflect the same change being offered in 1737.17(b). <u>1737.17(a) ~~Any premises~~ facility engaged in the compounding or handling of HDs shall maintain and follow written SOPs for all situations in which HDs are compounded or crushing or splitting tablets or opening capsules of antineoplastic HDs is performed are "otherwise manipulated"</u> Note: Additional conforming changes are necessary throughout the article to reflect this change from " 'other manipulations' include in Table 1 of the Chapter" to "crushing or splitting tablets or opening capsules" (or similar) and are reflected in the recommended proposed modified text throughout the article.

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1	1738.1	Assoc of NorCal Oncologists and Medical Oncology Assoc. California Rheumatology Alliance CA Medical Association CalDerm	We are concerned that the proposed regulations will require a pharmacist to be present during these types of activities, which would be an onerous burden on community sites of care, particularly those in rural settings. ANCO and MOASC are concerned that these proposed regulations, if adopted, would result in cancer patients being forced to obtain their chemotherapy at a hospital or infusion center, which would place new burdens on patients who are already fighting for their lives. 1738.1: In addition to the standards in the USP Chapter 825, the processing of Radiopharmaceuticals shall meet the requirements of this section. This article shall not apply to compounding by or under the direct supervision of a licensed physician and surgeon.	Board staff have reviewed the comment and do not recommend a change to the proposed text based on the comment. Staff note the Board only has jurisdiction over individuals and businesses within its practice act. Board staff read the comment as suggesting that the Board's proposed regulations would apply to a physician. Business and Professions Code section 4170(c) makes that the Medical Board of California is specifically charged with the enforcement of Pharmacy Law (Chapter 9, Division 2 of the Business and Professions Code) with respect to its licensees. It may be appropriate for the commenter to confer with their licensing board to determine in the practice described if the scenario described their comment is allowable. Board staff note that the Medical Board of California has previously provided a written response to individuals inquiring about the applicability of the Board of Pharmacy's regulations to individuals and practices that operate under the jurisdiction of the Medical Board of California. Below is the information provided from the Medical Board - - Dear Ms. Sodergren: I understand that some concerns have been raised by stakeholders about the applicability of the Board of Pharmacy's pending compounding regulations to licensees of the Medical Board of California (MBC). Existing statute (see Business and Professions Code (BPC) section 2220.5) makes it clear that only the MBC can discipline its physician licensees. Whenever a physician is engaging in compounding (or any other action that their medical license authorizes them to perform) they must always do so consistent with the standard of care. For the purposes of MBC's enforcement program, the standard of care is established

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				by expert testimony in the context of the facts and circumstances of a specific case. It is certainly possible that whatever regulations that are implemented by the Board of Pharmacy may influence the standard of care for physicians who are compounding, especially since some of the proposed regulations reflect what is already required for physician compounding under federal law, including, but not limited to, Section 503A of the Federal Food, Drug, and Cosmetic Act (BPC section 2225(b) allows MBC to investigate violations of federal law related to the practice of medicine). Feel free to share this message with others as you see fit who might also be concerned about the applicability of their pending regulations to the physician community. Please contact me if you have any further questions. Sincerely, Reji Varghese Business and Professions Code section 4001.1 provides that protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. The Board believes the proposed regulations are consistent with its statutory mandate.
2	1738.4	CSHP	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. We once more reiterate the comments by both us and others at various stages through this rulemaking process that USP has sufficient standards to promote and protect patients. Recommend the Board of Pharmacy remove the requirement of "PEC unique identifier".	Staff have reviewed the comment. Staff note that the requirement to document would occur once every three to six months. Staff note that the unique identifier is necessary to identify where the competency was performed. Staff note that maintaining the PEC unique identifier provides the facility with the location of the equipment and is consistent with the standard of practice. The language provides flexibility for each facility to determine the PEC unique identifier, e.g. hood 2.

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			Recommendation: (c) Aseptic manipulation competency initial training and competency and ongoing training and competency documentation shall include the Primary Engineering Control (PEC's) type <u>and PEC unique identifier</u> 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.	
3	1738.5(e)	Cedars-Sinai	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: <u>(d) Radiopharmaceutical compounding shall not take place in the SRPA.</u>	Board staff have reviewed the comment and believe that 1738.5(e) can be deleted from the proposed regulations. Staff note that the Chapter already specifically details what activities can be done in an SRPA. <u>~~(3e) Compounding shall not take place in the SRPA.~~</u>
4	1738.10(c)	CSHP	The proposed language is inconsistent with USP 825 recommendations, and will require health-systems to incorporate patient need which may not be pertinent information. We reiterate the comments by both us and others at various stages through this rulemaking process that USP has sufficient standards to promote and protect patients. This proposed regulation fails to demonstrate the necessity for patient safety beyond that required by USP. We recommend that this subsection be deleted.	Board staff have reviewed the comment and thank the commenter for highlighting this section. Upon review of the comment, staff believe the language of the proposed text may require additional amendment to clarify the requirement. Staff note that the intent of the proposed regulation is to ensure the facility has an SOP defining the conditions for minor deviations. Board staff recommend the following change to the proposed text. (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. <u>~~Such circumstances shall, at a minimum, include patient need~~</u>

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				~~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.~~ While the language specifically referring to a pharmacist's clinical judgement is being removed, it is important to note that the recommendation to change the language should not be interpreted as the Board suggesting that a pharmacist does not need to exercise clinical judgment. To the contrary, pharmacists as licensed health care providers must always exercise professional judgment in their practice. This requirement is memorialized in Business and Professions Code section 4306.5.
5	1738.10(c)	Cedars-Sinai	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, <u>include patient need or</u> 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 <u>of the pharmacist.</u>	Board staff have reviewed the comment and thank the commenter for highlighting this section. Upon review of the comment, staff believe the language of the proposed text may require additional amendment to clarify the requirement. Staff note that the intent of the proposed regulation is to ensure the facility has an SOP defining the conditions for minor deviations. Board staff recommend the following change to the proposed text. (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.~~

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				While the language specifically referring to a pharmacist's clinical judgement is being removed, it is important note to that the recommendation to change the language should not be interpreted as the Board suggesting that a pharmacist does not need to exercise clinical judgment. To the contrary, pharmacists as licensed health care providers must always exercise professional judgment in their practice. This requirement is memorialized in Business and Professions Code section 4306.5.
6	1738.14(b)	CSHP	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 an extended weekend. Recommendation: (b) The board shall be notified in writing within ~~72 hours~~ <u>three (3) business days</u> 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.	Board staff have reviewed the comment and do not recommend a change in the proposed text. Staff are concerned that the term "business day" could vary greatly based on the practice site and differing operating hours.
7	1738.14(b)	Cedars-Sinai	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. Recommend the board to revise language to be consistent with the updated CA BOP revised changes in section 1735.12 Quality Assurance and Quality Control subsection (b). Recommendation: (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. The Board shall be notified in writing within~~ <u>96 hours of the facility's receipt of a complaint of</u>	Board staff have reviewed the comment and recommend the following change. <u>(b) The Board shall be notified in writing within ~~72~~ <u>96</u> hours of the facility's receipt of a complaint of a, excluding delivery delays, involving a radiopharmaceutical. Recalls and adverse drug experiences as defined in 21 CFP 310.305(b), ~~events must~~ shall be reported to the Board and other agencies in compliance with relevant provisions of law.</u>

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			<u>a potential quality problem or the occurrence of an adverse drug experience as defined in 21 CFR 310.305(b) involving a CNSP.</u>	
8	1738.14(c)	CSHP Cedars-Sinai	The way the regulation is written, suggests that the review must be completed within 72 hours since it states that "such review shall be documented and dated as defined in the SOPs." The proposed language requirement for a documentation and dating of the review together with the preceding sentence's requirement for review within 72 hours from the receipt of the complaint could be seen as requiring the review to be completed within the 72 hours timeframe. A requirement of 72 hours may not provide sufficient time for pharmacies to thoroughly investigate and determine root causes. It is reasonable to expect that a review after a complaint be started within three business days. Investigation could take longer than this due to many factors involved in such an investigation that needs to be looked at. Many of these may not be available or apparent within this timeframe. Recommendation (BOLD): (c) In addition to subsection (b), all complaints made to the facility related to a potential quality problem with a CSP and all adverse drug experiences, as defined in 21 CFR 310.305(b) shall be reviewed by the pharmacist-in-charge and shall start within three (3) business days ~~within 72 hours~~ of receipt of the complaint or occurrence of the adverse drug experience. Such review shall be documented and dated as defined in the SOPs.	Board staff have reviewed the comment and do not recommend a change in the proposed text. Staff are concerned that the term "business day" could vary greatly based on the practice site and differing operating hours.

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1	General	Dan Baxter CA Veterinary Medical Assoc	CVMA requests that a specific statement be included in this proposed regulatory revision to affirmatively state that it does not apply to veterinarians who compound medications for patients in their practices. California Business and Professions Code section 4826.5 provides statutory authority for veterinarians to compound medications in practice pursuant to regulations promulgated by the Veterinary Medical Board. California Code of Regulations, Title 16, Article 11 in turn specifies requirements for veterinarians to perform compounding in practice. The CVMA has received multiple inquiries from confused veterinarians regarding which regulations apply to them. A clear statement from the Board of Pharmacy that its proposed regulations do not apply to veterinarians would alleviate that unnecessary confusion.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. Staff note the Board only has jurisdiction over individuals and businesses within its practice act. Board staff read the comment as suggesting it is unclear whether the Board's proposed regulations would apply to a veterinarian. Business and Professions Code section 4170(c) makes clear that the Veterinary Medical Board is specifically charged with the enforcement of Pharmacy Law (Chapter 9, Division 2 of the Business and Professions Code) with respect to its licensees. Note: Business and Professions section 4111 generally establishes prohibitions on individuals that can own a pharmacy. Specifically, 4111(a)(1) prohibits a person or persons authorized to prescribe or write a prescription from owning a pharmacy. It may be appropriate for the commenter to confer with the Veterinary Medical Board (VMB) to understand the requirements for veterinarian compounding under VMB authority.
2	General	CA Medical Association	We request that the Board revise the proposed compounding regulations to clarify that the regulations do not apply to compounding by licensed physicians, consistent with the Board's intended effect. While the Board does not have jurisdiction or disciplining authority over physicians and surgeons, the Medical Board may discipline a physician and surgeon for violating any provision of the Medical Practice Act or any other provision of Division 2 of the Business and Professions Code. It is certainly possible that whatever regulations that are implemented by the Board of Pharmacy may influence the standard of care for physicians	Board staff have reviewed the comment and do not recommend a change to the proposed text based on the comment. Staff note the Board only has jurisdiction over individuals and businesses within its practice act. Board staff read the comment as suggesting that the Board's proposed regulations would apply to a physician. Business and Professions Code section 4170(c) makes that the Medical Board of California is specifically charged with the enforcement of Pharmacy Law (Chapter 9, Division 2 of the Business and Professions Code) with respect to its licensees.

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			who are compounding, especially since some of the proposed regulations reflect what is already required for physician compounding under federal law, including, but not limited to, Section 503A of the Federal Food, Drug, and Cosmetic Act (BPC section 2225(b) allows MBC to investigate violations of federal law related to the practice of medicine)	Note: Business and Professions section 4111 generally establishes prohibitions on individuals that can own a pharmacy. Specifically, 4111(a)(1) prohibits a person or persons authorized to prescribe or write a prescription from owning a pharmacy. It may be appropriate for the commenter to confer with their licensing board to determine if the scenario described their comment is allowable within their practice. Board staff note that the Medical Board of California has previously provided a written response to individuals inquiring about the applicability of the Board of Pharmacy's regulations to individuals and practices that operate under the jurisdiction of the Medical Board of California. Below is the information provided from the Medical Board - - Dear Ms. Sodergren: I understand that some concerns have been raised by stakeholders about the applicability of the Board of Pharmacy's pending compounding regulations to licensees of the Medical Board of California (MBC). Existing statute (see Business and Professions Code (BPC) section 2220.5) makes it clear that only the MBC can discipline its physician licensees. Whenever a physician is engaging in compounding (or any other action that their medical license authorizes them to perform) they must always do so consistent with the standard of care. For the purposes of MBC's enforcement program, the standard of care is established by expert testimony in the context of the facts and circumstances of a specific case. It is certainly possible that whatever regulations that are implemented by the Board of Pharmacy may influence the standard of care for physicians who are compounding, especially since some of the proposed regulations reflect what is already required for physician compounding under federal law, including, but not limited

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				to, Section 503A of the Federal Food, Drug, and Cosmetic Act (BPC section 2225(b) allows MBC to investigate violations of federal law related to the practice of medicine). Feel free to share this message with others as you see fit who might also be concerned about the applicability of their pending regulations to the physician community. Please contact me if you have any further questions. Sincerely, Reji Varghese Business and Professions Code section 4001.1 provides that protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. The Board believes the proposed regulations are consistent with its statutory mandate.
3	General	Stanford Health Care	While we appreciate the Board's rationale outlined in the Initial Statement of Reasons document for the proposed changes, we do not share the sentiment that additional requirements are necessary to "strengthen" United States Pharmacopeia (USP) chapters <795>, <797>, or <800> standards. We strongly urge the Board to adopt USP chapters <795>, <797>, and <800> as currently written. We acknowledge that in the past, additional requirements for compounded drug products from the Board were necessary due to outdated USP standards; however, this is no longer a concern. The published revisions of USP <795>, <797>, and <800> have undergone extensive review and careful decision-making by an expert committee. Revised chapters are now both current and comprehensive. Furthermore, creating new	The Board thanks the commenter for their consideration and understanding of the Board's policy goals and consumer protection mandate. The Board notes that federal law and the USP Compounding Chapters serve as an important foundation. The Board has current regulations governing compounding, hazardous drugs, and radiopharmaceuticals. The Board's approach to regulation in this complex area of practice must remain for patient safety. The Board has determined that Board regulations generally will not restate federal law and USP Chapters but will clarify and make more specific requirements, consistent with this authority. The Board notes that USP Chapters, while comprehensive, are many times not written in an enforceable manner and, further, do not address all patient safety issues. As examples, USP throughout Chapters, defers to regulators for requirements. In addition, nothing in USP or federal law establishes requirements for notification to the Board for

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			requirements that do not align with other regulatory and accreditation bodies (e.g., California Department of Public Health, The Joint Commission) can lead to confusion and unnecessary challenges in maintaining compliance.	example of an adverse drug experience (ADE). As the primary regulator of sterile compounding pharmacies, it is vital for the Board to specify all necessary protections to ensure both the Board and the regulated public have a clear and comprehensive understanding of the requirements for compounding. The Board's proposed regulations therefore provide additional requirements and definitions to promote public protection. The Board relied on a variety of sources of information in developing its regulations, including information from the FDA, USP, ASHP, enforcement actions to name a few. The Board notes that its approach is similar to the approach taken in some other states as well as the National Association of Boards of Pharmacy (which perform inspections of compounding pharmacies for accreditation purposes.) Board regulations may go above what is required by other agencies in some instances; however, staff are not aware of any of its regulations that are in conflict with accreditation standards.
4	General	CA Hospital Association	CHA does not believe the proposed modifications will enhance protection or promote health and safety. Additionally, they are duplicative of federal law. CHA believes that when states implement their own regulations on areas already covered by federal law, it leads to regulatory redundancy, which burdens businesses, individuals, and government agencies with unnecessary compliance efforts, legal complexities, and costs. CHA believes that the Board has not produced empirical evidence indicating either systemic challenges or that patients have been placed in harm's way — or that hospital pharmacies are not meeting safety standards that might necessitate additional regulations. Regulations lacking a solid evidence base will lead to unnecessary compliance costs for hospitals, and they may lead to confusion and legal disputes between regulators and businesses.	Board staff have reviewed the comment and do not recommend changes to the proposed text based on comments received. Board staff respectfully disagree with the view that the proposed modifications will not enhance protection or promote health and safety. The Board has provided significant information through its rulemaking documents, public discussion, and presentations that supports the need for the regulations and has engaged in a collaborative process with the development of the proposed regulations. Further, through the formal rulemaking process the Board has thoughtfully considered comments received and, in response to comments, made additional changes to the proposed text. Board staff note that the Board's Enforcement and Compounding Committee receives annual presentations on inspection findings, citations issued and enforcement actions taken for all pharmacies, including hospitals. This information is available on the Board's website.

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5	General	CSHP	CSHP believes that the business and economic impact identified in the ISOR is a gross underestimation of the associated costs. The Board should actively seek input from experts who can inform the Board as it relates to both the Business and Economic Impact. CHA requests the regulations be suspended so the Board can re-evaluate the Business and Economic Impact and to provide evidence the current regulations fail to address patient safety outcomes.	Board staff have reviewed the comments and do not recommend any changes to the proposed text based on the comments. Board staff note that the proposed regulations have been developed over the course of several years, providing many opportunities for engagement with interested stakeholders. Board staff note that the changes in USP Chapter standards resulted in additional costs to facilities. The Board has amended some of the language of the proposed text to address costs in response to the 45-day comment period. Staff respectfully disagree with the assertion that the Board has not engaged with experts. Staff note that two members of the Board are experts in compounding and system implementation. Further, the Board has experts on staff that have been extensively involved in the development of the regulations. Board staff complete significant training in compounding including receiving trainings from experts in a variety of areas including experts in USP 825, USP 797 room certification, etc. Board staff routinely complete USP and FDA training and participate in national meetings on the topic. Board staff also attended all of the USP Compounding meetings before the USP released its final standards. In addition, the Board seeks expert advice through a variety of other means including consulting with experts with a variety of different backgrounds including laboratory experts, veterinary practice, radiopharmaceutical practice, certification of rooms and equipment, other state regulators and accrediting agencies. The Board also collaborates with the FDA.
6	General	FlavoRx	Commenter provided a comprehensive listing of every mention of medication flavoring at the state level, either in statute, rule, or guidance.	Board staff have reviewed the information provided and appreciate the information provided. While the commenter did not provide specific provisions of the proposed regulation text for suggested change, other commenters did. With the provisions identified by the other commenters, Board staff are recommending changes to the proposed text.

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				Board staff recommend the addition of a subdivision specifically related to flavoring agents and an addition to 1735.1 (i) and Section 1735.15 related to compounding by combining a flavoring agent with an FDA approved drug in an oral liquid solution.
7	General	React 19	Why These Regulations Harm Patients: Unnecessary Barriers to Critical Treatments - The proposed regulations impose restrictions that go beyond federal FDA guidelines. Implementing regulations that conflict with and exceed FDA guidelines creates unnecessary barriers to care for patients and burdens for providers. Disproportionate Impact on Vulnerable Populations - By restricting access, the Board risks leaving these individuals without any viable options, forcing them to endure worsened symptoms and diminished independence. Risks to Medical Innovation - Sterile compounded medications are indispensable for advancing research into neglected conditions like Long Vax. Undue Influence - These restrictions not only disregard the needs of patients but also raise concerns about the motivations driving them, suggesting undue influence by pharmaceutical interests over patient care. What's at Stake - The Board risks sending the message that their suffering is invisible and their lives expendable. Recommendations React19 urges the Board to: 1. Withdraw the Proposed Regulations and align policies with evidence-based federal standards under FDA sections 503A and 503B. 2. Engage Stakeholders—including patients, clinicians, and researchers—in developing patient-centered guidelines that reflect real-world needs. 3. Delay Implementation to assess the regulations'	Board staff have reviewed the comments and do not recommend any changes to the proposed text based on the comments. Board staff note that development of the proposed regulations have occurred over the course of several years, providing many opportunities for engagement with interested stakeholders. Staff note that two members of the Board are experts in compounding and system implementation. Further, the Board has experts on staff that have been extensively involved in the development of the regulations. Board staff complete significant training in compounding including receiving training from experts in a variety of areas including experts in USP 825, USP 797 room certification, etc. Board staff routinely complete USP and FDA training and participate in national meetings on the topic. Board staff also attended all of the USP Compounding meetings before the USP released its final standards. In addition, the Board seeks expert advice through a variety of other means including consulting with experts with a variety of different backgrounds including laboratory experts, veterinary practice, radiopharmaceutical practice, certification of rooms and equipment, other state regulators and accrediting agencies. The Board also collaborates with the FDA.

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			unintended consequences on patient care and research.	
8	General	Kaiser	In our view, the Board's continued efforts to advance these proposed compounding regulations demonstrate that the Board is either unwilling or unable to critically evaluate whether there is a bona fide need for regulations that exceed the compounding standards published in the United States Pharmacopeia (USP). First, throughout the proposed regulation, the Board suggests onerous requirements that are not supported by any empirical evidence; specifically, the Board does not reference any peer-reviewed studies, systematic reviews, or even any case reports to support the notion that additional regulations exceeding the USP standards are necessary to protect California patients. It seems that the Board's analysis hinges on the logical fallacy that more must be better. Second, time and again, the Board fails to consider the behaviors that its proposed regulations will incentivize and the second order effects that those practices will likely precipitate. During its November 2024 discussion of the proposed compounding regulations, the Board received two presentations about federal and California requirements for compounding and the Board's approach to the regulation of compounding. As part of the second presentation, entitled "Compounding," Board staff provided four "examples of items not covered in USP or where USP defers to the state," ostensibly to justify the need for the Board's proposed compounding regulations. The four items identified were: (1) recall provisions and notification to the Board, (2) adverse event reporting, (3) terms lacking definitions, and (4) pharmacist-in-charge responsibility. First, if these four areas are the only reasons that additional regulation beyond the USP	The Board reviewed the comment and did not make changes to the proposed text based on the comment. The Board noted that the proposed regulation text provides significant flexibilities beyond what is currently allowed in existing regulations. The Board disagreed with the assertion that the Board's regulations in this area will shift compounding to non-pharmacy personnel. Also noted is that the commenter appears to be speculating about business operation decisions that could be made that would make compliance less safe. The Board is not able to respond to speculation on business operation decisions outside of its purview. As stated elsewhere by the Board in this rulemaking, the Board's jurisdiction is limited to the licensees within its practice act. For commenters interested in understanding the requirements for nonpharmacy personnel compounding and the requirements for those individuals and entities, it would be appropriate to contact the respective regulatory agencies. The Board noted that a variety of nonpharmacy personnel have the authority to compound including, for example, physicians and veterinarians. Such individuals must comply with the requirements of their regulatory agencies including, for example, immediate use provisions, as applicable. There is no requirement for the Board to cite empirical data as part of its rulemaking. Rather, the Board is required to cite empirical data when such data is relied upon. The Board includes reference to documents relied upon in its Initial and Modified Statement of Reasons and elsewhere in the rulemaking, which include for example the minutes from public discussions where cost issues could have been raised. Specifically related to the cost of gloves, staff note that costs may vary depending on the types of HD gloves, sterile versus nonsterile, and vendors used. The Chapter determines the types of gloves that must be used

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			standards are necessary, then we believe that these issues could be effectively addressed in one or two pages of regulations rather than the 50 pages of regulation put forward by the Board. Second, and more importantly requirements in the Pharmacy Law already address most of these areas. Finally, during its presentation, the Board did not provide any concrete examples of relevant terms that are not already defined either in the Pharmacy Law or in the USP chapters. Moreover, if the Board chooses to simply enforce the USP standards, as required under existing law, we expect that the definitions provided in the USP chapters would suffice. Given the lack of evidence to support the need for these regulations and the negative second order effects that the regulations will almost certainly precipitate, Kaiser Permanente supports the following alternative approach: 1. The Board should accept the proposal to repeal sections 1708.3, 1708.4, and 1708.5 of Title 16, Division 17, Article 2 of the California Code of Regulations and to repeal 1735 et seq of Title 16, Division 17, Article 4.5 of the California Code of Regulations and to repeal 1751 et seq of Title 16, Division 17, Article 7 of the California Code of Regulations. 2. The Board should reject the proposal to add new sections 1735 et seq of Title 16, Division 17, Article 4.5 of the California Code of Regulations, and to add new sections/Article 1736 et seq of 3. sections/Article 1737 et seq of Title 16, Division 17, Article 4.7 of the California Code of Regulations, and to add new sections/Article 1738 et seq of Title 16, Division 17, Article 4.8 of the California Code of Regulations.	depending on the functions being performed and establish a number of requirements for changing gloves. Such costs are related to provisions of the Chapter, not the Board's regulations. Inspections performed by staff reveal a variation in how facilities operationalize requirements related to donning gloves when compounding hazardous preparations. Inspectors note that in many inspections compounding personnel are using two pairs of sterile gloves and changing the outer gloves in between hazardous preparations as a means to mitigate the potential for cross-contamination. These inspection findings demonstrate that this practice is already occurring in a variety of settings. It is important to note that the Board may establish requirements for a myriad of reasons related to consumer protection and based on a variety of information sources, including observations made during past investigations or inspections, best practices, based on information from experts and other regulatory agencies, including for example the FDA and USP. Although the Board did not receive any significant comments on costs throughout the development of the rulemaking that occurred over a series of public meetings, the Board independently identified and reported costs including for SOP development and review (using the estimated time and the BLS pharmacy salary from May 2022) incubator cleaning and calibration cost estimates, estimates for hazardous plastic containers, costs for disposable mats, etc. Costs could vary greatly as the practice of compounding varies greatly, for example, some facilities only engage in nonsterile compounding, where other facilities may engage in all types of compounding. Further, some facilities are already, as a standard of practice, changing gloves consistent with both the requirements of the Chapter as well as the

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			4. The Board should enforce the provisions of the USP compounding chapters as required by Business and Professions Code section 4126.8. the Board elects to finalize the proposed regulations, we continue to encourage the Board to establish a rational effective date for these 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.	Board's proposed regulations. The Board did not include estimated costs associated with compliance with other legal requirements (e.g. federal requirements, title 22, building code, etc.) nor did it include costs incurred to comply with provisions of USP (for examples costs to perform testing, training etc.) Costs that were identified by the Board were estimated for each license issued based on all factors. If an entity owns more than one license, their costs could increase based on the number of licenses held. Presumably the costs incurred could be spread over various licenses with policies and procedures for example being shared. Although cost related to gloves was not raised during the public meetings where text was developed, costs related to glove requirements were raised during the formal comment period where the Board received specific comments regarding the cost of gloves. The Board's second modified text in 1737.7(c) reflect the change that could reduce the overall cost related to gloves without compromising patient safety. Staff further note that the Chapter establishes provisions for changing gloves and where the Chapter requires the use of and changing of gloves, such costs are a function of compliance with the Chapter, not the Board's regulation. Staff further note that costs for compliance with the minimum standards of the regulation should not be conflated with costs incurred by a facility and how it chooses to operationalize the requirement. As an example, the costs for a facility that elects to compound a single type of HD such as methotrexate for multiple patients before changing to compound a different type of HD preparation would most likely have a lower cost than a facility that does not operationalize the requirements in the same manner. Further, the types of HD compounding performed (e.g. hazardous versus nonhazardous, sterile versus nonsterile) would also factor into costs.

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				It is important to highlight that some of the changes in the proposed regulation text could also result in cost savings to facilities, such as provisions that allow for the transfer of some training from one location to another and increased provisions for immediate use.
9	General	Kaiser	During the November 2024 full Board meeting, the Board asked for stakeholders to include suggestions in their written comments for a “path forward” for the addition of flavoring agents to oral liquid medications. As the Board is aware, pharmacists have added flavoring to liquid medications for decades to make them less foul-tasting. Without citing any health or safety risk with these long-standing flavoring practices, the Board has decided that flavoring a medication is compounding and that pharmacists must meet burdensome compounding requirements if they add flavoring to a medication. Predictably, pharmacies have responded by declining to offer flavoring services to their patients. As a result, a safe and effective tool to help children take their medications is no longer available to California families. Regrettably, the Board has repeatedly demonstrated that they are not willing to consider commonsense solutions that would facilitate flavoring of prescription medications. Therefore, Kaiser Permanente has no additional suggestions to offer for a regulatory framework for the addition of flavoring agents to oral liquid medications. For two years in a row, the legislature has offered the Board a way out of this problem of the Board's own making in the form of Assembly Bills 782 (2023) and 3063 (2024), both of which the Board opposed—a position that likely contributed to the veto of both bills. The Board's dogmatic approach to regulating the flavoring of medications has removed an important tool that pharmacists have used for decades to make it easier for children to take their medications. Now the Board should take	The Board reviewed the comment and did not make changes to the proposed text based on the comment. Board staff note that USP Chapter 795 says that adding flavoring to an FDA approved drug is compounding. The Board was seeking stakeholder feedback to develop a path forward that did not run afoul with USP and the FDA.

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10	General	Crystal Frost	responsibility for solving this problem that it has created. Commenter believes that the proposed regulations threaten to dismantle the fragile lifeline that many patients, caregivers, and healthcare providers depend on. Your decision to advance these regulations, which severely restrict access to Category 1 sterile compounded treatments, is not just a regulatory overreach—it is a decision with profound and unjustified human consequences. Impact on Patient Access: A Matter of Life and Death These compounded treatments are not a luxury or a choice for the patients who rely on them. They are a necessity. They represent the only effective medical interventions for individuals whose conditions cannot be addressed by standard pharmaceuticals. Arbitrary and Unjustifiable Regulations The proposed amendments exceed federal and U.S. Pharmacopeia (USP) standards in dozens of ways, going far beyond what is required to ensure patient safety. They introduce barriers that are unnecessary and unsupported by evidence. Redundant Stability Testing: An Unnecessary and Costly Barrier Rooted in Misinformation The proposed amendments introduce stringent stability testing requirements for compounded medications, imposing significant financial burdens on compounding pharmacies. These costs will inevitably be passed on to patients, many of whom are already struggling to afford these essential treatments. Custom medications from compounding pharmacies are often the only option for patients with unique health needs, and the added expense from redundant testing threatens to make these treatments inaccessible. Imposing redundant testing requirements appears	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on the comments received. Board staff believe that the commenter, may in part, be referring to proposed regulation 1736.9 and 1736.17 related to bulk drug substances. Staff note a recommendation is being offered to clarify the testing requirements in this section and the ability of the pharmacy to rely on testing performed by a manufacturer, repackager or wholesaler. Please refer to the sterile compounding responses for additional information. Board staff believe the approach currently being proposed strikes an appropriate and necessary balance that both creates a pathway for pharmacies to legally compound using Category 1 bulk drug substances while ensuring that appropriate and feasible patient protection measures are in place. Provided below is the specific language of federal law and the USP that the Board is seeking to add clarity through its regulations to provide a legal pathway to compound using bulk drug substances. As the Board has noted previously, until the FDA formally makes a determination regarding bulk drugs substances nominated for inclusion in 21 CFR 216.23, the Board has determined that there is a need at the state level to provide a pathway to allow for such compounding. ``SEC. 503A. PHARMACY COMPOUNDING</b></p> <p>``(a) In General.--Sections 501(a)(2)(B), 502(f)(1), and 505 shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order or a

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			to be less about addressing real gaps and more about creating excessive financial and logistical barriers for compounding pharmacies, effectively pricing out vulnerable patients and eliminating access to life-saving treatments. This approach is not only unjustified but harmful. Commenter believes that the Board is "fearmongering" and "misrepresenting" federal laws. Additionally, commenter states that the Board is enforcing underground regulations. Board has cited these underground regulations in a claim that certain compounded substances lack USP drug monographs or are not of "pharmaceutical grade." However, this reasoning is fundamentally flawed. The FDA does not define or regulate "pharmaceutical grade" as a standard for compounding substances. Instead, the FDA evaluates compounded medications based on whether they are prepared using components that comply with existing USP standards or are listed on the 503A Bulks List. The Board's reliance on non-existent terminology and unsubstantiated assertions demonstrates a lack of understanding of federal guidelines and creates unnecessary confusion for pharmacies and patients alike. Commenter states that the Board is ignoring federal law by restricting 503A Bulks list substances.	notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding-- ``(1) is by--</p> <p>``(A) a licensed pharmacist in a State licensed pharmacy or a Federal facility, or ``(B) a licensed physician, on the prescription order for such individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or</p> <p>``(2)(A) is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and ``(B) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between--</p> <p>``(i) the licensed pharmacist or licensed physician; and ``(ii)(I) such individual patient for whom the prescription order will be provided; or</p> <p>``(II) the physician or other licensed practitioner who will write such prescription order. ``(b) Compounded Drug.--</p> <p>``(1) Licensed pharmacist and licensed physician.--A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician--

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				“(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations-- “(i) that-- “(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding; “(II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or “(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (d); “(ii) that are manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); and “(iii) that are accompanied by valid certificates of analysis for each bulk drug substance; “(B) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding; “(C) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of

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				drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective; and “(D) does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product. “(2) Definition.--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. “(3) Drug product.--A drug product may be compounded under subsection (a) only if-- “(A) such drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and “(B) such drug product is compounded in a State-- “(i) that has entered into a memorandum of understanding with the Secretary which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State; or

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				“(ii) that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician. [Page 111 STAT. 2330] The Secretary shall, in consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by the States in complying with subparagraph (B)(i). “(c) Advertising and Promotion.--A drug may be compounded under subsection (a) only if the pharmacy, licensed pharmacist, or licensed physician does not advertise or promote the compounding of any particular drug, class of drug, or type of drug. The pharmacy, licensed pharmacist, or licensed physician may advertise and promote the compounding service provided by the licensed pharmacist or licensed physician. “(d) Regulations.-- “(1) In general.--The Secretary shall issue regulations to implement this section. Before issuing regulations to implement subsections (b)(1)(A)(i)(III), (b)(1)(C), or (b)(3)(A), the Secretary shall convene and consult an advisory committee on compounding unless the Secretary determines that the issuance of such regulations before consultation is necessary to protect the public health. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopoeia, pharmacy, physician, and consumer organizations, and other experts selected by the Secretary.

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				“(2) Limiting compounding.--The Secretary, in consultation with the United States Pharmacopoeia Convention, Incorporated, shall promulgate regulations identifying drug substances that may be used in compounding under subsection (b)(1)(A)(i)(III) for which a monograph does not exist or which are not components of drug products approved by the Secretary. The Secretary shall include in the regulation the criteria for such substances, which shall include historical use, reports in peer reviewed medical literature, or other criteria the Secretary may identify. “(e) Application.--This section shall not apply to-- “(1) compounded positron emission tomography drugs as defined in section 201(ii); or “(2) radiopharmaceuticals. “(f) Definition.--As used in this section, the term ‘compounding’ does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product’s manufacturer and other manufacturer directions consistent with that labeling.”. From USP: “When CSPs are used as components, see 16. Use of CSPs as Components. All APIs and other components used must be evaluated for suitability for use in sterile drug preparation. Components labeled with “not for pharmaceutical use”, “not for injectable use”, “not for human use” or an equivalent statement must not be used to compound for these purposes. The Board’s underlying data includes additional information specifically related to this issue. Board staff note that the commenter has provided information about medical claims for the use of some of these bulk drug substances. It is recommended that the commenter reach out of the FDA, which is the regulatory

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				agency responsible for reviewing and determining which bulk drug substances are appropriate for inclusion in the federal regulations as well as the determining the appropriate clinical use of such bulk drug substances.
11	General	54 Commenters	These commenters oppose the restriction of compounded medication, including B12, Glutathione.	Board staff have reviewed the comment and do not recommend changes to the proposed text based on the comments provided. Board staff note that the Board's regulations establish provisions for compounding using bulk drug substances that are NOT included as part of the federal regulations under 21 CFR216.23 and provide a path to meeting the component requirements established in the USP. As included in the proposed responses to comments received related to sterile compounding requirements described in other responses, staff are recommending clarification related to the proposed testing requirements.
12	General	47 Commenters	These commenters oppose the restriction of compounded medication. Additionally, the commenters indicate that: • There was an unexpected presentation at the November Board meeting that contained inaccurate and misleading information. • There has been no cooperation with pharmacies, hospitals, providers, or patients. • Would put an unreasonable financial burden on hospitals and other providers. Commenters request that the Board adopt the USP standards.	Board staff have reviewed the comments and do not recommend any changes to the proposed text based on these comments. The comments are general in nature. Staff provide the following general responses. 1. The Board's November 6-7, 2024, Board meeting agenda appropriately noticed the presentations. 2. The Board has provided multiple opportunities for stakeholders to engage in the development of the proposed text. Further the rulemaking process has so far provided two formal comment periods in addition to a regulation hearing. 3. The Board notes that many of the costs identified are not related to the cost of the Board's regulations but the costs to comply with the national standards established in the USP. A recommendation to further modify the proposed text is being offered specifically related to the testing of bulk drugs substances. (Refer to the comments in response to comments received related to sterile compounding requirements.) The Board has modified the text through the rulemaking process to address concerns related to costs,

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				including the requirements for use of disposable preparation mats, provisions for changing gloves, etc. Further additional proposed changes are being offered in this area. Compliance with the USP standards is established in federal and state law.
13	General	27 Commenters	These commenters oppose the restriction of Category 1 sterile compounds. Additionally, commenters indicate that the Board has not provided empirical evidence to justify the restrictions, has not engaged with stakeholders, and denied ADA accommodations. Commenters request exemption for medications with no FDA approved alternatives and request a one year delay in implementation.	Board staff have reviewed the general comments and do not recommend changes based solely on these comments. Staff have recommended changes based on specific comments received related to the use of Category 1 bulk drug substances. These recommendations are reflected in the responses to specific comments in the related regulation sections. Board staff respectfully disagree with the assertion that the Board has not engaged with stakeholders and direct the commenters to the Initial Statement of Reasons, which provides information on the public meetings convened in the development of the proposed regulations. The Board further respectfully disagrees with the assertion that the Board has improperly denied ADA accommodations. When accommodation requests are received, the Board works with legal counsel and adheres to applicable provisions of the law in evaluating and responding to the request. The Board has considered delayed implementation and identified specific areas that are appropriate for additional time to comply. In such instances the proposed regulation text reflects additional time to comply.
14	General	Chance Dite	The commenter expressed concern about the possible hindrance to effective care to treatments that are not available through standard channels. The commenter states false information was provided by individuals without medical expertise. The commenter request that the Board adopt the USP standards and allow Category 1 substances.	Board staff have reviewed the comment and do not recommend changes to the proposed text based on these general comments. Staff are recommending changes to the proposed text related to bulk drug substances to clarify that the SOP provisions in 1736.17 to more explicitly state that the testing does not need to be done by the pharmacy.

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				Further, Board staff note that the stability testing requirements established in the Chapter establish provisions to allow for the use of stability studies conducted by other entities under specified conditions. There is nothing in the Board's proposed regulation text that change that flexibility.
15	General	Julip Thomas	Commenter expressed concern about the regulations: No Evidence to Justify Restrictions: The Board hasn't provided any solid evidence that these changes are needed or that they'll prevent harm. Procedural Issues: Disabled stakeholders were denied ADA accommodations and forced to wait for hours to comment, worsening their health in the process. Harm to Patients: These rules would block access to life-saving therapies for people with conditions like Long COVID and ME/CFS, who rely on compounded medications because there are no FDA-approved options. Unanimous Public Opposition: Every comment submitted has been against these rules, but the Board continues to push them forward without addressing the concerns raised. Favoring Big Pharma: It seems that the regulations would benefit pharmaceutical companies, particularly in the case of GLP-1 therapies, while restricting access to compounded treatments that many patients depend on. At a minimum, I respectfully ask the Board to consider exemptions for Essential Compounded Medications: Please allow exemptions for critical compounded treatments like glutathione, NAD+, and vitamin B12 for patients who have no FDA-approved alternatives. One-Year Delay: A one-year delay would give stakeholders more time to adapt and allow for	Board staff have reviewed the comments and do not recommend any proposed changes in response to these general comments, but note that Board staff are recommending changes based on the specific comments received, included proposed changes to section 1736.17 related to SOPs for compounding with the bulk drug substances referenced in the comments from this commenter. The Board has considered delayed implementation and identified specific areas that are appropriate for additional time to comply. In such instances the proposed regulation text reflects the additional time to comply.

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16	General	Bobgo1970@gmail.com	better consultation to make sure the final decision is well-informed and doesn't disrupt patient care The standard to which the Board attempts to hold pharmacies accountable is based on their usage of a term - 'pharmaceutical grade' - which has no specified legal or official definition within the FDA's regulations. 'Pharmaceutical grade' is indeed a commonly utilized term, despite the fact that it lacks a concise definition. USP797, which deals exclusively with compounding of Sterile products, in section 9.3.1, states an API "Must comply with the criteria in the USP–NF monograph, if one exists", thus implying that an API MAY be used even if a USP-NF monograph does not exist. Commenter urges the Board to allow sterile compounding of substances that do not have USP drug monographs but are listed in the 503a category 1 bulk drug substances list and that do meet quality requirements for sterile compounding. Commenter requests clarification on the applicability of the regulations to Physicians, Veterinarians, and 503b substances. Remove need for category 3 CSP standards for compounding of category 1 bulk substances to preserve access for patients, as this is NOT an FDA requirement and we have not seen scientific validation for this requirement. Also remove need for these substances to be available only via 503a patient specific pharmacies, if these regulations ARE intended to apply to outsourcing facilities as well. Commenter summarizes with five summary issues. 1. Explicitly allow the sterile compounding of substances that do not have a USP pharmaceutical monograph but that appear on the category 1 Bulks list, if sterile	Board staff have reviewed these general comments. Board staff do not recommend any proposed changes to the text based on these general comments but note that Board staff are recommending changes based on the specific comments received. Board staff note that the commenter only provides a portion of section 9.3.1. Chapter 797 includes additional language that must also be read to understand the full requirements of the Chapter. Staff also note that federal law establishes provisions related to the types of substances that can be used in compounding, including provisions for the use of bulk drug substances. The Board's proposed regulations establish provisions for compounding using specified bulk drug substances under specified conditions and staff are recommending addition changes to the proposed modified text in CCR Section 1736.17 related to SOP requirements. The Board appreciates the commenter referencing the applicability of USP Chapter 232. The Board agrees with the applicability of this USP Chapter and references USP Chapter 232 in the proposed text related to SOPs in proposed section 1736.17. Below are responses to the specific summary issues. 1. The commenter requests that the Board explicitly add to the new regulations language that would allow sterile compounding of substances that do not have USP drug monographs but are listed in the 503a Category 1 bulk drug substances list and that do not meet quality requirements for sterile compounding. Board staff note that the proposed modified text released for the 30-day comment period include such provisions. (Refer to proposed regulations 1736.9(e)(1) and 1736.17(a)(2)(E) 2. The Board note that Board's regulations apply to licensees within the Board's jurisdiction. The Board's

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			compounding of such substances is not prohibited by the FDA bulks list document, and as long as they meet commonly accepted standards for pharmaceutical grade including impurity testing, regardless of whether a USP pharmaceutical monograph exists for that substance. 2. Revisions to explicitly limit your compounding regulations to pharmacists, not to in-office compounding by nurses, physicians, veterinarians, dentists, and naturopaths, as allowed in USP797, to prevent the CA BOP from targeting other professionals as practicing pharmacy without a license or attempting to regulate their compounding practices. 3. Include both 503a AND 503b bulk category 1 substances as those allowed to be compounded (as consistent with current FDA regulations), or explicitly state that the regulations are not intended to regulate outsourcing facilities so that their ability to compound 503b bulks substances is not impacted. 4. Remove need for category 3 CSP standards for compounding of category 1 bulk substances to preserve access for patients, as this is NOT an FDA requirement and we have not seen scientific validation for this requirement. Also remove need for these substances to be available only via 503a patient specific pharmacies, if these regulations ARE intended to apply to outsourcing facilities as well.	jurisdiction is limited to those businesses and individuals within its practice act. 3. The commenter requests that the Board discuss requirements for outsourcing facilities. Board staff note that outsourcing facilities must comply with current good manufacturing practices (cGMP) and separate Board regulations. The proposed regulations in sections 1735 et seq, 1736 et. seq, 1737 et seq, and 1738 et seq do not apply to outsourcing facilities. 4. The commenter suggests that the Board's proposed regulation text requires compliance with all requirements for Category 3 USP standards if compounding with Category 1 bulk drug substances. Board staff believe this comment is referring to requirements in proposed section CCR 1736.9(e)(2)(A)(i). The proposed regulation text in this area only require compliance with USP Chapter 797 stability testing, not all provisions related to Category 3 compounding. As indicated elsewhere in the Board's proposed responses to comments received, the USP Chapter establishes provisions to allow for an individual or entity to rely on the stability testing conducted by another entity under specified conditions.

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			The commenter also submitted a specific comment related to 1736.1(b)(1). Response to this comment is provided in the response to comments related to sterile compounding.	
17	General	Sara Johnson	Commenter opposes the regulation for the following reasons: Denial of Requested Accommodations: Commenter requested accommodations to make a comment early for an agenda item because the hours-long wait would exacerbate a disability. The request was supported by detailed medical documentation; however, the accommodation was denied, and no alternative solutions were offered. Lack of Transparent Stakeholder Engagement: Commenter states that the Board has not provided evidence of meaningful engagement with key stakeholder groups that the proposed regulations would directly impact. Violation of the Board's Mission Commenter states the proposed regulations directly contradict this mission by restricting access to therapies essential for vulnerable patients and critical research efforts. Harm to Vulnerable Patients Commenter states the proposed regulations fail to account for the real-world consequences of restricting sterile compounded medications for vulnerable populations. Patients with complex chronic illnesses like ME/CFS and Long COVID rely on compounded therapies as lifelines. Lack of Supporting Evidence in the ISOR Commenter states the Initial Statement of Reasons lacks empirical evidence demonstrating risks posed by current compounding practices and overlooks the well-established safety records of therapies like glutathione, NAD+, and vitamin B12. Absence of Evidence of Harm	Board staff have reviewed the general comments and do not recommend any changes to the proposed regulation text based on these general comments but note that staff are recommending a number of changes based on specific comments received, which may also address some of the issues suggested by the commenter. Denial of Requested Accommodation: Board staff respectfully disagree that the Board has improperly denied ADA accommodations. When an accommodation request is received, the Board works with legal counsel and adheres to applicable provisions of law in evaluating and responding to the request. Board staff further note that the commenter has been provided with the process to file a formal complaint consistent with DCA policy. Lack of Transparent Stakeholder Engagement: Board staff respectfully disagree. Staff refer commenter to the public rulemaking record that documents the development of the proposed regulations and opportunities for participation by interested stakeholders. Violation of the Board's Mission. Board staff respectfully disagree. Harm to Vulnerable Patients. Board staff believe the commenter may be referring specifically to provisions related to compounding with bulk drug substances. Board staff note recommendations are being made to further amend the proposed text in CCR 1736.17 related to compounding with bulk drug substances. Lack of Supporting Evidence in the ISOR: Board staff have reviewed the comment and respectfully disagree. The

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			Commenter states the ISOR does not present data showing harm from existing compounding practices in California. While there have been isolated incidents in other states—such as the 2012 New England Compounding Center (NECC) tragedy in Massachusetts—these events are not reflective of practices in California. Double Standards in Regulatory Scrutiny Commenter states the ISOR summarizes the regulations being proposed for compounded medications evidence, it overlooks significant failures associated with FDA-approved drugs. Scientific Evidence Supporting Compounded Therapies Commenter states research strongly supports the safety and efficacy of sterile compounded medications for conditions like ME/CFS and Long COVID. Impact on Research and Innovation Commenter states the proposed regulations pose a significant threat to critical research efforts to understand and treat ME/CFS, Long COVID, and related conditions. Sterile compounded medications are essential tools in clinical trials and translational research that seek to unravel the complexities of these debilitating illnesses. Misalignment with Federal Standards Commenter states the proposed regulations exceed FDA guidelines without clear justification, creating duplicative compliance requirements that are costly, impractical, and unnecessary. Marginalization of Compounded Medications: Protecting Pharmaceutical Interests Commenter states that framing compounded medications as "risky" or "unproven" appears to protect the market dominance of pharmaceutical companies producing FDA-approved drugs. Overwhelming Public Opposition	Initial Statement of Reasons, public records, as well as information released from the FDA including its evaluation on the safety of a number of bulk drug substances has been considered and is available for the public to review. Where the public believes that a bulk drug substance is appropriate for inclusion in the federal regulation 21 CFR 213.23, individuals should consider following the FDA process for recommending such. Until such time as such bulk drug substances are formally approved by the FDA for use in compounding and included in the federal law, pharmacies can follow the Board's proposed regulations to use specified substances in compounded preparations. Absence of Evidence of Harm: Board staff have reviewed the comment and respectfully disagree. Board investigations and public documents from the Board, the FDA, ISMP, the Pew Charitable Trust and others have identified harm stemming from compounding practices. Double Standards in Regulatory Scrutiny: The Board appreciates the comments and notes the FDA is responsible for the approval of drugs and the regulation of drug manufacturers. Concerns about the regulation of drug manufacturers should be provided to the FDA. The FDA and state boards have shared jurisdiction over compounding with provisions established in federal law, national standards (that must be met as required in federal law) and state law. Scientific Evidence Supporting Compounding Therapies: The Board recommends that the commenter provide this information to the FDA, the agency responsible for evaluating and approving bulk drug substances for inclusion in federal regulation. Impact on Research and Innovation: Board staff note that federal law establishes provisions for clinical research and human drug trials. One good source to learn more about the process is clinicaltrials.gov.

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			Commenter states that the regulation have faced large-scale and unanimous opposition from all stakeholders, including sitting Board members. Advocacy for Alternatives and Delayed Implementation Commenter states that rather than imposing sweeping restrictions, the Board should facilitate safety improvements that preserve access to essential therapies, including exemptions for essential sterile compounded medications such as glutathione, NAD+, and vitamin B12 to maintain access for patients managing debilitating conditions, provide grants or low-interest loans and streamline licensing processes to help pharmacies invest in necessary equipment and facilities without bureaucratic hurdles, offer extensive training programs on sterile compounding best practices and provide access to compliance guidelines and technical assistance to uphold high standards, and engage pharmacies, healthcare providers, and advocacy groups in rule-making to develop practical, evidence-based regulations and foster partnerships that support compliance. The commenter states that if the Board proceeds with the regulations, implementing a one-year delay is essential. Legal and Ethical Overreach Commenter states that the proposed regulations represent a violation of established federal standards and create unnecessary barriers to care. Restricting essential treatments without evidence of harm, the Board violates the ethical principle of non-maleficence—"do no harm." Commenter states that they are prepared to support legal challenges to ensure compliance with the APA and to hold the Board accountable	Misalignment with Federal Standards: As part of the comments, the commenter suggests that the Board, in developing its regulations has violated the APA process. Board staff respectfully disagree. Staff further note that as part of the proposed regulations, the Board is seeking to provide a legal pathway to compounding using bulk drug substances that have not been approved by the FDA and included in federal regulations, under specified conditions. The Board believes its proposed approach aligns with federal enforcement discretion policies while also providing clear guidance on how to comply with insanitary conditions requirements and USP components requirements. Marginalization of Compounded Medications: Board staff note that public documents from a number of entities including the FDA, ISMP, the Pew Charitable Trust and others have highlighted patient safety concerns with compounded medications. This should not be interpreted as suggesting that compounding cannot be safe. To the contrary, federal law, national standards and Board regulations all seek to promote consumer protection. Overwhelming Public Opposition: Board staff have reviewed the comment and do not recommend changes to the proposed text based on this comment. The requirements for compounding, whether the national standards or proposed Board regulations, generally elicit significant comments from interested stakeholders. For example, the USP received and responded to 178 comments relating to the development of the USP 795 national standards. The USP responded to each of the comments, accepting some comments, partially accepting some comments and not incorporating some of the comments.

#	Section	Commenter	Comment	Board Response
			for advancing regulations that lack evidence-based justification.	The USP received 1,705 comments in response to the development of USP Chapter 797 standards again accepting some comments in full, partially accepting some comments, and not incorporating some of the comments. Regarding the comment that sitting Board members are opposed to the proposed regulations, Board staff note that individual Board members frequently express their concerns in public meetings in response to public comments received. Board staff further note that the power of the Board is vested in the Board itself - which acts by collective decision at a meeting – and does not reside with any individual Board member. The purpose of a Board meeting is to allow for an open and frank discussion about proposed actions. Individuals interested in learning about the Board's discussion and action can view the meetings in their entirety through the livestreams posted on the Board's website. Advocacy for Alternatives and Delayed Implementation: The comments provided in this section do not appear related to the compounding text, but rather are offering recommendations to the Board on its approach to regulation. Commenter is requesting a delay in the effective date of the regulations. The Board has considered delayed implementation and identified specific areas that are appropriate for additional time to comply. In such instances the proposed regulation text reflects additional time to comply. Legal and Ethical Overreach: Board staff respectfully disagree that the proposed regulations represent a violation of established federal standards. The proposed regulations, as with any action taken by the Board, are pursued consistent with its statutory mandate and its rulemaking authority.

#	Section	Commenter	Comment	Board Response
				Upcoming Sunset Review and Oversight Implications: The comments provided in this section of the comment do not appear to be related to specific proposed regulation text. Staff note that it looks forward to working with the Legislature and the Administration during the sunset review process. The commenter is requesting five actions from the Board. 1. Reject the proposed regulations. Board staff disagree with this recommendation for numerous reasons detailed in public materials as well as this rulemaking record. 2. Adopt targeted alternatives: The Board has considered all recommendations to changes the proposed regulation text and will continue to do so in compliance with the APA. The Board has made significant changes to the proposed text based on all of the comments. To assist individuals in submitting comments, the Board provided a recommended template for submission of comments. While not required, comments submitted with specific language and details are easier to consider and respond to. 3. Delay Implementation: The Board has considered delayed implementation and identified specific areas that are appropriate for additional time to comply. In such instances the proposed regulation text reflects additional time to comply. 4. Engage stakeholders: The Board has provided numerous opportunities for stakeholders to engage in the process. Board staff note that the development of the proposed regulations have occurred over several years, providing an opportunity for engagement with interested stakeholders. Staff disagree with the assertion that the Board has not engaged with experts. Staff note that two members of the Board are experts in compounding and system implementation. Further, the Board has experts on staff that have

#	Section	Commenter	Comment	Board Response
				been extensively involved in the development of the regulations. In addition, the Board seeks expert advice through a variety of means including experts with a variety of different backgrounds including laboratory experts, veterinary practice, radiopharmaceutical practice, certification of rooms and equipment, other state regulators and accrediting agencies. Further, the Board dedicated significant time to review and evaluation of the USP Chapters along with the FAQs and commentary. The Board also collaborates with the FDA. 5. Ensure Compliance with APA and OAL standards: The Board is following the APA process. Several oversight and control agencies monitor the Board's rulemaking activities and evaluate the Board's actions to ensure compliance with the requirements.

#	Section	Commenter	Comment	Board Response
1	1735(d)	Novo Nordisk	Comment: We support the Board's revisions to the definition of "essentially a copy" in the nonsterile compounding regulations. In particular, the requirement that the prescriber determination of a clinically significant difference for an identified individual patient be verified and documented by the pharmacist is consistent with FDA's 503A Copies Guidance. The agency's guidance provides that a compounder should maintain records to show compliance with section 503A(b)(1)(D) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), which is the restriction on compounding "essentially copies of a commercially available drug product." FDA states in its guidance that, for example, "records should be kept of notations on prescriptions for identified individual patients that a prescriber has determined that the compounded drug has a change that produces a significant difference for the identified patient." Further, we agree that pharmacists should take steps to verify those determinations. The Board's updates to the definition of "essentially a copy" help to ensure that patients receive the benefit of the prescriber determination requirement, which is an important check on the compounding of unapproved compounded drug products. Specifically, the prescriber determination is intended to ensure that compounding of drug products is based on the legitimate medical need of an individual patient. We recommend adding to the definition of "essentially a copy" at Section 1735(d) the requirement that documentation of the prescriber determination be maintained in a readily retrievable format. This requirement was originally at Section 1735.1(e)(1) of the Second Modified Text, and our recommendation in this regard is not intended to make any substantive change to that requirement. Rather, we propose merely to	Board staff have reviewed the comment and do not recommend any change to the proposed text. Staff note that proposed regulation Section 1735.14(a) provides that records shall be maintained as required by USP Chapter 795 and this article in a readily retrievable form. The records suggested by the commenter would be covered by the provisions in Section 1735.14(a).

			relocate that language as a result of our recommended changes to Section 1735.1(e)(1), described below. Recommended language revision: “‘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 verified and documented by the pharmacist, between that compounded preparation and the comparable commercially available drug product. Such documentation must be maintained in a readily retrievable format.”	
2	1735(d)	CMA	CMA is concerned that the Board's proposed modified text establishes a new requirement for pharmacists to “verify” that a prescribed compounded drug product produces a clinically significant difference for the medical need of an identified individual patient under specific conditions. CMA acknowledges the role of pharmacists exercising professional judgment, as outlined in Business and Professions Code (BPC) section 4306.5. However, the proposed requirement to “verify” introduces unnecessary and unintended rigidity into the process. Contrary to the Board's assertion, mandating verification in every instance of compounding a drug that is otherwise commercially available and not on a shortage list sets a prescriptive standard for how pharmacists must exercise their professional judgment. The language of the regulations expressly requires pharmacists to verify the existence of a clinically significant difference for each compounded preparation in this situation, rather than allowing	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that this issue was previously considered by the Board, most recently during the January 8, 2025, Board Meeting. As approved by the Board during the January 8, 2025, board meeting, the second modified text included the requirement that a pharmacist verify that a prescribed medication is clinically appropriate for a patient, irrespective of whether it is a compounding medication.

			pharmacists to exercise their professional judgment as to when such verification may be warranted. This mandate impedes the flexibility the Board claims to seek to preserve and, as such, the language violates the clarity standard because it conflicts with the Board's description of the effect of the regulations in its response above. Pharmacists are already obligated to exercise judgment when dispensing dangerous drugs and are empowered by BPC section 733(b)(1) to refuse to dispense a prescription based on professional judgment, potential harm, or legal concerns. Eliminating the "verify" requirement from the proposed regulation would not abrogate pharmacists' statutory responsibilities but would instead maintain the flexibility pharmacists need to practice most effectively. The verification requirement would also impose significant administrative burdens on both pharmacists and prescribing physicians. For each compounded medication, pharmacists would need to collect and document proof of verified clinical significance for the prescribed drug, while physicians may be required to provide additional supporting evidence. This process could lead to delays in dispensing compounded medications, creating barriers for patients who rely on these treatments. For some patients, such delays could limit timely access to necessary therapies, ultimately harming their care. Finally, federal law, specifically 21 USC § 353a and 21 CFR Part 216, does not establish a documentation requirement, let alone a verification requirement for compounding. FDA guidance only recommends that "[...] the compounder should ensure that the determination is documented on the prescription." The guidance also clarifies that the FDA "[...] generally does not intend to question prescriber determinations that are documented in a prescription or notation."	

			Current state regulations require pharmacists to retain the documentation of the determination of clinical significance. The Board's proposal, however, goes beyond all of these standards by mandating that pharmacists both verify and document the prescriber's determination. This additional verification obligation introduces a new requirement, not a clarification of existing state or federal statute. By creating this new regulatory standard, the proposal could be interpreted to place an unprecedented burden on pharmacists, that of duplicating the evaluation already made by the prescriber. This shift in legal construction is unnecessary, given that pharmacists are already accountable for using their professional judgment to ensure compliance with established pharmacy laws. For these reasons, CMA recommends deleting "verify and" from proposed sections 1735(d), 1735.1(e)(1)(B), 1736(d), and 1736.1(e)(1)(B) of the second modified text. This would maintain the documentation standard established in current regulation while ensuring pharmacists retain the flexibility to perform verifications as deemed appropriate based on their professional judgment, as intended by the Board.	
3	1735(d)	Wedgewood	Prescribers' submission of a compounded preparation to a compounding pharmacy should be sufficient documentation to that an essentially a copy produces for that patient a clinically significant difference. The current definition allowed a pharmacist to use their professional judgement when determining whether a compound is essentially a copy. While we appreciate that clarity in the notes, the definition remains ambiguous to that intent and as such, we request that a clarifying statement be added to that	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that this issue was previously considered by the Board, most recently during the January 8, 2025, Board Meeting. As approved by the Board during the January 8, 2025, board meeting, the second modified text included the requirement that a pharmacist verify that a prescribed medication is clinically appropriate for a patient, irrespective of whether it is a compounding medication. Should it be helpful, Board staff refer the commenter to some specific provisions of the law that establish specific

			effect. Without that clarity, enforcement action could be taken against a pharmacist if their professional judgement were called into question. Additionally, we argue that it is a fact, not an opinion, that a licensed prescriber who executes a valid prescription for a compounded medication has made the clinical determination within their scope of practice, expertise, and licensure that the medication prescribed produces a clinically significant difference for that patient. Absent indications within the scope of a pharmacist's licensed scope of practice and professional judgement, a pharmacist cannot be required to make inquiries to the clinical rationale and professional judgement of the prescriber as the pharmacist is neither qualified nor licensed to make such a judgement and even attempting to endeavor to do so could be characterized as unlicensed and prohibited clinical practice. The Board is not authorized to require pharmacists to exercise clinical judgement outside of the practice of pharmacy.	requirements for pharmacists to evaluate prescriptions prior to dispensing including as examples:. Health and Safety Code section 11153 Business and Professions Code section 733 Title 16, California Code of Regulations Section 1707.3
4	1735.1	CA Rheumatology Alliance And CA Society of Plastic Surgery	We have reviewed the staff responses to our comments and continue to be concerned with the applicability of the proposed regulations on physicians and their ability to "compound" medications in their offices. Although physicians may not be under the enforcement jurisdiction of the Board of Pharmacy, we believe the proposed regulations would change the standard of care for when physicians compound medications and will not allow rheumatologists/ physicians to buffer injection/ infusion medications in-office. We are interpreting the proposed regulations to require a pharmacist be present or performing the buffering of the injection/ infusion medications. Rheumatology practices/physicians would not be able to afford to employ a pharmacist for this one purpose. This would lead to rheumatology practices no longer offering this service for our	Board staff have reviewed the comment and do not recommend a change to the proposed text based on the comment. Board staff note that the Board has previously considered this comment, most recently during the January 8, 2025, Board Meeting and determined that the requested change is not appropriate. As was previously shared, staff note the Board only has jurisdiction over individuals and businesses within its practice act. Board staff read the comment as suggesting that the Board's proposed regulations would apply to a physician. Business and Professions Code section 4170(c) makes clear that the Medical Board of California is specifically charged with the enforcement of Pharmacy Law (Chapter 9, Division 2 of the Business and Profession Code) with respect to its licensees.

		patients. Patients would then be forced to obtain their injection/infusions at a hospital or infusion center which would not only be less convenient for our patients, but it would be more expensive for the patient and the overall healthcare system. We believe it is important to note we are not aware of any issues with rheumatologists/physicians "compounding" injection/ infusion medications. We would like to propose the Board of Pharmacy adopt the language suggested by the California Medical Association as shown below: § 1735.1: In addition to the standards in USP Chapter 795 and, Food Drug Cosmetic Act (FDCA) section 503a (21 U.S.C. §353a) the compounding of a CNSP shall meet the following requirements of this article. <u>This article shall not apply to compounding by or under the direct supervision of a licensed physician and surgeon.</u>	It may be appropriate for the commenter to confer with their licensing board to discuss their concerns. Board staff note that the Medical Board of California has previously provided a written response to individuals inquiring about the applicability of the Board of Pharmacy's regulations to individuals and practices that operate under the jurisdiction of the Medical Board of California. Below is the information provided from the Medical Board - - <i>Dear Ms. Sodergren:</i> <i>I understand that some concerns have been raised by stakeholders about the applicability of the Board of Pharmacy's pending compounding regulations to licensees of the Medical Board of California (MBC). Existing statute (see Business and Professions Code (BPC) section 2220.5) makes it clear that only the MBC can discipline its physician licensees.</i> <i>Whenever a physician is engaging in compounding (or any other action that their medical license authorizes them to perform) they must always do so consistent with the standard of care. For the purposes of MBC's enforcement program, the standard of care is established by expert testimony in the context of the facts and circumstances of a specific case.</i> <i>It is certainly possible that whatever regulations that are implemented by the Board of Pharmacy may influence the standard of care for physicians who are compounding, especially since some of the proposed regulations reflect what is already required for physician compounding under federal law, including, but not limited to, Section 503A of the Federal Food, Drug, and Cosmetic Act (BPC section 2225(b) allows MBC to investigate violations of federal law related to the practice of medicine).</i> <i>Feel free to share this message with others as you see fit who might also be concerned about the applicability of their pending regulations to the physician community. Please contact me if you have any further questions.</i> <i>Sincerely,</i> <i>Reji Varghese</i>

				Reji Varghese is the Executive Director for the Medical Board of California. The Medical Board is charged with evaluating compounding practices and the standard of care relevant to its licensees.
5	1735.1	FLAVORx	Recommendation: "A facility that compounds using flavoring agents combined with a prescribed FDA approved drug in an oral liquid dosage form at the request of a prescriber, patient or patient's agent shall be exempt from the requirements established in subdivision (f) and Sections 1735.2 – 1735.13." Dropping the word "limits" clears up the confusion around whether sections 1735.2-1725.13 would apply to all flavorings should a facility also perform occasional compounding of Tamiflu, amoxicillin, magic mouthwash, etc.	Board staff have reviewed the comment and thank the commenter for highlighting that the second modified text needs clarification. Staff note that the examples provided by the commenter appear to be intending to expand the Board's policy - - limiting the applicability of Board's compounding exemption for a facility that is solely compounding by adding of a flavoring agent. Staff note that if a facility is flavoring a prescription that is reconstituted pursuant to the FDA approved labeling would meet the exemptions proposed. However, a facility that compounds, for example, magic mouthwash would NOT be exempt under this subdivision as the facility is NOT limiting its compounding solely to the adding of a flavoring agent. <u>1735.1(i) A facility that limits its compounding to combining a flavoring agent with a prescribed FDA approved drug in an oral liquid dosage form at the request of a prescriber, patient or patient's agent shall be exempt from the requirements established in subdivision (f) and Sections 1735.2 – 1735.13. A facility that performs any other form of nonsterile compounding at any time is not exempt as provided in this subdivision.</u>
6	1735.1(c)	Marie Cottman	Remove duplication of language "is necessary" because having the phrase twice in the same sentence is confusing. Recommend revision: (c) Notwithstanding subdivision (a), a limited quantity of a CNSP may be prepared and stored in advance of receipt of a patient specific prescription document where it is necessary, and solely in such quantity, ~~as is necessary~~, to ensure continuity of care of individual patients based on a documented	Board staff have reviewed the comment. Board staff believe that the language included in the second modified text is clear, however, receipt of this comment suggests otherwise. In response to the comment, Board staff recommend the following change: <u>1735.1(c) Notwithstanding subdivision (a), a limited quantity of a CNSP may be prepared and stored in advance of receipt of a patient specific prescription document where it is necessary, and solely in such quantity, ~~as is necessary~~, to ensure continuity of care</u>

			history of prescriptions for those patient populations.	<u>of individual patients based on a documented history of prescriptions for those patient populations.</u>
7	1735.1(d)	Wedgewood	Based on staff comments an amount of compounded drug may be furnished to a veterinarian based on the estimated need of the veterinarian as submitted on a purchase order will be considered the determination of a reasonable quantity. We appreciate the Board's recognition of Office Use (Stock) as an important service provided by pharmacies to veterinary medicine professionals and we appreciate the expansion of the ability to dispense from Office Stock to 14 days. We are concerned about the continuing ambiguity of the phrase "reasonable quantity" as it remains undefined in this draft. We are not opposed to placing limitations, but a lack of definition creates ambiguity, risks inconsistent enforcement, and further calls on pharmacists to exceed their scope of licensed practice. In the Board's response to our comment it was noted, "As the commenter notes, reasonable quantity is further clarified in paragraphs (1) and (2)". We interpret this to mean that the veterinarian's purchase order indicating that the order is for office administration, or application, and for dispensing no more than 14 days' supply constitutes a reasonable quantity and will proceed under that assumption unless further clarity is provided. As such, we will not be required to make a determination of whether the licensed prescriber "fairly estimated" the days' supply ordered.	Board staff have reviewed the comment and do not recommend a change to the proposed text. Board staff believe the proposed modified text is clear when read in its totality. This issue was considered most recently by the Board during its January 8, 2025, meeting. During this meeting the Board approved changes to this section that were included in the second modified text and allows for a 14-day supply as specified.
8	1735.1(e)	Outsourcing Facilities Assoc.	The proposed amendment should be revised for additional clarity, for the reasons stated below: The proposal demanded that pharmacists engage in the practice of medicine in	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that this issue was previously considered by the Board, most recently during the January 8, 2025, Board Meeting.

		contravention of California law, imposed obstacles to federal policies under the FDCA in contravention of federal law, and operated in erratic ways for no rational policy objective. The Second Modified Text appears to address OFA's objections or at least those along similar lines by requiring only that a "pharmacist verifies and documents" a clinically significant difference, rather than make the determination of clinically significant difference, which the prescribing practitioner must do under federal law. However, the Second Modified Text of Proposed § 1735.1(e) may fall short of achieving these objectives because it is arguably ambiguous concerning (1) what is to be verified and documented and (2) what verification and documentation is required. First, the shift from a determination standard to a verification and documentation standard indicates that the pharmacist under the Second Modified Text need only verify and document that a prescribing practitioner has made a finding of clinically significant difference. But there is an arguable ambiguity: the draft text's reference to verifying and documenting directly "that the compounding produces a clinically significant difference" could be misunderstood to require that pharmacists find an actual clinically significant difference in possible conflict with doctors' findings. The text should be revised to make clearer that the pharmacist must verify and document that the prescriber has made such a determination. Second, the Second Modified Text is also ambiguous as to what type of verification and documentation is sufficient. As drafted, the Modified Text of Proposed § 1735.1(e) may be misunderstood to require onerous, impractical, vague, or inconsistent verification and	As approved by the Board during the meeting, the second modified text included a requirement that a pharmacist verify that a prescribed medication is clinically appropriate for a patient. This is consistent with the practice of pharmacy and the requirement extends to all prescriptions, irrespective of whether it is a compounded medication. Board staff note that the commenter appears to suggest that a pharmacist does not have an obligation to exercise clinical judgment when compounding or dispensing a medication. The Board believes it is important to underscore that pharmacists must exercise clinical judgment in all aspects of practice and not simply defer their judgment to another individual. This obligation is memorialized throughout Pharmacy Law, including notably BPC Section 4306.5. Should it be helpful, Board staff refer the commenter to some specific provisions of the law that establish specific requirements for pharmacists to evaluate prescriptions prior to dispensing including, as examples: Health and Safety Code section 11153 Business and Professions Code section 733 Title 16, California Code of Regulations Section 1707.3

			documentation requirements that prove unworkable or overly burdensome in practice. This ambiguity can be resolved by making clear that a pharmacist who verifies, from a notation documented on the prescription itself or other similar communication from the prescriber to the pharmacist, that the prescriber has determined the clinically significant difference of the prescription—and adds a notation to the pharmacist's patient file recording this fact—meets the verification and documentation requirement of Proposed § 1735.1(e). The Board should clarify the text of Proposed § 1735.1(e) along the lines proposed above. At a minimum, it should clarify in the preamble of any final action promulgating this rule or in concurrently issued guidance that, under this provision, a pharmacist need only verify and document that a prescribing practitioner has made a finding of clinically significant difference in the manner described above.	
9	1735.1(e)(1)	Novo Nordisk	Comment: We recommend that the Board update Section 1735.1(e)(1) to state only the prohibition on compounding of “essentially a copy of one or more commercially available drug products,” as defined at Section 17735(d). The exceptions to the copies restriction at (e)(1)(A) in the Second Modified Text – related to shortage lists and inability of a health care facility to obtain a drug – are overly permissive and inconsistent with federal law and policy. The state regulations, as currently proposed, would allow drugs to be compounded under circumstances that are inconsistent with FDA’s current interpretation of Section 503A of the FDCA stated in the agency’s 503A Copies Guidance.⁵ In that guidance, FDA states that the agency does not consider a drug to be “commercially available” within the meaning of the federal copies restriction if it is present on	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that the proposed text in 1735.1(e)(2) related to the ability to compound within 60 days of the end of a shortage is consistent with the recent approach the FDA announced regarding the status of the firzepatide shortage. Further, the Board’s provisions specifically include additional flexibilities for health care facilities licensed pursuant to Health and Safety Code 1250 (which include hospitals), is consistent with the FDA’s guidance related to compounding a drug that is essentially a copy that acknowledges that the FDA is considering the applicability of its policies described in the guidance document to hospitals and health systems. As the FDA has not released this separate guidance, the Board believes its approach is consistent with the intent of federal law while ensuring hospitals have additional flexibility to take care of patients.

			FDA's drug shortage list, and when the drug product has been discontinued and is no longer marketed.⁶ The Board's proposed regulations go even further, and would also permit compounding of copies when a drug product appears on the ASHP list, and when a health care facility "cannot obtain" a drug from the manufacturer or wholesaler. These broad exceptions are inconsistent with federal law and current policy and could lead to compounding of unapproved drug products when the FDA-approved drugs are available to meet the patients' needs. Thus, the exceptions undermine a key check on compounding of unapproved drug products, posing risks to patient safety and the public health, and should be updated accordingly. Additionally, the requirement in the Second Modified Text that the compounding pharmacist verify and document the prescriber determination of a clinically significant difference for an identified individual patient is duplicative of the requirement stated in the definition of "essentially a copy" at Section 1735(d), and is thus unnecessary. Finally, as described above, we have proposed to add the requirement that documentation of the prescriber determination be maintained in a readily retrievable format to Section 1735(d). Therefore, we recommend that Section 1735.1(e)(1) be updated to state only the prohibition on compounding copies, referencing the relevant definition in the regulations. Recommended language revision: "(e) 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, as defined at Section 1735(d) of this article."	Board staff respectfully refer the commenter to the Modified Initial Statement of Reasons that includes the referenced FDA Guidance Document, Compounded Drug Products that Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act.

10	1735.1(e)(1)(B)	CMA	CMA is concerned that the Board's proposed modified text establishes a new requirement for pharmacists to "verify" that a prescribed compounded drug product produces a clinically significant difference for the medical need of an identified individual patient under specific conditions. CMA acknowledges the role of pharmacists exercising professional judgment, as outlined in Business and Professions Code (BPC) section 4306.5. However, the proposed requirement to "verify" introduces unnecessary and unintended rigidity into the process. Contrary to the Board's assertion, mandating verification in every instance of compounding a drug that is otherwise commercially available and not on a shortage list sets a prescriptive standard for how pharmacists must exercise their professional judgment. The language of the regulations expressly requires pharmacists to verify the existence of a clinically significant difference for each compounded preparation in this situation, rather than allowing pharmacists to exercise their professional judgment as to when such verification may be warranted. This mandate impedes the flexibility the Board claims to seek to preserve and, as such, the language violates the clarity standard because it conflicts with the Board's description of the effect of the regulations in its response above. Pharmacists are already obligated to exercise judgment when dispensing dangerous drugs and are empowered by BPC section 733(b)(1) to refuse to dispense a prescription based on professional judgment, potential harm, or legal concerns. Eliminating the "verify" requirement from the proposed regulation would not abrogate pharmacists' statutory responsibilities but would instead maintain the flexibility pharmacists need to practice most effectively.	Board staff have reviewed the comment and do not recommend a change to the proposed text because modifications in the second modified text addressed it. Staff note that this issue was previously considered by the Board, most recently during the January 8, 2025, Board Meeting. As approved by the Board during that meeting, the second modified text included a requirement that a pharmacist verify that a prescribed medication is clinically appropriate for a patient, irrespective of whether it is a compounded medication. While this commenter has not previously submitted comments in this area, it appears that the commenter is suggesting that a pharmacist does not have an obligation to exercise clinical judgment when compounding or dispensing a medication. The Board believes it is important to underscore that pharmacists must exercise clinical judgment in all aspects of practice and not simply defer their judgment to another individual. This obligation is memorialized throughout Pharmacy Law, including notably BPC Section 4306.5. Should it be helpful, Board staff refer the commenter to some specific provisions of the law that establish specific requirements for pharmacists to evaluate prescriptions prior to dispensing including, as examples: Health and Safety Code section 11153 Business and Professions Code section 733 Title 16, California Code of Regulations Section 1707.3

			The verification requirement would also impose significant administrative burdens on both pharmacists and prescribing physicians. For each compounded medication, pharmacists would need to collect and document proof of verified clinical significance for the prescribed drug, while physicians may be required to provide additional supporting evidence. This process could lead to delays in dispensing compounded medications, creating barriers for patients who rely on these treatments. For some patients, such delays could limit timely access to necessary therapies, ultimately harming their care. Finally, federal law, specifically 21 USC § 353a and 21 CFR Part 216, does not establish a documentation requirement, let alone a verification requirement for compounding. FDA guidance only recommends that “[...] the compounder should ensure that the determination is documented on the prescription.” The guidance also clarifies that the FDA “[...] generally does not intend to question prescriber determinations that are documented in a prescription or notation.” Current state regulations require pharmacists to retain the documentation of the determination of clinical significance. The Board’s proposal, however, goes beyond all of these standards by mandating that pharmacists both verify and document the prescriber’s determination. This additional verification obligation introduces a new requirement, not a clarification of existing state or federal statute. By creating this new regulatory standard, the proposal could be interpreted to place an unprecedented burden on pharmacists, that of duplicating the evaluation already made by the prescriber. This shift in legal construction is unnecessary, given that pharmacists are already accountable for using their professional judgment	

			to ensure compliance with established pharmacy laws. For these reasons, CMA recommends deleting “verify and” from proposed sections 1735(d), 1735.1(e)(1)(B), 1736(d), and 1736.1(e)(1)(B) of the second modified text. This would maintain the documentation standard established in current regulation while ensuring pharmacists retain the flexibility to perform verifications as deemed appropriate based on their professional judgment, as intended by the Board.	
11	1735.1(e)(2)	Wedgewood	The reference to a specific edition of a Guidance Document is troubling. Recommendation: This compound shall be in compliance with current industry guidance. the Center for Veterinary Medicine Guidance for Industry #256 – Compounding Animal Drugs from Bulk Drug Substances issued August 2022. We are grateful for the Board's clarification on the inclusion of the AMDUCA reference. While we appreciate the clarity provided, we are concerned that a direct reference to a Guidance Document (GFI 256), including a specific dated version, could be problematic should that document be modified or repealed. Rather than reference a specific document, we would recommend removing the language or changing it to simply reflect “applicable industry guidance” as noted below.	Board staff have reviewed the comment and do not recommend any change to the proposed text. Board staff note that to meet the requirements of the APA, the proposed regulation text must be sufficiently specific regarding the applicable standards of practice, if those standards are contained in a specific document.
12	1735.3(a)	Marie Cottman	Fix typo: (a) Facilities shall require individuals entering the compounding area to report if they have rashes... (and other grammatical issues) In practice, the supervising pharmacist will not be doing employee inspections looking for rashes, tattoos, or sores. Please remove the requirement for the supervising pharmacist to evaluate for these conditions.	Board staff have reviewed the comment. Board staff thank the commenter for highlighting the typographical error. Board staff note that nonsubstantive changes will be made as necessary consistent with the Board's direction to address numbering issues, typos, etc. Board staff believe that the commenter's request to remove the text can be done without risk to patients. In

			Recommend revision: (a) Facilities shall require individuals entering the compounding area to report if they <u>have</u> 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 per the facility's SOPs. ~~Prior to admitting any personnel into a compounding area, the supervising pharmacist shall evaluate whether personnel is experiencing any of the above conditions could contaminate a CNSP or the environment.~~ After such evaluation and determination, the supervising pharmacist shall not allow personnel with potentially contaminating conditions to enter the compounding area.	response to the comment, Board staff recommend the following change: <u>1735.3(a) Facilities shall require individuals entering the compounding area to report to the supervising pharmacist if they have 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 per the facility's SOPs. ~~Prior to admitting any personnel into a compounding area, the supervising pharmacist shall evaluate whether compounding personnel is experiencing any of the above conditions~~ 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, if the supervising pharmacist shall not allow personnel with potentially contaminating conditions to enter the compounding area.</u>
13	1735.3(e)	Marie Cottman	Though USP uses the term "reusable," your original term "Non-disposable" makes much more sense for this additional requirement. A compounder may reuse a mask, paper-gown, or booties during their compounding shift. These items will not tolerate (nor be effectively cleaned) by germicidal agent and IPA. Also, the wording of "before use by different personnel use." is awkward and confusing. Recommend revision: ~~Reusable~~ Non disposable garb and equipment shall be cleaned with a germicidal cleaning agent and sanitized with 70% isopropyl alcohol at least daily and before use by different personnel ~~use before re-use.~~ (1) Any reuseable gowns must be laundered, per the facility's SOPs before reuse.	Board staff have reviewed the comment and do not recommend a change to the proposed text. Board staff believe it is appropriate to use the same term that is used in the Chapter.
14	1735.7(c)(1)	PCCA	Recommend: We recommend that the clause in Section 1735.7(c)(1) be removed entirely.	Board staff have reviewed the comment and do not recommend changes to the proposed text.

		And CSHP	Rationale: 1. Protection of Corporate Proprietary Information: The identity of the manufacturer of an API is corporate proprietary information and is considered a trade secret for entities such as PCCA. The information holds significant value because disclosing the identity of carefully sourced suppliers would grant competitors a substantial and unfair business advantage. PCCA and other similar businesses, have invested heavily in developing relationships with manufacturers, performing rigorous vetting processes, and ensuring compliance with stringent quality standards. Public disclosure of this information would undermine these efforts and expose suppliers' business models to harm. Suppliers' customarily treat the identity of manufacturers as confidential and provide this information directly to FDA under strict assurances of privacy. The FDA recognizes the sensitivity of this information and allows suppliers to designate it as "confidential" when submitted through the Drug Registration and Listing System. Importantly, the FDA does not release this information publicly in its otherwise comprehensive National Drug Code (NDC) Directory. Similarly, the FDA excludes this information from reports it makes public regarding compounded drug products manufactured by outsourcing facilities. These practices reflect a consistent understanding of the confidential and proprietary nature of this information at the federal level. 2. California State Laws Protect Trade Secrets: California law explicitly protects proprietary information, including trade secrets relating to food, drugs, and cosmetics. Under the California Public Records Act, Cal. Gov. Code, §§ 6250 et seq., corporate records and trade secrets are exempt from public disclosure. Specifically, § 6254.15 shields "corporate proprietary information	The Board previously considered these comments on several occasions including as part of its discussion during the November 5-6, 2024, Board Meeting. As was noted at that time, Board staff reviewed the comment and do not recommend any changes to the proposed text based on the comments. Staff note that while existing law provides flexibility to record the manufacturer under limited circumstances, continuation of the current provision is not appropriate as it hampers the ability of a facility to respond appropriately in the event of a product recall. Staff further noted that the Board's proposed regulation text is more explicit than the Chapter for the reasons cited elsewhere in this response. Staff note that the Chapter requires either the recording of the manufacturers or vendors; however, in separate guidance issued by the FDA, the facility needs to have transparency into the supply chain and awareness of the manufacturer (where the manufacturer and vendor are different.) The FDA has released guidance in this area, including the importance of compounders knowing their suppliers - - https://www.fda.gov/drugs/human-drug-compounding/fda-compounders-know-your-bulks-and-excipientssuppliers. Lastly, requiring the identity of the manufacturer of a component to a compounder who is compounding with that component without requiring more information be provided does not appear to be requiring the disclosure of a trade secret under Civil Code section 3426.1(d). Moreover, vendors can take steps when contracting with compounders to protect the information related to their business arrangements with manufacturers. Staff refer the commenter to the underlying data portion of the Modified Initial Statement of Reasons, which includes the above referenced FDA guidance document.

			including trade secrets." Further, the California Health and Safety Code § 110165 precludes the state from disclosing any information acquired about trade secrets, emphasizing that such proprietary information are entitled to protection. 3. Alignment with Federal Standards: The proposed requirement goes beyond existing federal regulatory standards, including USP Chapters 795 and 797, which do not mandate disclosure of the manufacturer in compounding records. Instead, USP standards require documentation of the lot number, expiration date, and supplier information, which ensures traceability and accountability without risking the exposure of trade secrets.	
15	1735.9(c)	Marie Cottman	Recommend to remove this section. This is completely redundant. It just restates laws that already exist. As Compounding CNSPs are drugs, they already require all the labelling specified in 4076 and 1707.5. There is no implied exemption from labelling requirements in USP 795. (If one of your licensees thinks they only have to comply with USP and they can ignore the other body of laws relative to the practice of pharmacy in CA, you will have much bigger problems than the label.)	Board staff have reviewed the comment and recommend a change to the proposed text. Staff agree with the commenter's suggestion that even with deletion of the language, the requirements to comply with BPC 4076 and CCR section 1707.5 would continue to be relevant. Staff offer the following recommendation: ~~(c) The label for any 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. A CNSP that is administered to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code or to an inmate of an adult correctional facility or a juvenile detention facility shall be labeled with patient name, the directions for the use of the drug, and date of issuance, but is otherwise exempt from these requirements.~~
16	1735.10(b)(1)	Marie Cottman	This proposed rule is far too restrictive. What if no data exists? The study to determine chemical and physical stability data is literally \$30,000 or more! Under this rule, when a prescriber is identifying a	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff believe the commenter may be referring to stability of the end product.

			novel drug delivery solution for a unique patient experience, compounders will be unable to compound a new preparation because there is no existing DATA to demonstrate stability. Even if the pharmacist were to apply a conservative 14 day refrigerated BUD, without data, they would be in violation of this rule and subject to action against their license. <u><i>This will limit access to potential solutions for patients with unique needs!</i></u> USP 795 Chapter 10 allows for considerations to be used in determining a BUD, which MUST be conservative. Recommend to remove this section (USP already addresses what to consider when determining BUDs.) If you won't remove it, allowing recommendations in USP to stand on their own merit, then please consider rewrite: <i>(b) A CNSP's BUD shall be conservatively assigned when data is not readily available to validate chemical and physical stability or compatibility and degradation with the container-closure system.</i>	Staff believe the Chapter is referring to physical properties of an individual API. Staff note that all APIs affect quality and pursuant to the provisions of the Chapter, a compounder must therefore consider the chemical and physical stability of the API and any added substance. It appears the commenter is suggesting that such information may not be available in all circumstances. Staff note that APIs are generally sold with this information available. Neither the Chapter nor the Board's proposed regulation text are requiring testing; rather, the compounding pharmacist may rely upon data that is available.
17	1735.10(b)(2)	Marie Cottman	I have concerns that the inspectors could abuse this rule because it is not clear who has the burden of proof that the CNSP is non-reactive with the container- closure system. And again, the testing to provider proof is many \$1,000s! Under this rule, when a prescriber is identifying a novel drug delivery device for a unique patient experience, compounders will be unable to package the compound they don't have proof (even if there is good similar data available). If the pharmacist were to apply a conservative 14 day refrigerated BUD, without specific data, they could be in violation of this rule and subject to action against their license. <u><i>This will limit access to potential solutions for patients with unique needs!</i></u>	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that the proposed regulation text does not require a compounder to perform testing; rather, the compounder must rely on data available to make a determination.

			Recommend to remove this section (USP already addresses what to consider when determining BUDs.) If you won't remove it, allowing recommendations in USP to stand on their own merit, then please consider rewrite: <i>(b) A CNSP's BUD shall be conservatively assigned when data is not readily available to validate chemical and physical stability or compatibility and degradation with the container-closure system.</i>	
18	1735.11(a)(2)	Novo Nordisk	Comment: Aligned with our comments for sections 1735.2(b) and 17.35(c) below, we recommend that the Board reinsert reference to adverse drug experiences, as specified below, to ensure SOPs state that the pharmacist is responsible for reviewing complaints related to potential quality problems and adverse events. We also recommend that the Board require that SOPs describe written procedures for the surveillance, receipt, evaluation, and reporting of adverse drug experiences. Compounding pharmacies are not held accountable by FDA for any pharmacovigilance obligations. As such, they likely do not have the policies and procedures in place to conduct pharmacovigilance, including to ensure that adverse event reports are shared with the Board and FDA and to assess adverse event reports and take corrective action. A requirement for SOPs to include written procedures related to adverse drug experiences will help compounding facilities implement the Board's quality assurance and quality control provisions. Such a requirement also will ensure that compounding facilities are taking steps to protect patients from unnecessary harm from the use of unsafe and unapproved compounded products, as we describe further below. Recommended language revision:	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comment received. The Board's compounding regulations establish the minimum standards for compounding. While staff agree that written procedures for surveillance, receipt, evaluation and reporting of adverse drug experiences to the Board may be appropriate for some facilities, it does not appear necessary for smaller pharmacies such as those that only perform nonsterile compounding of products such as magic mouthwash. When the reporting issue was discussed during the November 5-6, 2024, Board Meeting, members determined that a new reporting requirement to the Board was not necessary for nonsterile compounding.

			“(F) The pharmacist responsible for the review of all complaints related to a potential quality problem with a CNSP and all adverse drug experiences in the event the PIC is not available within 72 hours of the receipt of the complaint or occurrence.” [NEW] “(H) Written procedures for the surveillance, receipt, evaluation, and reporting of adverse drug experiences to the Board.”	
19	1735.11(a)(2)(C)	Marie Cottman	Chapter 795 Section 6.2.3 already addresses evaluation of a component prior to use (compounding). It specifically states: “Before use, compounding personnel must visually re-inspect all components. Each packaging system must be inspected to detect any container breakage, looseness of the cap or closure, or deviation from the expected appearance or texture of the contents that might have occurred during storage. 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. If the identity, strength, purity, and quality of components intended for preparation of CNSPs cannot be verified (e.g., containers with damaged or incomplete labeling), the components must be immediately rejected. Any component found to be of unacceptable quality must be promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal. 1735.11(a)(2)(C) is redundant and unnecessary. Recommend to remove.	Board staff have reviewed the comment and disagree that the proposed language is redundant. Staff note that the proposed regulation text focuses on how a pharmacist, overseeing compounding, would identify and catch errors involving the use of inappropriate ingredients prior to compounding. Staff note that regrettably many compounding errors stem from compounding personnel using inappropriate ingredients when compounding. Ensuring a method exists that pharmacists follow to ensure compounding personnel are using the correct ingredients in the compounded preparation is necessary to prevent harm.
20	1735.11(a)(2)(D)	Marie Cottman	have additional SOPs addressing all the requirements in this chapter. Recommend to remove or rewrite:	Board staff have reviewed the comment. Board staff agree with the commenter that the language can be removed. Staff recommend the following:

			(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: Comply with the additional requirements described in this chapter.~~ (23) Also describe the following: (leave other lettered items) ~~(D) The method for complying with any other requirements specifically required to be addressed in the facility's SOPs as described in this article.~~	1735.11 ~~(a)(2)(D) The method for complying with any other requirements specifically required to be addressed in the facility's SOPs as described in this article.~~
21	1735.11(b)	Marie Cottman	I really don't think you want to open this can of worms. Potential quality problems are not ACTUAL quality problems. If a patient calls and complains that their bleaching cream is not working after 4 weeks... is that a potential quality problem? It could be, but it also might be that they didn't allow enough time (8-12 weeks to see results), or they just cannot see the subtle results, or they left the product at room temperature when it should have been refrigerated, but they are too ashamed to tell you so. Either way, since it COULD be a Potential quality problem, I would report it. I don't have a problem with sharing a TRUE quality issue— topical preparation caused a skin infection, oral medication got moldy before the BUD, an MBK suppository crumbled and could not be used... but what does the Board define as a potential quality? The existing complaint programs and BPC section 1711 already have documentation/evaluation requirements. Recommend to remove or rewrite with clarity of what you really want to be reported.	Board staff have reviewed the comment and note the commenter may be referring to proposed regulation text CCR section 1735.12(b). Board staff have reviewed the comment and do not recommend a change to the proposed text. The proposed regulation text require notification specifically regarding a complaint of a potential quality problem or an unexpected ADE. Board staff note that it is important for the Board to receive complaints of potential quality problems so it is aware of potential and actual quality problems with CNSPs to monitor for patient harm and ensure appropriate action is taken to protect patients.
22	1735.12(a)	Marie Cottman	For clarity, Recommend adding location of section 1711:	Board staff have reviewed the comment and thank the commenter for highlighting that the language may require amendment to provide clarity. Board staff recommend the following change:

			(a) The facility's quality assurance program shall comply with <u>BPC Title 16</u>, section 1711 and the Recalls, out of spec results are NOT scheduled. Recommend to remove the word scheduled. ...In addition, the program shall include a written procedure for ~~scheduled~~ action, such as a recall, in ... (this is also consistent with a change made in proposed rule 1736.18)	<u>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:~~</u> <u>~~A~~ a written procedure for ~~scheduled~~ action, such as a recall, in the event any compounded drug preparation is discovered to be outside the expected standards for integrity, quality, or labeled strength.</u>
23	1735.12(b)	Novo Nordisk	Comment: We appreciate the Proposed Rule's quality assurance and quality control provisions to address quality issues with compounded nonsterile products. Aligned with our comments for section 1735.12(c) below, we recommend that the Board reinsert reference to adverse drug experiences, as specified below, to ensure that compounding facilities are required to notify the Board of adverse events involving nonsterile compounded products. Unlike sponsors of FDA-approved medicines that are subject to expansive postmarketing reporting of adverse drug experiences,⁷ compounding pharmacies do not do surveillance, evaluation, or reporting of adverse events to FDA. In the wake of unprecedented demand for GLP-1 medicines, compounding facilities are mass marketing unsafe and unapproved compounded "semaglutide" products to patients, raising the risks of adverse events that go unreported. The rampant compounding of "semaglutide" is putting patients at risk. FDA's adverse event reporting system ("FAERS") database shows that 619 adverse events, including 144 hospitalizations and 12 deaths, have been reported to the Agency following use of a compounded "semaglutide" product.⁸ This is more than double the number of adverse events that FDA received	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comment received. The Board's compounding regulations establish the minimum standards for compounding. When the reporting issue was discussed during the November 5-6, 2024, Board Meeting, members determined that a new reporting requirement to the Board was not necessary for nonsterile compounding. It appears appropriate to note that the example cited by the commenter appears to be related to a sterile compounded product.

			for all compounded drugs in 2022.⁹ Yet the adverse events reported in FAERS are expected to be only a small portion of the adverse events patients are experiencing after taking compounded "semaglutide." Indeed, FDA has stated that "it is likely that adverse events from compounded versions of these drugs are underreported,"¹⁰ underscoring the importance of the Board instituting a requirement that compounding facilities report all adverse events associated with compounded products to the Board. Recommended language revision: "The Board shall be notified in writing within 96 hours of the facility's receipt of a complaint of a potential quality problem or the occurrence of an adverse drug experience as defined in 21 CFR 310.305(b) involving a CNSP."	
24	1735.12(c)	Novo Nordisk	Comment: Building on our comments for section 1735.12(b) above, we recommend that the Board reinsert reference to adverse drug experiences, as specified below, to ensure that compounding facilities are required to review adverse events involving nonsterile compounded products along with other quality problems as specified in the Proposed Rule. It is essential that compounding facilities review quality problems and adverse drug experiences to protect patients from unnecessary harm. Testing results have shown that certain compounded "semaglutide" samples have substantially lower or higher strengths than labeled. Testing results from compounding pharmacies marketing sublingual semaglutide products reveal high levels of impurities and inconsistencies between the labeled strength and calculated semaglutide content. One compounded sublingual "semaglutide" sample contained 170% of the labeled strength, while testing results from a	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comment received. The Board's compounding regulations establish the minimum standards for compounding. When the reporting issue was discussed during the November 5-6, 2024, Board Meeting, members determined that a new reporting requirement to the Board was not necessary for nonsterile compounding. Staff note that the proposed regulation text requires the pharmacy to develop a procedure and identify actions to be taken when a CNSP is discovered to be outside the expected standards for integrity, quality, or labeled strength. Further, the proposed regulation text requires a facility to review all complaints made to the facility related to potential quality problems with a CNSP, with actions to be taken as defined in the SOPs.

			different pharmacy's compounded sublingual "semaglutide" contained only 42% of the labeled strength. Some of these compounded sublingual samples had total impurities up to 41% of the sample. Subpotent and superpotent samples pose serious risks to patients. The reduced strength of compounded semaglutide formulations render such products potentially less effective than the FDA-approved semaglutide products. On the other hand, administering too much compounded semaglutide could lead to serious adverse events or even hospitalization, especially if the patient accidentally overdoses on a superpotent product. These differences and inconsistencies illustrate that compounding semaglutide dosage forms is a complex endeavor and are likely to lead to an adverse effect on the safety and efficacy of the drug products. Compounding facilities should take steps to address this growing and present risk posed by compounded drugs. Doing so requires that compounders assess reports of quality problems and adverse events and take corrective action. By reinserting reference to adverse drug experiences, the Board can ensure that compounders assume this responsibility to protect patients. Recommended language revision: "All complaints made to the facility related to a potential quality problem with a CNSP and all adverse drug experiences shall be reviewed consistent with the facility's SOPs within 72 hours of receipt of the complaint or occurrence of the adverse drug experience. Such a review shall be documented and dated as defined in the SOPs."	
25	1735.13	Marie Cottman	This is redundant because it is already required by 795. USP 795 13.1 Packaging of CNSPs states: "The facility's SOPs must describe packaging of CNSPs. Personnel should select and use packaging	Board staff have reviewed the comment and do not recommend changes to the proposed text. The proposed regulation text ensures the facility establishes specific SOPs for storage, shipping containers and temperature sensitive CNSPs.

			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 13.2 Transporting of CNSPs "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." Recommend to remove.	
26	1735.15	Marie Cottman	Since compounders who only add flavoring are exempt from 1735.2-1735.12, they would not be required to comply with 1735.12, reporting quality issues. Recommend adding an SOP requirement similar to 1735.12	Board staff have reviewed the comment and thank the commenter for the recommendation. An example of a quality problem could include a suspension that appears to become clumpy and/or nonuniform. Board staff recommend the following change: <u>1735.15(a)(7) Provisions for reporting to the Board the facility's receipt of a complaint of a potential quality problem involving the CNSP. ... At a minimum the provisions shall require notification to the Board within 96 hours of receipt of a complaint.</u>
27	1735.15	FLAVORx	Current Text: (a) <u>In addition to</u> the standards in USP Chapter 795 and the Food Drug Cosmetic Act (FDCA) section 503a (21 U.S.C. §353a) a facility that limits its compounding as described in Section 1735.1 (i) shall establish the following SOPs: The underlined text infers facilities would need to comply with USP 795 standards in order to flavor medications. If that is the Board's intention, then the exemptions spelled out in 1735.1 (i) will not bring flavoring back to California's pharmacies. The application of USP 795 standards to the practice of flavoring is what drove pharmacies away from providing the service.	Board staff have reviewed the comment and do not recommend a change in the proposed text. Staff note that recommended changes in section 1735.1 (i) will address the issue raised by the commenter.

			If that is not the Board's intention, then one possible solution is to remove that reference and go with: "(a) a facility that limits its compounding as described in Section 1735.1 (i) shall establish the following SOPs:"	
28	1735.15(b)	CVS	CVS Health greatly appreciates the collaboration that has led to numerous changes in pending language throughout this promulgation. Commenter recommends changing "on the prescription record" to "in the compounding record" to harmonize terminology, reduce confusion, and streamline operations. The commenter believes this requested change to be merely stylistic, and thus acceptance would not necessitate an additional comment period. (b)A pharmacist may compound by combining a flavoring agent with a prescribed FDA approved drug in an oral liquid dosage form at the request of the patient or patient's agent without consultation with the prescriber or the prescriber's authorized agent. A pharmacist performing such compounding must document the compounding ~~on~~ <u>in the prescription compounding</u> record.	Board staff have reviewed the comment and believe the recommendation by the commenter is acceptable; however, staff believe flexibility needs to be provided to allow the pharmacy to determine how it will operationalize the documentation requirement. Board staff is offering the following language: ~~1735.15(b)A pharmacist may compound by combining a flavoring agent with a prescribed FDA approved drug in an oral liquid dosage form at the request of the patient or patient's agent without consultation with the prescriber or the prescriber's authorized agent. A pharmacist performing such compounding must document the compounding on in the prescription or compounding record.~~

#	Section	Commenter	Comment	Board Response
1	1736	Marie Cottman	Recommend removing duplicate language. The definitions in this section shall be applicable to this Article and supplement the definitions provided in United States Pharmacopeia (USP) General Chapter 797 (USP Chapter 797), titled Pharmaceutical Compounding – Sterile Preparations. ~~The following definitions apply to this article and supplement the definitions provided in USP Chapter 797 for compounded sterile preparations (CSPs).~~	The Board reviewed the comment and thanked the commentator for pointing out that duplication, which resulted from multiple rewrites. <u>1736. Sterile Compounding Definitions.</u> ~~The definitions in in this section shall be applicable to this Article and supplement the definitions provided in United States Pharmacopeia (USP) General Chapter 797 (USP Chapter 797), titled Pharmaceutical Compounding – Sterile Preparations. The following definitions apply to this article and supplement the definitions provided in USP Chapter 797 for compounded sterile preparations (CSPs).~~
2	1736(d)	CMA	CMA is concerned that the Board's proposed modified text establishes a new requirement for pharmacists to "verify" that a prescribed compounded drug product produces a clinically significant difference for the medical need of an identified individual patient under specific conditions. CMA acknowledges the role of pharmacists exercising professional judgment, as outlined in Business and Professions Code (BPC) section 4306.5. However, the proposed requirement to "verify" introduces unnecessary and unintended rigidity into the process. Contrary to the Board's assertion, mandating verification in every instance of compounding a drug that is otherwise commercially available and not on a shortage list sets a prescriptive standard for how pharmacists must exercise their professional judgment. The language of the regulations expressly requires pharmacists to verify the existence of a clinically significant difference for each compounded preparation in this situation, rather than allowing pharmacists to exercise their professional judgment as to when such verification may be warranted. This mandate impedes the flexibility the Board	The Board reviewed the comment and did not make changes to the proposed text based on the comment because modifications in the second modified text addressed it. The Board notes that this issue was previously considered by the Board, most recently during the January 8, 2025, Board Meeting. As approved by the Board during that meeting, the second modified text was amended to require a pharmacist to verify that a prescribed medication is clinically appropriate for a patient, irrespective of whether it is a compounding medication. The Board noted that the commenter appears to suggest that a pharmacist does not have an obligation to exercise clinical judgment when compounding or dispensing a medication. The Board believes it is important to underscore that pharmacists must exercise clinical judgment in all aspects of practice and not simply defer their judgment to another individual. This obligation is memorialized throughout Pharmacy Law, including notably BPC Section 4306.5 and BPC 733. The Board referred the commenter to some specific provisions of the law that establish specific requirements

		claims to seek to preserve and, as such, the language violates the clarity standard because it conflicts with the Board's description of the effect of the regulations in its response above. Pharmacists are already obligated to exercise judgment when dispensing dangerous drugs and are empowered by BPC section 733(b)(1) to refuse to dispense a prescription based on professional judgment, potential harm, or legal concerns. Eliminating the "verify" requirement from the proposed regulation would not abrogate pharmacists' statutory responsibilities but would instead maintain the flexibility pharmacists need to practice most effectively. The verification requirement would also impose significant administrative burdens on both pharmacists and prescribing physicians. For each compounded medication, pharmacists would need to collect and document proof of verified clinical significance for the prescribed drug, while physicians may be required to provide additional supporting evidence. This process could lead to delays in dispensing compounded medications, creating barriers for patients who rely on these treatments. For some patients, such delays could limit timely access to necessary therapies, ultimately harming their care. Finally, federal law, specifically 21 USC § 353a and 21 CFR Part 216, does not establish a documentation requirement, let alone a verification requirement for compounding. FDA guidance only recommends that "[...] the compounder should ensure that the determination is documented on the prescription." The guidance also clarifies that the FDA "[...] generally does not intend to question prescriber determinations that are documented in a prescription or notation." Current state regulations require pharmacists to retain the documentation of the determination of clinical significance.	for pharmacists to evaluate prescriptions prior to dispensing including as examples: Health and Safety Code section 11153 Title 16, California Code of Regulations Section 1707.3

			The Board's proposal, however, goes beyond all of these standards by mandating that pharmacists both verify and document the prescriber's determination. This additional verification obligation introduces a new requirement, not a clarification of existing state or federal statute. By creating this new regulatory standard, the proposal could be interpreted to place an unprecedented burden on pharmacists, that of duplicating the evaluation already made by the prescriber. This shift in legal construction is unnecessary, given that pharmacists are already accountable for using their professional judgment to ensure compliance with established pharmacy laws. For these reasons, CMA recommends deleting "verify and" from proposed sections 1735(d), 1735.1(e)(1)(B), 1736(d), and 1736.1(e)(1)(B) of the second modified text. This would maintain the documentation standard established in current regulation while ensuring pharmacists retain the flexibility to perform verifications as deemed appropriate based on their professional judgment, as intended by the Board.	
3	1736(e)	Novo Nordisk	Comment: We support the Board's revisions to the definition of "essentially a copy" in the sterile compounding regulations for the same reasons as described in our comments regarding the updates to that definition at Section 1735(d) in the nonsterile compounding regulations. Requiring the pharmacist to verify and document the prescriber determination is consistent with FDA's 503A Copies Guidance and helps implement an important check on compounding of unapproved drug products. Additionally, consistent with our comments regarding Section 1735(d) above, we recommend adding to this Section 1736(e) the requirement that the documentation of the prescriber determination be maintained in a readily retrievable format, rather than including that	The Board reviewed the comment and did not make changes to the proposed text based on the comment. The Board noted that proposed regulation Section 1735.14(a) provides that records shall be maintained as required by USP Chapter 795 and this article in a readily retrievable form. The records suggested by the commenter would be covered by the provisions in Section 1736.20(a).

			requirement at Section 1736.1(e)(1). Our recommended changes to Section 1736.1(e)(1) are described directly below. Recommended language revision: “‘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 verified and documented by the pharmacist, between that compounded preparation and the comparable commercially available drug product. Such documentation must be maintained in a readily retrievable format.”	
4	1736(g)	Marie Cottman	This definition is different than the definition of quality in Section 1735 for CNSPs, which seems odd. What is the “degree” to which PICs, DPs, and compounding personnel should aim for to meet this definition of quality? Requirements for sterility, bacterial endotoxin limits, lack of particulates, and characteristics of the preparation must already be met through the application of USP 797. Who defines the standard, the “degree,” and what the “intended specifications” are for a particular CSP? Further, even without the confusing language, the definition still has the phrase, “including but not limited to” which allows very broad enforcement. Recommend to remove vague/undefined language and match CSP definition of Quality with CNSP definition of Quality. (g) “Quality” means ~~the degree to which the components and preparation meets the intended specifications, complies with relevant law and regulation, and means~~ the absence of harmful levels of contaminants, including but not limited to filth, putrid, or decomposed substances, the	The Board reviewed the language and thanked the commenter for raising this issue. The proposed text is intended to allow pharmacists to use professional judgment. However, given the comment, the Board updated the proposed regulation text to reflect the current requirements in the Board’s existing regulation text, CCR section 1735.1(g). 1736(g) “Quality” means ~~the degree to which the components and preparation meets the intended specifications, complies with relevant law and regulation, and means~~ the absence of harmful levels of contaminants, including but not limited to filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, or the absence of inactive ingredients other than those listed on the master formulation record as specified in USP Chapter 797.

			absence of active ingredients 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 797.	
5	1736.1	CA Rheumatology Alliance and CA Society of Plastic Surgery	We have reviewed the staff responses to our comments and continue to be concerned with the applicability of the proposed regulations on physicians and their ability to "compound" medications in their offices. Although physicians may not be under the enforcement jurisdiction of the Board of Pharmacy, we believe the proposed regulations would change the standard of care for when physicians compound medications and will not allow rheumatologists/physicians to buffer injection/ infusion medications in-office. We are interpreting the proposed regulations to require a pharmacist be present or performing the buffering of the injection/ infusion medications. Rheumatology practices/physicians would not be able to afford to employ a pharmacist for this one purpose. This would lead to rheumatology practices no longer offering this service for our patients. Patients would then be forced to obtain their injection/infusions at a hospital or infusion center which would not only be less convenient for our patients, but it would be more expensive for the patient and the overall healthcare system. We believe it is important to note we are not aware of any issues with rheumatologists/ physicians "compounding" injection/ infusion medications. We would like to propose the Board of Pharmacy adopt the language suggested by the California Medical Association as shown below: § 1736.1: In addition to the standards set forth in USP Chapter 797 and Food Drug Cosmetic Act (FDCA) section 503a (21 U.S.C. §353a) the following requirements apply throughout this article. <u>This article shall not apply to compounding by or under the direct supervision of a licensed physician and surgeon.</u>	The Board reviewed the comment and did not make changes to the proposed text based on the comment. The Board noted that they previously considered this comment, most recently during the January 8, 2025, Board Meeting and determined that the requested change is not appropriate. As was previously shared, the Board only has jurisdiction over individuals and businesses within its practice act. The Board read the comment as suggesting that the Board's proposed regulations would apply to a physician. Business and Professions Code section 4170(c) makes clear that the Medical Board of California is specifically charged with the enforcement of Pharmacy Law (Chapter 9, Division 2 of the Business and Profession Code) with respect to its licensees. It may be appropriate for the commenter to confer with their licensing board to discuss their concerns. The Board noted that the Medical Board of California has previously provided a written response to individuals inquiring about the applicability of the Board of Pharmacy's regulations to individuals and practices that operate under the jurisdiction of the Medical Board of California. Below is the information provided from the Medical Board - - <i>Dear Ms. Sodergren:</i> <i>I understand that some concerns have been raised by stakeholders about the applicability of the Board of Pharmacy's pending compounding regulations to licensees of the Medical Board of California (MBC). Existing statute (see Business and Professions Code (BPC) section 2220.5) makes it clear that only the MBC can discipline its physician licensees.</i>

				Whenever a physician is engaging in compounding (or any other action that their medical license authorizes them to perform) they must always do so consistent with the standard of care. For the purposes of MBC's enforcement program, the standard of care is established by expert testimony in the context of the facts and circumstances of a specific case. It is certainly possible that whatever regulations that are implemented by the Board of Pharmacy may influence the standard of care for physicians who are compounding, especially since some of the proposed regulations reflect what is already required for physician compounding under federal law, including, but not limited to, Section 503A of the Federal Food, Drug, and Cosmetic Act (BPC section 2225(b) allows MBC to investigate violations of federal law related to the practice of medicine). Feel free to share this message with others as you see fit who might also be concerned about the applicability of their pending regulations to the physician community. Please contact me if you have any further questions. Sincerely, Reji Varghese Reji Varghese is the Executive Director for the Medical Board of California. The Medical Board is charged with evaluating compounding practices and the standard of care relevant to its licensees.
6	1736.1(b)	CSHP	Public meeting discussions related to this proposed requirement have included the Board's opinion that this proposed rule is like the current requirement in CCR 1751.8(c) and deletion of this rule is a step back from a stricter rule in existence. This confounding opinion is made repeatedly while major alterations are being made after multiple and ongoing attempts by the public to request a change to an antiquated rule that is based off an old standard. USP removed the expectation for emergency use associated with emergencies and adjusted the new BUD to four hours. There is an	The Board reviewed the comment and did not make changes to the proposed text based on the comment. The Board noted that it is not banning provisions for immediate use compounding. Further, the Board considered this issue most recently during its November 5-6, 2024, Board meeting and made significant changes to the language in previously noticed modified text to increase flexibility for licensees, including adding specific provisions for rural hospitals. The Board also noted that the proposed regulation text could reduce costs that may be currently experienced

		allowance for USP to utilize immediate-use compounding in a vast variety of clinical settings. USP does not mandate that all sterile compounding take place in classified facility. USP does not require the need for emergent situations in order to perform immediate-use compounding. USP does not need to make allowances for when facilities and equipment are down because immediate-use is already available. Discussions during the Board of Pharmacy meetings have indicated that emergency-use is needed and that it would benefit patients. However, these regulations place many barriers on those who are caring for patients, that it is detrimental to those we are serving. There are no requirements for immediate-use compounding that limits its utilization for routine use. In fact, USP was changed so that it removes barriers for healthcare personnel so that they can care better for patients. The basis for the proposed requirement erroneously presumes the utilization of immediate-use is only for emergencies. To continue with the proposed requirement, in essence, means California pharmacists will be the only licensed professionals banned from utilizing the USP immediate-use allowance while every healthcare professional in United States of America is allowed to routinely use it. The hypothetical assumption that pharmacies with cleanrooms must have an emergency plan for when sterile compounding operations are down, sounds great on paper and in theory, practically, there are just not that many options available to health systems particularly if it's a rural hospital. Elimination of immediate use authority creates additional hurdles to acquiring the medication that might be insurmountable and therefore jeopardize patient safety. The Board failed to capture the economic impact to health systems in their ISOR. The board's	stemming from the current limited provisions for immediate use compounding that exist in the Board's current regulatory provisions. The additional flexibilities being proposed in the second modified text could therefore reduce costs where such provisions for immediate use do not currently exist. A review of the public record of the 2023 minutes from the various meetings during which the regulations were developed demonstrate that public comment raised this issue of costs during a single meeting specifically related to the costs of preparation mats. Since that time the Board has responded to comments throughout the rulemaking process and modified regulation text to address some of the specific cost concerns raised where patient safety would not be impacted. The Board also noted that requirements of federal law, state law, and the Chapter may all have associated costs. As an example, the Chapter describes tests that must be used, SOPs that must be developed, reviewed, etc. These are examples of costs to comply with the Chapter's requirements. Compounding facilities have a variety of practice settings and perform a variety of different types of compounding. Organizations may choose to standardize some operations across licenses operating under common ownership or control while others may not. The Board agreed that the Chapter does not establish limitations for immediate-use compounding; however, immediate-use provisions under the Board's regulation are available to a facility for use in several situations including in the event of an equipment failure when efforts to remediate do not remedy the issue. The Board remains concerned that, as has been witnessed in several board investigations, some compounding facilities will default to routine immediate use provisions, placing patients at higher risk of harm. The Board noted that the types of sterile products compounded are broad, including various routes and

			response to the question of "Business Impact" in ISOR states; "the board anticipates minimal ongoing costs ranging from approximately \$5,700 to \$15,000 per year related to administrative and maintenance workload." This statement applies to the multiple proposed regulations requiring the addition of new administrative procedures, reporting requirements, and enhanced testing. The amount stated is a gross underestimation of the true cost to health systems. Understandably the Board lacks the internal expertise to accurately reflect those anticipated costs associated with development of policies and procedures, monitoring implementation of those procedures, correctly reporting to the Board as proposed by this regulation and others, cost of monitoring visits by the Board, enhanced testing requirements, purchase of additional inventory for PPE, implementation of technology to support the deployment of the policies and procedures and hiring of additional staff to support compliance with the proposed regulation. Recommendation: Remove the requirement limiting the use of immediate-use CSP's to situations where failure to administer could result in loss of life or intense suffering due to this being deleted from the new USP 797 standards and the profound negative impact on patients. This will subsequently remove the need for reporting to the board as well as the allowance given to rural hospitals.	rates of infusion, creating risks to patients if the compounding is not performed under appropriate conditions. As an example, a sterile compound for intrathecal administration can be administered over a significant period of time, e.g., 30 days. During this time the preparation viable growth can occur. The Board's proposed regulation text seek to strike a balance with provisions for expanded use of immediate use provisions under certain conditions while ensuring immediate use provisions do not become the standard of practice for compounding by Board licensees.
7	1736.1(b)	Kaiser Perm.	Commenter requests that 1736.1(b) be stricken from the language. During the January 8, 2025 full Board meeting, the Board indicated that this regulation is necessary to prevent pharmacies from routinely preparing compounded sterile products under immediate use conditions. However, throughout the rulemaking process, the Board has not presented any	This comment was submitted during the 30-day comment period. The Board responded to it (on pages 3-4 of the Sterile grid). The Board reviewed the comment and did not make changes to the proposed text based on the comment. The Board noted that the proposed regulation text provides significant flexibilities beyond what is currently allowed in existing regulations. The Board disagreed with

			evidence that immediate use compounding, when it meets the required conditions in the "Immediate Use CSPs" section of the USP chapter, presents an unacceptable risk to California patients. In fact, the USP Expert Committee designed the chapter's immediate use provisions to balance the risks (i.e. the risk of microbial contamination) associated with immediate use compounding against the risks of delaying medication administration.¹ If the Board believes this regulation is necessary to prevent entities from "defaulting to immediate use provisions for all preparations," then the Board should provide evidence that shows how and why the USP expert committee has erred in allowing immediate use compounding without these stipulations. Additionally, the Board did not respond to our observation in our December 6, 2024 letter that continuing to enforce these requirements will incentivize organizations to shift compounding to non-pharmacy personnel in situations in which immediate use compounding is necessary. The Board should explain how shifting compounding to non-pharmacy personnel who are not subject to the Board's oversight will improve patient safety.	the assertion that the Board's regulations in this area will shift compounding to non-pharmacy personnel. Also noted is that the commenter appears to be speculating about business operation decisions that could be made that would make compliance less safe. The Board is not able to respond to speculation on business operation decisions outside of its purview. As stated elsewhere by the Board in this rulemaking, the Board's jurisdiction is limited to the licensees within its practice act. For commenters interested in understanding the requirements for nonpharmacy personnel compounding and the requirements for those individuals and entities, it would be appropriate to contact the respective regulatory agencies. The Board noted that a variety of nonpharmacy personnel have the authority to compound including, for example, physicians and veterinarians. Such individuals must comply with the requirements of their regulatory agencies including, for example, immediate use provisions, as applicable.
8	1736.1(b)(2) & (3)	Marie Cottman	I have no objection to these sections being present, however, I do not understand the rationale of differing timelines. Both allowances provide "an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering of an identifiable patient." But a critical access hospital has 5 days to get fixed and everyone else only 2 days. If the outcome of the patient is the same, loss of life or intense suffering, why the differential time line? Recommend to pick either 48 or 120 hours and make one rule for everyone.	The Board reviewed the comment and did not make changes to the proposed text based on the comment. The Board determined that the different authorities referenced by the comment are specifically intended to address challenges facing critical access hospitals that do not have the same access to resources to ensure continuity of patient care. Further, the differences in timeframe were previously established specifically in response to comments received during the 30-day comment period.

9	1736.1(d)	Wedgewood	Based on staff comments an amount of compounded drug may be furnished to a veterinarian based on the estimated need of the veterinarian as submitted on a purchase order will be considered the determination of a reasonable quantity. We appreciate the Board's recognition of Office Use (Stock) as an important service provided by pharmacies to veterinary medicine professionals and we appreciate the expansion of the ability to dispense from Office Stock to 14 days. We are concerned about the continuing ambiguity of the phrase "reasonable quantity" as it remains undefined in this draft. We are not opposed to placing limitations, but a lack of definition creates ambiguity, risks inconsistent enforcement, and further calls on pharmacists to exceed their scope of licensed practice. In the Board's response to our comment it was noted, "As the commenter notes, reasonable quantity is further clarified in paragraphs (1) and (2)". We interpret this to mean that the veterinarian's purchase order indicating that the order is for office administration, or application, and for dispensing no more than 14 days' supply constitutes a reasonable quantity and will proceed under that assumption unless further clarity is provided. As such, we will not be required to make a determination of whether the licensed prescriber "fairly estimated" the days' supply ordered.	The Board reviewed the comment and did not make changes to the proposed text based on the comment because modifications in the second modified text addressed it. The Board determined, when read in its totality, the proposed modified text is clear. The Board noted that one must read the relevant federal and state law, the USP Chapters, and the Board's proposed regulations to gain a full understanding of requirements. This issue was most recently considered by the Board during its January 8, 2025, discussion, during which the Board changed the proposed second modified text to allow for a 7-day supply as specified. Further, it appears the commenter has referenced a separate section of the law, related to CNSPs, in their suggestion that a 14-day supply is allowed. It is important to note that a 14-day supply is not allowed under Section 1736.1 unless the CSP is a topical ophthalmic preparation, which under the proposed regulations will allow for up to a 28-day supply of such a CSP. The commenter may be referencing the 14-day supply allowed in provisions in section 1735.1(d)(2).
10	1736.1(e)(1)	Novo Nordisk	Comment: We recommend that the Board amend Section 1736.1(e)(1) to state only the prohibition on compounding of "essentially a copy of one or more commercially available drug products," as defined at Section 17736(e), for the same reasons as described above in our comments on Section 1735.1(e)(1) of the nonsterile compounding regulations. The shortage provisions in the Second Modified Text are inconsistent with federal law and policy, and are overly permissive such that they	The Board reviewed the comment and did not make changes to the proposed text based on the comment. The Board's provisions specifically related to the comment provide additional flexibilities for health care facilities licensed pursuant to Health and Safety Code 1250 (which includes hospitals) and is consistent with the FDA guidance document that acknowledges that the FDA is considering the applicability of its policies described in the guidance document to hospitals and health systems. As the FDA has not released this separate guidance, the Board believes its approach is

			would pose risks to patient safety and the public health. Here again, the requirement at Section 1736.1(e)(1) of the Second Modified Text that the compounding pharmacist verify and document the prescriber determination of a clinically significant difference for an identified individual patient is duplicative of the requirement already stated in the definition of “essentially a copy” at Section 1736(e), and thus is unnecessary. Additionally, as noted above, we have proposed to add the requirement that documentation of the prescriber determination be maintained in a readily retrievable format to Section 1736(e), and it is therefore unnecessary here. Thus, we recommend updating Section 1736.1(e)(1) to state only the prohibition on compounding copies, and remove all other content. Recommended language revision: “(e) In addition to prohibitions and requirements for compounding established in federal law, no CSP shall be prepared that: (1) Is essentially a copy of one or more commercially available drug products, as defined at Section 1736(e) of this article.”	consistent with the intent of federal law while ensuring hospitals have additional flexibility to take care of patients. The Board directed the commenter to the Modified Initial Statement of Reasons that includes the referenced FDA Guidance Document, Compounded Drug Products that Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act.
11	1736.1(e)(1)(B)	CMA	CMA is concerned that the Board's proposed modified text establishes a new requirement for pharmacists to “verify” that a prescribed compounded drug product produces a clinically significant difference for the medical need of an identified individual patient under specific conditions. CMA acknowledges the role of pharmacists exercising professional judgment, as outlined in Business and Professions Code (BPC) section 4306.5. However, the proposed requirement to “verify” introduces unnecessary and unintended rigidity into the process. Contrary to the Board's assertion, mandating verification in every instance of compounding a drug that is otherwise	The Board reviewed the comment and did not make changes to the proposed text based on the comment because modifications in the second modified text addressed it. This issue was previously considered by the Board, most recently during the January 8, 2025, Board Meeting. As approved by the Board during that meeting, the second modified text requires a pharmacist to verify that a prescribed medication is clinically appropriate for a patient, irrespective of whether it is a compounding medication. It appears that the commenter is suggesting that a pharmacist does not have an obligation to exercise clinical judgment when compounding or dispensing a medication. The Board believes it is important to

		commercially available and not on a shortage list sets a prescriptive standard for how pharmacists must exercise their professional judgment. The language of the regulations expressly requires pharmacists to verify the existence of a clinically significant difference for each compounded preparation in this situation, rather than allowing pharmacists to exercise their professional judgment as to when such verification may be warranted. This mandate impedes the flexibility the Board claims to seek to preserve and, as such, the language violates the clarity standard because it conflicts with the Board's description of the effect of the regulations in its response above. Pharmacists are already obligated to exercise judgment when dispensing dangerous drugs and are empowered by BPC section 733(b)(1) to refuse to dispense a prescription based on professional judgment, potential harm, or legal concerns. Eliminating the "verify" requirement from the proposed regulation would not abrogate pharmacists' statutory responsibilities but would instead maintain the flexibility pharmacists need to practice most effectively. The verification requirement would also impose significant administrative burdens on both pharmacists and prescribing physicians. For each compounded medication, pharmacists would need to collect and document proof of verified clinical significance for the prescribed drug, while physicians may be required to provide additional supporting evidence. This process could lead to delays in dispensing compounded medications, creating barriers for patients who rely on these treatments. For some patients, such delays could limit timely access to necessary therapies, ultimately harming their care. Finally, federal law, specifically 21 USC § 353a and 21 CFR Part 216, does not establish a documentation requirement, let alone a	underscore that pharmacists must exercise clinical judgment in all aspects of practice and not simply defer their judgment to another individual. This obligation is memorialized throughout Pharmacy Law, including notably BPC Section 4306.5. The Board referred the commenter to some specific provisions of the law that establish specific requirements for pharmacists to evaluate prescriptions prior to dispensing including as examples: Health and Safety Code section 11153 Business and Professions Code section 733 Title 16, California Code of Regulations Section 1707.3

			verification requirement for compounding. FDA guidance only recommends that “[...] the compounder should ensure that the determination is documented on the prescription.” The guidance also clarifies that the FDA “[...] generally does not intend to question prescriber determinations that are documented in a prescription or notation.” Current state regulations require pharmacists to retain the documentation of the determination of clinical significance. The Board's proposal, however, goes beyond all of these standards by mandating that pharmacists both verify and document the prescriber's determination. This additional verification obligation introduces a new requirement, not a clarification of existing state or federal statute. By creating this new regulatory standard, the proposal could be interpreted to place an unprecedented burden on pharmacists, that of duplicating the evaluation already made by the prescriber. This shift in legal construction is unnecessary, given that pharmacists are already accountable for using their professional judgment to ensure compliance with established pharmacy laws. For these reasons, CMA recommends deleting “verify and” from proposed sections 1735(d), 1735.1(e)(1)(B), 1736(d), and 1736.1(e)(1)(B) of the second modified text. This would maintain the documentation standard established in current regulation while ensuring pharmacists retain the flexibility to perform verifications as deemed appropriate based on their professional judgment, as intended by the Board.	
12	1736.1(e)(2)	Wedgewood	The reference to a specific edition of a Guidance Document is troubling. Recommendation: This compound shall be in compliance with current industry guidance. the Center for Veterinary Medicine Guidance for Industry #256 –	The Board reviewed the comment and did not make changes to the proposed text based on the comment. The Board noted that to meet the requirements of the APA, the proposed regulation text must be specific about the standards of practice that will be enforced. If those standards are contained in a particular

			Compounding Animal Drugs from Bulk Drug Substances issued August 2022. We are grateful for the Board's clarification on the inclusion of the AMDUCA reference. While we appreciate the clarity provided, we are concerned that a direct reference to a Guidance Document (GFI 256), including a specific dated version, could be problematic should that document be modified or repealed. Rather than reference a specific document, we would recommend removing the language or changing it to simply reflect "applicable industry guidance" as noted below.	document, it must be referenced. The text cannot include a standard that might be contained in a future document.
13	1736.1(e)(4) Listed as 1736(e)(4) in submitted comment	Marie Cottman	This is duplicated in proposed 1736.10(e) (the section on sterility– more appropriate location). It also could be more direct if it needs to be in 2 places. Recommend to remove 1736(e)(4) in favor of leaving in 1736.10(3). If not removed, consider rewording: (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~~ <u>that cannot be completed within the same licensed compounding location.</u>	The Board reviewed the comment and believed the commenter is referring to section 1736.1(e)(4). The Board did not make changes to the proposed text based on the comment. The Board noted that the language in the referenced regulation text discusses the same concept, but it is being discussed in a different context, as such it is not duplicative.
14	1736.1(g) Listed as 1736(g) in submitted comment	Marie Cottman	This is largely not "in addition to." 1707.2(c)When oral consultation is provided, it shall include at least the following: (1) directions for use and storage and the importance of compliance with directions;... (4) precautions for preparation and administration by the patient... Further, 1707.2(e) allows an out for when the patient or the patient's agent refuse consultation. By having this special consultation for CSPs in section 1736, it becomes a SHALL <u>always</u>, even when the patient doesn't want it. This rule would be much better added to 1707.2 as an additional requirement. As a licensee, it is always frustrating to have to identify multiple sections that address the same requirements!	The Board reviewed the comment and believed the commenter is referring to section 1736.1(g)(1). The Board noted that consistent with the provisions of 1707.2, a pharmacist is required to initiate a consultation; however, a patient may decline the consultation to the pharmacist.

			Recommend to remove and add rulemaking to add this language to 1707.2	
15	1736.4(e)	Marie Cottman	This is not congruent with 1736.1(b)2&3. Recommend to reword: (e) No CSP shall be compounded if the compounding environment fails to meet criteria specified in law or the facility's SOPs unless designated as immediate use only in compliance with 1736.1(b)(2) or 1736.1(b)(3).	The Board reviewed the comment and thanked the commenter for their recommendation to clarify the language. <u>1736.4 (f) No CSP shall be compounded if the compounding environment fails to meet criteria specified in law or the facility's SOPs, unless such compounding is being performed consistent with immediate use provisions.</u>
16	1736.6	Marie Cottman	Comment: Great that this reference is incorporated– glad to know the standard! However, access to this standard costs \$295. As many compounders are conducting their own monthly sampling, we will have to purchase yet another reference. It is NOT readily available.	The Board reviewed the comment and did not make changes to the proposed text based on the comment. The Board noted that the commenter does not appear to be recommending changes to the proposed text. As noted in the Board's Initial Statement of Reasons, "CETA guidelines establish an industry-based minimum set of criteria appropriate for performance evaluation and certification of facility and environmental controls used for compounding sterile preparations. This minimum set of criteria are necessary to ensure consistent and repeatable testing at all facilities."
17	1736.8	Marie Cottman	This is not "in addition to the requirements of USP Chapter 797," rather it is a restatement of proposed rule 1736.17. Having the same rule in two locations just complicates things! Recommend remove, 1736.17 is clear enough.	The Board reviewed the comment and did not make changes to the proposed text based on the comment. As was stated in the prior response to a similar comment received during the 30-day comment period, inclusion in this section provides clarification to the regulated public that SOPs must address this practice and serves as a reminder.
18	1736.9(d)	Novo Nordisk	Comment: We appreciate the Proposed Rule's provisions requiring Certificates of Analyses (COAs) for API used to compound sterile products. We offer three recommendations to further bolster the Proposed Rule's provisions on COAs. 1. We recommend that the Board reinsert reference to excipient components to ensure that all components used to compound sterile products are accompanied by a COA. Excipient	The Board reviewed the comment and did not make changes to the proposed text based on the comment. The Board noted that in response to prior comments received, the Board agreed to remove explicit language related to excipient components. As the Board noted in its response to comments, a pharmacist must remain knowledgeable of current practice standards and legal requirements while exercising

		components in compounded products can cause dangerous adverse events and result in serious harm to patients. For example, FDA published a Compounding Risk Alert after receiving an adverse event report concerning a patient who experienced cardiac arrest and died after IV administration of a curcumin emulsion product compounded by ImprimisRx.¹¹ FDA identified the presence of an impurity in PEG 40 castor oil, an excipient used in the compounded product that may have caused the adverse event. The PEG 40 castor oil used was ungraded and not suitable for human consumption or therapeutic use. FDA thus warned against the “risks associated with compounded drugs, particularly those that use non-pharmaceutical grade components and ingredients lacking a USP monograph.” The Board can help to protect against these risks by reinserting COA requirements for excipient components used to compound sterile products. 2. We recommend that the Board adjust the Proposed Rule's carveout for components of commercially available drug products to ensure that the carveout only applies to ingredients sourced from and provided by the manufacturer of the commercially available drug product. Requiring the COA with the specified content in all other circumstances is critical to ensuring that ingredients used by compounding facilities do not lead to unsafe and ineffective compounded drugs. 3. We recommend that the Board add a requirement that the COA of any API that claims to be a component of an approved drug show that the API was manufactured by the process specified in the labeling of the approved drug. The importance of this requirement is particularly acute for the bulk “semaglutide” used in compounding. The FDA-approved labeling for	professional judgment. Failure to do so could constitute unprofessional conduct. Further, the Board noted that the proposed regulation text establishes the requirements for a COA consistent with the commenter recommendation. While the Board agrees with the examples provided by the commenter, the Board's compound regulations span a variety of different settings. The Board is generally seeking to align with federal law and supporting guidance documents. It appears that the commenter is suggesting that the Board's regulations expand beyond the provisions of federal law in section 503A.

		semaglutide medicines explains that the “peptide backbone is produced by yeast fermentation.” Unlike the yeast-produced semaglutide in NNI’s FDA-approved semaglutide medicines, the “semaglutide” in compounded drugs is produced using synthetic semaglutide unaffiliated with any approved application. Use of such API can introduce peptide-related impurities and other complexities and expose patients to safety and effectiveness risks. Indeed, testing revealed that compounded “semaglutide” samples contained high levels of impurities. This data reinforces the importance of requiring that the COA demonstrate that any API that claims to be a component of an FDA-approved drug was manufactured by the same process described in the FDA-approved drug labeling. The Board should thus (1) ensure that all components used to compound sterile products, including excipients, are accompanied by a COA; (2) limit its exemption to circumstances where a compounding facility sources and obtains its API from the manufacturer of a commercially available drug product; and (3) require that the COA show that any API that claims to be a component of an approved drug was manufactured by the process specified in the labeling of the approved drug. Adhering to these standards is critical to ensure that patients do not receive unsafe and ineffective compounded products that are unaffiliated with approved drug products. Recommended language revision: 1. “(d) All APIs used to compound a CSP shall be manufactured by an FDA-registered facility. All APIs and excipient components used to compound a CSP shall be accompanied by a Certificate of Analysis (COA) and be suitable for use in sterile pharmaceuticals. A COA that includes the compendial name, where one	

			exists, the grade of the material, and the applicable compendial designations on the COA, must be received and evaluated prior to use, unless components of the CSP are commercially available drug products that are sourced from and provided by the manufacturer of the commercially available drug product. The COA for any API used to compound a CSP that claims to be a component of an FDA-approved drug must show that the API was manufactured by the process specified in the labeling of the FDA-approved drug. When the COA is received from a supplier, it must provide the name and address of the manufacturer. An API and excipient components provided with a COA without this data shall not be used in a CSP."	
19	1736.9(d)	PCCA	<u>Recommend</u>: Remove the language: "When the COA is received from a supplier, it must provide the name and address of the manufacturer. An API provided with a COA without this data shall not be used in a CSP." <u>Rationale</u>: See comment in response to Section 1735.7(c)(1). 1. No Legal or Regulatory Requirement for Manufacturer Information on COAs: Neither the FDCA nor any FDA implementing regulation—or even a non-binding guidance document—includes a "requirement for the COA" from a supplier to disclose the manufacturer name or address. Under the FDCA the sole requirement for COAs is that compounded drugs must be accompanied by valid COAs for their bulk drug substances to qualify for exceptions to the FDCA. Specifically: - 21 U.S.C. § 353a(b)(1)(a)(iii) requires that compounded drugs must be accompanied by valid COAs to qualify under Section 503A exemptions.	The Board reviewed the comment and did not make changes to the proposed text based on the comment. The Board previously considered these comments on several occasions, including as part of its discussion during the November 5-6, 2024, Board Meeting. As was noted at that time, the Board noted that while existing law provides flexibility to record the manufacturer under limited circumstances, continuation of the current provision is not appropriate as it hampers the ability of a facility to respond appropriately in the event of a product recall. Further, the Board's proposed regulation text is more explicit than the Chapter for the reasons cited elsewhere in this response. The Board noted that the Chapter requires either the recording of the manufacturers or vendors; however, in separate guidance issued by the FDA, the facility needs to have transparency into the supply chain and awareness of the manufacturer (where the manufacturer and vendor are different.) The FDA has released guidance in this area, including the importance of compounders knowing their suppliers - - https://www.fda.gov/drugs/human-drug-

		- 21 U.S.C. § 353b(a)(2)(D) similarly requires valid COAs for bulk drug substances under Section 503B exemptions. Neither the FDCA nor FDA regulations impose any obligation to include the manufacturer's information on a COA. Instead, the FDA has long accepted the practice of suppliers providing COAs that incorporate quality testing data from the suppliers themselves as well as data from the manufacturer's own quality testing. 2. FDA Guidance Does Not Impose Such a Requirement: FDA guidance documents related to compounding further underscore the lack of any requirement to include manufacturer information on COAs. The FDA Guidance for Industry: Pharmacy Compounding of Human Drug Products Under Section 503A (June 2016) states only that compounded drug products must be accompanied by valid COAs for each bulk drug substance. There is no mention of manufacturer information being required on the COA. While the nonbinding FDA Guidance for Industry: Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients <i>recommends</i> including the manufacturer's name and address on COAs in the context of cGMP compliance for outsourcing facilities, it has no implication here as it applies solely to outsourcing facilities operating under Section 503B of the FDCA. It does not apply to compounding pharmacies operating under Section 503A, which are expressly exempt from cGMP requirements. See 21 U.S.C. § 353a(a) (exempting 503A compounded formulations from cGMP requirements imposed under 21 U.S.C. § 351(a)(2)(B)). This distinction is critical. cGMP compliance is irrelevant to Section 503A compounding pharmacies, and the FDA has	compounding/fda-compounders-know-your-bulks-and-excipientssuppliers. Lastly, requiring the identity of the manufacturer of a component to a compounder who is compounding with that component without requiring more information be provided does not appear to be requiring the disclosure of a trade secret under Civil Code section 3426.1(d). Moreover, vendors can take steps when contracting with compounders to protect the information related to their business arrangements with manufacturers. The Board referred the commenter to the underlying data portion of the Modified Initial Statement of Reasons, which includes the above referenced FDA guidance document.

			recognized that requiring manufacturer information on COAs is not necessary to meet the requirements of Section 503. 3. Unintended Negative Impacts: Mandating the inclusion of manufacturer information on COAs, as proposed by the California Board of Pharmacy, would impose unnecessary burdens on compounding pharmacies and suppliers alike. The harmful consequences of the proposed regulations include (1) exposing proprietary sourcing strategies—which are considered trade secrets—in violation of California law, and (2) a regulation that diverges from federal standards and guidance, creating unnecessary confusion and inconsistency for suppliers and compounding pharmacies operating across multiple jurisdictions.	
20	1736.9(d)	Marie Cottman	This is a misplaced rule! It belongs in the rules that wholesalers must comply with. The inspectors are aware that PCCA will not provide original COA nor reveal the manufacturer, except when requested by a Board Inspector. PCCA has a rigorous process to vet manufacturers, including that they are registered with the FDA. Further, they have a process of validating their wholesaler's COAs and rejecting components that don't meet standards (even if the COA says it does). Recommend to move this requirement to BPC Article 11 in the Wholesaler chapter for rules.	The Board reviewed the comment and did not make changes to the proposed text based on the comment. The Board noted that the requirements contained in the proposed regulation text is consistent with the FDA guidance in this area. As was included in the Board's prior response to the proposed regulation text in this area, the FDA has released guidance including the importance of a compounder knowing their supplier. Further, the Board noted that suppliers are under the jurisdiction of the Board.
21	1736.9(e)	Novo Nordisk	Comment: We recommend that the Board revise its provisions in 1736.9 related to the conditions under which sterile compounding can occur. By adopting this recommendation, the Board will align its Proposed Rule with Federal Food, Drug, and Cosmetic Act section 503A(b)(1)(A). We also recommend that the Board add a definition for "component of a drug approved by the FDA" to ensure that API used to compound sterile drugs is	The Board reviewed the comment and did not make changes to the proposed text based on the comment. The Board noted that the Board does not need to add a definition of component as recommended because a pharmacist must remain knowledgeable of current practice standards and legal requirements while exercising professional judgment. Failure to do so could constitute unprofessional conduct.

			the same API used to manufacturer FDA-approved drug products. In addition, for the reasons noted for section 1736.9(d) above, the Board should add a requirement that API that claims to be a component of an approved drug must be manufactured by the process specified in the labeling of the approved drug. Recommended language revision: 1736.9: "(e)(1) Except as provided in (2) or (4), when API is used to compound a CSP, it shall – (i) comply with a USP monograph; (ii) if such a monograph does not exist, be an API that is a component of a drug approved by the FDA; or (iii) if such a monograph does not exist and the API is not a component of a drug approved by the FDA, be listed in 21 C.F.R. § 216.23." [NEW] "(4) A drug product may be compounded if authorized by a public health official in an emergency use situation for a patient-specific compounded sterile preparation. (5) API used to compound a CSP that claims to be a component of an FDA-approved drug must be manufactured by the process specified in the labeling of the FDA-approved drug." 1736: [NEW] "(i) 'Component of a drug approved by the FDA' means an API that is the same as the API used in the manufacture of the approved drug, ."	The Board is seeking to align with federal law and supporting guidance documents. It appears that the commenter is suggesting that the Board's regulations should further restrict the provisions of federal law in section 503A.
22	1736.11(c)	CSHP	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	The Board reviewed the comment and did not make changes to the proposed text based on the comment. The Board noted that this issue has been considered by the Board on numerous occasions most recently during the January 8, 2025, Board meeting. As was previously noted, current regulations provide an exemption to the compounding record requirement. The Board did not believe that the exemption was still appropriate. The Board noted that inspections reveal

		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. Caring for patients in the fast-paced dynamic environment of a hospital is hampered by this restrictive proposed rule. Every additional requirement for documentation and additional information takes pharmacy staff away from patient care while not adding value for patient safety. To help pharmacy staff and hospitals take care of patients, we propose a change to our original proposal below. Recommendation (BOLD): We once more reiterate the comments by both us and others at various stages through this rulemaking process that USP standards adequately provide for safe and quality compounding of medications. The addition of this regulation exceeds the national standards in a manner that fails to demonstrate the benefit to patients. Add back the language above: 1736.11 Master Formulation and Compounding Records, subsection(c):	that health systems and other facilities generally maintain this information within its electronic system or other documentation. Recalls can occur requiring action at the patient level. Maintaining this information is essential to identify impacted patients. Collection of this information also allows facilities to maintain documentation of compliance with manufacturer approved labeling provisions. The changes made in the modified text provided further clarification that the information required in this subsection does not need to be maintained in a single document. Such an approach provides flexibility in how a pharmacy maintains this information. The Board noted that the Chapter, Section 11.2 requires a compounding record for each CSP. There is no exemption for hospitals in the Chapter. The request from the commenter to provide an exemption would not meet the minimum requirements of the Chapter.

			<u>(6) Exempt from the requirements in this paragraph are sterile preparations compounded for administration within twenty-four (24) hours to a single patient in a health care facility licensed under section 1250 of the Health and Safety Code.</u>	
23	1736.11(c)(2)	PCCA	<u>Recommend:</u> Remove the clause entirely. <u>Rationale:</u> See comment in response to Section 1735.7(c)(1).	The Board reviewed the comment and did not make changes to the proposed text based on the comment. The Board previously considered these comments on several occasions, including as part of its discussion during the November 5-6, 2024, Board Meeting. As was noted at that time, while existing law provides flexibility to record the manufacturer under limited circumstances, continuation of the current provision is not appropriate as it hampers the ability of a facility to respond appropriately in the event of a product recall. Staff further noted that the Board's proposed regulation text is more explicit than the Chapter for the reasons cited elsewhere in this response. The Board noted that the Chapter requires either the recording of the manufacturers or vendors; however, in separate guidance issued by the FDA, the facility needs to have transparency into the supply chain and awareness of the manufacturer (where the manufacturer and vendor are different.) The FDA has released guidance in this area, including the importance of a compounders knowing your suppliers - https://www.fda.gov/drugs/human-drug-compounding/fda-compounders-know-your-bulks-and-excipientssuppliers. Lastly, requiring the identity of the manufacturer of a component to a compounder who is compounding with that component without requiring more information be provided does not appear to be requiring the disclosure of a trade secret under Civil Code section 3426.1(d). Moreover, vendors can take steps when contracting with compounders to protect the

				information related to their business arrangements with manufacturers The Board referred the commenter to the underlying data portion of the Modified Initial Statement of Reasons which includes the above referenced FDA guidance document.
24	1736.17(a)(2)	Novo Nordisk	Comment: Aligned with our comments for section 1735.11(a)(2) above, NNI recommends that the Board require that SOPs describe written procedures for the surveillance, receipt, evaluation, and reporting of adverse drug experiences involving sterile compounded products. Recommended language revision: [NEW] "(G) Written procedures for the surveillance, receipt, evaluation, and reporting of adverse drug experiences to the Board."	The Board reviewed the comment and did not make changes to the proposed text based on the comment. The Board's compounding regulations establish the minimum standards for compounding. While the Board agrees that written procedures for surveillance, receipt, evaluation and reporting of adverse drug experiences to the Board may be appropriate for some facilities, it is not necessary for all compounding practices.
25	1736.17(a)(2)(E)	Marie Cottman	1736.9(f) does not exist in the most recent version of the proposed rules. Recommend to remove.	The Board reviewed the comment and thanked the commenter for highlighting this error that occurred when renumbering section 1736.9. To address this issue, the Board made the following change: 1736.17(a)(2)(E) <u>The methods by which the pharmacist compounding or supervising the compounding pursuant to section 1736.9(e)(2)(F) related to use of a bulk drug substance published in the section 503A Category 1 bulk substances list, will ensure each lot of the bulk drug substance is representatively sampled per USP Chapter 1097 (bulk powder sampling procedures), tested, and found to be in compliance with at least:</u>
26	1736.17(a)(2)(E) & (F)	Medisca	Medisca agrees with the Board's proposed amendment to Section 1736.17(a)(2) to include subsection (F), allowing compounders to use documentation as evidence of testing required by subsection (E). Medisca respectfully requests that the Board further amend Section 1736.17(a)(2)(E) to account for the fact that the testing requirements therein are applicable at different	The Board reviewed the comment and did not make changes to the proposed text based on the comment because modifications in the second modified text addressed it. The second modified text included changes requested by the commenter. The Board determined that the proposed regulation text is clear about the requirements to establish SOPs in this area and that compounding facilities have flexibility in determining how to implement the provisions through

			stages of the compounding process. Namely, testing required under subsections (ii) and (iii) can be performed on the bulk drug substance by manufacturers and/or wholesalers, while testing required under subsections (i) and (iv) is more appropriately performed on the compounded product by the compounder. Whether or not testing required by subsections (i) and (iv) is performed by the manufacturer and/or wholesaler, the tests will need to be ran and confirmed again on the compounded product. Medisca respectfully requests that the Board amend the regulations to provide that documentation, like the Certificate of Analysis, will be considered sufficient to satisfy subsections (ii) and (iii) whenever the required testing was conducted. However, if any of the required tests were not conducted by the manufacturer and/or wholesaler, the onus should be on the compounder to ensure that both the bulk drug substance(s) used and the compounded product meet all of the requirements.	the development of the SOPs. The Board was concerned about including additional regulation text that could reduce the flexibility intended for compounding facilities to determine the best means by which to operationalize the requirements.
27	1736.18(c)	CSHP	The board did not demonstrate that it understood and considered the comment in that it only responded to the part where 3 business days was recommended. There was no acknowledgement of understanding of our concern that the language seems to suggest that the review must be completed within a 72 hours timeframe. We pointed out that a review can start within 72 hours but it can take longer to complete once further investigation is needed. We would like to recommend again that the word "shall start" be added to the language. The way that the proposed regulation is written, seems to suggest that the review must be completed within 72 hours since it states that "such review shall be documented and dated as defined	The Board reviewed the comment and believed the intent of the regulation text is clear, in that the proposed regulation text does not specify that the investigation into the complaint must be completed within 72 hours; rather the regulation text states that the complaint shall be reviewed within 72 hours of receipt. To best address the issue raised by the commenter, however, the Board amended the text to read: <u>1736.18 (c) In addition to subsection (b), ~~the pharmacist in-charge shall initiate a review of any all~~ complaints made to the facility related to a potential quality problem with a CSP and ~~any all~~ adverse drug experiences events shall be reviewed by the pharmacist in-charge within 72 hours of receipt of the complaint or occurrence of the adverse drug experience. Such review shall be documented and</u>

		in the SOPs." The proposed language requirement for a documentation and dating of the review together with the preceding sentence's requirement for review within 72 hours from the receipt of the complaint could be seen as requiring the review to be completed within the 72 hours timeframe. A requirement of 72 hours may not provide sufficient time for pharmacies to thoroughly investigate and determine root causes. It is reasonable to expect that a review after a complaint be <u>started</u> within three business days. Investigation could take longer than this due to many factors involved in such an investigation that needs to be looked at. Many of these may not be available or apparent within this timeframe. Recommendation (BOLD): We recommend that the intent of this proposed regulation be clarified with the following proposed language: (c) In addition to subsection (b), all complaints made to the facility related to a potential quality problem with a CSP and all adverse drug experiences shall be reviewed by the pharmacist-in-charge and shall start within 72 hours of receipt of the complaint or occurrence of the adverse drug experience. Such review shall be documented and dated as defined in the SOPs.	<u>dated as defined in the SOPs.</u> The Board noted that nonsubstantive conforming changes in other areas of the third modified text would also be appropriate.

#	Section	Commenter	Comment	Board Response
1	1737	Marie Cottman	General statement of: In addition to the standards in the USP Chapter 800, the following requirements apply to a facility where compounding of HDs is performed. Vs. In addition to the standards in the USP Chapter 800, the following requirements apply to the compounding of HDs or performing crushing or splitting tablets or opening capsules of antineoplastic HDs. 1) This statement is used inconsistently throughout the proposed rules for hazardous compounding. Recommend you create a consistent statement that can be used at the beginning of each numbered rulemaking. Delete redundant and repetitive phrasing. 2) The expanded statement about crushing or splitting tablets is not included, but seems appropriate for sections 1737.2, 1737.7 PPE, 1737.8 Hazard Communications, 1737.12 Dispensing final dosage form, 1737.15 Deactivating, Decontamination, Cleaning and Disinfecting, 1737.16 Spill Control	The Board notes that nonsubstantive changes may be made in the proposed regulation text consistent with the Board's action where necessary. The commenter does not appear to be recommending substantive changes to the proposed regulation text in section 1737, rather appears to be recommending the Board review text for consistent use of language. Provided below is an example of a nonsubstantive change to standardize text. 1737. Handling of Hazardous Drugs. ~~In addition to the requirements in United States Pharmacopeia (USP) General Chapter 800 (USP Chapter 800), Hazardous Drugs – Handling in Healthcare Setting, This this article applies to the handling compounding of Hazardous Drugs (HDs) or performing “other manipulations” included in Table 1 of the Chapter crushing or splitting tablets or opening capsules of antineoplastic HDs, of Hazardous drugs established by United States Pharmacopeia (USP) General Chapter 800 (USP Chapter 800), titled Hazardous Drugs – Handling in Healthcare Setting. In addition to the standards in the USP Chapter 800, Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article.~~
2	1737.1	CA Rheumatology Alliance And CA Society of Plastic Surgery	We have reviewed the staff responses to our comments and continue to be concerned with the applicability of the proposed regulations on physicians and their ability to “compound” medications in their offices. Although physicians may not be under the enforcement jurisdiction of the Board of Pharmacy, we believe the proposed regulations would change the standard of care for when physicians compound medications and will not allow rheumatologists/physicians to buffer injection/ infusion	The Board reviewed the comment and did not make changes to the proposed text based on the comment. The Board noted that they considered this comment, most recently during the January 8, 2025, Board Meeting and determined that the requested change was not appropriate.

		medications in-office. We are interpreting the proposed regulations to require a pharmacist be present or performing the buffering of the injection/ infusion medications. Rheumatology practices/physicians would not be able to afford to employ a pharmacist for this one purpose. This would lead to rheumatology practices no longer offering this service for our patients. Patients would then be forced to obtain their injection/infusions at a hospital or infusion center which would not only be less convenient for our patients, but it would be more expensive for the patient and the overall healthcare system. We believe it is important to note we are not aware of any issues with rheumatologists/physicians "compounding" injection/ infusion medications. We would like to propose the Board of Pharmacy adopt the language suggested by the California Medical Association as shown below: § 1737.1: In addition to the requirements in USP Chapter 800 and Food Drug Cosmetic Act (FDCA) section 503a (21 U.S.C. §353a) the following requirements apply to the compounding of Hazardous Drugs. <u>This article shall not apply to compounding by or under the direct supervision of a licensed physician and surgeon.</u>	As was previously shared, the Board only has jurisdiction over individuals and businesses within its practice act. The Board reads the comment as suggesting that the Board's proposed regulations would apply to a physician. Business and Professions Code section 4170(c) makes clear that the Medical Board of California is specifically charged with the enforcement of Pharmacy Law (Chapter 9, Division 2 of the Business and Profession Code) with respect to its licensees. It may be appropriate for the commenter to confer with their licensing board to discuss their concerns. The Board noted that the Medical Board of California has previously provided a written response to individuals inquiring about the applicability of the Board of Pharmacy's regulations to individuals and practices that operate under the jurisdiction of the Medical Board of California. Below is the information provided from the Medical Board - - <i>Dear Ms. Sodergren:</i> <i>I understand that some concerns have been raised by stakeholders about the applicability of the Board of Pharmacy's pending compounding regulations to licensees of the Medical Board of California (MBC). Existing statute (see Business and Professions Code (BPC) section 2220.5) makes it clear that only the MBC can discipline its physician licensees. Whenever a physician is engaging in compounding (or any other action that their medical license authorizes them to perform) they must always do so consistent with the standard of care. For the purposes of MBC's enforcement program, the standard of care is established by expert testimony in the context</i>

				of the facts and circumstances of a specific case. <i>It is certainly possible that whatever regulations that are implemented by the Board of Pharmacy may influence the standard of care for physicians who are compounding, especially since some of the proposed regulations reflect what is already required for physician compounding under federal law, including, but not limited to, Section 503A of the Federal Food, Drug, and Cosmetic Act (BPC section 2225(b) allows MBC to investigate violations of federal law related to the practice of medicine).</i> <i>Feel free to share this message with others as you see fit who might also be concerned about the applicability of their pending regulations to the physician community.</i> <i>Please contact me if you have any further questions.</i> <i>Sincerely,</i> <i>Reji Varghese</i> Reji Varghese is the Executive Director for the Medical Board of California. The Medical Board is charged with evaluating compounding practices and the standard of care relevant to its licensees.
3	1737.1(a)	Marie Cottman	1707.2(e) allows an out for when the patient or the patient's agent refuses consultation. By having this special consultation for HDs in section 1737.1(a), it becomes a SHALL <i>always</i>, even when the patient doesn't want it. This rule would be much better added to 1707.2 as an additional requirement. As a licensee, it is always frustrating to have to identify multiple sections that address the same requirements! Recommend to remove and add rulemaking to add this language to 1707.2.	The Board reviewed the comment and did not make changes to the proposed text based on the comment. The Board noted that, consistent with the provisions in 1707.2, a pharmacist is required to initiate a consultation; however, a patient may decline the consultation with the pharmacist.

4	1737.2	Marie Cottman	The expanded statement about crushing or splitting tablets is not included, but seems appropriate for sections 1737.2	The Board reviewed the comment and did not make changes to the proposed text based on it. The Board's regulation text establishes minimum standards, specifically that for the list of hazardous drugs, the inclusion of "crushing or splitting tablets" is not necessary.
5	1737.5(c)	UCSD Health	One written comment response I would like to address is on 1737.5(c) that prohibits a pass through between a classified space and unclassified space. The board response is title 24, section 122 prohibits passthrough between classified and unclassified spaces in HD environment. This was an update to title 24 in 2022. The problem with putting building codes into pharmacy law is building codes apply at the time of permitting so if I applied for permits in 2018 those permits would apply not 2022. In fact, the change in 2022 was the result of a misreading of USP 800 by the California Building Standards Commission where USP says no pass-through refrigerator and not pass throughs. This has actually been corrected in the latest Title 24 version 2024 now is amended. The code now says: o Section 1224.19 "This section to align with USP which allows a passthrough from the buffer room to unclassified area but not the refrigerator". a. Recommendation: Revise language to be consistent with USP 800 or FDA language. I would ask the board align with USP 800 similar to the California Building Standards Commission and the FDA and allow for a pass through between hazardous classified and unclassified space. The provision on no pass-through refrigerator can replace the current proposed language.	The Board reviewed the comment and confirmed that the California Building Standards Commission is considering a change to the building code during its February 2025 meeting. Although the outcome of this meeting was not yet known, given that the change is being considered, it is appropriate to remove what was section 1737.5(c). ~~1737.5 (c) Where a pass through is installed in a containment secondary engineering control (C SEC), the doors must be gasketed and interlocking. Effective 10/01/insert six months following the effective date) A pass through is not allowed between the hazardous drug buffer room C SEC into an unclassified space.~~
6	1737.5(c)	Kaiser Perm And CSHP	Commenter requests that the section be stricken from the language. The California Building Standards Commission has proposed deleting the prohibition of a pass-through between a hazardous drug buffer room and an unclassified area in its 2024 Triennial Code Adoption Cycle, which will become effective on January 1, 2026. The Building Standards	The Board reviewed the comment and confirmed that the California Building Standards Commission is considering a change to the building code during its February 2025 meeting. Although the outcome of this meeting was not yet known, given that the change is being considered, it is appropriate to remove what was section 1737.5(c).

			Commission's recommendation is copied below for reference (emphasis added): 1224.19.3.3.2.8 Pass-throughs. HCAI proposes an amendment to remove the prohibition of a pass-through between the hazardous drug buffer room and any unclassified area and to add a restriction for refrigerator pass-through. The proposed amendment is to align with United States Pharmacopeia General Chapter, USP-GC Hazardous Drugs-Handling in Healthcare Settings (USP-GC). The USP-GC standards allow a passthrough from the buffer room to unclassified areas but not the refrigerator. This revision will align with USP-GC. It will not cause financial burden to the facilities. When the new building code goes into effect on January 1, 2026, only compounding suites that were permitted between January 1, 2020 and December 31, 2025 cannot have a pass-through between the HD buffer room and unclassified areas. If the Board chooses to adopt this restriction in its regulations, it will be cherry-picking a standard that is not included in current building code (as of 1/1/2026) and is not supported by the USP chapters. If the Building Standards Commission's recommendation alone is not persuasive, then logically evaluating the most significant source of microbial contamination should be. The personnel entering the sterile compounding suite present the greatest risk for microbial contamination in the cleanroom. A pass-through reduces human traffic in and out of the buffer room thus reducing opportunities for microbial contamination in the sterile compounding suite.	1737.5 ~~(c) Where a pass through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking. Effective [OAI insert six months following the effective date] A pass through is not allowed between the hazardous drug buffer room C-SEC into an unclassified space.~~
7	1737.6	Marie Cottman	If 1737.6 does not require the use of environmental wipe sampling, what is the point of writing ANOTHER SOP? Documentation of consideration should be sufficient. Recommend to reword: The premises shall consider environmental wipe sampling and if implemented, SOPs of a premises where HDs are handled shall address describe provisions for environmental wipe sampling for HD surface residue, its frequency, and areas of testing, levels of measurable contamination, and actions when those levels are exceeded. Nothing in this	The Board reviewed the comment and did not make changes to the proposed text based on the comment. The Board noted that documentation within the SOP shall memorialize the facility's consideration of the use of environmental wipe sampling along with the provisions for use when determined appropriate. The Board made clarifying changes to the text to make clear the requirement.

			section is intended to require the use of environmental wipe sampling.	1737.6 <u>In addition to the standards in USP Chapter 800, the following requirements apply to a facility where compounding of HDs is performed. Hazardous Drugs Handling in Healthcare Setting shall meet the following requirements of this article.</u> <u>The premises shall consider environmental wipe sampling, and SOPs of a premises where HDs are handled shall address describe the consideration of and provisions for environmental wipe sampling for HD surface residue, its frequency, and areas of testing, levels of measurable contamination, and actions when those levels are exceeded. Nothing in this section is intended to require the use of environmental wipe sampling.</u>
8	1737.7	Marie Cottman	The expanded statement about crushing or splitting tablets is not included, but seems appropriate for sections 1737.7	The Board reviewed the comment and did not make changes to the proposed text based on the comment. The Board noted that the regulation text establishes minimum standards and that specific provisions for PPE in the Board's proposed regulations do not need to extend to "crushing or splitting tablets"
9	1737.7(b)	Marie Cottman	In section A, the phrase "chemotherapy gloves that meets the ASTM D-6978 standard" is also used. But at the end of this provision, there is a sneaky distinction that the gloves be "labeled to meet ASTM D-6978." NOT ALL ASTM compliant gloves are labeled as such. The ASTM designation is a 'pay to play' label and many gloves meet the standard as is indicated in their COA, but do <i>not</i> pay to have the ASTM label. Further, USP 800 section 7 already requires "...two pairs of chemotherapy gloves are required for compounding sterile and nonsterile HDs." Recommend to revise by removing "labeled to meet the ASTM standard".	The Board reviewed the comment and appreciated the commenter highlighting their concern. After reviewing the comment, the Board determined that the language is generally covered in the Chapter and noted that some of the activities described fall under the purview of CalOSHA. The proposed text established in subdivisions (a) & (b) does not appear to create patient safety issues but is more directed at personnel safety. Although the commenter is specifically referring to subdivision (b), the Board determined that removing subdivisions (a) and (b) was appropriate.

			(b) The outer pair of chemotherapy gloves that meets the ASTM D-6978 standard shall be changed as 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.	1737 (a) ~~Two pairs of chemotherapy 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 chemotherapy gloves that meets the ASTM D-6978 standard shall be changed every 30 minutes during HD compounding unless otherwise as 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.~~
10	1737.7(c)	Marie Cottman	As was presented to the board previously, this is an expensive and unnecessary rule. Either the compounder can prepare sterile preparations without cross contamination, or they cannot, and gloves should be changed for every different preparation (HD or NOT)! Sterile gloves are costing \$1.50 to \$3.85 / pair. In addition to the expense, the change in process for all sterile compounders might result in a shortage of gloves because the use will not double, but it might increase by 10 or 20 fold! IF you cannot provide evidence of the NEED to change the gloves more often than required by the manufacturer, then Recommend to remove.	The Board reviewed the comment and did not make changes to the proposed text based on the comment. The Board noted that information released by USP explicitly states, "Consider all PPE worn when handling HDs to be contaminated with, at minimum, trace quantities of HDs..." The Chapter in section 3 provides examples of potential opportunities for exposures based on activity, including compounding. If gloves are contaminated, it can result in cross-contamination of preparations for patients. The proposed second modified text provides flexibilities to allow for multiple HD preparations of the same drug or when preparing HDs for a single patient where the risk of cross-contamination is not present. Further, costs may vary depending on the types of HD gloves, e.g. sterile versus nonsterile, and vendors used, etc. The Chapter determines the types of gloves that must be used depending

				on the functions being performed and establish a number of requirements for changing gloves. The Board's proposed regulations are addressing the potential for cross-contamination. As established in USP and in the conclusions of published research, Hazardous Drugs Contamination of Drug Preparation Devices and Staff: A Contamination Studies Simulating the use of Chemotherapy Drugs in a Clinical Setting¹, "In 4 of the 5 CSTD systems, residue from HD-contaminated vials spread as the vial was handled in a pharmacy environment. HD contamination transferred initially to pharmacy PPE, then spread to ancillary products such as IV bags, IV sets, and transport bags, which, in turn contaminated nursing PPE..." As this study demonstrates, cross-contamination can occur even with the use of CSTDs.
11	1737.7(c)	Stanford Health	Comment: While we acknowledge that Closed System Transfer Devices (CSTDs) do not completely eliminate contamination risks, they are specifically designed to prevent the escape of hazardous drugs or vapors outside the system. Most hazardous drug compounding in hospital practice involves the use of closed system drug vials, which, when paired with CSTDs, further reduces the potential for contamination. Taken together, implementing a requirement for excessive glove changes, in addition to the use of CSTDs with closed-system vials, offers negligible added safety benefits to patients. The proposed requirement introduces operational burden and significant costs incurred for HD gloves and HD waste disposal. Recommendation: Remove language to be consistent with USP 800 or revise language to require changing outer HD	The Board reviewed the comment and did not make changes to the proposed text based on the comment. As the studies provided reveal, the use of a CSTD may reduce the risk of contamination but does not eliminate the risk. The Board appreciates the use of the technology as an important safety measure and notes the following from USP. As included in previous response to comments, USP Commentary provides, "CSTD provides adjunct control during compounding; however, additional controls are needed to prevent HD contamination, especially during the movement of ingredients and materials into and out of the C-PEC."

¹ Evan Call, Brian Bill, Chad McLean, Nathan Call, Allyn Bernkopf, Craig Oberg. (2017) Hazardous Drug Contamination of Drug Preparation Devices and Staff: A Contamination Study Simulating the Use of Chemotherapy Drugs in a Clinical Setting, *Hospital Pharmacy*, 52(8): 551-558, <https://pubmed.ncbi.nlm.nih.gov/Compounded Drug Products> Second Modified Text Summarized Comments with Board Response Hazardous (1737 et seq.)

			gloves, between each different HD preparation, <u>if compounding is performed without a CSTD.</u>	Further, in the conclusions of published research, Hazardous Drugs Contamination of Drug Preparation Devices and Staff: A Contamination Studies Simulating the use of Chemotherapy Drugs in a Clinical Setting², “In 4 of the 5 CSTD systems, residue from HD-contaminated vials spread as the vial was handled in a pharmacy environment. HD contamination transferred initially to pharmacy PPE, then spread to ancillary products such as IV bags, IV sets, and transport bags, which, in turn contaminated nursing PPE...” As this study demonstrates, cross-contamination can occur even with the use of CSTDs. This study also supports the USP Commentary statements related to this area that were previously noted in staff recommended responses. Photos included in Figure 1 clearly show the contamination of gloves.
12	1737.7(c)	Kaiser Perm	Commenter recommends that this section should be stricken. Anything short of deleting this section of regulation is inadequate. There is no evidence to support the notion that requiring compounders to change their outer HD gloves more frequently than the USP 800 recommended frequency of every 30 minutes will prevent contamination with HD residues. Commenter previously outlined several negative second-order effects that this change will precipitate. Commenter states that the Board has never weighed the purely speculative benefits of more frequent outer HD glove changes against the real negative outcomes that the regulation will cause.	The Board reviewed the comment and did not make changes to the proposed text based on the comment. (Note that the language referenced is now section 1737.7(a) because of the proposed deletion of subsections (a) and (b).) The Board notes that the intent of the Chapter in part is to protect patients from harm associated with exposure to hazardous drugs. USP was developed to provide guidance on protecting any individual who may have exposure to HDs. As the Chapter establishes, gloves must be changed if contaminated. This is a requirement of the Chapter. The Chapter further provides in Section 7.6, “Consider all PPE

² Evan Call, Brian Bill, Chad McLean, Nathan Call, Allyn Bernkopf, Craig Oberg. (2017) Hazardous Drug Contamination of Drug Preparation Devices and Staff: A Contamination Study Simulating the Use of Chemotherapy Drugs in a Clinical Setting, *Hospital Pharmacy*, 52(8): 551-558, <https://pubmed.ncbi.nlm.nih.gov/Compounded Drug Products>

Second Modified Text Summarized Comments with Board Response

Hazardous (1737 et seq.)

		Correctly donning sterile gloves is critically important to safe compounding and is a significant risk point for introducing microbial contamination into the sterile compounding environment; consequently, facilities are required to perform initial gloved fingertip sampling “to ensure that personnel... put on sterile gloves without contaminating them.” Because each glove change carries some risk of microbial contamination, basic probability dictates that mandating that compounders change the outer HD glove more frequently increases the overall risk of contamination. For example, the two equations below give the respective probabilities of microbial contamination for two scenarios. The first equation, p1, is the imagined probability of contamination for an individual who performs ten glove changes in a shift with the probability of contamination during any one glove change of 0.2%. The second equation, p2, is the imagined probability of contamination for the same individual who now performs fourteen glove changes in a shift (an increased frequency of glove changes based on the Board's proposed regulation) with the probability of contamination during any one glove change of 0.2%. The estimated probability of contamination for glove changes of 0.2% is a conservative estimate based on a study in the peer-reviewed literature that found a contamination rate of 0.34% for glove changes in a pharmacy sterile compounding suite when sterile gloves were used. As demonstrated by equations below, the risk of microbial contamination during this fictitious employee's shift will markedly increase with more frequent glove changes: $p1=1-(0.998)^{10}=1.98\%$ $p2=1-(0.998)^{14}=2.76\%$ Commenter states that the Board has also materially failed to meet the basic minimum procedural requirements of the California Procedure Act (APA). First, while the law allows a regulator to “aggregate and summarize repetitive... comments as a group... and... respond to repetitive comments... as a group,” as described in <i>Sims v.</i>	worn when handling HDs to be contaminated with, at a minimum, trace quantities of HDs.” The use of a CSTD may reduce the risk of contamination but does not eliminate the risk. The Board appreciates the use of the technology as an important safety measure and notes the following from USP. As included in previous response to comments, USP Commentary provides, “CSTD provide adjunct control during compounding; however, additional controls are needed to prevent HD contamination, especially during the movement of ingredients and materials into and out of the C-PEC.” The Board's proposed regulations are addressing the potential for cross-contamination. As established in USP and in the conclusions of published research, Hazardous Drugs Contamination of Drug Preparation Devices and Staff: A Contamination Studies Simulating the use of Chemotherapy Drugs in a Clinical Setting³, “In 4 of the 5 CSTD systems, residue from HD-contaminated vials spread as the vial was handled in a pharmacy environment. HD contamination transferred initially to pharmacy PPE, then spread to ancillary products such as IV bags, IV sets, and transport bags, which, in turn contaminated nursing PPE...” As this study demonstrates, cross-contamination can occur even with the use of CSTDs. This study also supports the USP Commentary statements related to this area that were previously noted in Board responses. Photos included in Figure 1 clearly show the contamination of gloves.

³ Hazardous Drug Contamination of Drug Preparation Devices and Staff: A Contamination Study Simulating the Use of Chemotherapy Drugs in a Clinical Setting, Hosp Pharm, 2017 Aug, 20;52(8): 551-558, Accessed in NIH National Library of Medicine

		<i>Department of Corrections & Rehabilitation</i>, the regulator is still required to respond to each comment. In our comment letter dated December 6, 2024, we highlighted three areas of concern with the proposed regulation: (1) the lack of evidence to support the proposed regulation, (2) the significant cost that the proposed regulation will impose on California businesses, and (3) the likely negative environmental impacts of the proposed regulation. In the Board staff's response to public comments, Kaiser Permanente's comments were aggregated with several other commenters. The Board staff's response to the aggregated comments addressed the reasons why the Board does not believe that the use of a CSTD would obviate the need to the proposed requirement; however, there was no response to the three areas of concern outlined in Kaiser Permanente's December comment letter. Therefore, the Board likely failed in its obligation to respond to each public comment received. As outlined in <i>Western States Petroleum Association v. Board of Equalization</i>, under the APA, regulators are required to "provide in the [rulemaking] record facts, evidence, documents, testimony, or other evidence upon which the agency relies to support its initial determination [of economic impact]." Moreover, the regulator must demonstrate "that there was some factual basis for [its] determination," and this requirement is not met "by an opaque calculation unsupported by any facts or other evidence explaining its validity as a reasonable estimate." In our December 6, 2024 comment letter, we attempted to correct a significant error in the Board's estimate of the cost of a pair of sterile gloves used for HD compounding. In the Modified Initial Statement of Reasons, the Board states, "an online search reveals that the cost of a pair of gloves is about \$.14 [per] pair." In our comments, we indicated that one pair of sterile, ASTM D6978 gloves (the gloves required for sterile HD compounding) cost between \$1 and \$4 per pair. The Board's erroneous estimate of the cost of sterile HD gloves likely contributed to its finding in the Modified Initial Statement of Reasons that there will be "minimal ongoing costs" associated with the proposed regulations including	The Board noted that compounding personnel must demonstrate competency in aseptic techniques routinely. Further while the changing of gloves may potentially create an opportunity for microbial contamination, those risks can be mitigated. Mitigation strategies can be developed by facilities based on their likely risks. Further, the Board notes that the commenter is asserting that the Board has failed to meet the requirements of the APA. Board staff disagree with this comment and note that under the APA the Board is required to respond to all comments received. The Final Statement of Reasons is the document used to memorialize the Board's response to each of the comments received. All comments, however, have also been made available during board discussions of this issue. There is no requirement for the Board to cite empirical data as part of its rulemaking. Rather, the Board is required to cite empirical data when such data is relied upon. The Board includes reference to documents relied upon in its Initial and Modified Statement of Reasons and elsewhere in the rulemaking, which include for example the minutes from public discussions where cost issues could have been raised. Specifically related to the cost of gloves, staff note that costs may vary depending on the types of HD gloves, sterile versus nonsterile, and vendors used. The Chapter determines the types of gloves that must be used depending on the functions being performed and establish a number of requirements for changing gloves. Such costs are related to provisions of the Chapter, not the Board's regulations.

		"up to \$150,000 over a ten-year period for administrative and maintenance workload and Suppl[y] [costs]" and the overall determination "the proposed regulations will not have a significant statewide adverse economic impact...". Therefore, the Board likely failed in its obligation to make an initial economic impact determination that is "supported by facts or evidence".	Inspections performed by Board staff revealed a variation in how facilities operationalize requirements related to donning gloves when compounding hazardous preparations. Inspectors note that in many inspections compounding personnel are using two pairs of sterile gloves and changing the outer gloves in between hazardous preparations as a means to mitigate the potential for cross-contamination. These inspection findings demonstrate that this practice is already occurring in a variety of settings. It is important to note that the Board may establish requirements for a myriad of reasons related to consumer protection and based on a variety of information sources, including observations made during past investigations or inspections, best practices, based on information from experts and other regulatory agencies, including for example the FDA and USP. Although the Board did not receive any significant comments on costs throughout the development of the rulemaking that occurred over a series of public meetings, the Board independently identified and reported costs including for SOP development and review (using the estimated time and the BLS pharmacy salary from May 2022) incubator cleaning and calibration cost estimates, estimates for hazardous plastic containers, costs for disposable mats, etc. Costs could vary greatly as the practice of compounding varies greatly, for example, some facilities only engage in nonsterile compounding, where other facilities may engage in all types of compounding. Further, some facilities are

				already, as a standard of practice, changing gloves consistent with both the requirements of the Chapter as well as the Board's proposed regulations. The Board did not include estimated costs associated with compliance with other legal requirements (e.g. federal requirements, title 22, building code, etc.) nor did it include costs incurred to comply with provisions of USP (for examples costs to perform testing, training etc.) Costs that were identified by the Board were estimated for each license issued based on all factors. If an entity owns more than one license, their costs could increase based on the number of licenses held. Presumably the costs incurred could be spread over various licenses with policies and procedures for example being shared. Although cost related to gloves was not raised during the public meetings where text was developed, costs related to glove requirements were raised during the formal comment period where the Board received specific comments regarding the cost of gloves. The Board's second modified text in 1737.7(c) reflect the change that could reduce the overall cost related to gloves without compromising patient safety. The Board further noted that the Chapter establishes provisions for changing gloves and where the Chapter requires the use of and changing of gloves, such costs are a function of compliance with the Chapter, not the Board's regulation. Further, the Board noted that costs for compliance with the minimum standards of the regulation should not be conflated with costs incurred by a facility and how it chooses to operationalize the requirement. As an example, the costs for a

				facility that elects to compound a single type of HD such as methotrexate for multiple patients before changing to compound a different type of HD preparation would most likely have a lower cost than a facility that does not operationalize the requirements in the same manner. Further, the types of HD compounding performed (e.g. hazardous versus nonhazardous, sterile versus nonsterile) would also factor into costs. It is important to highlight that some of the changes in the proposed regulation text could also result in cost savings to facilities, such as provisions that allow for the transfer of some training from one location to another and increased provisions for immediate use.
13	1737.7(c)	CSHP	The board did not demonstrate that it understood and considered the comment in that it only responded to our comment regarding CSTD's, the board did not demonstrate that it understood and considered the comment the risk to staff created via repeated change of outer gloves. The board did not demonstrate that it understood and considered the comment regarding the increase in waste. The board did not demonstrate that it understood and considered the comment regarding the inappropriateness of the use of online prices for gloves. We would like to request that the board make public their source of information and the brand name, type and quality of the gloves they found online. The board did not demonstrate that it understood and considered the comment regarding contracting and the difference in pricing available to pharmacies. The board did not demonstrate that it understood and considered the comment regarding the need to purchase gloves at increased prices for staff that are allergic to cheap gloves. The board did not demonstrate that it understood and considered the comment regarding the fact that this economic impact was inadequately addressed in the economic impact section of the ISOR.	The Board reviewed the comment and did not make changes to the proposed text based on the comment. The Board noted that the commenter appears to be suggesting that interested parties did not have an opportunity to previously engage with the Board on the development of the regulations or provide information on potential cost impacts to the Board's regulations. The Board notes that the public record in this matter demonstrates that interested stakeholders were provided numerous opportunities to engage with the Board through the regulation development process and through the rulemaking process, which included numerous opportunities to provide both written and oral public comments on the draft proposals, including costs. As an example, during the April 2023 Enforcement and Compounding Committee, public comment suggested an increase in the cost of care stemming from the proposed requirement to use preparation mats

		Double-gloving is primarily designed to offer extra protection against hazardous drug compounds, with the outer glove serving as a first line of defense. If the outer glove is repeatedly removed or exposed to rough conditions, it may wear down, possibly increasing the risk of puncturing or compromising the inner glove. This could lead to reduced protection, especially when handling hazardous drug compound. Frequent removal and disposal of outer glove changes creates significant waste. Board staff's response that they performed an online search of the pricing and availability of appropriate gloves reflects a lack of understanding of the practice of pharmacy and the intricacies of purchasing contracts at large organizations. Pharmacies cannot simply go to an online vendor of these sterile gloves and buy it on a credit card. Purchasing is usually done on contracts with vetted suppliers to ensure supply chain integrity. Due to this, the pricing advertised online from unvetted suppliers, is generally unavailable to organizations. Furthermore, the cheapest online price may not reflect the product that is selected for use by the pharmacy since there are factors to be considered such as ease of use, quality of the product and in some cases, impact on staff that could experience allergic skin reactions to cheap products. The board response regarding the price of gloves highlights board staff's limited understanding of pharmacy business. The one-dimensional view of product price as an economic impact fails to consider indirect costs associated with this proposed regulation such as increased time it will take to compound hazardous drugs and the associated cost of labor. It further fails to consider the economic impact of slower compounding on reduced turnover in chairs at infusion centers. These are only to name a few economic impacts that the board fails to take into consideration and illustrates our point that the board lacks the internal expertise to accurately reflect those anticipated costs. Yet, board staff's comments regarding this section and others reflects a high level of misguided confidence in the ability	which at the time was proposed in CCR Section 1737.13. Based on the comments received, at that time, changes were made to the language to clarify the requirements and address in part the cost issue while balancing patient protection. During this same meeting, the Board's proposed regulations related to the changing of outer gloves was discussed. Record of this meeting reveal that no additional public comments were made related to costs. It is important to note that during the formal rulemaking process in response to comments received, the Board further modified requirements related to the use of preparation mats, making such use permissive. Again, in response to comments related to costs. In addition, the Board updated its proposed language related to minimum requirements for changing gloves, removing the requirement to change every 30 minutes. The Board further noted that the Board routinely encourages public participation in its meetings and include a policy that encourages written comments. The Board's proposed regulation establish minimum requirements for compounding. The Board does not mandate how these requirements will be operationalized. Workflows, compounding practices, staffing and other business decisions many times drive the costs for an organization.

			to determine impacts on the topic of economics at a level sufficient to make such determinations. We would like to invite the board to engage with CSHP and our health system leaders with the knowledge, experience, and expertise to gather the true economic impact of this proposal. Recommendations: We once more reiterate the comments by both us and others at various stages through this rulemaking process that USP has sufficient standards to promote and protect patients and this regulation fails to demonstrate its expected enhancement of patient safety efforts. Delete the proposed language: ~~(c) Outer gloves used for HD compounding shall be changed between each different HD preparation., unless preparing multiple HD preparations of the same drug or preparing multiple HD preparations for a single patient.~~	
14	1737.7(d)	Marie Cottman	This is a <u>non-functional</u> rule for facilities designed with a designated HD anteroom connected to a C-SEC HD Buffer Room. In practice, without pass-throughs (which are frowned upon), the compounder may need to return to the anteroom between compounds for additional supplies or to remove excess materials from the work area. An anteroom as defined by USP, is a transitional area for activities that generate particles (such as doffing) A) If the compounder must doff in the C-SEC, then the ungowned/dirty compounder will re-enter the "clean side" of the anteroom ungarded thus eliminating the possibility of a clean and dirty side to the HD ante room (which is still required in USP)! B) Doffing as required in this proposed rule will generate an unnecessary particulate load to the C-SEC increasing the risk of contamination as doffing is an activity that produces a lot of particulates! C) It is unreasonable to require doffing within the C-SEC when the facility has a dedicated HD anteroom.	The Board reviewed the comment and did not make changes to the proposed text based on the comment. The Board was not clear on the comments. The Board referred the commenter to the USP Chapter and the related USP FAQs. For example, FAQs 52 and 53 provide additional information related to this issue.

			D) If this remains in place, in an effort to avoid doffing and wasting gowns (in HD, gowns cannot be reused) compounders may take in too many materials at one time increasing an opportunity for errors. USP 800 states (emphasis added) "Although <u>not</u> a recommended facility design, <u>if</u> the negative-pressure HD buffer room is entered through the positive-pressure <u>non</u>-HD buffer room, the following is also required: • A line of demarcation must be defined within the negative-pressure buffer room for donning and doffing PPE" This is the ONLY situation to require doffing within the buffer room (aka C-SEC). USP 797 states "The area within 1 m of the PEC should be dedicated only for sterile compounding (e.g., not storage, hand hygiene, donning and doffing garb, or other highly particle-generating activities such as patient care)." I recommend that you remove section 1737.7(d) and allow USP 800 section 5.3.2 to stand as written.	
15	1737.8	Marie Cottman	The expanded statement about crushing or splitting tablets is not included, but seems appropriate for sections 1737.8	The Board reviewed the comment and did not make changes to the proposed text based on the comment. The Board noted that the regulation text establishes minimum standards and have determined that provisions for a hazardous drug communication plan does not need to extend to "crushing or splitting tablets.". Additionally, the Board reminded the commenter to review CalOSHA requirements.
16	1737.11(b)	Marie Cottman	This is limiting. Impervious plastic chemo bags have "CHEMOTHERAPY" printed on the bag. Would we be required by this proposed rule to ALSO add a label that says HAZARDOUS DRUGS?? Recommend to add "or Chemotherapy" to this wording. (b) All compounded antineoplastic HDs shall be transported from the facility in an impervious plastic container and labeled as Hazardous Drugs <u>or Chemotherapy</u> on the outside of the container.	The Board reviewed the comment and changed the proposed text to clarify that a second label is not required if the hazardous label is available through the outer container. Board staff offer the following recommendation. <u>1736.11 (b) All ~~HD APIs and compounded~~ antineoplastic HDs shall be transported from the facility in an impervious plastic container and labeled as Hazardous Drugs ~~HD~~ on the</u>

				outside of the container unless the label is visible through the outer container.
17	1737.12	Marie Cottman	But what if the equipment is being used for the same HD, different strength? For example, Progesterone capsules. First preparation is progesterone 5mg capsule, second preparation is progesterone 50mg capsule. Decontaminating the capsule plates is a process that involves wetting the plates. This will prevent further compounding using that equipment for no less than an hour. (capsules melt when exposed to liquids– the plates must be 100% dry!) Recommend wording change to allow for equipment to be used without full decontamination for the same HD. Equipment used in nonsterile HD compounding shall be dedicated for use with HDs and shall be decontaminated <u>after each use, prior to use with a different HD and at the end of the shift.</u> The expanded statement about crushing or splitting tablets is not included, but seems appropriate for sections 1737.12	The Board reviewed the comment and did not make changes to the proposed text based on the comment. The Board noted that comments provided in this area appear new. The Board's proposed text is based on the recommendation from the Chapter to perform decontamination after every use.
18	1737.13(a)	Marie Cottman	a) Changing the mat if a spill occurs is already required in section 13, USP 800. b) It is excessive and wasteful to change the mat when no spill or contamination is present. Sterile prep mats cost ~\$3.00 each. In addition to the expense, the change in process for all sterile compounders might result in a shortage of mats because the use will not double, but it might increase by 10 or 20 fold! c) If you have to spell out that the mat has to be removed at the end of the compounding activity, likely your compounders are not cleaning! (you cannot clean the PEC if there is a mat in it!) IF you cannot provide evidence of the NEED (not assumption) to change the mat for EVERY preparation, then Recommend to remove.	The Board reviewed the comment and did not make changes to the proposed text based on the comment. The Board noted that the Chapter provides permissive language related to the changing of mats. Further, the Board noted that nothing in the Board's regulation text requires the use of a mat; rather, it establishes the provisions where a facility determines that the use of disposable mats is appropriate.

19	1737.14(b)	Marie Cottman	This is poorly phrased. Gloves to not allow for appropriate administration or disposal of the HD. Gloves are merely used to handle the compound during administration or disposal. Recommend to reword: (b) When dispensing a compounded antineoplastic HD to a patient or patient's agent, the pharmacy shall provide, or offer for purchase, a sufficient supply of ASTM D-6978 standard chemotherapy gloves, to allow for appropriate administration, handling, and disposal of the HD during administration and disposal. A compounded antineoplastic HD preparation that is administered to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code is exempt from this requirement.	The Board reviewed the comment and made a change to provide clarity of the language. ~~(b) When furnishing dispensing on a compounded antineoplastic HD to a patient or patient's agent, the pharmacy shall provide, or offer for purchase, a sufficient supply of ASTM D-6978 standard chemotherapy gloves, that meet the ASTM D-6978 standard, and shall be provided to the patient or the patient's agent, to allow for appropriate administration, handling, and disposal of the HD, drugs by the patient or the patient's agent shall be provided. A compounded antineoplastic HD preparation that is administered to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code is exempt from this requirement.~~
20	1737.15	Marie Cottman	The expanded statement about crushing or splitting tablets is not included, but seems appropriate for sections 1737.15.	The Board reviewed the comment and did not make changes to the proposed text based on the comment. The Board noted that the Board's regulation text establishes minimum standards and that specific provisions for deactivating, decontaminating, cleaning, and disinfecting do not need to extend to "crushing or splitting tablets." The Board reminded the commenter to review CalOSHA requirements.
21	1737.15(a)	Kaiser Perm	Deactivating, decontaminating, cleaning, disinfecting, and sporicidal agents shall be used in accordance with manufacturers' specifications, or subsequent ~~manufacturer approved published~~ studies, and shall be surface compatible. We appreciate the modifications that the Board made to the proposed regulation based on the recommendation in our December 6, 2024 comment letter. However, we are concerned that the phrase "manufacturer approved studies" is likely to limit the usefulness of this flexibility. Manufacturers are only likely to approve/sanction a study if they perceive both potential scientific and financial	The Board reviewed the comment and did not make changes to the proposed text based on the comment. The Board noted that the commenter's change would not require nor establish any baseline for published studies that could be relied upon. For example, if the Board accepted the proposed regulation text, an entity could perform a study and publish in its own newsletter and such action would comply with the suggested text.

			benefits associated with the study. Conversely, if a manufacturer believes that a study is a threat to one or more of their products, they may be less likely to support a study. Contrast that with the motivations of academic institutions and healthcare organizations that do not have the same financial incentives as a manufacturer. Therefore, we recommend changing the phrase "manufacturer approved studies" to "published studies" to ensure that published studies that are unrelated to a manufacturer may be used to support the selection of an alternative agent for deactivating, decontaminating, cleaning, disinfecting, and or and/or killing bacterial and fungal spores in the compounding suite.	
22	1737.16	Marie Cottman	The expanded statement about crushing or splitting tablets is not included, but seems appropriate for sections 1737.16.	The Board reviewed the comment and did not make changes to the proposed text based on it. The Board noted that the regulation text establishes minimum standards and that specific provisions for spill control do not need to extend to "crushing or splitting tablets." The Board reminded the commenter to review CalOSHA requirements.
23	1737.17(a), (b), and (c)	Marie Cottman	This is overly repetitive and poorly worded. Recommend to consolidate and renumber. (a) A facility shall maintain and follow written SOPs <u>that include at least the following</u> for all situations in which HDs are compounded or crushing or splitting tablets or opening capsules of antineoplastic HDs is performed. ~~(b) A facility where compounding of HDs is performed or where crushing or splitting tablets or opening capsules of antineoplastic HDs is performed shall have SOPs that include at least the following:~~ (1) Hazard communication program (2) Occupational safety program (3) Designation of HD areas, if compounding (4) Receipt, if compounding (5) Storage, if compounding (6) Compounding, if applicable	The Board reviewed the comment and did not make changes to the proposed text based on the comment. The commenter appears to be recommending nonsubstantive changes to the proposed regulation text.

			(7) Use and maintenance of proper engineering controls (e.g., C-PECs, C-SECs, and CSTDs), if applicable (8) Hand hygiene and use of PPE based on activity (e.g., receipt, transport, compounding, manipulation, administration, spill, and disposal), as applicable (9) Deactivation, decontamination, cleaning, and disinfection (10) Dispensing, if applicable (11) Transport, if compounding (12) Administering, if applicable (13) Environmental monitoring (e.g., wipe sampling), if compounding (14) Disposal, if compounding (15) Spill control, if compounding (16) Medical surveillance, if compounding ~~(e)~~ (b) The pharmacist-in-charge, professional director of a clinic, or designated representative-in-charge, as applicable, shall work with the facility's designated person to ensure SOPs are reviewed at least every 12 months and this review is documented. Documentation of compliance with ~~the~~ <u>this</u> subdivision shall be maintained for three years.	

#	Section	Commenter	Comment	Board Response
1	1738 et seq	T. McConnell	The proposed designated person language should align with the <825> definition in that one or more individuals should be able to be this designated person simply because the responsibilities are such that a single person would not be able to take a vacation otherwise. Furthermore, the language should mirror the <795> and <797> text. This language would be the following: Designated person (s) means one or more individuals assigned by the pharmacist-in-charge to be responsible and accountable for the performance and operation of the facility and the personnel as related to the preparation of radiopharmaceuticals. Nothing in this definition allows for a designated person to exceed the scope of their issued license. When the designated person is not a pharmacist, the Pharmacist-in-Charge (PIC) must review all practices related to the operations of the facility that require the professional judgment of a pharmacist. Nothing in this definition prohibits the PIC from also serving as the designated person.	The Board reviewed the comment and note that as part of the proposed changes to the second modified text, the Board included text to clarify that nothing in the definition prohibits the PIC from also serving as the designated person. The Board determined that such a change may also be appropriate in this article. <u>1738 (c) "Designated person" means a pharmacist identified as assigned, responsible, and accountable for the performance and operation of the radiopharmaceutical processing facility and for personnel who prepare, compound, dispense, and repack radiopharmaceuticals. Nothing in this definition prohibits the PIC from also serving as the designated person.</u>
2	1738.1	CA Rheumatology Alliance And CA Society of Plastic Surgery	We have reviewed the staff responses to our comments and continue to be concerned with the applicability of the proposed regulations on physicians and their ability to "compound" medications in their offices. Although physicians may not be under the enforcement jurisdiction of the Board of Pharmacy, we believe the proposed regulations would change the standard of care for when physicians compound medications and will not allow rheumatologists/physicians to buffer injection/ infusion medications in-office. We are interpreting the proposed regulations to require a pharmacist be present or performing the buffering of the injection/ infusion medications. Rheumatology practices/physicians would not be able to afford to employ a pharmacist for this one purpose. This would lead to rheumatology practices no longer offering this service for our patients. Patients would then be forced to obtain their injection/infusions at a hospital or infusion center which would not only be less	The Board reviewed the comment and did not change the proposed text based on it. The Board has previously considered this comment, most recently during the January 8, 2025, Board Meeting, and determined that the requested change is not appropriate. As was previously shared, the Board only has jurisdiction over individuals and businesses within its practice act. The Board read the comment as suggesting that the Board's proposed regulations would apply to a physician. Business and Professions Code section 4170(c) makes clear that the Medical Board of California is specifically charged with the enforcement of Pharmacy Law (Chapter 9, Division 2 of the Business and Profession Code) with respect to its licensees.

		convenient for our patients, but it would be more expensive for the patient and the overall healthcare system. We believe it is important to note we are not aware of any issues with rheumatologists/physicians "compounding" injection/ infusion medications. We would like to propose the Board of Pharmacy adopt the language suggested by the California Medical Association as shown below: § 1738.1: In addition to the standards in the USP Chapter 825, the processing of Radiopharmaceuticals shall meet the requirements of this section. <u>This article shall not apply to compounding by or under the direct supervision of a licensed physician and surgeon.</u>	It may be appropriate for the commenter to confer with their licensing board to discuss their concerns. The Board noted that the Medical Board of California has previously provided a written response to individuals inquiring about the applicability of the Board of Pharmacy's regulations to individuals and practices that operate under the jurisdiction of the Medical Board of California. Below is the information provided from the Medical Board - - <i>Dear Ms. Sodergren:</i> <i>I understand that some concerns have been raised by stakeholders about the applicability of the Board of Pharmacy's pending compounding regulations to licensees of the Medical Board of California (MBC). Existing statute (see Business and Professions Code (BPC) section 2220.5) makes it clear that only the MBC can discipline its physician licensees.</i> <i>Whenever a physician is engaging in compounding (or any other action that their medical license authorizes them to perform) they must always do so consistent with the standard of care. For the purposes of MBC's enforcement program, the standard of care is established by expert testimony in the context of the facts and circumstances of a specific case.</i> <i>It is certainly possible that whatever regulations that are implemented by the Board of Pharmacy may influence the standard of care for physicians who are compounding, especially since some of the proposed regulations reflect what is already required for physician compounding under federal law, including, but not limited to, Section 503A of the Federal Food, Drug, and Cosmetic Act (BPC section 2225(b) allows MBC to investigate violations of federal law related to the practice of medicine).</i>

				Feel free to share this message with others as you see fit who might also be concerned about the applicability of their pending regulations to the physician community. Please contact me if you have any further questions. Sincerely, Reji Varghese Reji Varghese is the Executive Director for the Medical Board of California. The Medical Board is charged with evaluating compounding practices and the standard of care relevant to its licensees.
3	1738.5	T. McConnell	With regards to 1738.5 Facilities and Engineering Controls (d), the intention of the hot cell can be the total of the SRPA because it provides a full physical barrier on the outside. This would eliminate the need for (1) under this section that reads: Except for walls, the SRPA's visible perimeter shall be at least 1 meter from all sides of the PEC or in a separate room.	The Board reviewed the comment and did not change the proposed text based on it. The Board noted that not every facility engaged in radiopharmaceuticals uses a hot cell.
4	1738.10(c)	CSHP	The proposed language is inconsistent with USP 825 recommendations, and will require health-systems to incorporate patient need which may not be pertinent information. Recommendation(BOLD): We once more reiterate the comments by both us and others at various stages through this rulemaking process that USP has sufficient standards to promote and protect patients. This proposed regulation fails to demonstrate the necessity for patient safety beyond that required by USPR. We recommend that this subsection be deleted. ~~(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~~	The Board reviewed the comment and did not change the proposed text based on it. The Board noted that this subdivision was discussed at the January 8, 2025, Board meeting. At that time, the Board approved changes for the second modified text to provide additional clarification of the requirement, which specifically requires that an SOP be developed. The Board noted that minor deviations are not always patient specific. There is nothing in the second modified regulation text requiring health-systems to incorporate patient need, unless the facility's SOPs establish such a requirement. The Chapter defines "preparation with minor deviations" as, "The act of preparing a conventionally manufactured kit with a conventionally manufactured radionuclide with

			~~or facts that support the deviation that maintains the appropriate quality and purity (radiochemical purity and radionuclides purity) as specified in individual monographs, and other applicable parameters as clinically appropriate in the professional judgment of the pharmacist.~~	volume, and/or radioactivity, and/or step-by-step deviations from the manufacturers recommended labeling while ensuring that the final preparation maintains appropriate radiochemical and radionuclidic purity for the entirety of the BUD. Examples of minor deviations include, but are not limited to, altering the amount of activity or volume added to the vial, changes in step-by-step operations (e.g., dilute Tc-99m solution after, rather than before, addition to the vial, use of a venting needle or filter), using alternative devices or equipment (e.g., a heating block rather than a hot water bath), and using alternative radiochemical purity testing methods." Upon review of the second modified text, however, the need for nonsubstantive changes to the language were identified, which is reflected in the recommended third modified text.
5	1738.11(b)	PCCA	<u>Recommend:</u> Remove the language: "When the COA is received from a supplier, it must provide the name and address of the manufacturer." <u>Rationale:</u> See comment in response to Sections 1735.7(c)(1) and 1736.9(d).	The Board reviewed the comment and did not change the proposed text based on it. The Board previously considered these comments on several occasions including as part of its discussion during the November 5-6, 2024, Board Meeting. As was noted at that time, the Board reviewed the comment and did not recommend any changes to the proposed text based on the comments. The Board noted that while existing law provides flexibility to record the manufacturer under limited circumstances, continuation of the current provision is not appropriate as it hampers the ability of a facility to respond appropriately in the event of a product recall. Further the Board's proposed regulation text is more explicit than the Chapter for the reasons cited elsewhere in this response.

				The Board notes that the Chapter requires either the recording of the manufacturers or vendors; however, in separate guidance issued by the FDA, the facility needs to have transparency into the supply chain and awareness of the manufacturer (where the manufacturer and vendor are different.) The FDA has released guidance in this area, including the importance of compounders knowing their suppliers - - https://www.fda.gov/drugs/human-drug-compounding/fda-compounders-know-your-bulks-and-excipientssuppliers. Lastly, requiring providing the identity of the manufacturer of a component to a compounder who is compounding with that component without requiring more information be provided does not appear to be requiring the disclosure of a trade secret under Civil Code section 3426.1(d). Moreover, vendors can take steps when contracting with compounders to protect the information related to their business arrangements with manufacturers. The Board referred the commenter to the underlying data portion of the Modified Initial Statement of Reasons, which includes the above referenced FDA guidance document.
6	1738.14(c)	CSHP	The board did not demonstrate that it understood and considered the comment in that it only responded to the part where 3 business days was recommended. There was no acknowledgement of understanding of our concern that the language seems to suggest that the review must be completed within a 72 hours timeframe. We pointed out that a review can start within 72 hours but it can take longer to complete once further investigation is needed. We would like to recommend again that the word "shall start" be added to the language.	The Board reviewed the comment and determined that the regulation text is clear, in that the proposed regulation text does not expressly require that the investigation into the complaint must be completed within 72 hours; rather the regulation text states that the complaint shall be reviewed within 72 hours of receipt.

		The way that the proposed regulation is written, seems to suggest that the review must be completed within 72 hours since it states that “such review shall be documented and dated as defined in the SOPs.” The proposed language requirement for a documentation and dating of the review together with the preceding sentence’s requirement for review within 72 hours from the receipt of the complaint could be seen as requiring the review to be completed within the 72 hours timeframe. A requirement of 72 hours may not provide sufficient time for pharmacies to thoroughly investigate and determine root causes. It is reasonable to expect that a review after a complaint be <u>started</u> within three business days. Investigation could take longer than this due to many factors involved in such an investigation that needs to be looked at. Many of these may not be available or apparent within this timeframe. Recommendation (BOLD): We recommend that the intent of this proposed regulation be clarified with the following proposed language: (c) In addition to subsection (b), all complaints made to the facility related to a potential quality problem with a CSP and all adverse drug experiences events shall be reviewed by the pharmacist-in-charge and shall start within 72 hours of receipt of the complaint or occurrence of the adverse drug experience. Such review shall be documented and dated as defined in the SOPs.	To best address the issue raised by the commenter, however, the Board made the following change: 1738.14 (c) In addition to subsection (b), <u>the pharmacist-in-charge shall initiate a review of any all complaints made to the facility related to a potential quality problem with a radiopharmaceutical and any all reported adverse drug experiences as defined in 21 CFR 310.305(b) events shall be reviewed by the pharmacist-in-charge</u> within 72 hours of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs. <u>In the event the PIC is not available within 72 hours, the PIC will define in the SOPs the pharmacist who will be required to review.</u>

#	Section	Commenter	Comment	Board Response
1	General	Novo Nordisk	Novo Nordisk is a healthcare company with a 100-year history of innovation in developing medicines to treat serious chronic diseases, like diabetes and obesity. NNI appreciates the Board's efforts to align its regulations with USP standards and to build upon those standards to further enhance the health and welfare of Californian patients who are given compounded drug products. The risks posed by compounded drugs are growing as compounders have expanded their reach by entering into new and unanticipated commercial agreements to engage in aggressive nationwide distribution, including the mass distribution of unapproved and clinically untested compounded "semaglutide." While there are no verified estimates of how many patients are using compounded "semaglutide," some "industry officials" have recently estimated that the number of patients on compounded "semaglutide" could be in the millions. These compounders are compounding "semaglutide" without adhering to all the legal guardrails intended to ensure that compounding occurs only in appropriate circumstances and are engaging in these operations without the supply chain integrity and pharmacovigilance protections provided by sponsors of FDA-approved medications. We thus urge the Board to continue to bolster patient-centered policies at the state-level to protect patients from the risk of harm from compounded products. See Dani Blum, <i>More People Are Overdosing on Ozempic Alternatives</i>, NY TIMES (Aug. 6, 2024), https://www.nytimes.com/2024/08/06/well/ozempic-semaglutide-overdose-risks.html; see also Arthur Allen, <i>Why Millions Are Trying FDA-Authorized Alternatives to Big Pharma's Weight Loss Drugs</i>, KFF HEALTH NEWS (July 23, 2024), https://kffhealthnews.org/news/article/glp1-	Board staff thank the commenter for their comments, recognition of the Board's consumer protection mandate and acknowledges the patient safety concerns highlighted by the commenter. Board staff do not recommend any changes to the proposed text based on these comments.

			compounding-pharmacies-wegovy-zepbound-copycat-drugs-shortages/ .	
2	General	Kaiser Permanente	The commenter indicates that the Board has failed to provide empirical evidence to support the need for additional regulations that exceed USP compounding chapters. The commenter indicates that the Board has not considered the behaviors that its proposed regulations will incentivize and the second order effects that those practices will likely precipitate. Commenter believes that the problematic second order effects that these regulations will cause coupled with the lack of evidence to support the proposed regulations will have a net negative effect of California patients and California pharmacies. The commenter supports the following alternative: 1. The Board should repeal sections 1708.3, 1708.4, and 1708.5, 1735 et seq, 1751 et seq. 2. The Board should reject the proposed regulatory action. 3. The Board should enforce the provisions of the USP compounding chapters as required by California Business and Professions Code section 4126.8. If the Board elects to finalize the proposed regulations, the commenter encourages the Board to establish a rational effective date for these regulations that will provide the regulated public with ample time to come into compliance with these new requirements. The Board rejected our proposal because the USP compounding standards have been in effect since November 1, 2023, and because some of the provisions in the proposed regulations are in the Board's current compounding regulations. Both of those observations, which we do not dispute, are immaterial to the work that organizations will need to do to come into full compliance with the proposed regulations.	Board staff have reviewed the comments and do not recommend changes to the proposed text based on the comments received. Staff note that the Board have previously considered the comments, most recently during its January 8, 2025. The Board does not believe a delay in effective date is appropriate except were identified in the proposed regulation text. It has been common practice for the Board to focus on education of new requirements to facilitate compliance when immediate public harm is not at stake and where the licensee is making a good faith effort to come into compliance with new requirements.

			Commenter states as written, Kaiser Permanente will need to make extensive updates to our policies and standard operating procedures, update our pharmacy information systems, and remodel some of our compounding facilities. These tasks are time-consuming, costly, or both. Commenter suggests at least one year from the date that the regulation is filed with the Secretary of State would be a reasonable effective date.	
3	General	CA Health Coalition Advocacy	CHCA opposes the regulations and expressed concern that the regulations supersede the FDA and exceed US Pharmacopeia standards and would restrict access to treatments that Californians find essential to their health. The commenter states that the proposed regulations would make Category 1 bulk substances, inaccessible through 503a pharmacies and therefore no longer available to patients in California. Finally, the commenter states that adoption of the regulations would cause harm to vulnerable patients, limit healthcare provider autonomy, and increase healthcare inequalities. The commenter indicates that Doctors should be able to prescribe treatments for their patients based on their expertise, research, and experience without interference from the Board of Pharmacy.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on the comments received. Board staff believe that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to bulk drug substances. Board staff believe the approach currently being proposed strikes an appropriate and necessary balance that both creates a pathway for pharmacies to legally compound using Category 1 bulk drug substances while ensuring that appropriate and feasible patient protection measures are in place. Provided below is the relevant language from both federal law and the USP with respect to bulk substances. The Board's proposed regulations provide a legal pathway to compound using bulk drug substances. As the Board has noted previously, until the FDA formally makes a determination regarding bulk drugs substances nominated for inclusion in 21 CFR 216.23, the Board has determined that there is a need at the state level to provide a pathway to allow for such compounding. ``SEC. 503A. PHARMACY COMPOUNDING</b></p> <p>``(a) In General.--Sections 501 (a)(2)(B), 502(f)(1), and 505 shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding--

				“(1) is by-- “(A) a licensed pharmacist in a State licensed pharmacy or a Federal facility, or “(B) a licensed physician, on the prescription order for such individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or “(2)(A) is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and “(B) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between-- “(i) the licensed pharmacist or licensed physician; and “(ii)(I) such individual patient for whom the prescription order will be provided; or “(II) the physician or other licensed practitioner who will write such prescription order. “(b) Compounded Drug.-- “(1) Licensed pharmacist and licensed physician.--A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician-- “(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations-- “(i) that--

				“(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding; “(II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or “(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (d); “(ii) that are manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); and “(iii) that are accompanied by valid certificates of analysis for each bulk drug substance; “(B) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding; “(C) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective; and “(D) does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product. “(2) Definition.--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. “(3) Drug product.--A drug product may be compounded under subsection (a) only if-- “(A) such drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and “(B) such drug product is compounded in a State-- “(i) that has entered into a memorandum of understanding with the Secretary which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State; or “(ii) that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician. [Page 111 STAT. 2330] The Secretary shall, in consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by the States in complying with subparagraph (B)(i). “(c) Advertising and Promotion.--A drug may be compounded under subsection (a) only if the pharmacy, licensed pharmacist, or licensed physician does not advertise or promote the compounding of any particular drug, class of drug, or type of drug. The pharmacy, licensed pharmacist, or licensed physician

				may advertise and promote the compounding service provided by the licensed pharmacist or licensed physician. “(d) Regulations.-- “(1) In general.--The Secretary shall issue regulations to implement this section. Before issuing regulations to implement subsections (b)(1)(A)(i)(III), (b)(1)(C), or (b)(3)(A), the Secretary shall convene and consult an advisory committee on compounding unless the Secretary determines that the issuance of such regulations before consultation is necessary to protect the public health. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopoeia, pharmacy, physician, and consumer organizations, and other experts selected by the Secretary. “(2) Limiting compounding.--The Secretary, in consultation with the United States Pharmacopoeia Convention, Incorporated, shall promulgate regulations identifying drug substances that may be used in compounding under subsection (b)(1)(A)(i)(III) for which a monograph does not exist or which are not components of drug products approved by the Secretary. The Secretary shall include in the regulation the criteria for such substances, which shall include historical use, reports in peer reviewed medical literature, or other criteria the Secretary may identify. “(e) Application.--This section shall not apply to-- “(1) compounded positron emission tomography drugs as defined in section 201(ii); or “(2) radiopharmaceuticals. “(f) Definition.--As used in this section, the term ‘compounding’ does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.”. From USP: “When CSPs are used as components, see 16. Use of CSPs as Components. All APIs and other components used must be evaluated for suitability for use in sterile drug preparation.

				Components labeled with “not for pharmaceutical use”, “not for injectable use”, “not for human use” or an equivalent statement must not be used to compound for these purposes. Further, from the FDA Guidance Document, Insanitary Conditions are Compounding Facilities (dated November 2020) which provides examples of insanitary conditions including “ Using active ingredients, inactive ingredients, or processing aides, that have or may have higher levels of impurities compared to compendial or pharmaceutical grade equivalents (e.g., ingredients with potentially harmful impurities, ingredients labeled with “not for pharmaceutical use” or an equivalent statement) The Board's underlying data included in the Modified Initial Statement of Reasons contains additional information specifically related to this issue including as an example item 21, “FDA highlights concerns with using dietary ingredient glutathione to compound sterile injectables.” Further, it appears that the commenter is suggesting that a pharmacist does not have an obligation to exercise clinical judgment when compounding or dispensing a medication. The Board believes it is important to underscore that pharmacists must exercise clinical judgment in all aspects of practice and not simple defer their judgment to another individual. This is obligation is memorialized throughout Pharmacy Law, including notably BPC Section 4306.5, Business and Professions Code Section 733, Health and Safety Code Section 11153 and California Code of Regulations Section 1707.3.
4	General	Alliance for PHY Compounding	We continue to have serious concerns regarding the pathway outlined in the proposed regulations for compounding with active pharmaceutical ingredients (APIs) included in FDA's Interim Category 1. While the pathway appears to establish a mechanism for compounding, the associated testing and documentation requirements you propose create significant barriers that make compounding for all necessary dosage forms and	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on the comments received. Board staff believe that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to bulk drug substances. Staff note a recommendation was previously accepted to clarify the testing requirements in this section and the ability of the pharmacy to rely on testing performed by a manufacturer, repackager, or wholesaler.

		strengths impractical under the revised proposed regulations. 1. Stability Studies: - o USP Standards: USP does not require full stability studies for sterile compounding under Category 1 or 2. Instead, USP aligns required tests with the beyond-use date (BUD) assigned to the compound. Full stability-indicating studies are only required for Category 3, which pertains to larger-scale compounding (typically batches of 250 units). - o California's Proposed Rules: The requirement for full stability studies in all cases goes far beyond USP and FDA standards. Stability studies are expensive, costing \$10,000–\$30,000 or more per formulation. - o Impact on Pharmacies and Patients: This requirement would force pharmacies to limit the formulations they produce, focusing only on the most common ones that justify the cost of stability studies. For example, a pharmacy might conduct a study for glutathione 200 mg/mL multi-dose vials, which serve the largest number of patients (IV, IM, and inhalation use, even though preservatives should not be inhaled). However, more specialized formulations, such as an NAC/glutathione inhalation combination or preservative-free individual inhalation vials, would become financially unviable. 2. API Testing Requirements: - o California proposes additional testing requirements for APIs that exceed what is required by USP or FDA. - o These tests could be performed by the manufacturer, repackager, or wholesaler, but initial reviews suggest that these tests are not typically listed on Certificates of Analysis	Board staff believe the approach currently being proposed strikes an appropriate and necessary balance that both creates a pathway for pharmacies to legally compound using Category 1 bulk drug substances while ensuring that appropriate and feasible patient protection measures are in place. Board staff note that under the provisions of the Chapter and the Board's proposed regulation text, a pharmacy can use the stability studies performed by another entity, including stability studies performed by professional organizations and associations. There is nothing in the regulation text requiring pharmacies to repeat these studies. Specifically related to the API comments, staff would recommend that a facility seeking to rely upon the tests performed either in full or in part to meet the requirements in 1736.17 should work with their supplier to provide the necessary information. Staff note that the proposed regulation text in this section does not require the testing results to be included on the COA, rather it needs to be available. As the Board has previously noted and the commenter suggests, USP provides, "Although it is possible for FDA or another government authority in the U.S. or elsewhere to require the use of a USP General Chapter numbered 1000 to 1999, the authority in question would need to make this requirement expressly applicable under law, regulation, or another appropriate vehicle that prescribes enforceable requirements." The Board's proposed regulation text is consistent with this approach and the Board, in some instances, is explicitly adopting a Chapter.

			(COAs). This means pharmacies would likely need to perform the tests themselves, incurring additional costs and delays. USP Chapters Above 1000 USP chapters numbered above 1000, such as Chapter 1097 (which is referenced by the testing required for API in FDA's interim category 1), are intended for informational purposes and are not enforceable unless explicitly adopted. To illustrate the financial burden, a stability study quote of \$40,000 for a commonly requested NAC/glutathione combination, used for its antioxidant effects to protect lung tissue from damage caused by free radicals and oxidative stress.	
5	General	Wedgewood	We also continue to advocate that the compounding standards should default to the clinical standards set by the United States Pharmacopeia in USP 795, 797, and 800 which have been adopted by most states with no additional requirements. We do not believe that reasonable clinical, or policy-based, justifications for exceeding these standards has been presented, which puts California residents' (both human and animal) access to safe and effective compounded medications prescribed by California-licensed providers at risk.	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Board staff respectfully recommend that the commenter review the rulemaking package in its entirety along with underlying data and referenced materials to gain a full understanding of the necessity for these proposed regulations.
6	General	CMA	CMA is disappointed by the Board's refusal to revise its proposed language to clarify that the regulations do not apply to physicians. In its response to public comment requesting clarification on whether the regulations apply to physicians and other licensed practitioners, the Board effectively stated the regulations do not apply to licensees of other healing arts boards, noting: "[...] [the] Board's regulations apply to licensees within the Board's jurisdiction. The Board's jurisdiction is limited to those businesses and individuals within its practice act." The language of the proposed regulations, however, is written in a manner that could be	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. The Board has considered this issue on several occasions most recently during its January 8, 2025, Board meeting. After consideration, the Board determined that the Board's regulations to not need to specify that the regulations do not apply to physicians and surgeons. As was previously shared, staff note the Board only has jurisdiction over individuals and businesses within its practice act. Board staff read the comment as suggesting that the Board's proposed regulations would apply to a physician. Business and Professions Code section 4170(c) makes clear that the Medical Board of California is specifically charged with the enforcement of

		construed to apply to compounding in any setting and by any individual, because their scope is not expressly limited to pharmacists and pharmacies, unlike the current regulation.	Pharmacy Law (Chapter 9, Division 2 of the Business and Profession Code) with respect to its licensees. It may be appropriate for the commenter to confer with their licensing board to discuss their concerns. Board staff note that the Medical Board of California has previously provided a written response to individuals inquiring about the applicability of the Board of Pharmacy's regulations to individuals and practices that operate under the jurisdiction of the Medical Board of California. Below is the information provided from the Medical Board - - Dear Ms. Sodergren: I understand that some concerns have been raised by stakeholders about the applicability of the Board of Pharmacy's pending compounding regulations to licensees of the Medical Board of California (MBC). Existing statute (see Business and Professions Code (BPC) section 2220.5) makes it clear that only the MBC can discipline its physician licensees. Whenever a physician is engaging in compounding (or any other action that their medical license authorizes them to perform) they must always do so consistent with the standard of care. For the purposes of MBC's enforcement program, the standard of care is established by expert testimony in the context of the facts and circumstances of a specific case. It is certainly possible that whatever regulations that are implemented by the Board of Pharmacy may influence the standard of care for physicians who are compounding, especially since some of the proposed regulations reflect what is already required for physician compounding under federal law, including, but not limited to, Section 503A of the Federal Food, Drug, and Cosmetic Act (BPC section 2225(b) allows MBC to investigate violations of federal law related to the practice of medicine). Feel free to share this message with others as you see fit who might also be concerned about the applicability of their pending regulations to the physician community. Please contact me if you have any further questions. Sincerely, Reji Varghese

				Reji Varghese is the Executive Director for the Medical Board of California. The Medical Board is charged with evaluating compounding practices and the standard of care relevant to its licensees.
7	General	T. Tizon-Damiano, S. Guevara, P. Mirdamadi, M. O'Neil, M. Domyancic, K. Oleinik, E. Peterson, D. Valdez, C. Cohen	Commenters oppose the proposed regulations because they limit access to Category 1 sterile compounds.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on the comments received. Board staff believe that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to bulk drug substances. Board staff believe the approach in the second modified text strikes an appropriate and necessary balance that both creates a pathway for pharmacies to legally compound using Category 1 bulk drug substances while ensuring that appropriate and feasible patient protection measures are in place. Provided below is the relevant provisions from both federal law and the USP with respect to compounding with bulk substances. The Board's proposed regulations provide a legal pathway to compound using bulk drug substances. As the Board has noted previously, until the FDA formally makes a determination regarding bulk drugs substances nominated for inclusion in 21 CFR 216.23, the Board has determined that there is a need at the state level to provide a pathway to allow for such compounding. ``SEC. 503A. PHARMACY COMPOUNDING</b></p> <p>``(a) In General.--Sections 501(a)(2)(B), 502(f)(1), and 505 shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding-- ``(1) is by--</p> <p>``(A) a licensed pharmacist in a State licensed pharmacy or a Federal facility, or

				“(B) a licensed physician, on the prescription order for such individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or “(2)(A) is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and “(B) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between-- “(i) the licensed pharmacist or licensed physician; and “(ii)(I) such individual patient for whom the prescription order will be provided; or “(II) the physician or other licensed practitioner who will write such prescription order. “(b) Compounded Drug.-- “(1) Licensed pharmacist and licensed physician.--A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician-- “(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations-- “(i) that-- “(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

				“(II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or “(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (d); “(ii) that are manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); and “(iii) that are accompanied by valid certificates of analysis for each bulk drug substance; “(B) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding; “(C) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective; and “(D) does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product. “(2) Definition.--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.

				“(3) Drug product.--A drug product may be compounded under subsection (a) only if-- “(A) such drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and “(B) such drug product is compounded in a State-- “(i) that has entered into a memorandum of understanding with the Secretary which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State; or “(ii) that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician. [Page 111 STAT. 2330] The Secretary shall, in consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by the States in complying with subparagraph (B)(i). “(c) Advertising and Promotion.--A drug may be compounded under subsection (a) only if the pharmacy, licensed pharmacist, or licensed physician does not advertise or promote the compounding of any particular drug, class of drug, or type of drug. The pharmacy, licensed pharmacist, or licensed physician may advertise and promote the compounding service provided by the licensed pharmacist or licensed physician. “(d) Regulations.--

				“(1) In general.--The Secretary shall issue regulations to implement this section. Before issuing regulations to implement subsections (b)(1)(A)(i)(III), (b)(1)(C), or (b)(3)(A), the Secretary shall convene and consult an advisory committee on compounding unless the Secretary determines that the issuance of such regulations before consultation is necessary to protect the public health. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopoeia, pharmacy, physician, and consumer organizations, and other experts selected by the Secretary. “(2) Limiting compounding.--The Secretary, in consultation with the United States Pharmacopoeia Convention, Incorporated, shall promulgate regulations identifying drug substances that may be used in compounding under subsection (b)(1)(A)(i)(III) for which a monograph does not exist or which are not components of drug products approved by the Secretary. The Secretary shall include in the regulation the criteria for such substances, which shall include historical use, reports in peer reviewed medical literature, or other criteria the Secretary may identify. “(e) Application.--This section shall not apply to-- “(1) compounded positron emission tomography drugs as defined in section 201(ii); or “(2) radiopharmaceuticals. “(f) Definition.--As used in this section, the term ‘compounding’ does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.”. From USP: “When CSPs are used as components, see 16. Use of CSPs as Components. All APIs and other components used must be evaluated for suitability for use in sterile drug preparation. Components labeled with “not for pharmaceutical use”, “not for injectable use”, “not for human use” or an equivalent statement must not be used to compound for these purposes.

				Further, from the FDA Guidance Document, Insanitary Conditions are Compounding Facilities (dated November 2020) which provides examples of insanitary conditions including " Using active ingredients, inactive ingredients, or processing aides, that have or may have higher levels of impurities compared to compendial or pharmaceutical grade equivalents (e.g., ingredients with potentially harmful impurities, ingredients labeled with "not for pharmaceutical use" or an equivalent statement) The Board's underlying data included in the Modified Initial Statement of Reasons contains additional information specifically related to this issue including as an example item 21, "FDA highlights concerns with using dietary ingredient glutathione to compound sterile injectables."
8	General	M. Lindemann	The commenter opposes the proposed regulations for the following reasons: 1.Remove access to critical treatments. 2.Increase the financial burden on patients to access treatment. 3.Endanger patients by requiring patients to obtain the medication from underground sources.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on the comments received. Board staff believe that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to bulk drug substances. Board staff believe the approach in the second modified text strikes an appropriate and necessary balance that both creates a pathway for pharmacies to legally compound using Category 1 bulk drug substances while ensuring that appropriate and feasible patient protection measures are in place. Provided below is the relevant provisions from both federal law and the USP with respect to compounding with bulk substances. The Board proposed regulations provide a legal pathway to compound using bulk drug substances. As the Board has noted previously, until the FDA formally makes a determination regarding bulk drugs substances nominated for inclusion in 21 CFR 216.23, the Board has determined that there is a need at the state level to provide a pathway to allow for such compounding. ``SEC. 503A. PHARMACY COMPOUNDING

				“(a) In General.--Sections 501(a)(2)(B), 502(f)(1), and 505 shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding-- “(1) is by-- “(A) a licensed pharmacist in a State licensed pharmacy or a Federal facility, or “(B) a licensed physician, on the prescription order for such individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or “(2)(A) is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and “(B) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between-- “(i) the licensed pharmacist or licensed physician; and “(ii)(I) such individual patient for whom the prescription order will be provided; or “(II) the physician or other licensed practitioner who will write such prescription order. “(b) Compounded Drug.-- “(1) Licensed pharmacist and licensed physician.--A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician--

				“(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations-- “(i) that-- “(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding; “(II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or “(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (d); “(ii) that are manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); and “(iii) that are accompanied by valid certificates of analysis for each bulk drug substance; “(B) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding; “(C) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective; and

				“(D) does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product. “(2) Definition.--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. “(3) Drug product.--A drug product may be compounded under subsection (a) only if-- “(A) such drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and “(B) such drug product is compounded in a State-- “(i) that has entered into a memorandum of understanding with the Secretary which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State; or “(ii) that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician. [Page 111 STAT. 2330] The Secretary shall, in consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of

				understanding for use by the States in complying with subparagraph (B)(i). “(c) Advertising and Promotion.--A drug may be compounded under subsection (a) only if the pharmacy, licensed pharmacist, or licensed physician does not advertise or promote the compounding of any particular drug, class of drug, or type of drug. The pharmacy, licensed pharmacist, or licensed physician may advertise and promote the compounding service provided by the licensed pharmacist or licensed physician. “(d) Regulations.-- “(1) In general.--The Secretary shall issue regulations to implement this section. Before issuing regulations to implement subsections (b)(1)(A)(i)(III), (b)(1)(C), or (b)(3)(A), the Secretary shall convene and consult an advisory committee on compounding unless the Secretary determines that the issuance of such regulations before consultation is necessary to protect the public health. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopoeia, pharmacy, physician, and consumer organizations, and other experts selected by the Secretary. “(2) Limiting compounding.--The Secretary, in consultation with the United States Pharmacopoeia Convention, Incorporated, shall promulgate regulations identifying drug substances that may be used in compounding under subsection (b)(1)(A)(i)(III) for which a monograph does not exist or which are not components of drug products approved by the Secretary. The Secretary shall include in the regulation the criteria for such substances, which shall include historical use, reports in peer reviewed medical literature, or other criteria the Secretary may identify. “(e) Application.--This section shall not apply to-- “(1) compounded positron emission tomography drugs as defined in section 201(ii); or “(2) radiopharmaceuticals. “(f) Definition.--As used in this section, the term ‘compounding’ does not include mixing, reconstituting, or other such acts that are

				performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling." From USP: "When CSPs are used as components, see 16. Use of CSPs as Components. All APIs and other components used must be evaluated for suitability for use in sterile drug preparation. Components labeled with "not for pharmaceutical use", "not for injectable use", "not for human use" or an equivalent statement must not be used to compound for these purposes. Further, from the FDA Guidance Document, Insanitary Conditions are Compounding Facilities (dated November 2020) which provides examples of insanitary conditions including " Using active ingredients, inactive ingredients, or processing aides, that have or may have higher levels of impurities compared to compendial or pharmaceutical grade equivalents (e.g., ingredients with potentially harmful impurities, ingredients labeled with "not for pharmaceutical use" or an equivalent statement) The Board's underlying data included in the Modified Initial Statement of Reasons contains additional information specifically related to this issue including as an example item 21, "FDA highlights concerns with using dietary ingredient glutathione to compound sterile injectables." Board staff note that the costs of medications are outside of the Board's purview; however, note that the Board has made a number of changes to the proposed regulation text where possible to address cost issues raised. Board staff note that under the law, patients can be dispensed medications from a variety of sources including physicians (and other practitioners authorized in the law), pharmacies, and outsourcing facilities. Patients may choose to explore other sources of compounded preparations.
9	General	W. Hicks Taylor And	The commenter opposes the proposed regulation for the following reasons: 1. The Board is denying patient access to oral & IV Vitamin B12 and Glutathione.	Board staff have reviewed the comment and do not recommend changes to the proposed text. Board staff respectfully refer the commenter to prior responses to this issue included throughout the

		N. Holt	2. The Board of Pharmacy has offered no scientific or legal justification for blocking access to Category 1 substances. 3. The Board has targeted the specialized pharmacies that compound & dispense Category 1 substances with these regulations and using taxpayer money to file lawsuits, claiming they were dispensing Category 1 substances improperly.	rulemaking record and public discussion explaining that access is not being blocked; instead, a pathway is being allowed. Board staff would also recommend that the commenter review information regarding provisions in the Government Code to gain an understanding of the disciplinary process. The Board has received presentations from representatives from the Office of the Attorney General on the process during public meetings including during the July 18, 2023 Enforcement and Compounding Committee. The presentation slides are included in attachment 2 meeting materials available here and a livestream of the meeting is available on the Board's website and can be accessed from the following webpage - - https://www.pharmacy.ca.gov/about/meetings_enforcement.shtml. Further the Board notes that it is a special fund agency that does not rely on general taxpayer funding.
10	General	M. Morgenstern	As a Lyme Patient that has found B12 & Glutathione injections imperative and beyond helpful in my treatment I am horrified that you are ignoring an abundance of intelligent public comments from MDs, Naturopaths, Veterinarians, and Pharmacists along with Firefighters regarding your proposed new restrictions on compounded supplements. Your desire to tighten restrictions on compounded medications is senseless and overreaching. The current regulations are already enough to keep patients safe. Our firefighters that have been working diligently to save lives and homes in California deserve your support instead of your overly controlling restrictions. Please do not make it more difficult and more costly for our firefighters, immune compromised patients and pets to detox utilizing glutathione and other supplements. Your reasons for wanting to tighten restrictions are transparent and lack integrity. Medical Doctors do not need anymore needless restrictions from the	Board staff have reviewed the comment and do not recommend any changes to the text. Board staff respectfully refer commenter to prior responses to this issue included throughout the rulemaking record and public discussion regarding providing a pathway for the appropriate and legal use of bulk substances in compounding.

			board regarding how they choose to treat and help patients. Same with Pharmacists. As a California Councilmember I am appalled at the fact that you are not listening to public comments. Listen to the people of California! Do better!!! I know I am not the only person in Sonoma County California that is appalled with your inability to listen to the public. The board is pretending they know best and that medical doctors and pharmacists do not. Come back down to earth and start listening to the residents and voters of California. Some of the condescending comments the board makes are offensive.	
11	General	C. Frost	These regulations, as currently written, will devastate patient access to life-saving treatments in California, despite no evidence of safety risks warranting such measures. USP does not require full stability studies for Category 1 or 2 sterile compounding. These requirements only apply to Category 3 compounding. For the Board to mandate such studies—which can cost \$10,000 to \$30,000 per formulation—imposes an insurmountable financial burden on pharmacies. This will force them to limit offerings to the most generic formulations, eliminating the ability to create customized treatments based on individual prescriber orders. • The additional documentation of clinical circumstances for APIs on the FDA's interim Category 1 list far exceeds FDA requirements. These APIs are already treated like any other active ingredient under FDA guidelines, with no such documentation mandate. • The requirement to perform multiple tests on APIs, including tests listed in USP Chapters above 1000 (informational-only chapters), is both excessive and unprecedented. California would be the only state enforcing such standards on 503As, further restricting access without improving safety.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Board staff respectfully refer the commenter to the public record of this rulemaking including responses provided related to the commenter's statements related to stability studies, documentation for clinical necessity and provisions related to incorporation of USP Chapters above 1000. Board staff note that under the provisions of the Chapter and the Board's proposed regulation text, a pharmacy can use the stability studies performed by another entity, including stability studies performed by professional organizations and associations. There is nothing in the regulation text requiring pharmacies to repeat these studies. Staff note APIs included in the FDA's Interim Bulk Substances Guidance document are not treated exactly like other active ingredients. The Board is adhering to the rulemaking process and the Board's consumer protection mandate. Specifically related to the four specific requests the Board provides the following responses. 1. The Board's regulations align with federal standards and help licensees navigate the federal law and national standards that

			As a regulatory body, your job is to listen to public comments and adjust your actions accordingly. Under no circumstances is it appropriate to hold it against the public that the Board's hard work went into a proposal when said proposal ultimately harms the public interest. This Board has a moral and ethical obligation to protect the public. Instead of actively making it harder for Californians to access critical treatments, preserve access by fixing this proposal. Our asks are simple: 1. Align California's regulations with federal standards to ensure patients have access to essential Category 1 sterile compounded medications. 2. Adhere to USP by allowing Category 2 compounding without requiring full stability studies, provided sterility and endotoxin testing is performed and a reasonable beyond-use-date (e.g., 45 days refrigerated) is applied. 3. Eliminate adherence to USP Chapters above 1000, which are not enforceable requirements and are meant for informational purposes only. 4. Amend the language to specify that Title 16 sterile compounding regulations apply specifically to pharmacists and not to doctors. The Board's mission should be to protect public health—not restrict access to therapies that enhance patient outcomes.	would otherwise prohibit compounding of substances such as glutathione. 2. The Board's requirements for stability studies align with the USP Chapters with one deviation specifically related to the use of Category 1 substances. As articulated elsewhere in the public rulemaking file, this deviation is necessary to ensure the stability of a compounding preparation that uses a chemical that is not approved by the FDA. 3. As stated elsewhere in the public rulemaking document, As the Board has previously noted and the commenter suggests, USP provides, "Although it is possible for FDA or another government authority in the U.S. or elsewhere to require the use a USP General Chapter numbered 1000 to 1999, the authority in question would need to make this requirement expressly applicable under law, regulation, or another appropriate vehicle that prescribes enforceable requirements." 4. Board staff respectfully refer the commenter to row 6 of this document for its response to this item. The Board has stated clearly that its authority is regulating licensees within its jurisdiction. The Board has provided information from the Medical Board, who is vested with the authority to regulate physicians specifically related to this issue.
12	General	S. Johnson	The proposed regulations exceed the Board's statutory authority, as they impose restrictions that are not supported by substantiated evidence or scientific justification. The Board has failed to substantiate the regulatory basis for these actions, which contravenes the requirement for evidence-based decision-making in rulemaking processes. These restrictions contradict federal guidelines for legally permitted FDA Category 1 substances, and	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Staff note that these comments mirror the comments previously considered by the Board including most recently at the January 8, 2025, board meeting. Staff respectfully refers the commenter to the Board's prior response. Board staff note that nothing in the Board's regulations would disrupt research being conducted.

			the Board has provided no scientific justification, constituting an overreach of regulatory authority. A biased, inaccurate “education” presentation at the November meeting further reflects the Board’s lack of transparency. These regulations exceed FDA standards without demonstrating added safety benefits, as outlined in the Initial Statement of Reasons (ISOR). They would disrupt pioneering research by institutions such as Stanford, UCSF, Scripps, and the Open Medicine Foundation, global leaders in Long Covid and ME/CFS studies. By denying access to FDA Category 1 substances in sterile compounds, the California Board of Pharmacy will directly contribute to the worsening health crisis facing our state. The Board’s actions will not only undermine public health but will increase suffering for millions of Californians who need these treatments to manage their health in the aftermath of an ongoing environmental disaster. New stability testing requirements will create undue financial hardship on pharmacies and patients, making life-saving medications less affordable and accessible. The Board has ignored the overwhelming public opposition and expert testimony, failing to address concerns from healthcare professionals and patients. The failure to accommodate patients with disabilities by restricting access to compounded medications and restricting their meaningful engagement as key stakeholders throughout the public rulemaking process violates their rights under the Americans with Disabilities Act (ADA). See comment for provided reference material.	During the January 8, 2025, Board Meeting, information was provided about the opportunity for research through the California Firefighter Cancer Prevention and Research Program through the University of California. The proposed regulations do not disrupt research efforts. . The FDA has information available about how to conduct clinical drug trials. Board staff respectfully suggest that a source to learn more about clinical trials for drugs can be found on the FDA website. As is indicated in prior responses, the Board’s regulations do not ban access to FDA Category I substances. Board staff note that under the provisions of the Chapter and the Board’s proposed regulation text, a pharmacy can use the stability studies performed by another entity, including stability studies performed by professional organizations and associations. There is nothing in the regulation text requiring pharmacies to repeat these studies. Board staff have considered the references provided by the commenter. The references include videos and articles and other websites providing information related to environment hazards and long-term consequences including respiratory health. Based on staff review these references do not appear to be related to compounded preparations but appear to document, for example, how to improve air quality, steps to improve environmental quality, etc. Reference was also provided to the DQSA, which the Board also references in its public rulemaking file.
13	General	W. Hamik	Commenter shares deep concern and strong opposition to the proposed regulations that would	Board staff have reviewed the comment and do not recommend changes to the proposed text. Board staff respectfully refer the

		severely restrict access to Category 1 sterile compounds like glutathione (GSH) and methylcobalamin (methyl B12). I feel compelled to voice how detrimental this overreach could be to the health and well-being of countless Californians. • Compounded medications like glutathione and methylcobalamin are indispensable for managing chronic illnesses such as long COVID, Lyme Disease, and ME/CFS. These conditions are complex and debilitating, often leaving patients without effective conventional treatments. • These compounds are also crucial for detoxifying individuals exposed to hazardous chemicals. • There are no true alternatives to these compounded medications. Over-the-counter supplements simply do not offer the potency or bioavailability that compounded IV infusions or subcutaneous injections provide. Without access to these therapies, many patients will face worsening health crises and deteriorating quality of life. Restricting access to these compounds would disproportionately harm those with complex medical needs who have no other viable treatments. By moving forward with these restrictive regulations, the state risks abandoning this legacy and falling behind the rest of the nation in providing patient-centered care. Reconsider the broader implications of these regulations and prioritize the needs of Californians who depend on access to these life-changing treatments.	commenter to the public record of this rulemaking including responses provided above in this document related to the chemicals listed in the comment.

#	Section	Commenter	Comment	Board Response
1	1735(d)	Eli Lilly	Some of the Board's proposed revisions to the defined term "essentially a copy" are necessary and appropriate to ensure that patients are treated with a compounded drug only when those patients cannot be served by an FDA-approved medicine. The "essentially a copy" ("EAC") prohibition is one of the key legal prohibitions that prevents compounding pharmacies from selling knockoffs of FDA-approved medicines. For it to serve its intended purpose (which is to prevent end runs around the new drug approval requirement in the guise of compounding), the EAC prohibition must be broad and must not be easily evaded. To that end, Lilly offers the following comments. 1. We applaud the Board's proposal to define "essentially a copy" to include any compounded drug "that includes the same active pharmaceutical ingredient(s) (API(s))" as an approved medicine. This broad definition will ensure that the EAC prohibition protects the public health as it was intended by ensuring that compounding pharmacies cannot evade the prohibition through minor or pretextual formulation changes. 2. We also applaud the Board's proposal to limit the exception to the EAC prohibition to situations where the pharmacist has "verified and documented" that the compounded drug will produce a "clinically significant difference" for the specific patient. This verification also is essential to protect the public health and prevent evasion. All too often, providers and pharmacists (often working together pursuant to contracted commercial arrangements) have attempted to evade the EAC prohibition through sham prescriptions and other illicit measures. Requiring the pharmacist to use his or her professional judgment to verify that the compounded drug makes a real change that will be clinically significant will help to ensure that patients receive FDA-approved medicines whenever possible.	The Board thanks the commenter for the information that is in support of the Board's proposed modified text. The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received.

			We support the Board's proposed revision as it provides the necessary and appropriate flexibility for pharmacists to use their professional judgment in determining whether a compounded drug is essentially a copy. Contrary to the suggestion by other commenters, exercising that professional judgment does not impinge a prescriber's judgment, but rather preserves the ability for pharmacists to exercise their clinical judgment as well. As the Board has previously observed, federal law requires that the compounded drug produce a significant difference for the patient. The proposed revision makes it clear that the pharmacist must independently verify, and then document, that the compounded drug will indeed produce a clinically significant difference from an FDA-approved medicine for a given patient.	
2	1735(d)	CMA	CMA remains concerned that the Board's new proposed requirement for pharmacists to "verify" that a compounded drug produces a clinically significant difference for a patient creates an undue burden and restricts the professional judgment the Board intended to preserve. Mandating verification for every instance of compounding a commercially available drug that is not on a shortage list establishes a rigid, prescriptive standard. This contradicts the Board's stated goal of maintaining flexibility, and, as such, the language violates the clarity standard because it conflicts with the Board's description of the effect of the regulations in its formal response to members of the public regarding this issue. Pharmacists are already required to use their professional judgment in dispensing compounded drugs. Eliminating the "verify" requirement from the proposed regulation would not abrogate pharmacists' statutory responsibilities, but would instead maintain the flexibility pharmacists need to practice most effectively. As written, the requirement could be interpreted to mean pharmacists must contact prescribers for verification in all cases where they compound a commercially available drug, leading to unnecessary delays in patient care. As a result, the lack of clarity within this requirement risks limiting access to necessary treatments, particularly in cases where compounded medications are essential alternatives to commercially available drugs. Federal law does not impose a verification or documentation requirement on pharmacists. Instead, the FDA, in non-binding guidance, recognizes	The Board noted that the comments are outside of the 15-day comment period. The Board also notes that the Board has previously considered this and similar comments and determined that a change was not appropriate. The Board respectfully referred the commenter to the Board's prior response to this comment from this commenter in row 2 available here, (https://www.pharmacy.ca.gov/meetings/agendas/2025/25_feb_bd_mat_1735_comments.pdf) that includes "Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that this issue was previously considered by the Board, most recently during the January 8, 2025, Board Meeting. As approved by the Board during the January 8, 2025, board meeting, the second modified text included the requirement that a pharmacist verify that a prescribed medication is clinically appropriate for a patient, irrespective of whether it is a compounding medication."

			documentation of a prescriber's determination as sufficient. The Board's proposal, by contrast, creates a new obligation without clear justification, increasing administrative complexity without improving patient safety.	
3	1735(d)	CSHP	We add our voice to others who commented on this section who pointed out their concern with the wording of this section. We appreciate the board's position that the intent is to rely on the professional judgement of the pharmacist. At the same time, we object to the wording of the regulation and wish to point out that this section has the potential to be misinterpreted as written, both currently and in the future. It is important to get this right so that the intent is clear and does not cause confusion. The wording of "'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," could be interpreted to mean that ANY compound being made is defined as essentially a copy of a commercially available drug product. The trouble here is that any compounded drug that has the same API as a commercially available drug product will violate this regulation. Using the example of a hospital pharmacy that compounds 10 bags of Oxytocin 30 Units in 500ml Normal Saline for use in their Labor and Delivery (L&D) unit. The Oxytocin bag is made by using three 1ml vials of Oxytocin 10units/1ml. By the definition above, it will be a violation of this proposed regulation since these bags are made in bulk and they include the same API as the commercially available drug product of Oxytocin 1ml. These bags are made in bulk, so, by definition, it is not being compounded specifically for an identified individual patient that produces for that patient a clinically significant difference. These bags are being used for almost every patient that will have a delivery on the unit, so one cannot argue that it is being made for a specific individual patient. This proposed regulation, if it is read simply for the way it is stated, will imply that the pharmacist verifying the order will need to go through a process of verifying with the prescriber and then documenting each and every order for Oxytocin bags that the change from the commercially available 10 unit per 1ml vial to a compounded 30 unit per 500ml Oxytocin bag	The Board noted that the comments are outside of the 15-day comment period. The Board notes that the commenter appears to be describing what would be considered sterile compounded preparations. The Board notes that the FDA guidance does not address the practice described by the commenter. The Board's proposed regulation text provides greater flexibility to pharmacists in the healthcare setting where the FDA guidance is silent. The Board also refers the commenter to the provisions included in 1735.1(e)(1)(A) that provides additional flexibilities for health care facilities.

		produces a clinically significant difference for each individual patient. In the ISOR, the board states that the FDA guidance document is being utilized to provide guidance regarding this definition (ISOR section copied herewith for reference). It is important to note that the definition taken from the FDA guidance document and used in this proposed regulation, is only one part of three of the definition in the guidance document. Herewith the guidance document section on “Essentially a Copy” for reference: FDA intends to consider a compounded drug product to be essentially a copy of a commercially available drug product if: • the compounded drug product has the same active pharmaceutical ingredient(s) (API) as the commercially available drug product; • the API(s) have the same, similar, or an easily substitutable dosage strength; and • the commercially available drug product can be used by the same route of administration as prescribed for the compounded drug, unless, as provided by section 503A(b)(2), a prescriber determines that there is a change, made for an identified individual patient, which produces, for that patient, a significant difference from the commercially available drug product. The proposed regulation definition crucially leaves out the requirements for a same or similar dosage strength and route. By leaving out these clarifying terms, the definition is now so broad that it is inclusive of every single non-sterile and sterile compound being compounded by a pharmacy in the state of California. From our example above, it is open to interpretation by both the regulated public and board staff of what “essentially a copy” is because it will be everything with the same API. By the proposed definition, since diazepam tablets are commercially available, a pharmacy may not compound a diazepam drip from IV vials since the tablets contains an API that is commercially available (even though it is available in a completely different non-sterile dosage form). According to the definition, a hospital making a batch of oral suspension from tablets on a regular basis for its neonatal of	

		pediatric unit, will be making essentially copies of the API in the tablets and will have to call and verify with the prescriber and then document the self-evident information that the change was made for each and every identified individual patient that produces for that patient a clinically significant difference. We are sure that we can all agree that this is not the intent of the regulation. By adding the crucial elements of strength and route it narrows the definition and it is much clearer and is aligned with both the FDA and board's intent. This addition of language provides clarification while still allowing flexibility for the pharmacist to use professional judgement. By adding the components that aligns with FDA guidance, it becomes clear that it will be the same as federal statute and guidance, and we recommend that this regulation be deleted. While all involved currently in the creation and comments for the definition of "essentially a copy" may have a grasp and understanding of the intent of this proposed regulation, we must take the multiple comments from all stakeholders as an indicator that there will be future misunderstanding and misinterpretations of this language. It is of the utmost importance to recognize that ten to fifteen years from now these interpretations and intent will be forgotten, and the only guidance left to enforce are the words as written. We are sure that the current board would not want future board members and staff to enforce this rule under the misunderstandings that we and others took great pains to point out at this moment in time. Recommendation: (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, the API(s) have the same, similar, or an easily substitutable dosage strength; and the commercially available drug product can be used by the same route of administration as prescribed for the compounded drug 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 verified and documented by the pharmacist, between that	

			compounded preparation and the comparable commercially available drug product.	
4	1735(e)	Sutter Health	The recommendation reiterates concerns about California's definition of "essential copy" in hopes of further providing detail of the broad definition and the impact. The Board aims to align with the federal 503A standard, but the nonspecific definition lends to comprehensive noncompliance and does not capture the compounding activities which the Board intends to take regulatory action on. According to section 207.3(a)(4) of title 21 of the Code of Federal Regulations, compounding "essentially a copy" involves using bulk drug substances (APIs), not finished drug products. The current and proposed California definitions exceed federal 503A exemptions, especially within healthcare facilities, creating compliance issues. In a medium to large California hospital, compounding pharmacies prepare over 1,000 patient-specific compounds daily under USP 797 standards. These compounds, sharing APIs with commercial products, are deemed "essential copies" under California's restrictive code, requiring extensive documentation for each patient, which is impractical and not the intent of the Board to regulate the activities within scope of the existing and proposed definition. The California Board's definition does not align with FDA's 503A exemption, which allows professional judgment. The state's definition demands documentation of clinical differences for every compound, unlike the federal standard. Examples of discrepancies include: 1. Vancomycin oral solution (DIFICID) for C. difficile treatment, vancomycin lyophilized sterile powder vials, and vancomycin premix IVPB Xellia bags with PEG all share the same API. Compounding a weight-based IVPB for surgical prophylaxis in orthopedic surgery the day prior to anticipated need for intravenous therapy is compounding an essential copy under the CA definition but not under the FDA. 2. Cefazolin oral suspension (FDA-approved dosage form) shares the same API as cefazolin 2-gram sterile lyophilized powder.	The Board believes the commenter is referring to Section 1735(d). The Board noted that the comments are outside of the 15-day comment period. This comment has been previously considered during the 45-day comment period. At that time the Board responded, <i>"Board staff have considered the comment and do not recommend a change to the proposed text. Staff note that as written, the language provides flexibility for a clinician to use their professional judgment when determining if a compound is essentially a copy. Should the Board amend the language to include the recommended language, the Board would be limiting this flexibility and a clinician's professional judgment."</i> The Board also refers the commenter to the provisions included in 1735.1(e)(1)(a) that provides additional flexibilities for health care facilities.

			3. Vasopressin premix bags of IV solution and the FDA-approved vials of vasopressin solution with an FDA-approved package insert that details making an IV infusion is compounding an essential copy. 4. Creating clonidine oral suspension compound for a neonate shares the same API as clonidine tablets. 5. Repackaging a Zosyn premix IVPB product into a syringe to administer to a neonate is defined in CA as an essential copy. 6. Compounding Daptomycin lyophilized powder sterile vial to compound rather than the Baxter premix Daptomycin vial. The California Board should adopt either the FDA's definition or clarify the specificity of API/bulk drug substance compounding to provide clear expectations and enforcement standards to support the necessary compounding practices. The current regulation is impractical and burdensome, forcing hospitals to violate the law, lack clarity or over-document. Updating the definition to reflect safe, practical compounding under the federal 503A exemption is essential. Let's establish a meaningful, enforceable standard.	
5	1735.1	B. Go	The response by the Board that both proposed as well as existing regulations on compounding, as currently worded, do not infringe on the practice of compounding by non-pharmacist licensees under the jurisdiction of other California professional boards, is not satisfactory for the following reasons: 1. You responded with comments from only one board, the Medical Board of California, which only regulates MD's. This does not apply to other licensees such as DO's, nurses, ND's, dentists, and veterinarians, who may also have the right to compound medications in-office without a pharmacist and without interference by the Board of Pharmacy. Furthermore, even the MD's right to compound is still in jeopardy based on current wording of the Board's regulations, for the following reasons: a. The Medical Board's letter noted that only the Medical Board has the right to discipline its licensees. This would only apply if the licensee was being disciplined as an MD, not if they were being disciplined as a person practicing pharmacy	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board noted that the comments are outside of the 15-day comment period. The Board has previously considered this and similar comments and provided responses throughout the rulemaking, including for example the response, <i>"Board staff have reviewed the comment and do not recommend a change to the proposed text based on the comment. Board staff note that the Board previously considered this comment, most recently during the January 8, 2025, Board Meeting and determined that the requested change is not appropriate. As was previously shared, staff note the Board only has jurisdiction over individuals and businesses within its practice act. Board staff read the</i>

		without a license. Again as previously stated, the Board of Pharmacy's jurisdiction is to regulate the practice of pharmacy, and therefore practicing pharmacy without a license would fall within their purview. Both currently existing regulations as well as the proposed changes exclude non-pharmacists from being able to compound, specifically defining the practice of compounding as that which occurs by a pharmacist ONLY. (See proposed regulation 1736.1a (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." And see currently existing regulation: CCR 1735(a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist") b): The Medical Board's letter notes: "It is certainly possible that whatever regulations that are implemented by the Board of Pharmacy may influence the standard of care for physicians who are compounding." - they admit that your regulations may affect MD's practice of compounding. I'm not sure why you have so much resistance to adding wording which would only help to clarify the limitations of your role, and would limit the confusion and ambiguity which the current wording is creating. Instead, you have specifically chosen to include wording which is overly broad, and which implies that compounding only may be performed by a pharmacist. 2. You claim that regulations specifically state you cannot regulate other practitioners 3. Furthermore, you have not directly responded to previous comments that noted the contradiction between your stance on the above and the fact that you are currently making preparations to attempt to regulate what you refer to as 'IV hydration clinics'. These clinics do not have pharmacists, however they do have other non-pharmacist licensees who have the right to compound. The term 'IV hydration clinic' itself	<i>comment as suggesting that the Board's proposed regulations would apply to a physician. Business and Professions Code section 4170(c) makes clear that the Medical Board of California is specifically charged with the enforcement of Pharmacy Law (Chapter 9, Division 2 of the Business and Profession Code) with respect to its licensees."</i> The Board respectfully refers the commenter to Business and Professions Code section 4170 as well as the Board's jurisdiction. The Board also recommends that the commenter review the Board's Initial Statement of Reason that describes the Board's jurisdiction to gain a better understanding of the applicability of the Board's regulations. The commenter also appears to be provided comments about a statutory proposal related to the regulation if IV hydration clinics. The Board referred the commenter to the Board's proposed statutory proposal for an understanding of the Board's legislative proposal. The Board notes that the language in the statutory proposal does include explicit language that it would not apply to a facility for which a professional director is on site while sterile compounding occurs.

			is not well-defined by the board, and it is foreseeable that the board could choose to include any medical office that provides IV hydration or IV nutrients in this category, offices in which compounding might be conducted by any of a variety of types of licensed non-pharmacist practitioners who should not be under the purview of the Board if it were not for the current language in your regulations. Therefore, the claim that your compounding regulations do not or will not interfere with compounding by non-pharmacist licensees is disingenuous. Please do note and respond to this paragraph in full in your reply as well.' Given all of the above, I recommend you add the following or similar wording somewhere within Title 16 CCR: "The regulations in Title 16 CCR Sections 1735 et seq, 1736 et seq, 1737 et seq, and 1738 et seq do not in any way apply to the practice of compounding by non-pharmacist licensees who have the right to compound based on their own practice act." If however, you do want to have the ability to regulate non-pharmacist licensees, and are therefore unwilling to add the above language, it is imperative that you change all language in the current and proposed regulations that limit compounding to pharmacists alone - including the statement that compounding occurs by pharmacists only, and any language that requires you to have a pharmacist-in-charge in a facility that performs compounding.	
6	1735.1(d)(2)	K. Scott Guess	In my first public comment, I criticized the Board for duplicating much of what was already published by the United States Pharmacopeia (USP), and adding costly extra, and, in my opinion, unnecessarily complicating processes that did not appear to add to patient protections. Though not perfect I must complement the Board for taking into consideration the large number of public comments it received and crafting a much better, more concise set of regulations. What is the purpose for restricting veterinarian office use medications to 14 days? There is no reason why veterinarians should not be afforded the same office use parameters as	The Board has reviewed the comments and made no changes to the proposed text based on the comments received. It does not appear the commenter is recommending any changes to the proposed text. The Board referred the commenter to 1735.1(d)(1) related to veterinarian office use provisions that do not include a day's supply limitation for office use provisions. Further, the Board noted that the commenter may not be drawing the distinction in the regulation specifically related to these

			human practitioners under CCR 1735.2[c][1], sub section [3] seems to imply that veterinarians are a lesser class of prescriber.	provisions that are separate, 1) provisions for in office use and 2) for dispensing by the veterinarian.
7	1735.1(e)	Outsourcing Facilities Assoc.	The proposed amendment should be revised for additional clarity. The December 2024 comment explained, inter alia, that a requirement that a finding of clinically significant difference be made by "the prescribing practitioner," "the compounding pharmacist," and "the dispensing pharmacist(s)" was arbitrary, capricious and contrary to law. The proposal demanded that pharmacists engage in the practice of medicine in contravention of California law, imposed obstacles to federal policies under the FDCA in contravention of federal law, and operated in erratic ways for no rational policy objective. The Second Modified Text of Proposed § 1735.1 avoids demanding that pharmacists practice medicine by requiring only that a "pharmacist verifies and documents" a clinically significant difference, rather than make the determination of clinically significant difference, which the prescribing practitioner must do under federal law. With the text so understood, the objections stated in the December 2024 Comment would be resolved. However, the Second Modified Text of Proposed § 1735.1(e) may fall short of achieving these objectives because it is arguably ambiguous concerning (1) what is to be verified and documented and (2) what verification and documentation is required. First, the shift from a determination standard to a verification and documentation standard indicates that the pharmacist under the Second Modified Text need only verify and document that a prescribing practitioner has made a finding of clinically significant difference. But there is an arguable ambiguity: the draft text's reference to verifying and documenting directly "that the compounding produces a clinically significant difference" could be misunderstood to require that pharmacists find an actual clinically significant difference in possible conflict with doctors' findings, which would raise all the flaws identified in the December 2024 Comment and be unlawful on the grounds stated there. The text should be revised to make clearer that the pharmacist	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board noted that the comments are outside of the 15-day comment period. This comment was previously considered by the Board. The Board referred the commenter back to the Board's prior response to this comment included in row 8 available here (https://www.pharmacy.ca.gov/meetings/agendas/2025/25_feb_bd_mat_1735_comments.pdf) that included, "Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that this issue was previously considered by the Board, most recently during the January 8, 2025, Board Meeting. As approved by the Board during the meeting, the second modified text included a requirement that a pharmacist verify that a prescribed medication is clinically appropriate for a patient. This is consistent with the practice of pharmacy and the requirement extends to all prescriptions, irrespective of whether it is a compounded medication. Board staff note that the commenter appears to suggest that a pharmacist does not have an obligation to exercise clinical judgment when compounding or dispensing a medication. The Board believes it is important to underscore that pharmacists must exercise clinical judgment in all aspects of practice and not simply defer their judgment to another individual. This obligation is memorialized throughout Pharmacy Law, including notably BPC Section 4306.5. Should it be helpful, Board staff refer the commenter to some specific provisions of the

			must verify and document that the prescriber has made such a determination. Second, the Second Modified Text is also arguably ambiguous as to what type of verification and documentation is sufficient. As drafted, the Modified Text of Proposed § 1735.1(e) may be misunderstood to require onerous, impractical, vague, or inconsistent verification and documentation requirements that prove unworkable or overly burdensome in practice. That, again, would raise all the flaws identified in the December 2024 Comment. This ambiguity can be resolved, however, by making clear that a pharmacist who verifies, from a notation documented on the prescription itself or other similar communication from the prescriber to the pharmacist, that the prescriber has determined the clinically significant difference of the prescription—and adds a notation to the pharmacist's patient file recording this fact—meets the verification and documentation requirement of Proposed § 1735.1(e). The Third Modified Text, published on or about February 6, 2025 does not address the ambiguity or flaws identified. The Board should clarify the text of Proposed § 1735.1(e) along the lines proposed above. At a minimum, it should clarify in the preamble of any final action promulgating this rule or in concurrently issued guidance that, under this provision, a pharmacist need only verify and document that a prescribing practitioner has made a finding of clinically significant difference in the manner described above. Furthermore, to ensure consistent implementation, OFA strongly encourages the California Board of Pharmacy to draft a Frequently Asked Questions (FAQ) document, as previously requested by stakeholders, to address and clarify any potential ambiguities surrounding the verification and documentation requirements. This FAQ will provide critical guidance for both prescribers and pharmacists, helping to prevent misunderstandings and ensuring patients receive safe and effective compounded medications under the new regulatory framework	<i>law that establish specific requirements for pharmacists to evaluate prescriptions prior to dispensing including, as examples:</i> <i>Health and Safety Code section 11153</i> <i>Business and Professions Code section 733</i> <i>Title 16, California Code of Regulations Section 1707.3"</i>
8	1735.1(e)(1)	Partnerships of Safe Medications	5. The determination of medical need for a compounded medication should involve the prescribing practitioner o The proposal to remove the tripartite requirement that the prescribing practitioner, the compounding pharmacist, and	The Board agrees that federal law requires a determination by a medical provider. As the Board does not regulate prescribers, the requirement was removed from the proposed

			the dispensing pharmacist all agree that compounding this product is based on medical need is a step back. It does not seem wise to cut the prescribing physician out of the decision-making of patient care here, and we oppose this.	regulation text. The authorized healing arts Board responsible for oversight of the prescriber would be responsible for evaluating for compliance with the medical need determination established in federal law.
9	1735.1(e)(1)	Novo Nordisk	We reiterate our request that the Board update Section 1735.1(e)(1) to state only the prohibition on compounding of “essentially a copy of one or more commercially available drug products,” as defined at Section 17735(d), and to remove the exceptions to the copies restriction at (e)(1)(A) in the Third Modified Text related to shortage lists and inability of a health care facility to obtain a drug. In doing so, we ask that the Board reconsider the positions stated in the Staff Responses to NNI’s comments to the Second Modified Text. As explained in NNI’s prior comments, the exemptions in the proposed regulations from the copies prohibition are overly permissive and inconsistent with federal law and policy. The regulations would allow drugs to be compounded under circumstances that are inconsistent with FDA’s current interpretation of Section 503A of the FDCA stated in the agency’s 503A Copies Guidance.² There, FDA states that the agency does not consider a drug to be “commercially available” within the meaning of the federal copies restriction if it is present on FDA’s drug shortage list, and when the drug product has been discontinued and is no longer marketed.³ The exemption that would permit compounding of copies when a drug product appears on the ASHP drug shortage list is clearly inconsistent with FDA’s stated position – FDA has nowhere recognized that listing on the ASHP Drug Shortage list can permit compounding of copies; the agency has only stated as such with regard to FDA’s drug shortage list. The proposed regulations are untenable in this respect, evidenced by the fact that the Staff Response to NNI’s prior comments does not defend the reference to the ASHP list. Additionally, the proposed regulations would allow for compounding of copies when a health care facility “cannot obtain” a drug from the manufacturer or wholesaler. The Staff Responses point to a footnote in FDA’s 503A Copies Guidance that states that the agency is considering the applicability of its policies described in the guidance to hospitals and health	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board has previously considered this comment and refers the commenter to the Board’s prior response in row 9 available here (https://www.pharmacy.ca.gov/meetings/agendas/2025/25_feb_bd_mat_1735_comments.pdf) that included in part, “Further, the Board’s provisions specifically include additional flexibilities for health care facilities licensed pursuant to Health and Safety Code 1250 (which include hospitals), is consistent with the FDA’s guidance related to compounding a drug that is essentially a copy that acknowledges that the FDA is considering the applicability of its policies described in the guidance document to hospitals and health systems. As the FDA has not released this separate guidance, the Board believes its approach is consistent with the intent of federal law while ensuring hospitals have additional flexibility to take care of patients. Board staff respectfully refer the commenter to the Modified Initial Statement of Reasons that includes the referenced FDA Guidance Document, Compounded Drug Products that Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act.”

			systems. Contrary to the staff's statement, FDA has promulgated draft guidance regarding application of the restriction on compounding copies to hospital and health system pharmacies.⁴ Therein, FDA states that "[i]n general, FDA intends to apply the policies described in the 503A copies guidance when it regulates compounding by hospital and health system pharmacies that are not registered as outsourcing facilities."⁵ While the agency does provide some flexibilities for such entities with regard to the prescriber determination requirement, FDA does not state any policy that would exempt these compounders from the copies restriction altogether based on the inability of the compounder to obtain a drug product from the manufacturer or wholesaler. Rather, FDA's policies regarding shortage stated in the 503A Copies Guidance would apply equally to hospitals and health systems. To best protect patient safety and the public health, and to avoid undermining a key check on compounding of unapproved drug products, we request removing, or at the very least narrowing, the broad permission for health care facilities to compound copies. Recommended language revision: "(e) 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, as defined at Section 1735(d) of this article. Documentation by the pharmacist that the compounded drug product produces a clinically significant difference for the medical need of an identified individual patient, as provided for at Section 1735(d) of this Article, must be maintained in a readily retrievable format."	
10	1735.1(e)(1)(a) and (c)	K. Scott Guess	How long must the documentation of drug shortage be retained?	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board directs the commenter to proposed section 1735.14 to understand records requirements.
11	1735.1(e)(1)(A)	Obesity Action Coalition	We recommend that the Board update Section 1735.1(e)(1)(A) to align with FDA's interpretation of Section 503A that would only allow drugs to be compounded under certain circumstances. The proposed exceptions to the copies	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received.

			restriction at (e)(1)(A) in the Third Modified Text – are overly discretionary for healthcare facilities related to shortage lists and their inability to obtain a drug. The proposed Third Modified Text, would further allow drugs to be compounded under circumstances when a drug product appears on the American Society of Health-System Pharmacists (ASHP) list. These broad exceptions are inconsistent with federal law and current policy and could perpetuate the manufacturing of illicit and unapproved compounded drug products when FDA-approved drugs are available to patients.	The Board notes that the proposed regulation text related to the reference to the ASHP Drug Shortage List is consistent with current provisions of the law. The Board has received testimony from hospitals encountering significant challenges with drug shortages that are not timely included on the FDA Drug Shortages Database. This testimony has included that the ASHP Drug Shortages List is another reliable source from drug shortage information. As part of the ASHP drug shortage list, ASHP also provides mitigation strategies for hospitals to ensure continuity of patient care. The FDA has stated its expectations that a manufacturer report discontinuation of or a supply interruption to and FDA approved drug. Further FDA includes information on its website that states the following, <i>“When a medication is not available, it can be helpful to make FDA’s Drug Shortages staff aware. Usually when a drug is not in stock, it’s a temporary, localized issue and more product is on the way. Occasionally local supply issues can be a signal of a future drug shortage.</i> <i>When FDA receives reports of new local shortages, we contact the manufacturers to confirm if their available supply will meet the national demand for the drug. If a drug is at risk of going into shortage, sometimes this advanced notice helps FDA take early action to prevent or shorten the duration of a shortage.”</i> It is the Board’s understanding that such notifications and evaluation by the FDA may not be timely necessitating the need for an

				alternative source for assessing drug shortages that is more real-time.
12	1735.1(e)(1)(B)	CMA	CMA remains concerned that the Board's new proposed requirement for pharmacists to "verify" that a compounded drug produces a clinically significant difference for a patient creates an undue burden and restricts the professional judgment the Board intended to preserve. Mandating verification for every instance of compounding a commercially available drug that is not on a shortage list establishes a rigid, prescriptive standard. This contradicts the Board's stated goal of maintaining flexibility, and, as such, the language violates the clarity standard because it conflicts with the Board's description of the effect of the regulations in its formal response to members of the public regarding this issue. Pharmacists are already required to use their professional judgment in dispensing compounded drugs. Eliminating the "verify" requirement from the proposed regulation would not abrogate pharmacists' statutory responsibilities, but would instead maintain the flexibility pharmacists need to practice most effectively. As written, the requirement could be interpreted to mean pharmacists must contact prescribers for verification in all cases where they compound a commercially available drug, leading to unnecessary delays in patient care. As a result, the lack of clarity within this requirement risks limiting access to necessary treatments, particularly in cases where compounded medications are essential alternatives to commercially available drugs. Federal law does not impose a verification or documentation requirement on pharmacists. Instead, the FDA, in non-binding guidance, recognizes documentation of a prescriber's determination as sufficient. The Board's proposal, by contrast, creates a new obligation without clear justification, increasing administrative complexity without improving patient safety.	The Board noted that the comments are outside of the 15-day comment period. The Board noted that it previously considered the comment and determined that a change was not appropriate. Further, the Board referred the commenter to the Board's prior response to this comment from this commenter in row 10 available here (https://www.pharmacy.ca.gov/meetings/agendas/2025/25_feb_bd_mat_1735_comments.pdf), that includes, "Board staff have reviewed the comment and do not recommend a change to the proposed text because modifications in the second modified text addressed it. Staff note that this issue was previously considered by the Board, most recently during the January 8, 2025, Board Meeting. As approved by the Board during that meeting, the second modified text included a requirement that a pharmacist verify that a prescribed medication is clinically appropriate for a patient, irrespective of whether it is a compounded medication. While this commenter has not previously submitted comments in this area, it appears that the commenter is suggesting that a pharmacist does not have an obligation to exercise clinical judgment when compounding or dispensing a medication. The Board believes it is important to underscore that pharmacists must exercise clinical judgment in all aspects of practice and not simply defer their judgment to another individual. This obligation is memorialized throughout Pharmacy Law, including notably BPC Section 4306.5.

				<i>Should it be helpful, Board staff refer the commenter to some specific provisions of the law that establish specific requirements for pharmacists to evaluate prescriptions prior to dispensing including, as examples: Health and Safety Code section 11153 Business and Professions Code section 733 Title 16, California Code of Regulations Section 1707.3"</i>
13	1735.1(e)(2)	M. Cottman	Recommendation: Amend to remove the last sentence: ~~This compound shall be in compliance with the Center for Veterinary Medicine Guidance for Industry #256—Compounding Animal Drugs from Bulk Drug Substances issued August 2022.~~ Comments: "Shall be in compliance with a [document]" This statement is far too non-specific as the GFI document contains Intro, Background, Paperwork Reduction Act and Appendices that link to websites. Specifically, what part of the 21 page GUIDANCE document SHALL we comply with? And what happens to 1735.1(e)(2) when the document changes or goes obsolete (yes the OMB has an expiration date on the document)? If you want additional required items that compounders should comply with for veterinary preparations, please don't make us hunt and peck for the language you are looking for, spell it out. Labeling? Documentation? Bulk Drugs for office use? Reporting ADEs to the FDA? What are you looking for???? It describes "The circumstances under which, at this time, FDA does not generally intend to take enforcement action against drugs compounded from bulk drugs substances for violations of the FD&C Act's requirements for approval, adequate directions for use, and CGMPs." The FDA states that it "generally does not intend to take enforcement action against" NINE (9) times in the document! GFI 256 is written as GUIDANCE, not as regulation nor law. It describes "The circumstances under which, at this time, FDA does not generally intend to take enforcement action	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board noted that the comments are outside of the 15-day comment period and note that reference to the GFI included in 1735.1(e)(2) was made in response to commenters requesting that the language reference the document. Prior to recommending inclusion of the GFI, Board staff conferred with an expert on veterinary practice who confirmed that including the document was appropriate.

			against drugs compounded from bulk drugs substances for violations of the FD&C Act's requirements for approval, adequate directions for use, and CGMPs." Several items that are vague or open to interpretation. As well as statements that outright conflict with each other. Do compounders comply with the statement on pg 5 that: "drugs compounded from bulk drug substances violate the FD&C Act because they are not approved or indexed, are not made according to CGMP, and cannot satisfy the FD&C Act's adequate directions for use provision (which requires, among other things, that a prescription drug have FDA-approved labeling). " Or the statement also on pg 5: "[the] FDA recognizes that there are circumstances in which no FDA-approved or indexed drug (including the extralabel use of an FDA-approved animal or human drug) can be used to treat an animal with a particular condition. In those limited circumstances, an animal drug compounded from bulk drug substances may be a medically appropriate treatment. " Do we, as licensees assume that we should replace BOP wherever we see FDA in the document such as "This guidance describes: • The types of drugs compounded from bulk drug substances that FDA[BOP] has determined present the greatest risk to human and animal health and intends to make priorities for enforcement action; and • The circumstances under which, at this time, FDA [BOP] does not generally intend to take enforcement action against drugs compounded from bulk drugs substances..."	
14	1735.1(f)	M. Cottman	Recommendation: Remove this section. ~~(f) Prior to allowing any CNSP to be compounded within a pharmacy, the pharmacist in charge shall complete a self-assessment consistent with the requirements established in section 1715.~~	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board noted that the comments are outside of the 15-day comment period. The Board notes that section 1715 does not establish a

			Comments: Redundant. This is not making a new rule, it is just reminding compounders to follow existing regulation 1715 to complete a self-assessment. To comply with 1715, a PIC must fill out the form before July 1 of every odd numbered year... What is it that you want done differently? We are already so highly regulated! Wasting text on re-stating existing laws doesn't help clarify anything. Further, a more appropriate approach would be to create a separate rule making process to address adding the Compounding Self Assessment requirement to section 1715, in line with all the other references to Self Assessments since CCR 1735.2[k] will be repealed if this text is adopted.	requirement to complete the self-assessment specifically related to compounding.
15	1735.1(g)	M. Cottman	Recommendation: Amend redundant language. (g) In addition to the provisions in section 1707.2, consultation includes proper use, storage, handling, and disposal of the CNSP and related supplies furnished. Comments: 1707.2 already includes "(c) When oral consultation is provided, it shall include at least the following: (1) directions for use and storage and the importance of compliance with directions;" Restating these items here does not clarify anything.	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. As was discussed previously by the Board, the provisions in CCR 1707.2 do not include requirements related to handling and disposal nor does it require consultation on provisions for related supplies furnished.
16	1735.1(i)	CVS	CVS Health greatly appreciates the collaboration that has led to numerous changes in pending language throughout this promulgation, including 1735.15(b), which allows flavoring without a patient specific prescription. However, the language and methodology used to craft 1735.1(i) and 1735.15(a), which create two pathways for flavoring compliance, causes confusion and is not clear to the regulated community. The first pathway is to follow USP Chapter 795, FDCA section 503a, 1735.1 through 1735.14, and 1735.15(b), which I'll refer to as "pathway A". The second pathway is to follow 1735.14, 1735.15, USP Chapter 795, and FDCA section 503a, however a pharmacy cannot otherwise engage in nonsterile compounding in order to utilize this pathway, which I'll refer to as "pathway B". Although pathway B has been billed as an exception, CVS Health believes that pathway B arguably establishes a greater	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board cannot waive provisions of federal law. The Board can provide clarity to the requirements. The Board's proposal related to flavoring allows for maximum flexibility for a pharmacy to operationalize the requirements when a pharmacy adds a flavoring agent. The Board reminds the commenter about provisions in exist law related to maintaining facilities found in CCR Section 1714 which states in part that "a pharmacy shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed." This section further provides that "the pharmacy

			mandate than just adhering to pathway A, as 1735.15(a)(5) requires a labeling mandate when flavoring while 1735.5 does not. Otherwise, 1735.1 through 1735.14 largely reiterate USP Chapter 795, and as 1735.15 also requires adherence to USP Chapter 795, it is questionable why pathway B exists. Pathway B would truly be an exception, if adherence to USP 795 was struck from 1735.15(a), as requested below. Since it is unlikely community pharmacies will ease offering patients non-sterile compounding services in lieu of flavoring services exclusively, pathway B is not an option. Community pharmacies are simply highly unlikely to engage in flavoring if adherence to USP Chapter 795 is required. While there are several portions of USP Chapter 795 that we believe are too onerous without benefit to public safety to be applied to the act of flavoring a prescription, I'll offer one example. USP Chapter 795 requires gloves to be worn and the cleaning and sanitizing of the surfaces in the nonsterile compounding area on a regular basis or as specified in the USP. CVS Health's request: pathway B not be tied to abstaining from engaging in nonsterile compounding and for pathway B to not require adherence with USP Chapter 795, as depicted below. Otherwise, community pharmacies will likely not be able to offer California patients flavoring, which deviates from the overwhelming majority of other states. (i) A facility that ~~limits its compounding to~~ combining a flavoring agent with a prescribed FDA approved drug in an oral liquid dosage form at the request of a prescriber, patient, or patient's agent shall be exempt from the requirements established in subdivision (f) and Sections 1735.2 – 1735.13. ~~A facility that performs any other form of nonsterile compounding at any time is not exempt as provided in this subdivision.~~	and fixtures and equipment shall be maintained in a clean and orderly condition." Board staff believe that a pharmacy that is compliant with the provisions in 1714 would also be compliant with the USP 795 Chapter when flavoring.
17	1735.1(i)	FLAVORx	If the intention of the Board is to bring medication flavoring back to California's pharmacies and families, which you've indicated it is, then the language you are considering for approval will not accomplish that. The caveat language in 1735.1 (i), which ties the regulation of flavoring to other	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board noted that federal law and national standards establish the combining of a

			pharmacy activities, is the problem. Tethering flavoring to totally unrelated products or services offered in the pharmacy will prevent pharmacies from reintroducing the service. Why is the sole act of flavoring FDA approved liquid medications being tied to other, totally unrelated activities in the pharmacy? What does producing a Magic Mouthwash solution for a chemotherapy patient have to do with flavoring an amoxicillin prescription for a child with strep throat? Why can't pharmacies that choose to flavor just abide by the provisions in 1735.15 and leave it at that? The Board itself appears confused and confounded by this language as well, as evidenced by comments from Member Sandhu at the January 8 meeting and Chair Oh and Member Crowley at the February 5 meeting. The practical implication of approving the language as is will be to perpetuate the freeze on pharmacies offering flavoring to their customers. The pharmacies I've spoken with would like to start flavoring again AND continue to provide basic non-sterile compounding to their customers. But these same pharmacies have indicated clearly, in both their words and actions, that they cannot and will not have flavoring regulated the same as, for example, preparing Magic Mouthwash. You are forcing this language, which is not in any way beneficial to consumers. If the Board is OK with the exemptions for flavoring that are provided in 1735.15, then it should be OK with them in all cases, independent of what other services the pharmacy provides. Here's the easy fix: "A facility that compounds using flavoring agents combined with a prescribed FDA approved drug in an oral liquid dosage form at the request of a prescriber, patient or patient's agent shall be exempt from the requirements established in subdivision (f) and Sections 1735.2 – 1735.13." Plain. Simple. No caveats. You have made great progress with the exemptions contained in 1735.15. Please don't make it all for naught.	flavoring agent with a prescribed FDA approved drug in an oral liquid dosage form. Further, the Board notes that the FDA and the USP committee made this determination. The Board's approach to establish maximum flexibility through establishing SOP. The Board determined that the provisions related to flavoring have been amended significantly since the formal rulemaking began in response to public comments. In the original version of the proposed regulation text, the Board did not include any exemptions to the Board's regulation requirements.
18	1735.2(c)	K. Scott Guess	How long must this documentation be retained?	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board directs the commenter to proposed

				section 1735.14 to understand records requirements.
19	1735.4(b)	K. Scott Guess	Please define "high quality water". Is any municipal water supply high quality?	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board noted that the comments are outside of the 15-day comment period. The Board also notes that the commenter is not accurately reflecting the proposed text, which reads "Purified water, distilled water, reverse osmosis water, or higher quality water shall be used for rinsing equipment and utensils." Further, the Board previously considered a comment related to water quality and noted the following, <i>"Staff note that USP identifies various grades of water including in Section 4.3 of the Chapter. Staff notes that water quality is important for patient safety."</i>
20	1735.5(a)	K. Scott Guess	The cleaning and sanitizing supplies used are stated in the Policy and Procedure manual. It is unnecessary to record this information daily and only adds to costs without adding to patient safety.	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board noted that the comments are outside of the 15-day comment period. The Board noted that they previously considered similar comments on this issue and provided the following response, <i>"Staff believe that documentation of the cleaning process as described in the proposed language is appropriate and consistent with the actions necessary to maintain and clean compounding environment. Staff note that operationalizing the requirements could be quite simple, including a prepared log that already has the items listed..."</i>
21	1735.6(a)	K. Scott Guess	Compounding is an art form. Techniques, tools, and equipment are subject to being used in new and unique ways to achieve a product that a patient can use/tolerate. From a patient outcomes view, restricting equipment use to manufactures specifications inhibits innovation that can result in good patient outcomes. It is my opinion this section should	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board noted that the comments are outside of the 15-day comment period. Further, the Board noted that it is not appropriate to use

			be eliminated. The sole purpose of compounding is to adopt existing drugs to a specific patients' needs.	equipment for other than its intended purpose and that doing so could compromise public safety. For example, using a food grade blender for chemicals could leach into the compounded preparation.
22	1735.8(a)	K. Scott Guess	Including the dispensing pharmacist as being responsible for the integrity, strength, quality, and labeled strength places undue liability on the dispensing pharmacist who may not have been on duty when the CNSP was compounded; therefor has no process other than the compounding record to base that decision on; a compounding record that was already checked and approved by another licensed pharmacist. The "dispensing pharmacist" should be eliminated, and limited to the pharmacist that made, or signed off on the compound.	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board noted that the comments are outside of the 15-day comment period. The Board noted that, in response to a comment received during 45-day comment period, the proposed text was modified to include the dispensing pharmacist. Further, the language in the proposed text incorporates a change requested by prior comments received during the 45-day comment period. That commenter suggested that the dispensing pharmacist is responsible for the patient label. The Board agreed and accepted the change requested.
23	1735.10(b)(2)	M. Cottman	Recommendation: Remove this section. If you won't remove it, then please consider a rewrite: <i>(b) A CNSP's BUD shall be conservatively assigned when data is not readily available to validate chemical and physical stability or compatibility and degradation with the container-closure system.</i> Comment: USP already addresses what to consider when determining BUDs. I repeat my previous concerns! It is not clear who has the burden of proof that the CNSP is reactive or non-reactive with the container- closure system. This data is rarely readily available (compounder or Board)! Amber bottles, ointment jars, and oral syringe container closures are standard in the field of compounding, but where are the studies for the hundreds of APIs that we use to solve unique patient issues? And again, the testing to provide proof of compatibility is many \$1,000s! Under this proposed rule, when a prescriber identifies a novel drug delivery device for a unique patient experience, compounders will be unable to package the	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board noted that the comments are outside of the 15-day comment period. Further, The Board notes that USP 795 specifies that "a compounder MUST consider parameters that may affect quality, including but not limited to the following...compatibility of the container closure system with the finished preparation (e.g., leachables, interactions, ...)" The Board's reference to the container closure provisions in the section referenced by the commenter is consistent with the provisions of the chapter.

			compound they don't have proof (even if there is good similar data available). If the pharmacist were to apply a conservative 14 day refrigerated BUD, without specific data, they <i>could</i> be in violation of this rule and subject to action against their license. <i>This will limit access to compounds for patients with unique needs!</i>	
24	1735.11(a)(2), 1735.12(b) & (c)	Partnership For Safe Medicines	The Board's proposal to eliminate adverse event reporting requirements (sections 1735.11(a)(2), 1735.12(b), 1735.12(c), and 1736.17(a)(2)) presents severe risks, including: • Delayed Detection of Drug Safety Issues: Without a diminished reporting system, it will take longer to identify harmful trends associated with specific medications. • Reduced Transparency: Patients and healthcare providers will have less access to critical safety data that inform medical decision-making. • Increased Harm from Compounded Medications: The absence of adverse event reporting will make it harder to promptly identify and respond to dangerous medications before widespread harm occurs. A Step Backward in Drug Safety California has historically been a leader in pharmaceutical regulation and patient protection. Removing adverse drug experience review would reverse this progress, making the state an outlier in drug safety oversight. Regulatory bodies, including the FDA and WHO, emphasize the necessity of adverse event monitoring as a fundamental component of a responsible healthcare system. The California Board Of Pharmacy should reject this proposed rule change and reiterate the responsibilities of compounders to have a standard operating procedure that requires mandatory reporting of all adverse events promptly.	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board noted that the comments are outside of the 15-day comment period. The Board's proposed compounding regulations are seeking to establish minimum requirements while relying on pharmacists to use their professional judgment. The Board, as part of its January 8, 2025 meeting, and in response to public comment, determined that removal of the requirement for a pharmacist to review all adverse drug experiences for nonsterile preparations was not necessary to be included in the proposed regulation text but would be a best practice for pharmacists to evaluate for trends with product quality issues where unexpected adverse drug experiences are reported. The Board noted that such action is not required under federal law. Further, the commenter included reference to the compounding of GLP-1s which are sterile compounding preparations. The requirements for sterile compounding preparations are included in Article 4.6.
25	1735.11 and 1735.12	Obesity Action Coalition	Compounded drugs lack the same level of safety, efficacy, and quality assurances of FDA-approved drugs, and compound facilities and pharmacies lack adequate systems for tracking and tracing and reporting adverse events associated with their drugs. OAC strongly recommends reinserting all references to "adverse drug experiences" to ensure that compounding facilities are required to notify the	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board noted that the comments are outside of the 15-day comment period. The Board agreed with the commenters concerns about patient safety and potential risks from

			Board of adverse events involving compounded products. As you know, compounding pharmacies are not required to do surveillance, evaluation, or reporting of adverse events to FDA. It is unacceptable to put the onus on the patient who purchases a compounded drug from a retail pharmacy to report adverse events to the outsourcing compounding facility. How could they, given they have no knowledge or direct connection? The risk of missed adverse events is amplified when compounding facilities partner with telehealth companies and other online vendors that do not conduct adverse event reporting. Requiring adverse event reporting and limiting distribution to products strengthens safety, control of the process, and communication to patients.	compounded preparation. The Board's proposed compounding regulations are seeking to establish minimum requirements while relying on pharmacists to use their professional judgment. As part of its January 8, 2025 meeting, and in response to public comment, the Board determined that the removal of the requirement for a pharmacist to review all adverse drug experiences for nonsterile preparations was not necessary to be included in the proposed regulation text but would be a best practice for pharmacists to evaluate for trends with product quality issues where unexpected adverse drug experiences are reported. The Board noted that such action is not required under federal law. Further,, the commenter included a reference to the compounding of GLP-1s, which are sterile compounding preparations. The requirements for sterile compounding preparations are included in Article 4.6.
26	1735.12(b)	K. Scott Guess	The Board is asking to be inundated with unnecessary paperwork to evaluate. There are many reasons a patient might complain about a compounded product: flavor, texture, dosage form preference, etc. ONLY VALIDATED complaints regarding integrity, strength, and quality should be reported to the board. The board does not to spend time and money investigating complaints of flavors, or texture, or even a complaint about strength IF the pharmacy sends the product in question for testing and the product results are within specifications. Respectfully, the board made this mistake already with the reporting ANY loss of controlled substance found during the controlled substances reconciliation.	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board noted that the comments are outside of the 15-day comment period. The Board noted that nonresident pharmacies are currently required to report such complaints. The proposed regulation text will create parity in reporting for resident pharmacies and provide the Board with the opportunity to evaluate the issue and where necessary conduct an investigation.
27	1735.12(b)	CSHP	The way that this regulation is worded could be misinterpreted. This proposed regulation was discussed by the board during the last board meeting, and it was mentioned that the intent is for complaints that indicate true quality problems be reported	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board noted that the comments are outside of

			to the board. From the way that it is written, the understanding that one could derive from the language is that the board must be notified of all complaints that could potentially indicate a quality problem. For example, a patient given a compounded gel, could complain that from their recollection it appears to have a slightly different opacity from one dispensed previously. Since this could potentially indicate a quality problem, the pharmacist will then report the complaint of a potential quality problem to the board. The pharmacist then investigates and finds that the medication was compounded correctly but the master formula was changed to a different gel base due to a change in manufacturers. One of members reported to CSHP that they started to report all complaints that could indicate a potential complaint to the board. They were instructed by board staff that they should only report it when there was an actual quality problem since they were inundating the board with reports. It shows that there has been confusion with the current regulations. It is important that we use this opportunity to make the language as clear as possible. While all involved currently in the creation and comments may have a grasp and understanding of the intent of this proposed regulation, we must take the multiple comments from all stakeholders as an indicator that there will be future misunderstanding and misinterpretations of this language. It is of the utmost importance to recognize that ten to fifteen years from now these interpretations and intent will be forgotten, and the only guidance left to enforce are the words as written. We are sure that the current board would not want future board members and staff to enforce this rule under the misunderstandings that we and others took great pains to point out at this moment in time. Recommendation: (b) The pharmacy shall report in writing a product quality issue for any compounded product to the board within 96 hours after the pharmacy receives notice of the product quality issue.	the 15-day comment period. The Board did not share the concerns suggested by the commenter about potential overreporting and potential workload impact to Board staff. The proposed regulation text will create parity in reporting for resident pharmacies and provide the Board with the opportunity to evaluate the issue and where necessary conduct an investigation.
28	1735.12(b)	M. Cottman	Recommendation: Amend to clarify. The Board shall be notified in writing within 96 hours of the facility's receipt of a complaint ~~of a~~ <u>determined to be a</u> potential quality problem involving a CNSP.	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board's policy and the proposed regulation

			Comments: Clarifying this wording will prevent unnecessary communications with the Board about complaints NOT related to a compounding <u>quality</u> issue.	text are clear. A PIC is responsible for evaluating the issue consistent with the facility's SOPs. The PICs evaluation and conclusion will determine if the Board is required to be notified.
29	1735.13	M. Cottman	Recommendation: Remove Comments: This statement does not provide anything in addition to USP 795 quoted here: USP 795 13.1 Packaging of CNSPs states: "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 13.2 Transporting of CNSPs "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."	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board noted that the comments are outside of the 15-day comment period. The Board previously considered this comment. The Board respectfully refers the commenter to its prior response in row 25 available here, (https://www.pharmacy.ca.gov/meetings/agendas/2025/25_feb_bd_mat_1735_comments.pdf), that includes "The proposed regulation text ensures the facility establishes specific SOPs for storage, shipping containers and temperature sensitive CNSPs."
30	1735.15(a)	CVS	CVS Health greatly appreciates the collaboration that has led to numerous changes in pending language throughout this promulgation, including 1735.15(b), which allows flavoring without a patient specific prescription. However, the language and methodology used to craft 1735.1(i) and 1735.15(a), which create two pathways for flavoring compliance, causes confusion and is not clear to the regulated community. The first pathway is to follow USP Chapter 795, FDCA section 503a, 1735.1 through 1735.14, and 1735.15(b), which I'll refer to as "pathway A". The second pathway is to follow 1735.14, 1735.15, USP Chapter 795, and FDCA section 503a, however a pharmacy cannot otherwise engage in nonsterile compounding in order to utilize this pathway, which I'll refer to as "pathway B". Although pathway B has been billed as an exception, CVS Health believes that pathway B arguably establishes a greater mandate than just adhering to pathway A, as 1735.15(a)(5) requires a labeling mandate when flavoring while 1735.5 does	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. It appears the commenter is suggesting that the Board promulgate regulations contrary to federal law and national standards. The Board's proposed regulation text provide maximum flexibility to facilities to meet the requirements of the national standards. As cited elsewhere in the requirements, facilities are required to meet operational conditions including for example maintaining facilities as established in CCR 1714.

		not. Otherwise, 1735.1 through 1735.14 largely reiterate USP Chapter 795, and as 1735.15 also requires adherence to USP Chapter 795, it is questionable why pathway B exists. Pathway B would truly be an exception, if adherence to USP 795 was struck from 1735.15(a), as requested below. Since it is unlikely community pharmacies will ease offering patients non-sterile compounding services in lieu of flavoring services exclusively, pathway B is not an option. Community pharmacies are simply highly unlikely to engage in flavoring if adherence to USP Chapter 795 is required. While there are several portions of USP Chapter 795 that we believe are too onerous without benefit to public safety to be applied to the act of flavoring a prescription, I'll offer one example. USP Chapter 795 requires gloves to be worn and the cleaning and sanitizing of the surfaces in the nonsterile compounding area on a regular basis or as specified in the USP. CVS Health's request: pathway B not be tied to abstaining from engaging in nonsterile compounding and for pathway B to not require adherence with USP Chapter 795, as depicted below. Otherwise, community pharmacies will likely not be able to offer California patients flavoring, which deviates from the overwhelming majority of other states. (a) In addition to the standards in USP Chapter 795 and the Food Drug Cosmetic Act (FDCA) section 503a (21U.S.C. 353a) a facility that limits its compounding flavors as described in Section 1735.1 (i) shall establish the following SOPs:	

#	Section	Commenter	Comment	Board Response
1	1736(d)	CMA	CMA remains concerned that the Board's new proposed requirement for pharmacists to "verify" that a compounded drug produces a clinically significant difference for a patient creates an undue burden and restricts the professional judgment the Board intended to preserve. Mandating verification for every instance of compounding a commercially available drug that is not on a shortage list establishes a rigid, prescriptive standard. This contradicts the Board's stated goal of maintaining flexibility, and, as such, the language violates the clarity standard because it conflicts with the Board's description of the effect of the regulations in its formal response to members of the public regarding this issue. Pharmacists are already required to use their professional judgment in dispensing compounded drugs. Eliminating the "verify" requirement from the proposed regulation would not abrogate pharmacists' statutory responsibilities, but would instead maintain the flexibility pharmacists need to practice most effectively. As written, the requirement could be interpreted to mean pharmacists must contact prescribers for verification in all cases where they compound a commercially available drug, leading to unnecessary delays in patient care. As a result, the lack of clarity within this requirement risks limiting access to necessary treatments, particularly in cases where compounded medications are essential alternatives to commercially available drugs. Federal law does not impose a verification or documentation requirement on pharmacists. Instead, the FDA, in non-binding guidance, recognizes documentation of a prescriber's determination as sufficient. The Board's proposal, by contrast, creates a new obligation without clear justification, increasing administrative complexity without improving patient safety.	The Board noted that the comments are outside of the 15-day comment period. The Board also noted that they had previously considered the comment and determined that a change was not appropriate. The Board referred the commenter to the Board's prior response to this comment from this commenter, in row 2, available here (https://www.pharmacy.ca.gov/meetings/agendas/2025/25_feb_bd_mat_1736_comments.pdf), and includes, "Board staff have reviewed the comment and do not recommend a change to the proposed text because modifications in the second modified text addressed it. Staff note that this issue was previously considered by the Board, most recently during the January 8, 2025, Board Meeting. As approved by the Board during that meeting, the second modified text was amended to require a pharmacist to verify that a prescribed medication is clinically appropriate for a patient, irrespective of whether it is a compounding medication. The Board noted that the commenter appears to suggest that a pharmacist does not have an obligation to exercise clinical judgment when compounding or dispensing a medication. The Board determined that it is important to underscore that pharmacists must exercise clinical judgment in all aspects of practice and not simply defer the judgment to another individual. This obligation is memorialized throughout Pharmacy Law, including notably BPC Section 4306.5 and BPC 733. Should it be helpful, the Board referred the commenter to some specific provisions of the law that establish specific requirements for pharmacists to evaluate prescriptions prior to dispensing including as examples: Health and Safety Code section 11153 Title 16, California Code of Regulations Section 1707.3."

2	1736(e)	Eli Lilly	Some of the Board's proposed revisions to the defined term "essentially a copy" are necessary and appropriate to ensure that patients are treated with a compounded drug only when those patients cannot be served by an FDA-approved medicine. The "essentially a copy" ("EAC") prohibition is one of the key legal prohibitions that prevents compounding pharmacies from selling knockoffs of FDA-approved medicines. For it to serve its intended purpose (which is to prevent end runs around the new drug approval requirement in the guise of compounding), the EAC prohibition must be broad and must not be easily evaded. To that end, Lilly offers the following comments. 1. We applaud the Board's proposal to define "essentially a copy" to include any compounded drug "that includes the same active pharmaceutical ingredient(s) (API(s))" as an approved medicine. This broad definition will ensure that the EAC prohibition protects the public health as it was intended by ensuring that compounding pharmacies cannot evade the prohibition through minor or pretextual formulation changes. 2. We also applaud the Board's proposal to limit the exception to the EAC prohibition to situations where the pharmacist has "verified and documented" that the compounded drug will produce a "clinically significant difference" for the specific patient. This verification also is essential to protect the public health and prevent evasion. All too often, providers and pharmacists (often working together pursuant to contracted commercial arrangements) have attempted to evade the EAC prohibition through sham prescriptions and other illicit measures. Requiring the pharmacist to use his or her professional judgment to verify that the compounded drug makes a real change that will be clinically significant will help to ensure that patients receive FDA-approved medicines whenever possible.	The Board thanked the commenter for the information that is in support of the Board's proposed modified text. The Board reviewed the comments and did not recommend any change to the proposed text of the regulation.

			We support the Board's proposed revision as it provides the necessary and appropriate flexibility for pharmacists to use their professional judgment in determining whether a compounded drug is essentially a copy. Contrary to the suggestion by other commenters, exercising that professional judgment does not impinge a prescriber's judgment, but rather preserves the ability for pharmacists to exercise their clinical judgment as well. As the Board has previously observed, federal law requires that the compounded drug produce a significant difference for the patient. The proposed revision makes it clear that the pharmacist must independently verify, and then document, that the compounded drug will indeed produce a clinically significant difference from an FDA-approved medicine for a given patient.	
3	1736(e)	CSHP	We add our voice to others who commented on this section who pointed out their concern with the wording of this section. We appreciate the board's position that the intent is to rely on the professional judgement of the pharmacist. At the same time, we object to the wording of the regulation and wish to point out that this section has the potential to be misinterpreted as written, both currently and in the future. It is important to get this right so that the intent is clear and does not cause confusion. The wording of "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," could be interpreted to mean that ANY compound being made is defined as essentially a copy of a commercially available drug product. The trouble here is that any compounded drug that has the same API as a commercially available drug product will violate this regulation. Using the example of a hospital pharmacy that compounds 10 bags of Oxytocin 30 Units in 500ml Normal Saline for use in their Labor and Delivery (L&D) unit. The Oxytocin bag is made by using three 1ml vials of Oxytocin 10units/1ml. By the definition above, it will be a violation of this proposed regulation since these bags are made in bulk and they include the same API as the commercially available drug product of Oxytocin 1ml. These	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board noted that the comments are outside of the 15-day comment period. The Board noted that the commenter appears to be describing what would be considered sterile compounded preparations. The Board notes that the FDA guidance does not address the practice described by the commenter. The Board's proposed regulation text provides greater flexibility to pharmacists in the healthcare setting where the FDA guidance is silent. The Board also refers the commenter to the provisions included in 1736.1(e)(1)(A) and (B) that provide additional flexibilities for health care facilities.

		bags are made in bulk, so, by definition, it is not being compounded specifically for an identified individual patient that produces for that patient a clinically significant difference. These bags are being used for almost every patient that will have a delivery on the unit, so one cannot argue that it is being made for a specific individual patient. This proposed regulation, if it is read simply for the way it is stated, will imply that the pharmacist verifying the order will need to go through a process of verifying with the prescriber and then documenting each and every order for Oxytocin bags that the change from the commercially available 10 unit per 1ml vial to a compounded 30 unit per 500ml Oxytocin bag produces a clinically significant difference for each individual patient. In the ISOR, the board states that the FDA guidance document is being utilized to provide guidance regarding this definition. It is important to note that the definition taken from the FDA guidance document and used in this proposed regulation, is only one part of three of the definition in the guidance document. Herewith the guidance document section on “Essentially a Copy” for reference: FDA intends to consider a compounded drug product to be essentially a copy of a commercially available drug product if: • the compounded drug product has the same active pharmaceutical ingredient(s) (API) as the commercially available drug product; • the API(s) have the same, similar, or an easily substitutable dosage strength; and • the commercially available drug product can be used by the same route of administration as prescribed for the compounded drug, unless, as provided by section 503A(b)(2), a prescriber determines that there is a change, made for an identified individual patient, which produces, for that patient, a significant difference from the commercially available drug product.	

			The proposed regulation definition crucially leaves out the requirements for a same or similar dosage strength and route. By leaving out these clarifying terms, the definition is now so broad that it is inclusive of every single non-sterile and sterile compound being compounded by a pharmacy in the state of California. From our example above, it is open to interpretation by both the regulated public and board staff of what “essentially a copy” is because it will be everything with the same API. By the proposed definition, since diazepam tablets are commercially available, a pharmacy may not compound a diazepam drip from IV vials since the tablets contain an API that is commercially available (even though it is available in a completely different non-sterile dosage form). According to the definition, a hospital making a batch of oral suspension from tablets on a regular basis for its neonatal or pediatric unit, will be making essentially copies of the API in the tablets and will have to call and verify with the prescriber and then document the self-evident information that the change was made for each and every identified individual patient that produces for that patient a clinically significant difference. We are sure that we can all agree that this is not the intent of the regulation. By adding the crucial elements of strength and route it narrows the definition and it is much clearer and is aligned with both the FDA and board's intent. This addition of language provides clarification while still allowing flexibility for the pharmacist to use professional judgement. By adding the components that aligns with FDA guidance, it becomes clear that it will be the same as federal statute and guidance, and we recommend that this regulation be deleted. While all involved currently in the creation and comments for the definition of “essentially a copy” may have a grasp and understanding of the intent of this proposed regulation, we must take the multiple comments from all stakeholders as an indicator that there will be future misunderstanding and misinterpretations of this language. It is of the utmost importance to recognize that ten to fifteen years from now these interpretations and intent will be forgotten, and the only guidance left to enforce are the words as written. We are sure that the current board would not want future board members	

			and staff to enforce this rule under the misunderstandings that we and others took great pains to point out at this moment in time. Recommendation: (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, the API(s) have the same, similar, or an easily substitutable dosage strength; and the commercially available drug product can be used by the same route of administration as prescribed for the compounded drug 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 verified and documented by the pharmacist, between that compounded preparation and the comparable commercially available drug product.	
4	1736.1	B. Go	The response by the Board that both proposed as well as existing regulations on compounding, as currently worded, do not infringe on the practice of compounding by non-pharmacist licensees under the jurisdiction of other California professional boards, is not satisfactory for the following reasons: 1. You responded with comments from only one board, the Medical Board of California, which only regulates MD's. This does not apply to other licensees such as DO's, nurses, ND's, dentists, and veterinarians, who may also have the right to compound medications in-office without a pharmacist and without interference by the Board of Pharmacy. Furthermore, even the MD's right to compound is still in jeopardy based on current wording of the Board's regulations, for the following reasons: a. The Medical Board's letter noted that only the Medical Board has the right to discipline its licensees. This would only apply if the licensee was being disciplined as an MD, not if they were being disciplined as a person practicing pharmacy without a license. Again as previously stated, the Board of Pharmacy's jurisdiction is to regulate the practice of	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board noted that the comments are outside of the 15-day comment period. The Board has previously considered this and similar comments and provided responses throughout the rulemaking, including for example the response provided in row 5 available here, (https://www.pharmacy.ca.gov/meetings/agendas/2025/25_feb_bd_mat_1736_comments.pdf), which included in part," Board staff have reviewed the comment and do not recommend a change to the proposed text based on the comment. Board staff note that the Board previously considered this comment, most recently during the January 8, 2025, Board Meeting and determined that the requested change is not appropriate. As was previously shared, staff note the Board only has jurisdiction over individuals and businesses within its practice act. Board staff read the comment as suggesting that the Board's proposed regulations would apply to a

		pharmacy, and therefore practicing pharmacy without a license would fall within their purview. Both currently existing regulations as well as the proposed changes exclude non-pharmacists from being able to compound, specifically defining the practice of compounding as that which occurs by a pharmacist ONLY. (See proposed regulation 1736.1a (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." And see currently existing regulation: CCR 1735(a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist") b): The Medical Board's letter notes: "It is certainly possible that whatever regulations that are implemented by the Board of Pharmacy may influence the standard of care for physicians who are compounding." - they admit that your regulations may affect MD's practice of compounding. I'm not sure why you have so much resistance to adding wording which would only help to clarify the limitations of your role, and would limit the confusion and ambiguity which the current wording is creating. Instead, you have specifically chosen to include wording which is overly broad, and which implies that compounding only may be performed by a pharmacist. 2. You claim that regulations specifically state you cannot regulate other practitioners 3. Furthermore, you have not directly responded to previous comments that noted the contradiction between your stance on the above and the fact that you are currently making preparations to attempt to regulate what you refer to as 'IV hydration clinics'. These clinics do not have pharmacists, however they do have other non-pharmacist licensees who have the right to compound. The term 'IV hydration clinic' itself	<i>physician. Business and Professions Code section 4170(c) makes clear that the Medical Board of California is specifically charged with the enforcement of Pharmacy Law (Chapter 9, Division 2 of the Business and Profession Code) with respect to its licensees."</i> The Board refers the commenter to Business and Professions Code section 4170 as well as the Board's jurisdiction. The Board respectfully recommends that the commenter review the Board's Initial Statement of Reason that describes the Board's jurisdiction to gain a better understanding of the applicability of the Board's regulations. The commenter also appears to be providing comments about a statutory proposal related to the regulation if IV hydration clinics which is outside the scope of this regulation. The Board referred the commenter to the Board's proposed statutory proposal for an understanding of the Board's legislative proposal. The Board also noted that the language in the statutory proposal includes explicit language that it would not apply to a facility for which a professional director is on site while sterile compounding occurs.

			is not well-defined by the board, and it is foreseeable that the board could choose to include any medical office that provides IV hydration or IV nutrients in this category, offices in which compounding might be conducted by any of a variety of types of licensed non-pharmacist practitioners who should not be under the purview of the Board if it were not for the current language in your regulations. Therefore, the claim that your compounding regulations do not or will not interfere with compounding by non-pharmacist licensees in disingenuous. Please do note and respond to this paragraph in full in your reply as well.'	
5	1736.1(b)	Kaiser	In their response to our January 24, 2025 comment letter, Board staff intimated that Kaiser Permanente was speculating about the likely second-order effects of this proposed regulation.³ The Board can call these comments speculation if it wishes, but we contend that we are engaging in deductive reasoning to assess the incentives and behaviors that the proposed regulations are likely to precipitate—something we assume the entire Board should do throughout any rulemaking process. Even if the Board is not interested in critically evaluating these proposed regulations for likely second-order effects, as a responsible pharmacy stakeholder, Kaiser Permanente will continue to highlight the probable unintended consequences of these unnecessary regulations. In the case of this proposed regulation, if there are additional restrictions placed on pharmacy licensees engaging in immediate use compounding, it would naturally follow that some entities would choose to have non-pharmacy personnel take over immediate use compounding to avoid the burden of meeting the Board's regulations. As such, if the Board's desired outcome is that non-pharmacy personnel are more frequently engaged in compounding sterile products for Californians, then we believe that the Board has written a regulations that will achieve that result. If, instead, it is the Board's intent to incentivize immediate use compounding by pharmacy personnel who complete extensive training and competency validation and are subject to the Board's oversight, then we strongly encourage the Board to delete this proposed regulation and enforce the USP standards for immediate use compounding.	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board noted that the comments are outside of the 15-day comment period. The Board has previously considered this and similar comments and provided responses throughout the rulemaking, including for example the response provided in row 7 available here, (https://www.pharmacy.ca.gov/meetings/agendas/2025/25_feb_bd_mat_1736_comments.pdf), which included in part," "Board staff have reviewed the comment and do not recommend a change to the proposed text based on the comment received. Board staff note that the proposed regulation text provides significant flexibilities beyond what is currently allowed in existing regulations. Board staff disagree with the assertion that the Board's regulations in this area will shift compounding to non-pharmacy personnel. Also noted is that the commenter appears to be speculating about business operation decisions that could be made that would make compliance less safe. The Board is not able to respond to speculation on business operation decisions outside of its purview. As stated elsewhere by the Board in this rulemaking, the Board's jurisdiction is limited to the licensees within its practice act. For commenters interested in understanding the requirements for nonpharmacy personnel compounding and the requirements for

				<i>those individuals and entities, it would be appropriate to contact the respective regulatory agencies."</i> The Board noted that various nonpharmacy personnel, including physicians and veterinarians, have the authority to compound. Such individuals must comply with the requirements of their regulatory agencies. Further, as a reminder, current provisions of the law related to immediate-use compounding are more restrictive than the proposed regulation text. Board staff routinely inspect facilities and report that even under the current more restrictive conditions, pharmacy personnel continue to compound.
6	1736.1(b)	CSHP	We would like to continue our objections to this proposed regulation for the reasons that we and others have pointed out both in writing and written comments up to this point. As stated before, we object to the proposed regulation since it would severely limit pharmacies' ability to utilize the immediate-use provision to only those limited situations where the failure to administer such CSP could result in loss of life or intense suffering of an identifiable patient. This continues to narrow the scope of application of the immediate use provisions of USP to a point where it is practically unusable. We and others continue to point out the unintended consequences that this rule has been responsible for in the past, such as shifting compounding to disciplines that do not fall under the jurisdiction of the board. We are concerned that the board's response to stated concerns negates the complexity of health system operations by implying our practices are inefficient and potentially inaccurate. . The Board's responses, at times, fails to provide evidence for the continued support of the proposed regulations that have been identified by the regulated entities as potentially harmful to the patients we serve. We object to the proposed regulation for the reason that the regulation lacks clarity regarding the reporting expectations. It is not clear if a pharmacy must report each and every use of equipment failure and its associated utilization of immediate use compounding. During a conference with multiple	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board noted that the comments are outside of the 15-day comment period. The Board has previously considered this and similar comments and provided responses throughout the rulemaking, including for example the response provided in row 6 available here, (https://www.pharmacy.ca.gov/meetings/agendas/2025/25_feb_bd_mat_1736_comments.pdf), "Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that the Board is not banning provisions for immediate use compounding. Board staff considered this issue most recently during its November 5-6, 2024, Board meeting and made significant changes to the language in previously noticed modified text to increase flexibility for licensees, including adding specific provisions for rural hospitals. Board staff note that the proposed regulation text could reduce costs that may be currently experienced stemming from the current limited provisions for immediate use compounding that exist in the Board's current regulatory provisions. The additional flexibilities being proposed in the second modified text could therefore

		pharmacy compounding leaders from all across the state, this regulation was discussed and it became quickly apparent that there were different interpretations of the reporting requirement. Some thought that they would only have to report to the board if their equipment failure lasts past 48 hours. While others thought they should report every single equipment failure and immediate use utilization. Some were also wondering about scenarios that come up regularly for many pharmacies. For example, if a cleanroom pressure is out of specification and staff stop compounding while waiting for it to either self-correct or call engineering staff to fix. While it is being fixed, there is an order for an IV that must be started within an hour. The pharmacist makes it under the proposed immediate use allowance and shortly thereafter the cleanroom pressure is within normal limits. Is the expectation that this be reported? The next day, engineering has a scheduled HVAC maintenance. While they are working on the HVAC, an immediate use IV is being made. Is this then reportable again to the board? Is the board prepared to start receiving these regular reports from hospitals all over the state? Is this the intended consequence? We recommend that the board clarify their expectations via regulations for clarity to the regulated public. The board's proposal for immediate use in instances where there may be equipment and engineering control failures is inadequate. It does not account for both catastrophic failures of the equipment and environment or for catastrophes like natural disasters. We once more reiterate our stance that the additional allowance for critical access hospitals only addresses the problem partially. We object to this partial addressing of this problem and again recommend that the board recognize that there are many rural hospitals that are not designated as critical access hospitals. These hospitals can run into the exact same problems with equipment and engineering controls as critical access hospitals with equally devastating consequences. There are even standalone, single owner hospitals in metropolitan areas without the benefit of belonging to a health system that can be impacted. While we highly recommend that subsection (b) be changed to our recommendation below under the bolded heading of	<i>reduce costs where such provisions for immediate use do not currently exist. A review of the public record of the 2023 minutes from the various meetings during which the regulations were developed demonstrate that public comment raised this issue of costs during a single meeting specifically related to the costs of preparation mats. Since that time the Board has responded to comments throughout the rulemaking process and modified regulation text to address some of the specific cost concerns raised where patient safety would not be impacted. Staff also note that requirements of federal law, state law, and the Chapter may all have associated costs. As an example, the Chapter describes tests that must be used, SOPs that must be developed, reviewed, etc. These are examples of costs to comply with the Chapter's requirements. Compounding facilities have a variety of practice settings and perform a variety of different types of compounding. Organizations may choose to standardize some operations across licenses operating under common ownership or control while others may not."</i> The Board's prior response remains appropriate to respond to a portion of the comment. Further, the Board did not agree with the recommendation to expand provisions specifically related to critical access hospitals to additional hospitals as proposed. The current proposed regulation text provides flexibilities for critical access hospitals that experience unique challenges. The Board again note that the proposed regulation text expands current provisions for immediate use compounding. Further, the commenter's second recommendation to generally expand immediate use provisions to address an immediate patient need exceed the provisions of USP 797.

		'Recommendation", absent an acceptance of this recommendation, we recommend that the allowances of subsection (3) be changed to: 3) If the sterile compounding equipment or environment fail(s) to meet any required specification in a ~~critical access hospital~~ that are not within 40 road miles of a hospital of the same corporate ownership, as defined in the Social Security Act 42 U.S.C. 1395i-4 section (c)(2)(B), after attempts to remediate pursuant to the facility's SOPs are unsuccessful, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering or an identifiable patient. This provision may be used for 120 hours after such failure(s). All such failures shall be documented in accordance with facility's SOPs and shall be reported to the Board within 72 hours. To continue with the proposed requirement, in essence, means California pharmacists will be the only licensed professionals banned from utilizing the USP immediate-use allowance. We object to the requirement for reporting immediate use to the board. As stated on multiple occasions by us and others during the rulemaking process, we once more reiterate our position that the newly proposed requirement to report each instance of immediate use compounding associated with a temporary engineering control malfunction will place a burden on both pharmacy personnel and board staff. The benefit of reporting each minor malfunction to the board is questionable and it is difficult to see how reporting to the board a temporary operational decision to utilize immediate-use compounding to care for patients while an issue is addressed with engineering controls will add value and enhance the safety of the public. Reporting of issues to regulatory agencies are usually reserved for serious matters and only those issues that are within the regulatory agency's' jurisdiction to act. It must be pointed out that immediate use compounding is an allowable action under USP797 standards, it is utilized routinely, regularly and safely in healthcare practice settings worldwide. Performing a simple and safe immediate-use compound for a patient by a pharmacy licensee while an engineering control malfunction is being	Although the Board believed the language was clear, submission of the comment suggests otherwise. The Board made the following changes for clarity. <u>1736.1(2) If the sterile compounding equipment or environment fail(s) to meet any required specification, after attempts to remediate pursuant to the facility's SOPs are unsuccessful, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering of an identifiable patient. This provision may only be used for ~~24 48~~ hours after such failure(s). All such failures must be documented in accordance with facility's SOP, and Failures requiring use of immediate use provisions shall be reported to the ~~BOP Board~~ within 72 hours of the transition to immediate use provisions.</u> <u>(3) If the sterile compounding equipment or environment fail(s) to meet any required specification in a critical access hospital, as defined in the Social Security Act 42 U.S.C. 1395i-4 section (c)(2)(B), after attempts to remediate pursuant to the facility's SOPs are unsuccessful, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering ~~or of an identifiable patient~~. This provision may be used for 120 hours after such failure(s). All such failures shall be documented in accordance with facility's SOPs, and Failures requiring use of immediate use provisions shall be reported to the Board within 72 hours of the transition to immediate use provisions.</u>

		addressed is not serious enough to warrant a report to the board. There is a possible unintended consequence of entities shifting this simple temporary task to disciplines functioning outside the scope of these regulations and the jurisdiction of the Board. Requiring reporting of each instance of compounding of an immediate-use CSP will lead to increased administrative requirements, increased personnel needs, and will have the unintended consequence of potentially diverting resources from patient care activities or worse patients will be unable to access compounded medications due to onerous requirements and fear of inability to comply. We recommend that this requirement be deleted. It is concerning that other than stating that "this is existing language at section 1751.8(e)..." there are no reasons provided in the ISOR for the requirement that CSPs used for immediate administration be limited to situations where the failure to administer could result in loss of life or intense suffering. This requirement was created based on the old USP standards when there was limited understanding of the applicable microbiological principles and the wide clinical barriers it creates as it relates to immediate use. It is important that the board consider the negative impact on patient care that this antiquated rule creates. Since the ISOR does not address the objective and scientific reasons for the limitation on immediate use, we recommend that the regulation be deleted. The expectation of an emergency plan to provide compounding services when the hospital's sterile compounding operations are down are ideal and hospitals are required by federal regulations to have emergency plans. However, the regulations are implying the hospital must have a backup cleanroom. This is a multi-million dollar investment which is not possible for most hospitals and especially for rural and stand alone hospitals. . The impact of the proposed regulations will have significant impact on hospitals financial solvency with unintended consequences to patient care. Elimination of low complexity immediate use provision creates additional hurdles to acquiring the medication that might be insurmountable and therefore jeopardize patient safety. We wish to provide the following realistic example: when a rural	

		non-critical access hospital pharmacy has a sterile compounding airflow hood malfunction, and the replacement hood must be ordered and shipped, they can use immediate use compounding for two days. After this they must stop compounding. What is a pharmacy supposed to do then? Think about it, a licensee has the drugs in their hands, but they cannot go through the simple process of mixing it together in a few seconds to treat a patient. . In the absence of a workable solution, we recommend that the immediate use regulation be deleted. We object to the boards business impact numbers. The immediate use regulation alone will cause a loss in income totaling millions of dollars if a hospital must close their doors and ship patients out to a hospital with a working cleanroom. The Board failed to capture the economic impact to health systems in their ISOR. The board's response to the question of "Business Impact" in ISOR states; "the board anticipates minimal ongoing costs ranging from approximately \$5,700 to \$15,000 per year related to administrative and maintenance workload." This statement applies to the multiple proposed regulations requiring the addition of new administrative procedures, reporting requirements, and enhanced testing. The amount stated is a gross underestimation of the true cost to health systems. Understandably the Board lacks the internal expertise to accurately reflect those anticipated costs associated with development of policies and procedures, monitoring implementation of those procedures, correctly reporting to the Board as proposed by this regulation and others, cost of monitoring visits by the Board, enhanced environmental and personnel testing requirements, purchase of additional inventory for PPE, implementation of technology to support the deployment of the policies and procedures and hiring of additional staff to support compliance with the proposed regulation. The Board further states in the ISOR under the header of "Business Impact" as it relates to the issue of cost the following: "This initial determination is based on the absence of testimony to that effect during the public discussion and development of the proposed regulation." The public meetings mandate testimony be limited to a few minutes and	

		attendees tend to focus their input on the specific wording of the proposed regulation and not the cost. It is incumbent on the Board to actively pursue input from those that can accurately project the cost to health system of the proposed regulation. The Board should, during public meetings, or by other means seek input from experts who can inform the Board's ISOR development as it relates to both "Business Impact" and Economic Impact Assessment" to ensure the ISOR is an accurate reflection of the impact to health systems on cost and health care access. We wish to further point out that the board has not responded to our comments regarding the economic impact of this proposed rule since they have not approached senior health system leaders who are best situated to assess and assist them with economic impact of this rule. Neither has the board shared their assessment of how this rule will increase their cost of enforcement of the proposed rule. USP 797 provides sufficient guidance in their improved and updated standards for immediate-use compounding, and we once more recommend that the board to require USP's standards and not engage in additional regulations that are not based on an articulated and proven evidence that such proposed regulations will enhance patient safety efforts beyond the national standards. We appreciate the complexities of regulating sterile compounding across the diversity of health system procedures and processes and we would like to invite board members and staff to consider doing site visits to gain a greater appreciation for how health systems promote patient safety and quality of compounded drug preparations. We would be happy to set up those site visits with our members. We agree that the routine utilization of immediate use in a hospital is an inappropriate practice. CSHP and our members have the same goals for patient safety as the board. It is unfortunate that some have engaged in this practice and now the many law-abiding facilities and pharmacy licensees must suffer the consequences. To account for the unfortunate choices of the few, whilst not punishing the majority we would recommend a more measured approach by limiting the time that an immediate use sterile compound can be used for up	

			to 12 hours maximum from the time that compounding starts. This way the concerns for patient safety is addressed while it is also not so restrictive to the vast majority of ethical and law-abiding licensees. It also has the added benefit that it will not lock both licensees and board staff in a burden of reporting and administrative duties. Additionally, this problem does not have to be solved with multiple layers of regulation that attempts to solve for endless 'what-if' scenarios. As we have taken pains to point out in the aforementioned, these regulations will be creating insurmountable obstacles to patient care, which could in practice only be overcome by licensees making immediate use sterile compounds which would be a violation of the regulations if enacted. Please see our recommendation below. Recommendation: Remove the requirement limiting the use of immediate-use CSP's to situations where failure to administer could result in loss of life or intense suffering due to this being deleted from the new USP 797 standards and the profound negative impact on patients. This will subsequently remove the need for reporting to the board. Recommended Text: (b) CSPs for direct and immediate administration shall only be compounded in such quantity as is necessary to meet the immediate need of the patient. A compound made for immediate use shall have a maximum beyond use date of 4 hours and shall expire after 12 hours.	
7	1736.1(b) (2)	Sutter Health	Clarify the highlighted requirement for reporting to the Board within 72 hours. Does the Board intend for licensees to report all failures that result in using the provision for immediate use, or all sterile compounding equipment or environment failures that do not meet any required specification, regardless of whether immediate use CSPs are compounded? Please clarify the reporting expectation with clear language. While larger facilities may have alternative compounding locations, as discussed during the Board Committee's discussion of this allowance, onsite compounding with shorter beyond-use dates for immediate use is much preferred over offsite compounding and shipment. There is no determination	The Board reviewed the comment and determined it was appropriate to establish specific provisions for critical access hospitals in response to previously submitted comments. It is important to note that the provisions for such hospitals is allowed for five days (as opposed to 10 days as suggested by the commenter.) The Board noted that the proposed regulation text requires failures to be reported to the Board where the transition to immediate use provisions is necessary. Although the Board believed the language was clear, the submission of the comment suggests otherwise. The Board made the following changes.

			that critical access designation should allow for 10 days, while other facilities can also require this reasonable time to mitigate a major failure appropriately by implementing a robust, pharmacy-driven immediate use program and reporting to the Board. Please do not create differing standards for critical access versus other health care facilities when, across the nation and within all other non-pharmacy care settings, immediate use is an allowable federal standard of practice with aseptic training and documented competency. The goal of the immediate use provision is to ensure patient access with a higher standard of care. If you keep a differing standard, provide for allowance to all hospitals without an alternative or secondary compounding area onsite.	<u>(1736.1(2) If the sterile compounding equipment or environment fail(s) to meet any required specification, after attempts to remediate pursuant to the facility's SOPs are unsuccessful, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering of an identifiable patient. This provision may only be used for 24 48 hours after such failure(s). All such failures must be documented in accordance with facility's SOP, and Failures requiring use of immediate use provisions shall be reported to the BOP Board within 72 hours of the transition to immediate use provisions.</u> <u>(3) If the sterile compounding equipment or environment fail(s) to meet any required specification in a critical access hospital, as defined in the Social Security Act 42 U.S.C. 1395i-4 section (c)(2)(B), after attempts to remediate pursuant to the facility's SOPs are unsuccessful, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering or of an identifiable patient. This provision may be used for 120 hours after such failure(s). All such failures shall be documented in accordance with facility's SOPs, and Failures requiring use of immediate use provisions shall be reported to the Board within 72 hours of the transition to immediate use provisions.</u>
8	1736.1(e)	CSHP	The FDA does not classify repackaging or admixing a commercially available product according to its package insert as compounding activities. Consequently, section 1736.1 (e)'s prohibition on compounding a copy or essentially a copy does not apply to these activities. There should be the ability for facilities that repackage Category 3 CSP's. The products are repackaged under sterile conditions while adhering to stringent sterility standards and they also perform container closure potency studies that exceed basic requirements. These facilities minimize contamination risks through advanced testing protocols and high-quality control, offering enhanced safety and efficacy for sterile preparations. For	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board noted that the recommendation offered by the commenter would run contrary to USP 797 provisions which provides, "Sterile compounding is defined as combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance to create a sterile preparation." The Board believed it may be helpful for the commenter to also consider the provisions of the FDA

			example repackaging from sterile manufactured vials into syringes that contain doses that are ready to be administered safely without further manipulation. Add the following language: (D) the drug is a sterile product, repackaged or admixed in a centralized hospital repackaging facility in a USP Category 3 compliant facility, and those sterile products are only used within that health system at that health system's acute care facilities.	guidance document, "Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities" available here. (https://www.fda.gov/media/90978/download)
9	1736.1(e)(1)	Novo Nordisk	We recommend that the Board amend Section 1736.1(e)(1) to state only the prohibition on compounding of "essentially a copy of one or more commercially available drug products," as defined at Section 17736(e), for the same reasons as described above in our comments on Section 1735.1(e)(1) of the nonsterile compounding regulations. In doing so, we ask that the Board reconsider the positions stated in the Staff Responses to NNI's comments to the Second Modified Text. The shortage provisions in the Third Modified Text are inconsistent with federal law and policy and are overly permissive such that they would pose risks to patient safety and the public health. Here again, the Staff Response to NNI's prior comments does not defend the reference to the ASHP list, which is inconsistent with FDA's 503A Copies Guidance. For the same reasons as explained above, to best protect patient safety and the public health, and to avoid undermining a key check on compounding of unapproved drug products, we also ask the Board to remove, or at the very least significantly narrow, the broad permission for health care facilities to compound copies. Again, these provisions are inconsistent with FDA's 503A Copies Guidance and are not supported by FDA's 503A Hospital and Health System Compounding Draft Guidance, as described above. Recommended language revision: "(e) In addition to prohibitions and requirements for compounding established in federal law, no CSP shall be prepared that: (1) Is essentially a copy of one or more commercially available drug products, as defined at Section 1736(e) of this article. Documentation by the pharmacist that the compounded drug product produces a clinically significant difference for	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board has previously considered this comment and refers the commenter to the Board's prior response included in row 10, available here (https://www.pharmacy.ca.gov/meetings/agendas/2025/25_feb_bd_mat_1736_comments.pdf), which includes in part, "Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that the Board's provisions specifically related to the comment provide additional flexibilities for health care facilities licensed pursuant to Health and Safety Code 1250 (which includes hospitals) is consistent with the FDA guidance document that acknowledges that the FDA is considering the applicability of its policies described in the guidance document to hospitals and health systems. As the FDA has not released this separate guidance, the Board believes its approach is consistent with the intent of federal law while ensuring hospitals have additional flexibility to take care of patients."

			the medical need of an identified individual patient, as provided for at Section 1736(e) of this Article, must be maintained in a readily retrievable format."	
10	1736.1(e)(1)	Partnership For Safe Medicines	The board's proposal to expand the list of medicines that can be compounded beyond medicines on the FDA shortage list (section 1736.1(e)(1)) raises serious concerns about patient safety and the integrity of the pharmaceutical supply chain: Concerns About the Expansion of Rules on Compounded Medications 1. The FDA Should Be the Sole Authority on Drug Shortages o The FDA drug shortage list is compiled based on rigorous criteria and is overseen by experts responsible for ensuring medication safety and efficacy. o Unlike the FDA, ASHP is a respected trade organization but is not a regulatory body. Including its shortage list in determining which drugs may be compounded undermines the authority of the FDA and risks inconsistent or overly broad application of compounding exceptions. 2. Compounded Medications Carry Greater Risks o Compounded drugs are not FDA-approved, meaning they do not undergo the same stringent review process for safety, efficacy, and quality. o Expanding the eligibility for compounding beyond the FDA shortage list increases the likelihood that patients will receive medications with varying potency, sterility, and consistency issues. 3. The "Cannot Obtain from Manufacturer or Wholesaler" Standard Is Vague and Problematic o The proposed rule change introduces a broad standard that could be exploited to justify compounding for economic or convenience reasons rather than genuine medical necessity. o Without clear, enforceable definitions, healthcare facilities and compounding pharmacies may interpret the rule differently, leading to unnecessary compounding when FDA-approved alternatives are still available. 4. Undermining the Drug Supply Chain Security Act (DSCSA) o The DSCSA was enacted to ensure the traceability of	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board has previously considered similar comments. The Board's prior response remains appropriate in response to comments 1 and 3, that included in part, <i>"Staff note that the Board's provisions specifically related to the comment provide additional flexibilities for health care facilities licensed pursuant to Health and Safety Code 1250 (which include hospitals), is consistent with the FDA's guidance document that acknowledges that the FDA is considering the applicability of its policies described in the guidance document to hospitals and health systems. As the FDA has not released this separate guidance, the Board believes its approach is consistent with the intent of federal law while ensuring hospitals have additional flexibility to take care of patients."</i> The Board respectfully referred the commenter to the Modified Initial Statement of Reasons that includes the referenced FDA Guidance Document, Compounded Drug Products that Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act. Specifically related to comment 2, the Board agrees that compounded medications carry greater risks. The Board's compounding regulations are intended to address the risks to patients by generally clarifying and making more specific federal requirements including guidance documents and provisions in national standards. Related to comment 4, the Board agrees that compounded products are exempt from the DCSCA

		medications and reduce counterfeit drug risks. However, compounded drugs are exempt from its serialization requirements. o Expanding compounding eligibility increases the presence of untraceable medications, posing additional risks of counterfeiting, contamination, and supply chain vulnerabilities. o Today using the NABP's Pulse product, you can instantly scan a branded or generic pharmaceutical product and confirm it is real or not. In fact this tool was just used in Arkansas to detect a unit of counterfeit Ozempic. This is not possible to do with a compounded product, as these are not serialized. As compounding has grown from a pharmacist compounding a product and handing it to a patient to what it is today, the danger of the lack of traceability has grown as well. 5. The determination of medical need for a compounded medication should involve the prescribing practitioner o The proposal to remove the tripartite requirement that the prescribing practitioner, the compounding pharmacist, and the dispensing pharmacist all agree that compounding this product is based on medical need is a step back. It does not seem wise to cut the prescribing physician out of the decision-making of patient care here, and we oppose this. Shortages in the GLP-1 space have created significant patient safety issues that the FDA has repeatedly warned both patients and healthcare professionals about, including but not limited to: • Lax labeling standards leading to dangerous dosing problems; • Substantiated concerns about compounders using unapproved ingredients; and • Warnings to compounders about sterility issues. Conclusion Adverse event reporting is a vital patient safety tool that saves lives. The proposed rule changes jeopardize the well-being of Californians and weakens the integrity of the pharmaceutical	provisions. This is federal law and exceeds the scope of the Board's authority to regulate provisions of the DCSCA as the Board's requirements for e-pedigree were preempted by federal law. Finally, related to a determination of medical need (comment 5), the Board agrees that federal law requires a determination by a medical provider. As the Board does not regulate prescribers, the requirement was removed from the proposed regulation text. The authorized healing arts board responsible for oversight of the prescriber would be responsible for evaluating for compliance with the medical need determination established in federal law. The Board appreciates the concerns raised by the commenter and recognizes that the FDA has a significant role in the regulation of GLP-1s. This responsibility was underscored in a recent joint letter from the National Association of Attorneys General, dated February 19, 2025. The Board continues to monitor information released from the FDA related to these products including conditions of insanitary conditions. The Board assesses for insanitary conditions for all compounding practices, not just those related to GLP-1s.

			supply chain. Furthermore, the inclusion of ASHP's drug shortage list weakens patient protections by introducing a non-regulatory decision-making process into compounding rules. We strongly urge the California State Board of Pharmacy to reject this dangerous proposal and uphold its commitment to protecting public health.	
11	1736.1(e)(1)	Pacific Research Institute	The Board is considering regulations that would eliminate the necessity for pharmacists to review and report adverse drug experiences to the Board for compounded drugs. Further, the rule seeks to broaden the circumstances under which drugs can be compounded during a shortage. Specifically, the Board's proposed regulations would permit compounding of copies when a drug product appears on the American Society of Health System Pharmacists (ASHP) list, and when a health care facility "cannot obtain" a drug from the manufacturer or wholesaler. These modifications are ill-advised as they will raise serious patient safety concerns. Unlike sponsors of FDA-approved medications, which are subject to extensive postmarketing reporting of adverse drug experiences, compounding pharmacies do not engage in surveillance or evaluation and are already subject to less stringent adverse event reporting requirements. As the Food and Drug Administration notes, "compounded drugs should only be used in patients whose medical needs cannot be met by an FDA-approved drug. Unnecessary use of compounded drugs may expose patients to potentially serious health risks. For example, poor compounding practices can result in serious drug quality problems, such as contamination of a drug that contains too much or too little active ingredient. This can lead to serious patient injury and death." The safety concerns that have arisen with respect to compounded GLP-1 drugs (the brand name drugs of Ozempic, Wegovy, Mounjaro and Zepbound) validate the FDA's concerns and exemplify the potential adverse consequences that will likely arise from these proposed changes. In response to the unprecedented demand for GLP-1 medications, compounding facilities are mass-marketing unsafe and unapproved compounded semaglutide products	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board has previously considered similar comments. The Board's prior response remains appropriate in response to comments 1 and 3, that included in part, <i>"Staff note that the Board's provisions specifically related to the comment provide additional flexibilities for health care facilities licensed pursuant to Health and Safety Code 1250 (which include hospitals), is consistent with the FDA's guidance document that acknowledges that the FDA is considering the applicability of its policies described in the guidance document to hospitals and health systems. As the FDA has not released this separate guidance, the Board believes its approach is consistent with the intent of federal law while ensuring hospitals have additional flexibility to take care of patients."</i> The Board respectfully referred the commenter to the Modified Initial Statement of Reasons that includes the referenced FDA Guidance Document, Compounded Drug Products that Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act. The Board noted that current law, Business and Professions Code section 4127.1 established mandatory reporting requirements to the board including adverse effected report or potentially attributable to a pharmacy's sterile drug product. This section also requires reporting to the MedWatch program. The Board shares the patient safety

		to patients, thereby increasing the risks of unreported adverse events. Due to the proliferation of compounded GLP-1s in Illinois, for example, the state's attorney general issued a consumer alert warning patients "to be aware that many sellers advertising these name brand medications are instead offering unapproved versions of these products that may put people's health at risk." In South Carolina the state's attorney general issued a consumer alert warning that "unapproved and compounded products can be risky for consumers because they are not reviewed by FDA for safety, quality, or effectiveness." It further notes that "many unscrupulous sellers are making misleading health claims and promoting unapproved and compounded tirzepatide and semaglutide products in formulations that have never been evaluated by any regulatory agency and may never have been tested in humans at all." In support of the AGs' concerns, the FDA's Adverse Event Reporting System (FAERS) database reports 695 cases of adverse events associated with compounded semaglutide. Of those cases, 506 were classified as serious adverse events, 159 reported hospitalization, and 13 involved deaths. These rates are more than triple the number of adverse events for all compounded drugs in 2022. Unfortunately, the actual harm could be much worse. According to the FDA "it is likely that adverse events from compounded versions of these drugs are underreported" because compounding pharmacies are not required to report adverse events to FDA. Many more patients may have already experienced serious harm associated with compounded semaglutide. As a result of these adverse events, the FDA has issued risk alerts concerning compounded semaglutide and tirzepatide. The FDA further noted that some of these reports and hospitalizations may relate to dosing errors of compounded GLP-1s, including several patients who mistakenly administered five to 20 times more than the intended dose of compounded semaglutide. The experience with GLP-1s	concerns raised by the commenter and believes the current statutory requirements remain appropriate.

			argues for increasing, not decreasing, the reporting requirements for adverse events associated with compounding medicines. It also argues for stricter controls over their use. Conclusion The broad exceptions that the Board of Pharmacy are considering are inconsistent with federal law and could lead to compounding of unapproved drug products when the FDA-approved drugs are available to meet the patients' needs. Consequently, it is important that the Board retain and re-incorporate a reference to adverse drug experiences within the Standard Operating Procedures (SOPs) for compounders. This will ensure that pharmacists are responsible for reviewing complaints related to potential quality issues and adverse events. It is equally essential that Board mandate compounding facilities to report adverse events associated with sterile and nonsterile compounded products by reinstating the clause pertaining to adverse drug experiences	
12	1736.1(e)(1)(B)	CMA	CMA remains concerned that the Board's new proposed requirement for pharmacists to "verify" that a compounded drug produces a clinically significant difference for a patient creates an undue burden and restricts the professional judgment the Board intended to preserve. Mandating verification for every instance of compounding a commercially available drug that is not on a shortage list establishes a rigid, prescriptive standard. This contradicts the Board's stated goal of maintaining flexibility, and, as such, the language violates the clarity standard because it conflicts with the Board's description of the effect of the regulations in its formal response to members of the public regarding this issue. Pharmacists are already required to use their professional judgment in dispensing compounded drugs. Eliminating the "verify" requirement from the proposed regulation would not abrogate pharmacists' statutory responsibilities, but would instead maintain the flexibility pharmacists need to practice most effectively. As written, the requirement could be interpreted to mean pharmacists must contact prescribers for	The Board notes that the comments are outside of the 15-day comment period. The Board also noted that this comment was previously considered and determined that a change was not appropriate. The Board refers the commenter to the Board's prior response to this comment included in row 11, available here (https://www.pharmacy.ca.gov/meetings/agendas/2025/25_feb_bd_mat_1736_comments.pdf), which includes, "Board staff have reviewed the comment and do not recommend a change to the proposed text because modifications in the second modified text addressed it. This issue was previously considered by the Board, most recently during the January 8, 2025, Board Meeting. As approved by the Board during that meeting, the second modified text requires a pharmacist to verify that a prescribed medication is clinically appropriate for a patient, irrespective of whether it is a compounding medication.

			verification in all cases where they compound a commercially available drug, leading to unnecessary delays in patient care. As a result, the lack of clarity within this requirement risks limiting access to necessary treatments, particularly in cases where compounded medications are essential alternatives to commercially available drugs. Federal law does not impose a verification or documentation requirement on pharmacists. Instead, the FDA, in non-binding guidance, recognizes documentation of a prescriber's determination as sufficient. The Board's proposal, by contrast, creates a new obligation without clear justification, increasing administrative complexity without improving patient safety.	<i>It appears that the commenter is suggesting that a pharmacist does not have an obligation to exercise clinical judgment when compounding or dispensing a medication. The Board believes it is important to underscore that pharmacists must exercise clinical judgment in all aspects of practice and not simply defer their judgment to another individual. This is obligation is memorialized throughout Pharmacy Law, including notably BPC Section 4306.5. The Board referred the commenter to some specific provisions of the law that establish specific requirements for pharmacists to evaluate prescriptions prior to dispensing including as examples:</i> <i>Health and Safety Code section 11153</i> <i>Business and Professions Code 733</i> <i>Title 16, California Code of Regulations Section 1707.3"</i>
13	1736.1(e)(1)(D)	D. Burger	(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) Drug Shortages List or FDA Drug Shortages Database of drugs that are in short supply at the time of compounding and at the time of dispensing, or in a health care facility licensed pursuant to Health and Safety Code Section 1250 where the drug product cannot be obtained from the manufacturer or wholesaler and documentation is maintained, or (B) The pharmacist determines verifies and documents that 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). (C) Documentation describing the conditions in subsections (1)(A) & (1)(B) is maintained in a readily retrievable format	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board noted that the recommendation offered by the commenter would run contrary to USP 797 provisions which provides, "Sterile compounding is defined as combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance to create a sterile preparation." The Board believe it may be helpful for the commenter to also consider the provisions of the FDA guidance document, "Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities" available here. (https://www.fda.gov/media/90978/download)

		<u>(D) the drug is a sterile product, repackaged or admixed in a centralized hospital repackaging facility in a USP Category 3 compliant facility, and those sterile products are only used within that health system at that health system's acute care facilities.</u> Rationale: The FDA does not classify repackaging or admixing a commercially available product according to its package insert as compounding activities. Consequently, section 1736.1 (e)'s prohibition on compounding a copy or essentially a copy does not apply to these activities. There should be the ability for facilities that repackage Category 3 CSP's. The products are repackaged under sterile conditions while adhering to stringent sterility standards and they also perform container closure potency studies that exceed basic requirements. These facilities minimize contamination risks through advanced testing protocols and high-quality control, offering enhanced safety and efficacy for sterile preparations. For example, repackaging from sterile manufactured vials into syringes that contain doses that are ready to be administered safely without further manipulation. Additional Rationale: In additional support, Category 3 facilities that have extended BUDs in place must test their products to establish that extended BUD. The testing includes testing for; 1. Stability, 2. Sterility, 3. Container closure integrity, 4. pH, 5. Appearance , 6. Particulate, 7. Endotoxin. In addition, the Category 3 facilities are held to the highest standard in USP 797 as far as personnel training, environmental testing, and end batch sterility testing. With this testing rigor in place the maximum allowable BUD is 60 days at room temperature which. The mandated quality control present in a Category 3 facility is recognized and as a result would be a safe environment to produce any available sterile product on the market and therefore should be carved out as an exception to section 1736.1 prohibitions.	

			In addition, if the NEW regulations include the activity of repackaging into the definition of sterile compounding, then a clear incongruency would exist as there is no such exclusion detailed in the repackaging of oral solids, liquids or in the outlined scope of practice found in a CHP repackaging license.	
14	1736.1(e)(2)	M. Cottman	Recommendation: Amend to remove the last sentence: ~~This compound shall be in compliance with the Center for Veterinary Medicine Guidance for Industry #256—Compounding Animal Drugs from Bulk Drug Substances issued August 2022.~~ Comments: "Shall be in compliance with a [document]" This statement is far too non-specific as the GFI document contains Intro, Background, Paperwork Reduction Act and Appendices that link to websites. Specifically, what part of the 21 page GUIDANCE document SHALL we comply with? And what happens to 1735.1(e)(2) when the document changes or goes obsolete (yes the OMB has an expiration date on the document)? If you want additional required items that compounders should comply with for veterinary preparations, please don't make us hunt and peck for the language you are looking for, spell it out. Labeling? Documentation? Bulk Drugs for office use? Reporting ADEs to the FDA? What specifically are you looking for???? It describes "The circumstances under which, at this time, FDA does not generally intend to take enforcement action against drugs compounded from bulk drugs substances for violations of the FD&C Act's requirements for approval, adequate directions for use, and CGMPs." The FDA states that it "generally does not intend to take enforcement action against" NINE (9) times in the document! GFI 256 is written as GUIDANCE, not as regulation nor law. It describes "The circumstances under which, at this time, FDA does not generally intend to take enforcement action against drugs compounded from bulk drugs substances for violations of the FD&C Act's requirements for approval, adequate directions for use, and CGMPs." Several items that are vague	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board noted that the comments are outside of the 15-day comment period. Further, reference to the GFI included in 1736.1(e)(2) was made in response to commenters requesting that the language reference the document. Prior to recommending inclusion of the GFI, the Board conferred with an expert on veterinary practice who confirm including the document was appropriate.

			or open to interpretation. As well as statements that outright conflict with each other. Do compounders comply with the statement on pg 5 that: "drugs compounded from bulk drug substances violate the FD&C Act because they are not approved or indexed, are not made according to CGMP, and cannot satisfy the FD&C Act's adequate directions for use provision (which requires, among other things, that a prescription drug have FDA-approved labeling). " Or the statement also on pg 5: "[the] FDA recognizes that there are circumstances in which no FDA-approved or indexed drug (including the extralabel use of an FDA-approved animal or human drug) can be used to treat an animal with a particular condition. In those limited circumstances, an animal drug compounded from bulk drug substances may be a medically appropriate treatment. " Do we, as licensees assume that we should replace BOP wherever we see FDA in the document such as "This guidance describes: • The types of drugs compounded from bulk drug substances that FDA[BOP] has determined present the greatest risk to human and animal health and intends to make priorities for enforcement action; and • The circumstances under which, at this time, FDA [BOP] does not generally intend to take enforcement action against drugs compounded from bulk drugs substances..."	
15	1736.1(f)	M. Cottman	Recommendation: Remove this section. ~~(f) Prior to allowing any CNSP to be compounded within a pharmacy, the pharmacist in charge shall complete a self-assessment consistent with the requirements established in section 1715.~~ Comments: Redundant. This is not making a new rule, it is just reminding compounders to follow existing regulation 1715 to complete a self-assessment. To comply with 1715, a PIC must fill out the form before July 1 of every odd numbered year... What is it that you want done differently? We are already so highly regulated! Wasting text on re-stating existing laws doesn't help clarify anything.	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board noted that the comments are outside of the 15-day comment period. Further, the Board noted that section 1715 established a requirement to complete the self-assessment specifically related to compounding.

			Further, a more appropriate approach would be to create a separate rule making process to address adding the Compounding Self Assessment requirement to section 1715, in line with all the other references to Self Assessments since CCR 1735.2[k] will be repealed if this text is adopted.	
16	1736.1(g)	M. Cottman	Recommendation: Amend redundant language. (g) In addition to the provisions in section 1707.2 of this Division, consultation includes ~~proper use, storage,~~ handling, and disposal of the CNSP and related supplies furnished. Comments: 1707.2 already includes "(c) When oral consultation is provided, it shall include at least the following: (1) directions for use and storage and the importance of compliance with directions;" Restating these items here does not clarify anything.	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. As discussed previously by the Board, the provisions in CCR 1707.2 do not include requirements related to handling and disposal, nor does it require consultation on related supplies furnished.
17	1736.2(d)	Sutter Health	Argument Against Mandatory Removal for Aseptic Competency Failures Establish Different Standards: Differentiate between initial and ongoing aseptic manipulation assessments and those with non-technique related aseptic testing failures. A blanket requirement for all compounding scenarios does not align with USP standards and due to the rigor of testing can significantly impact critical operations without determining that the failure was related to poor aseptic practices (new fingerprint and surface samples have many opportunities more for potential contamination over technique related failure). Observation Over growth: The standard should emphasize the importance of observing aseptic technique adherence and correcting deviations. Growth results should not automatically disqualify a compounder, as contamination may not always be technique-related. Consider allowing SOP Alternative Mitigations: Implement SOP-driven mitigations for non-technique related contamination, such as unexpected growth on TSA plates when techniques adhered to compounding protocols.	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board noted that the comments are outside of the 15-day comment period. The Board notes that the board has carefully considered the provisions and do not believe it is appropriate to allow a person that has failed any aspect of aseptic manipulation to continue compounding. Appropriate aseptic manipulation is fundamental to safe compounding practices. The Board also believes it is important to reiterate that the USP 797 Chapter underscores the importance of aseptic manipulation competency evaluation, specifically providing that prior to beginning compounding, personnel must successfully complete an aseptic manipulation competency evaluation. The chapter further establishes the frequency and timeframe for ongoing competency evaluation. These requirements establish the timeframe within which the evaluation must be completed. The Board notes that an individual that fails any aseptic manipulation can compromise the integrity of

			Allow flexibility in SOPs to address different contamination scenarios. Proposed Actions Require Immediate Retraining and Supervision: Retrain affected personnel immediately on aseptic techniques. Allow them to continue working under direct supervision until competency is re-established. Enhanced Monitoring: Increase environmental monitoring and conduct additional or follow up aseptic competency personnel sampling. Implement additional checks, like more frequent glove and gown changes, to minimize contamination risks. Removing experienced compounders from duties for non-technique related failures is impractical and disrupts operations. Adopt a balanced approach with targeted retraining and enhanced monitoring to maintain safety and efficiency.	the product. Further, the proposed regulation text includes provisions that allow for an individual that has failed aspects of aseptic manipulation to continue oversight of compounding for 30-days. This time period was established to allow for retraining and sufficient time to process the results of the retesting.
18	1736.8	M. Cottman	Recommendation: Remove this section. Comment: I reiterate my previous comments that this is addressed adequately in proposed 1736.17. The rationale provided by Staff after the last revision that "this section serves as a reminder," is a substandard rulemaking justification. I respectfully submit that reminders should not be drafted into rules or regulations. Instead, create an FAQ! We already have to comply with hundreds of pages of rules, regulations, and guidelines. Don't create unnecessary extra text by putting the same rule in two places, it just creates confusion.	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board noted that the comments are outside of the 15-day comment period, and as the commenter also notes, the Board has previously considered this comment and determined that a change was not appropriate. The Board referred the commenter to the Board's prior response to this comment, that is in row 17 available here (https://www.pharmacy.ca.gov/meetings/agendas/2025/25_feb_bd_mat_1736_comments.pdf) that includes "Board staff have reviewed the comment and do not recommend a change to the proposed text. As was stated in the staff response to a similar comment received during the 30-day comment period, inclusion in this section provides clarification to the regulated public that SOPs must address this practice and serves as a reminder."
19	1736.9(d)	Novo Nordisk	We appreciate the Proposed Rule's provisions requiring Certificates of Analyses (COAs) for API used to compound sterile products. We ask the Board to reconsider or clarify its	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board noted that the comments are outside of the 15-day comment period.

		positions offered in the Staff Responses to NNI's comments to the Second Modified Text. First, we recommend that the Board reconsider removing language relating to excipient components to ensure that all components used to compound sterile products are accompanied by a COA. While we agree with the Board that pharmacists must be knowledgeable of current practice standards and legal requirements, excipient components in compounded products can cause dangerous adverse events and result in serious harm to patients regardless of any one pharmacist responsible for compounding a drug. For example, FDA published a Compounding Risk Alert after receiving an adverse event report concerning a patient who experienced cardiac arrest and died after IV administration of a curcumin emulsion product compounded by ImprimisRx.⁶ FDA identified the presence of an impurity in PEG 40 castor oil, an excipient used in the compounded product that may have caused the adverse event. The PEG 40 castor oil used was ungraded and not suitable for human consumption or therapeutic use. FDA thus warned against the "risks associated with compounded drugs, particularly those that use non-pharmaceutical grade components and ingredients lacking a USP monograph."⁷ The Board can help to protect against these risks by reinserting COA requirements for excipient components used to compound sterile products. Second, in the Staff Responses, the staff notes that "the proposed regulation text establishes the requirements for a COA consistent with the commenter recommendation." We request that the Board confirm that the staff response intends to convey that the Proposed Rule's carveout for components of commercially available drug products only applies to ingredients sourced from and provided by the manufacturer of the commercially available drug product. We also ask that the Board consider adopting the recommend language revision below to make the Board's position even clearer. Third, we recommend that the Board reconsider adding a requirement that the COA of any API that claims to be a component of an approved drug show that the API was manufactured by the process specified in the labeling of the approved drug. The importance of this requirement is	The Board refers the commenter to the Board's prior response included in row 18 available here (https://www.pharmacy.ca.gov/meetings/agendas/2025/25_feb_bd_mat_1736_comments.pdf) that includes "Board staff have reviewed the comments and do not recommend any changes to the proposed text. Staff note that in response to prior comments received, the Board agreed to remove explicit language related to excipient components. As the Board noted in its response to comments, a pharmacist must remain knowledgeable of current practice standards and legal requirements while exercising professional judgment. Failure to do so could constitute unprofessional conduct. Staff notes that the proposed regulation text establishes the requirements for a COA consistent with the commenter recommendation. While Board staff agree with the examples provided by the commenter, the Board's compound regulations span a variety of different settings. The Board is generally seeking to align with federal law and supporting guidance documents. It appears that the commenter is suggesting that the Board's regulations expand beyond the provisions of federal law in section 503A."

		particularly acute for the bulk “semaglutide” used in compounding. The FDA-approved labeling for semaglutide medicines explains that the “peptide backbone is produced by yeast fermentation.” Unlike the yeast-produced semaglutide in NNI’s FDA-approved semaglutide medicines, the “semaglutide” in compounded drugs is produced using synthetic semaglutide unaffiliated with any approved application. Use of such API can introduce peptide-related impurities and other complexities and expose patients to safety and effectiveness risks. Indeed, testing revealed that compounded “semaglutide” samples contained high levels of impurities.⁸ The peptide-related impurities⁹ identified in the samples have the potential to stimulate immunological processes to produce antibodies against semaglutide peptides, potentially posing immunogenicity risks that can lead to serious and life-threatening reactions like anaphylaxis.¹⁰ This data reinforces the importance of requiring that the COA demonstrate that any API that claims to be a component of an FDA-approved drug was manufactured by the same process described in the FDA-approved drug labeling. The Board should thus (1) ensure that all components used to compound sterile products, including excipients, are accompanied by a COA; (2) confirm that its exemption is limited to circumstances where a compounding facility sources and obtains its API from the manufacturer of a commercially available drug product; and (3) require that the COA show that any API that claims to be a component of an approved drug was manufactured by the process specified in the labeling of the approved drug. Adhering to these standards is critical to ensure that patients do not receive unsafe and ineffective compounded products that are unaffiliated with approved drug products. Recommended language revision: “(d) All APIs used to compound a CSP shall be manufactured by an FDA-registered facility. All APIs and excipient components used to compound a CSP shall be accompanied by a Certificate of Analysis (COA) and be suitable for use in sterile pharmaceuticals. A COA that includes the compendial name, where one exists, the grade of the material, and the	

			applicable compendial designations on the COA, must be received and evaluated prior to use, unless components of the CSP are commercially available drug products that are sourced from and provided by the manufacturer of the commercially available drug product. The COA for any API used to compound a CSP that claims to be a component of an FDA-approved drug must show that the API was manufactured by the process specified in the labeling of the FDA-approved drug. When the COA is received from a supplier, it must provide the name and address of the manufacturer. An API and excipient components provided with a COA without this data shall not be used in a CSP."	
20	1736.9(d)	M. Cottman	Recommend to move this requirement to BPC Article 11 in the Wholesaler chapter for rules. Comment: Board Staff is incorrect when they say that this proposed rule "is consistent with the FDA Guidance in this area." This statement is FALSE! Here is the statement from the FDA https://www.fda.gov/drugs/human-drug-compounding/fda-compounders-know-your-bulks-and-excipients-suppliers "FDA Urges Compounders to: ● know your bulk drug substance and excipient suppliers ● know the quality of the materials you get from your suppliers, including what testing the supplier does to determine the quality of the components you purchase ● meet the conditions regarding bulk drug substances in sections 503A and 503B of the Federal Food, Drug and Cosmetic Act, including: ○ API compliance with applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph standards ○ sourcing API from FDA-registered facilities ○ valid certificates of analysis ○ excipient compliance with applicable USP or NF monograph standards" NOTE There is no requirement NOR recommendation of the FDA to have the compounder actually see the COA from the original manufacturer. In contrast Compounders are urged to	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board noted that the comments are outside of the 15-day comment period. The Board refers the commenter to the Board's prior response included in row 20 available here (https://www.pharmacy.ca.gov/meetings/agendas/2025/25_feb_bd_mat_1736_comments.pdf) that includes, "Board staff have reviewed the comment and do not recommend a change to the proposed text. Board staff note that the requirements contained in the proposed regulation text is consistent with the FDA guidance in this area. As was included in the Board's prior response to the proposed regulation text in this area, the FDA has released guidance including the importance of a compounder knowing their supplier. Staff note that suppliers are under the jurisdiction of the Board."

			know their SUPPLIERS and have a VALID COA!!! As is evidenced by the number of chemicals that are rejected by valid wholesalers (i.e. PCCA and Medisca), the original COA is not always sufficient. I reiterate that this is still a misplaced rule! IF you are concerned about your licensed wholesalers, repackagers, and suppliers of providing poor quality chemicals for your compounders, go to the source and require that wholesalers must comply with.	
21	1736.9(e)	Novo Nordisk	We appreciate the Board's goal of aligning the Proposed Rule with federal standards. For that reason, we ask that the Board align with federal law by revising its provisions in 1736.9 related to the conditions under which sterile compounding can occur. By adopting this recommendation, the Board will align its Proposed Rule with Federal Food, Drug, and Cosmetic Act section 503A(b)(1)(A). We also ask that the Board reconsider adding a definition for "component of a drug approved by the FDA" to ensure that API used to compound sterile drugs is the same API used to manufacturer FDA-approved drug products. Here too, we agree with the Board that pharmacists must be knowledgeable of current practice standards and legal requirements. However, our recommendation is focused squarely on the quality of the API used to compound drugs, which is an issue distinct from a pharmacist following practice standards to compound drugs. In addition, for the reasons noted for section 1736.9(d) above, the Board should add a requirement that API that claims to be a component of an approved drug must be manufactured by the process specified in the labeling of the approved drug. Recommended language revision: 1736.9: "(e)(1) Except as provided in (2) or (4), when API is used to compound a CSP, it shall – (a) comply with a USP monograph; (b) if such a monograph does not exist, be an API that is a component of a drug approved by the FDA; or (c) if such a monograph does not exist and the API is not a component of a drug approved by the FDA, be listed in 21C.F.R. § 216.23."	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board noted that the comments are outside of the 15-day comment period. The Board notes that should the Board accept the changes recommended, the Board would eliminate the pathway it is creating to allow for compounding using a bulk drug substances that has been nominated for inclusion in 21 CFR section 216.23(a) and that appears on the published 503A Category 1 bulk drug substances list. Further, the Board has previously considered this comment. The Board respectfully refers the commenter to its prior response in row 21 available here, (https://www.pharmacy.ca.gov/meetings/agendas/2025/25_feb_bd_mat_1736_comments.pdf) that includes, "Board staff have reviewed the comments and do not recommend any changes to the proposed text. Staff note that the Board does not need to add a definition of component as recommended because a pharmacist must remain knowledgeable of current practice standards and legal requirements while exercising professional judgment. Failure to do so could constitute unprofessional conduct. The Board is seeking to align with federal law and supporting guidance documents. It appears that the commenter is suggesting that the Board's regulations should further restrict the provisions of federal law in section 503A."

			[NEW]"(4) A drug product may be compounded if authorized by a public health official in an emergency use situation for a patient-specific compounded sterile preparation. (5) API used to compound a CSP that claims to be a component of an FDA-approved drug must be manufactured by the process specified in the labeling of the FDA-approved drug." 1736: [NEW] "(i) 'Component of a drug approved by the FDA' means an API that is the same as the API used in the <u>manufacture of the approved drug.</u>"	
22	1736.17(a)(2)	Partnership For Safe Medicines	The Board's proposal to eliminate adverse event reporting requirements (sections 1735.11(a)(2), 1735.12(b), 1735.12(c), and 1736.17(a)(2)) presents severe risks, including: • Delayed Detection of Drug Safety Issues: Without a diminished reporting system, it will take longer to identify harmful trends associated with specific medications. • Reduced Transparency: Patients and healthcare providers will have less access to critical safety data that inform medical decision-making. • Increased Harm from Compounded Medications: The absence of adverse event reporting will make it harder to promptly identify and respond to dangerous medications before widespread harm occurs. A Step Backward in Drug Safety California has historically been a leader in pharmaceutical regulation and patient protection. Removing adverse drug experience review would reverse this progress, making the state an outlier in drug safety oversight. Regulatory bodies, including the FDA and WHO, emphasize the necessity of adverse event monitoring as a fundamental component of a responsible healthcare system. The California Board Of Pharmacy should reject this proposed rule change and reiterate the responsibilities of compounders to have a standard operating procedure that requires mandatory reporting of all adverse events promptly.	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board noted that the comments are outside of the 15-day comment period. The Board's proposed compounding regulations are seeking to establish minimum requirements while relying on pharmacists to use their professional judgment. The Board notes that current law, Business and Professions Code section 4127.1(f) establishes mandatory reporting requirements to the Board including adverse effects reported or potentially attributable to a pharmacy's sterile drug product. This section also requires reporting to the MedWatch program. The Board shares the patient safety concerns raised by the commenter and believes the current statutory requirements remain appropriate.

#	Section	Commenter	Comment	Board Response
1	1737.1	B. Go	The response by the Board that both proposed as well as existing regulations on compounding, as currently worded, do not infringe on the practice of compounding by non-pharmacist licensees under the jurisdiction of other California professional boards, is not satisfactory for the following reasons: 1. You responded with comments from only one board, the Medical Board of California, which only regulates MD's. This does not apply to other licensees such as DO's, nurses, ND's, dentists, and veterinarians, who may also have the right to compound medications in-office without a pharmacist and without interference by the Board of Pharmacy. Furthermore, even the MD's right to compound is still in jeopardy based on current wording of the Board's regulations, for the following reasons: a. The Medical Board's letter noted that only the Medical Board has the right to discipline its licensees. This would only apply if the licensee was being disciplined as an MD, not if they were being disciplined as a person practicing pharmacy without a license. Again as previously stated, the Board of Pharmacy's jurisdiction is to regulate the practice of pharmacy, and therefore practicing pharmacy without a license would fall within their purview. Both currently existing regulations as well as the proposed changes exclude non-pharmacists from being able to compound, specifically defining the practice of compounding as that which occurs by a pharmacist ONLY. (See proposed regulation 1736.1a (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." And see currently existing regulation: CCR 1735(a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist") b): The Medical Board's letter notes: "It is certainly possible that whatever regulations that are implemented by the Board of Pharmacy may influence the standard of care for physicians who	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board noted that the comments are outside of the 15-day comment period. The Board has previously considered this and similar comments and provided responses throughout the rulemaking, including for example the response provided in row 5 available here: (https://www.pharmacy.ca.gov/meetings/agendas/2025/25_feb_bd_mat_1736_comments.pdf), which included in part, "Board staff have reviewed the comment and do not recommend a change to the proposed text based on the comment. Board staff note that the Board previously considered this comment, most recently during the January 8, 2025, Board Meeting and determined that the requested change is not appropriate. As was previously shared, staff note the Board only has jurisdiction over individuals and businesses within its practice act. Board staff read the comment as suggesting that the Board's proposed regulations would apply to a physician. Business and Professions Code section 4170(c) makes clear that the Medical Board of California is specifically charged with the enforcement of Pharmacy Law (Chapter 9, Division 2 of the Business and Profession Code) with respect to its licensees." The Board refers the commenter to Business and Professions Code section 4170 as well as the Board's jurisdiction. The Board also recommends that the commenter review the Board's Initial Statement of Reason that describes the Board's jurisdiction to gain a better

			are compounding." - they admit that your regulations may affect MD's practice of compounding. I'm not sure why you have so much resistance to adding wording which would only help to clarify the limitations of your role, and would limit the confusion and ambiguity which the current wording is creating. Instead, you have specifically chosen to include wording which is overly broad, and which implies that compounding only may be performed by a pharmacist. 2. You claim that regulations specifically state you cannot regulate other practitioners 3. Furthermore, you have not directly responded to previous comments that noted the contradiction between your stance on the above and the fact that you are currently making preparations to attempt to regulate what you refer to as 'IV hydration clinics'. These clinics do not have pharmacists, however they do have other non-pharmacist licensees who have the right to compound. The term 'IV hydration clinic' itself is not well-defined by the board, and it is foreseeable that the board could choose to include any medical office that provides IV hydration or IV nutrients in this category, offices in which compounding might be conducted by any of a variety of types of licensed non-pharmacist practitioners who should not be under the purview of the Board if it were not for the current language in your regulations. Therefore, the claim that your compounding regulations do not or will not interfere with compounding by non-pharmacist licensees is disingenuous. Please do note and respond to this paragraph in full in your reply as well.'	understanding of the applicability of the Board's regulations. The commenter also appears to be provided comments about a statutory proposal related to the regulation of IV hydration clinics. The Board refers the commenter to the Board's proposed statutory proposal for an understanding of the Board's legislative proposal. The Board notes that the language in the statutory proposal does include explicit language that it would not apply to a facility for which a professional director is on site while sterile compounding occurs.
2	1737.5	K. Scott Guess	Please validate the augmentation above USP 800 to certify C-PEC's every 6 months over the annual certification codified in USP 800.	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board noted that the comments are outside of the 15-day comment period. The Board further notes that the commenter may be confusing requirements as USP Chapter 800 does not include certification requirements; rather, it builds upon Chapters 795 and 797. The certification requirements established in USP 797 (Section 5) establish the

				requirement for biannual certification for sterile compounding. The certification requirements established in USP 795 (Section 6.1) establishes the requirement for certification at least every 12 months for nonsterile compounding.
3	1737.6	K. Scott Guess	The Board wants to codify a wish, a suggestion, an idea for environmental sampling, then goes on to state this sampling is not required. Considerations, and suggestions best left to professional organizations who develop "best practice" models. They do not belong in codified law. Strike this section.	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board's proposed regulation text requires the facility to evaluate if the use of wipe sampling in their respective facility is appropriate. The Board notes that wipe sampling may not be appropriate in all facilities, but at a minimum, consideration of the use of wipe sampling must be performed and documented.
4	1737.7(a)	M. Cottman	Recommend to remove. Comment: Board Staff appears to be finding evidence to fit it's narrative. The evidence that this proposed regulation is "addressing the potential for cross-contamination" references an article. Hazardous Drugs Contamination of Drug Preparation Devices and Staff: A Contamination Study Simulating the use of Chemotherapy Drugs in a Clinical Setting. This is a seriously flawed study to demonstrate cross contamination in an ACTUAL HD Cleanroom!!! Did Staff read the methods? In this demonstration, the methods state that "Fifteen drug vials, containing only sterile saline, were placed in a separate room and coated with the Glo Germ powder at 90% coverage." OF COURSE YOU WILL HAVE CROSS CONTAMINATION!! The results of this intentional 90% contamination of a powder on the outside of the vials is not a scenario that is transferable to real-world sterile HD situations! This study was published in 2017, several years prior to the widespread use of 800 rooms and HD protocols. To advocate for this expensive and time consuming regulation, you will need better evidence that typical chemo/HD vials are significantly externally contaminated often enough directly from the manufacturers to warrant the proposed HD cleanroom gloving behavior change. Additionally, USP 800 FAQ 53. When do HD PPE components need to be removed? The outer pair of sterile HD gloves (tested to ASTM D6978) are removed inside the	The Board reviewed this comment and made a change to the regulation text after consideration of this and other comments received related to this provision. It is important to note that numerous sources have been cited by the Board demonstrating risks of cross contamination and contamination of gloves. Additional information from OSHA (https://www.osha.gov/hazardous-drugs/controlling-occex#occ_environmental) provides further examples of manipulations that can cause escape of HD residue by splattering, spraying, and aerosolization include: • piercing drug vial septa with needles or dispensing pins; • withdrawal of needles or pins from drug vials; • drug transfer using syringes and needles or dispensing pins; • breaking open of ampules; • drug transfer from ampules using filtered needles or filter straws;

			C-PEC prior to leaving the C-PEC. They must be placed in a trace HD container (such as a bag or small rigid yellow bin) inside the hood. USP does NOT recommend that Gloves be changed between each preparation. As I presented to the board previously, this proposed rule remains an expensive and unnecessary rule. Sterile gloves cost \$1.50 to \$3.85 / pair. In addition to the expense, this change in process for all sterile HD compounders might result in a shortage of gloves because the use will not double, but it might increase by 10 or 20 fold!	- expulsion of air from a drug-filled syringe; - piercing injection ports of IV bags or bottles with needles to inject HDs; - spiking delivery ports of HD-containing IV bags or bottles with the sharp spike of IV administration sets; and - removing air from the IV administration sets by running HD containing fluid through the set (i.e., priming the line). (5a) Outer gloves used for HD compounding shall be carefully removed and discarded immediately into a waste container approved for trace contaminated waste inside the C-PEC or contained in a sealable bag for discarding outside the C-PEC as established in USP 800 Section 7.6 changed between each different HD preparation, unless preparing multiple HD preparations of the same drug or preparing multiple HD preparations for a single patient
5	1737.7(c)	Kaiser	In attempting to impose the requirement that compounding personnel change their outer HD gloves after each different HD preparation or each different patient, the Board is proposing a regulation that will increase the risk of microbial contamination and is likely to increase the risk of medication errors with no evidence to support the contention that the practice will reduce the risk of contamination with HD residues. In our comment letter dated January 24, 2025, we demonstrated that, based on probability and peer-reviewed literature, increasing the frequency of glove changes will increase the risk of microbial contamination due to inevitable breaks in technique during the garbing process. The Board's response to this feedback was that "facilities can develop strategies to mitigate those risks." This response fails to recognize that humans are fallible and, as such, even with the best mitigation strategies, occasional breaks in technique are inevitable to occur and create the opportunity for contamination. Therefore, it is indisputable that mandating more frequent glove changes will increase the risk of microbial	The Board reviewed this comment and made a change to the regulation text after consideration of this and other comments received related to this provision. It is important to note that numerous sources have been cited by the Board demonstrating risks of cross contamination and contamination of gloves. Additional information from OSHA (https://www.osha.gov/hazardous-drugs/controlling-occex#occ_environmental) provides further examples of manipulations that can cause escape of HD residue by splattering, spraying, and aerosolization include: piercing drug vial septa with needles or dispensing pins;

		contamination. The proposed regulation indicates that the outer HD gloves must be changed “between each different HD preparation unless preparing multiple HD preparations of the same drug or preparing multiple HD preparations for a single patient.” This will almost certainly incentivize pharmacies to compound preparations of the same HD in “batches.” Such an approach to compounding could result in several preparations of the same drug for different patients in the compounding area at the same time—an error-prone practice. The Board has provided two references to support this proposed regulation. First, in the Modified Initial Statement of Reasons the Board claims that “ASHP guidance” supports the notion that outer HD gloves should be changed more frequently but does not provide a citation to a specific ASHP guidance document.⁵ In our comment letter dated December 6, 2024, we conjectured that the Board was referencing ASHP’s Guidelines on Handling Hazardous Drugs.⁶ If that is the case, we want to be clear that the guideline makes no reference to changing gloves after each different HD preparation or each patient and instead recommends that gloves be changed “every 30 minutes during compounding or immediately when damaged or contaminated,” consistent with the USP 800 chapter and the standard of practice.⁷ The Board also references a single-center simulation study from 2017.⁸ The intent of that study was to assess the spread of a simulated HD residue “placed on the exterior vial surface to downstream surfaces.” The study was conducted by covering drug vials with a fluorescent simulated HD residue (Glo Germ powder), compounding a small-volume parenteral solution using the drug in the vial and one of five different Closed System Transfer Devices (CSTD), and then assessing various simulated pharmacy materials and work surfaces and simulated drug administration materials and work surfaces for fluorescence. After each simulated compound was prepared, compounding personnel changed their personal protective equipment, including their gloves, and cleaned and disinfected the pharmacy work surfaces. The study concluded that the use of a closed barrier system—a unique component of one of the five CSTD systems used—might reduce the risk of transferring HD residue from a vial to the drug delivery system. For several reasons, relying on this study to support the notion that outer HD gloves should be changed after each	• withdrawal of needles or pins from drug vials; • drug transfer using syringes and needles or dispensing pins; • breaking open of ampules; • drug transfer from ampules using filtered needles or filter straws; • expulsion of air from a drug-filled syringe; • piercing injection ports of IV bags or bottles with needles to inject HDs; • spiking delivery ports of HD-containing IV bags or bottles with the sharp spike of IV administration sets; and • removing air from the IV administration sets by running HD containing fluid through the set (i.e., priming the line). (5a) Outer gloves used for HD compounding shall be <u>carefully removed and discarded immediately into a waste container approved for trace contaminated waste inside the C-PEC or contained in a sealable bag for discarding outside the C-PEC as established in USP 800 Section 7.6</u> ~~changed between each different HD preparation, unless preparing multiple HD preparations of the same drug or preparing multiple HD preparations for a single patient.~~

		different HD preparation or each different patient in our opinion exposes deeply flawed reasoning on the Board's part. First, the study did not assess whether changing gloves more frequently than every 30 minutes during HD compounding reduces the spread of HD residue. Moreover, the study only evaluated the spread of HD residue within a compounding cycle for one compounded sterile product; it did not evaluate the spread of HD residue between compounding cycles. In fact, during the study, compounding personnel changed their gloves after each simulated HD preparation was prepared. We invite the Board to explain how they arrived at the conclusion that outer HD gloves cannot safely be used across compounding cycles based on the results of a study that only assessed the spread of HD residue within one compounding cycle. This faulty conclusion should be enough to disqualify this study as "evidence" to support the proposed regulation; however, there is another oversight by the Board that is equally, if not more, disqualifying. This study was conducted on or before 2017, at which time the national standard for sterile compounding practices was the 2008 revision of USP 797. In the list of "suggested standard operating procedures," the 2008 revision of USP 797 encouraged, but did not require decontaminating supplies that are introduced into the aseptic work area.⁹ In contrast, Section 8 of the 2023 revision of USP 797 requires articles to be wiped with a disinfectant or 70% isopropyl alcohol before being introduced into a Secondary Engineering Control and before being introduced into a Primary Engineering Control.¹⁰ The ASHP Guidelines on Handling Hazardous Drugs recognize wiping surfaces with 70% isopropyl alcohol as an effective method to remove HD surface contamination.¹¹ California Business and Professions code section 4126.8 already requires pharmacies to meet the requirements of the current USP compounding chapters.¹² Therefore, unlike the referenced study, California law already requires that drug vials are wiped at least twice before they are introduced into a PEC. It is unreasonable to assume that the degree of HD contamination on a vial that was never cleaned, or in the case of the referenced study intentionally 'contaminated', is the same as that of a vial that has been wiped at least twice with 70% isopropyl alcohol or another disinfectant; therefore, the Board's reasoning that this study provides evidence that it is necessary for compounding	

			personnel to change their outer HD gloves after each different HD preparation or each different patient is not justified. All told, nothing has changed from when this proposed regulation was introduced in the spring of 2024; there is no evidence to support the Board's contention that the regulation is "necessary to prevent inadvertent cross contamination."¹³ This proposed regulation is a solution in search of a problem that will significantly increase supply costs to pharmacies—which will almost certainly be passed on to consumers—increase medical waste entering the waste stream, increase the likelihood of microbial contamination of compounded sterile products, and incentivize unsafe practices. Given the obvious lack of evidence to support this proposed regulation and the unintended consequences it will likely precipitate, we urge the Board to remove this requirement from the regulations.	
6	1737.7(c)	CSHP	We re-state our separate recommendations as before since the board failed to include either an explanation of how each objection or recommendation of the proposed action has been changed to accommodate our comment or state the reasons for rejecting our comments. In summarizing and responding to our comments, the board did not demonstrate that it understood and considered the comment in that board did not demonstrate that it understood and considered the comment the risk to staff created via repeated change of outer gloves. Double-gloving is primarily designed to offer extra protection against hazardous drug compounds, with the outer glove serving as a first line of defense. If the outer glove is repeatedly removed or exposed to rough conditions, it may wear down, possibly increasing the risk of puncturing, drug permeation, or compromising the inner glove. This could lead to reduced protection and potential occupational exposure, especially when handling hazardous drug compound. We recommend that the regulation section be deleted since consideration was not given for the risk to staff. The board did not demonstrate that it understood and considered the comment regarding the inappropriateness of the use of online prices for gloves. Since the board is unable to justify its use of internet pricing, we recommend that the regulation be deleted due to inadequate economic impact analysis. The glove prices that board staff looked up online is not available to all	As was previously noted in prior responses to these comments, the practice of changing gloves as proposed in the regulation text is currently in practice in numerous facilities as a means to prevent cross contamination. Incorporating best practices implemented by hospitals and other facilities into the Board's regulation is appropriate and necessary to reduce patient harm and inappropriate exposure to hazardous drugs. Below is an example of an excerpt from the facility's SOP submitted to the Board in December 2024, <i>"Outer gloves used for compounding must be changed between each different HD drug."</i> Below is another example from SOPs submitted to the Board in January 2025 from a health system, <i>"Outer gloves used for compounding must be changed between each different HD drug."</i> The Board reviewed this comment and made a change to the regulation text after consideration of this and other comments received related to this provision.

	pharmacies due to limitations on contracting. Board staff's response that they performed an online search of the pricing and availability of appropriate gloves reflects a lack of understanding of the practice of pharmacy and the intricacies of purchasing contracts at large organizations. Pharmacies cannot simply go to any online vendor of these sterile gloves and buy it on a credit card. Purchasing is usually done on contracts with vetted suppliers to ensure supply chain integrity. Due to this workflow, the pricing advertised online from unvetted suppliers, is generally unavailable to organizations. Furthermore, the cheapest online price may not reflect the product that is selected for use by the pharmacy since there are factors to be considered such as ease of use, quality of the product and in some cases, impact on staff that could experience allergic skin reactions to cheap products. We would like to request that the board make public their source of information and the brand name, type and quality of the gloves they found online. Reports from CSHP members indicate that the price for a pair of high quality sterile hazardous drug gloves on contract is \$1.30. Assuming that a staff member works 10 hours per day in a biological safety cabinet, they will have to replace gloves every 30 minutes (which is 20 times). This is an additional cost of \$26 per day, which translates to \$130 per week and \$6,760 annually. This is the presumptive cost per biological safety cabinet (BSC) for the price of gloves alone. It is also anticipated that the exchange of gloves will translate to a minimum of 10% reduction in productivity. This means for every 30 drugs being compounded per day, there is now 3 less. This means at least one patient per day per BSC cannot be accommodated in an infusion center, with a resulting decreased patient access to care. The charges for 3 drugs can range between \$1000 up \$30,000, depending on the drugs. This translates in an economic impact of loss of revenue of up to \$30,000 per day. Even a low estimate of \$2000 per infusion day translates to \$520,000 loss off revenue per year per BSC. Even an unrealistic loss of revenue of \$500 per day translates to a loss of \$130,000 per BSC per year due to lost productivity. This economic impact on the exchange of sterile gloves alone far exceeds the total estimates of the economic impact provided by the board for all of the compounding regulations combined. Due to gross underestimation of the board of the impact of glove exchanges alone, we recommend that this section be deleted.	It is important to note that numerous sources have been cited by the Board demonstrating risks of cross contamination and contamination of gloves. Additional information from OSHA (https://www.osha.gov/hazardous-drugs/controlling-occex#occ_environmental) provides further examples of manipulations that can cause escape of HD residue by splattering, spraying, and aerosolization include: • piercing drug vial septa with needles or dispensing pins; • withdrawal of needles or pins from drug vials; • drug transfer using syringes and needles or dispensing pins; • breaking open of ampules; • drug transfer from ampules using filtered needles or filter straws; • expulsion of air from a drug-filled syringe; • piercing injection ports of IV bags or bottles with needles to inject HDs; • spiking delivery ports of HD-containing IV bags or bottles with the sharp spike of IV administration sets; and • removing air from the IV administration sets by running HD containing fluid through the set (i.e., priming the line). (6a) Outer gloves used for HD compounding shall be carefully removed and discarded immediately into a waste container approved for trace contaminated waste inside the C-PEC or contained in a sealable bag for discarding outside the C-PEC as established in USP 800 Section 7.6 changed between each different HD preparation, unless preparing multiple HD preparations of the same drug or preparing multiple HD preparations for a single patient

		The board did not demonstrate that it understood and considered the comment regarding the need to purchase gloves at increased prices for staff that are allergic to cheap gloves. Due to the non-universal application of the use of cheap gloves, we recommend that this regulation be deleted. The board did not demonstrate that it understood and considered the comment regarding the fact that this economic impact was inadequately addressed in the economic impact section of the ISOR. The board response regarding the price of gloves highlights board staff's limited understanding of pharmacy business. The one-dimensional view of product price as an economic impact fails to consider indirect costs associated with this proposed regulation such as increased time it will take to compound hazardous drugs and the associated cost of labor. It further fails to consider the economic impact of slower compounding on reduced turnover in chairs at infusion centers. These are only to name a few economic impacts that the board fails to take into consideration and illustrates our point that the board lacks the internal expertise to accurately reflect those anticipated costs.. Given the information is not available, we recommend that this regulation be deleted. We once more are compelled to note that, as with other proposed regulations, the "business impact" and "economic impact" of the ISOR fails to accurately reflect the cost and impact to businesses by this and other regulations. The board's response to the question of "Business Impact" in the Initial Statement Of Reasons (ISOR) states; "the board anticipates minimal ongoing costs ranging from approximately \$5,700 to \$15,000 per year related to administrative and maintenance workload." This statement applies to the multiple proposed regulations requiring the addition of new administrative procedures, increased purchase of PPE, increased testing and enhanced reporting requirements. The amount stated is a gross underestimation of the true cost to health systems. Understandably the Board lacks the internal expertise to accurately reflect those anticipated costs associated with development of policies and procedures, monitoring implementation of those procedures, correctly reporting to the Board as proposed by this regulation and others, cost of monitoring visits by the Board, implementation of technology to	

			support the deployment of the policies and procedures and hiring of additional staff to support compliance with the proposed regulation. The Board further states in the ISOR under the header of "Business Impact" as it relates to the issue of cost the following: "This initial determination is based on the absence of testimony to that effect during the public discussion and development of the proposed regulation." The public meetings mandate testimony be limited to a few minutes and attendees tend to focus their input on the specific wording of the proposed regulation and not the cost. It is incumbent on the Board to actively pursue input from those that can accurately project the cost to health system of the proposed regulation. The Board should, during public meetings, or by other means seek input from experts who can inform the Board's ISOR development as it relates to both "Business Impact" and "Economic Impact Assessment." For these reasons, we recommend that this regulation be deleted.	
7	1737.15(a)	Kaiser	We acknowledge the Board's perspective that there should be some mechanism in place to ensure the methodological rigor of studies that are relied upon to justify the use of an alternative agent for deactivating, decontaminating, cleaning, disinfecting, and or and/or killing bacterial and fungal spores in the compounding suite. However, manufacturer "approval" alone does not guarantee methodological rigor any more than publishing the study does. If the Board's primary concern is to ensure methodological rigor in any study that is referenced to justify the use of an alternative agent, then we suggest modifying the regulation text to indicate that the study must be peer reviewed.	The Board reviewed this comment and did not make a change to the proposed text. The Board noted that the recommendation to add provisions for the study to be "peer-reviewed" does not ensure that an independent reviewer was part of the process.
8	1737.16	K. Scott Guess	Spill control is already addressed in USP 800. It is unnecessary for the Board to restate the need for spill control SOP.	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board noted that the comments are outside of the 15-day comment period. Further, the Board notes that the proposed regulation ensures that the facility's SOPs ensure a qualified person is available at all times.

#	Section	Commenter	Comment	Board Response
1	1738.1	B. Go	The response by the Board that both proposed as well as existing regulations on compounding, as currently worded, do not infringe on the practice of compounding by non-pharmacist licensees under the jurisdiction of other California professional boards, is not satisfactory for the following reasons: 1. You responded with comments from only one board, the Medical Board of California, which only regulates MD's. This does not apply to other licensees such as DO's, nurses, ND's, dentists, and veterinarians, who may also have the right to compound medications in-office without a pharmacist and without interference by the Board of Pharmacy. Furthermore, even the MD's right to compound is still in jeopardy based on current wording of the Board's regulations, for the following reasons: a. The Medical Board's letter noted that only the Medical Board has the right to discipline its licensees. This would only apply if the licensee was being disciplined as an MD, not if they were being disciplined as a person practicing pharmacy without a license. Again, as previously stated, the Board of Pharmacy's jurisdiction is to regulate the practice of pharmacy, and therefore, practicing pharmacy without a license would fall within their purview. Both currently existing regulations and the proposed changes exclude non-pharmacists from being able to compound, explicitly defining the practice of compounding as that which occurs by a pharmacist ONLY. (See proposed regulation 1736.1a (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." And see currently existing regulation: CCR 1735(a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist") b): The Medical Board's letter notes: "It is certainly possible that whatever regulations that are implemented by the Board of	The Board reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board noted that the comments are outside of the 15-day comment period. The Board has previously considered this comment and provided responses throughout the rulemaking, including the Board's response in row 2 of the response to comments posted here: (https://www.pharmacy.ca.gov/meetings/agendas/2025/25_feb_bd_mat_1738_comments.pdf). The Board respectfully refers the commenter to Business and Professions Code section 4170 as well as the Board's jurisdiction. The Board also recommends that the commenter review the Board's Initial Statement of Reason, which describes the Board's jurisdiction, to better understand the applicability of the Board's regulations. The commenter also appears to be providing comments about a statutory proposal related to the regulation of IV hydration clinics. The Board refers the commenter to the Board's proposed statutory language for an understanding of the Board's legislative proposal. The Board noted that the language in the statutory proposal does include explicit language that it would not apply to a facility for which a professional director is on site while sterile compounding occurs. Further, the Board is not aware of any IV hydration clinics that would prepare radiopharmaceuticals.

		Pharmacy may influence the standard of care for physicians who are compounding." - they admit that your regulations may affect MD's practice of compounding. I'm not sure why you have so much resistance to adding wording which would only help to clarify the limitations of your role, and would limit the confusion and ambiguity which the current wording is creating. Instead, you have specifically chosen to include wording which is overly broad, and which implies that compounding only may be performed by a pharmacist. 2. You claim that regulations specifically state you cannot regulate other practitioners 3. Furthermore, you have not directly responded to previous comments that noted the contradiction between your stance on the above and the fact that you are currently making preparations to attempt to regulate what you refer to as 'IV hydration clinics'. These clinics do not have pharmacists, however they do have other non-pharmacist licensees who have the right to compound. The term 'IV hydration clinic' itself is not well-defined by the board, and it is foreseeable that the board could choose to include any medical office that provides IV hydration or IV nutrients in this category, offices in which compounding might be conducted by any of a variety of types of licensed non-pharmacist practitioners who should not be under the purview of the Board if it were not for the current language in your regulations. Therefore, the claim that your compounding regulations do not or will not interfere with compounding by non-pharmacist licensees is disingenuous. Please do note and respond to this paragraph in full in your reply as well.' Given all of the above, I recommend you add the following or similar wording somewhere within Title 16 CCR: "The regulations in Title 16 CCR Sections 1735 et seq, 1736 et seq, 1737 et seq, and 1738 et seq do not in any way apply to the practice of compounding by non-pharmacist licensees who have the right to compound based on their own practice act."	

#	Section	Commenter	Comment	Board Response
1	General	Loh Francis	The commenter expressed frustration with the Board and the proposed compounding regulations. Although the commenter indicated that they understand the need for everyone to have an opportunity to comment, the commenter indicated that it is frustrating to that those opposing the regulation are interfering and delaying the regulations. Based on all the discussions the commenter has listened to and read, they indicate that it is clear that the vast majority of commenters are requesting access to specific compounded products from bulk drug substances that are outside the purview of the Board. The Board cannot approve these drugs and cannot authorize them to be compounded. The commenters stated that these individuals need to take their fight where it belongs: the FDA. The commenter stated that it is shocking that these commenters are threatening Board members and making crazy accusations without any evidence but then demanding the Board provide evidence. Protect Californians and pass these regulations now. This has gone on long enough! Stop accepting the false narrative being put forth by a few and amplified by their followers.	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board appreciates the commenter's focus on public protection and notes that the Board is required to follow the legal requirements to promulgate regulations.
2	General	L. Linton	The commenter has Neuro Lyme Disease. The commenter references a letter from Stop The Bop stating why these compounds are critical to survival for so many Californians. The commenter adds that finding the right treatment for their Lyme Disease, doctors need to know that they have access to these compounds whenever they feel they're needed in my treatment plan as do the doctors of Long COVID patients, firefighters that just fought the Palisades and Eaton fires and thousands of other California patients for whom these drugs are their hope to better health or even a cure. Please do not cut off access to these compounds or the compounding pharmacies that provide access to these critical drugs. They are widely available across the rest of the United States so it seems if California wants to be seen as a shining example to	The Board believes that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk substances. After further consideration of the issue, the Board determined an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate.

			the rest of the US of how to live a healthy lifestyle the state needs to make sure access to these compounds is available to some of its sickest patients. Without it there will be patients with diseases or illnesses similar to mine who will never be able to live a healthy life again. In 2025 it is totally unacceptable to ban safe and studied compounds that can heal people.	Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
3	General	J. Smith	The commenter has multiple rare chronic illnesses. Some of their only good days are because of compounded intravenous things like glutathione, b12 and other b vitamins. Please, do not take these things away. The commenter adds "If my health gets any worse I don't know what point there is for me to stay alive. These compounds give me the health and hope I need to continue."	The Board believes that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk substances. After further consideration of the issue, the Board determined an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
4	General	J. Boren	The commenter is against the banning of any natural medicine, specifically glutathione. The commenter states that taking Glutathione will destroy lives, if not kill those who desperately need it like firefighters, but there are thousands of people who need glutathione for their health. Please, do not do this.	The Board believes that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk substances. After further consideration of the issue, the Board determined an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to

				Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
5	General	D. Nicholas	I'd like to ask that you please reconsider the proposed regulations that would severely limit access to critical sterile compounded medications like injected and nebulized glutathione, methylcobalamin, NAD+, and others. These treatments are essential for many, including firefighters and chronic illness patients such as my wife, who counts on them to live an unencumbered life. During the February 5, 2025 meeting, board members briefly considered the possibility of pulling out the part of these regulations that was causing the most stir with people, and I'm begging you to consider that option, if you cannot outright reject these new regulations in full.	The Board believes that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk substances. After further consideration of the issue, the Board determined an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
6	General	C. Weis	I was diagnosed with Chronic Lyme and Bartonella in 2017. Since that time I have received Glutathione in all its forms with potentially life saving results. After experiencing both cognitive and memory impairments I became disabled from my career as a Masters Prepared RN. I subsequently received IV antibiotics which significantly caused elevated liver enzymes to alarming levels. Glutathione allowed me to continue my antibiotic therapy by normalizing my liver function. Since completing my IV antibiotics, I now take oral antibiotics on an intermittent basis when my cognitive function begins to once again decline. During these periods; usually twice each year, I also take glutathione supplements orally or topically. Additionally I receive IV glutathione with positive results within just a few days. My mind clears and my memory rebuilds itself. I become "me" again.	The Board believes that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk substances. After further consideration of the issue, the Board determined an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.

			I rely on my infusions of glutathione to help me regain the part of me that has been lost to this horrible chronic and life altering disease. Please do not remove Glutathione. Like so many others, I value it. Glutathione has saved my life.	
7	General	C. Orr	Please do not restrict patients' access to glutathione and other modes of detoxing! When I had Lyme disease, I infused some on a daily basis and it helped tremendously. People who are fighting toxins of any kind need access to these treatments in order to support their bodies' fight to get rid of them and take the burden off their system.	The Board believes that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk substances. After further consideration of the issue, the Board determined an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
8	General	C. Miller	The commenter is a patient and these(?) are their treatment and to be dented(?) this is not fair.	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board was challenged to provide a more significant response as the comment submitted does not appear complete.
9	General	C. Auerbach	The commenter got Lyme Disease during a hike in S. California in 1996 and got the bull's eye rash, but the approved medical blood test came back negative. With continually worsening health, TWO tests in 2005 that confirmed Lyme Disease. Short-term antibiotics were obviously no longer applicable. The commenter started having Grand Mal seizures in 2007 and has had a long and expensive journey back to functionality, which involved many different alternative therapies. Do not cut off people from treatments that actually work.	The Board believes that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk substances. After further consideration of the issue, the Board determined an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance

				documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
10	General	B. Mockus	Please stop creating bureaucracy and roadblocks that will change patients ability to CHOOSE for their own health and access these medications at prices we can afford. As a Lyme disease and co-infection patient, these medications help me keep functioning. Without them, my quality of life will dramatically fail. There are so many areas of healthcare where we need to increase access, not reduce it. Please don't add to this problem. Please do not further regulate or restrict our access to the point where manufacturers and pharmacies will cease to make these items available. They are life sustaining for us.	The Board believes that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk substances. After further consideration of the issue, the Board determined an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
11	General	A. Johnston	The commenter has been a private family nurse practitioner since 2017 and has been in healthcare since 2003. The commenter quickly realized that many patients are not optimally treated with prescription pharmaceuticals. Typically, these are a bandaid for the root cause of the issue, and the patient ends up with more adverse effects and symptomology that needs additional medications. The commenter began using compounded medications, vitamins, and molecular repair options such as NAD+ and NMN and saw amazing benefits in their patient population, including patients with neurogenerative disorders, alcoholics, severe cardiovascular and neurovascular disease. Without these options, these patients typically require hospitalization,	The Board believes that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk substances. After further consideration of the issue, the Board determined an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate.

			infusions of iron, antibiotics, experience severe infections sometimes leading to death. And even mild cases of patients that experience chronic fatigue, depression and anxiety, and obesity have greatly improved their health and wellness. This impacts not only their day to day, but their ability to show up to work, show up in their community, and be present for their families. Taking these options away for patients would be like shooting them in the foot and expecting them to continue to walk at their usual pace. It's just not possible. The commenter strongly advises the Board to allow these options to be produced, manufactured, and shipped into the state, to prevent increasing morbidity, mortality, and even the exodus of patients leaving the state permanently or going to other states or countries to obtain their healthcare.	Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
12	General	A. Griffin	Please do not eliminate access to safe and critical Category 1 substances like glutathione, NAD+ and methylcobalamin. These products have been critical to our family's health as we try to recover from multiple rounds of Lyme disease and co-infections and the immunological and neurological issues those diseases cause. Glutathione is one of the very few substances my damaged body has been able to tolerate and benefit from in my 20+-year Lyme journey. Genetic testing has shown that I cannot make enough on my own and will likely need access to treatment with it for the rest of my days. It's bad enough that we have had to pay out-of-pocket for these substances for over two decades because of America's broken healthcare systems.	The Board believes that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk substances. After further consideration of the issue, the Board determined an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
13	General	L. Mendelovich	The commenter is writing, as someone who needs glutathione to treat chronic illness, to express strong opposition to the proposed regulations that would severely limit access to critical sterile compounded medications like injected and nebulized glutathione, methylcobalamin,	The Board believes that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk substances.

			NAD+, etc. and to urge the Board to carve out the section about Category 1 bulk compounds from the larger regulation package.	After further consideration of the issue, the Board determined an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
14	General	L. Vorhees	Please do not restrict lifesaving compounds such as glutathione and methyl b12 in California. I need these compounds regularly to address chronic Lyme disease and genetic issues. I need all the help I can get, and there are many others like me. Please do not add more chaos into a medical system that already fails me.	The Board believes that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk substances. After further consideration of the issue, the Board determined an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
15	General	M. Millon	I want you to know that my son would be dead by now if it were not for his IV glutathione. Please do not make it impossible to get. This would be a crime against humanity.	The Board believes that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk substances. After further consideration of the issue, the Board determined an approach that relies on a

				pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
16	General	N. Serocki	Do NOT restrict this effective treatment. I used it personally under the supervision of Dr. C. Martinez years ago. After nothing else was working in my serious debilitating illness, this is what gave me my life back, and it was a turning point that showed me I could recover and not stay bedridden. It was effective and did its job. I no longer needed them and recovered. Without it, I don't know if I would be here today. PLEASE do not restrict what I and many other patients have known for over 12 years. It works, it did not harm, and it gave my body the ability to recover from a devastating illness. I had gone to many a doctor in San Diego before I found Dr. Martinez, MD, and her decision to use the IV Glutathione therapy and a couple of other items gave me my life back. There is no reason after years of safety and efficacy to remove this from patients. It is wrong to take this away and why would you want to reverse what patients have found helped them get their lives back, like me.	The Board believes that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk substances. After further consideration of the issue, the Board determined an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
17	General	M. Morgenstern	The commenter asks for the Board to listen to and pay attention to the public's comments about Category 1 Sterile Compounds. It appears that only three board members are actually listening to public comments. The rest of the board appears to be married to their own old tired biased agenda. As a local elected official I find it extremely disappointing that public comments from Pharmacists, Medical Doctors, Veterinarian's, Firefighters, Lyme Disease and Chronic Fatigue Patients and any other patient that has found using Category. 1 Sterile Compounds helpful for treatment are not being listened to and respected.	The Board believes that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk substances. After further consideration of the issue, the Board determined an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance

			We do not need stricter regulations on Category 1 Sterile Compounds. The fact that so many of the board members are ignoring public comments is beyond disturbing and lacks integrity. I have contacted both of my Assemblymembers' offices to inform my Assemblymembers that the public's comments are being ignored. Please stop the farce and listen to the good people of California and then act accordingly. You are suppose to actually listen to public comment and to represent the residents of California. So far only three board members are actually listening. I personally have found compounded Glutathione and B12 extremely helpful for treating Lyme Disease. Do not make it harder for Lyme Patients who are already suffering enough to receive treatment. Many of us are living in poverty after spending thousands of dollars attempting to get well. We do not need any added hardships inflicted on us from a board with their own agenda. The proposed amendments to Title 16 of the California Code of Regulations, Sections 1735-1738, impose unnecessary restrictions on access to Category 1 sterile compounds, such as glutathione, methylcobalamin, and NAD+. These regulations, as currently written, will devastate patient access to life-saving treatments in California, despite no evidence of safety risks warranting such measures. In the wake of the Palisades and Eaton fires, Californians are grappling with the health consequences of prolonged toxic smoke inhalation, including toxin buildup in lung tissue. For many, the only effective treatment to address these toxins is nebulized and intravenous glutathione. These therapies are utilized by firefighters, Lyme Disease and Long COVID patients, and individuals with conditions like ME/CFS and methylation impairment. Denying access to these critical treatments endangers vulnerable populations and ignores the unique health challenges faced by our state.	documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.

			USP does not require full stability studies for Category 1 or 2 sterile compounding. These requirements only apply to Category 3 compounding. For the Board to mandate such studies—which can cost \$10,000 to \$30,000 per formulation—imposes an insurmountable financial burden on pharmacies. This will force them to limit offerings to the most generic formulations, eliminating the ability to create customized treatments based on individual prescriber orders.	
18	General	R. Horowitz	The commenter is a board-certified internist with 41 years of experience who regularly uses compounded medication by excellent licensed pharmacists. Glutathione is part and parcel of the 9-week oral antibiotic protocol using dapsone combination therapy (see the articles below) which helps to lower methemoglobin levels, support detoxification and lower Herxheimer reactions by blocking NFκB during Lyme treatment. It has also been essential in protecting patients from the effects of COVID-19. I published the first article in the world medical literature on the use of GSH in COVID-19 in April 2020 and not one of my patients died during the pandemic using higher dose GSH helped decrease oxidative stress (and the virus needs to lower GSH to replicate). Horowitz, R.I., Freeman P, Bruzzese, J. Efficacy of glutathione therapy in relieving dyspnea associated with COVID-19 pneumonia: A report of 2 cases. Respiratory Medicine Case Reports, April 21, 2020. Article Number: 101063 https://doi.org/10.1016/j.rmcr.2020.101063 Along with compounded glutathione, some of my patients require compounded B12 and other medication because of chemical sensitivity and mast cell activation. They can not live without them. Please do not restrict these essential compounded medications which are life saving in my patient population. Dapsone documentary: https://players.brightcove.net/6314452011001/PAMDt93Yi_de_fault/index.html?videoid=6353288590112	The Board believes that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk substances. After further consideration of the issue, the Board determined an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.

		10 Dapsone Articles on The Effective Treatment of Chronic LD & Associated Co-infections Including Bartonella: As of May 11, 2024 Horowitz, R.I.; Fallon, J.; Freeman, P.R. Combining Double-Dose and High-Dose Pulsed Dapsone Combination Therapy for Chronic Lyme Disease/Post-Treatment Lyme Disease Syndrome and Co-Infections, Including Bartonella: A Report of 3 Cases and a Literature Review. <i>Microorganisms</i> 2024, 12, 909. https://doi.org/10.3390/microorganisms12050909 Horowitz, R.I.; Fallon, J.; Freeman, P.R. Comparison of the Efficacy of Longer versus Shorter Pulsed High Dose Dapsone Combination Therapy in the Treatment of Chronic Lyme Disease/Post Treatment Lyme Disease Syndrome with Bartonellosis and Associated Coinfections. <i>Microorganisms</i> 2023, 11, 2301. https://doi.org/10.3390/microorganisms11092301 Horowitz RI, Freeman PR. Efficacy of Short-Term High Dose Pulsed Dapsone Combination Therapy in the Treatment of Chronic Lyme Disease/Post-Treatment Lyme Disease Syndrome (PTLDS) and Associated Co-Infections: A Report of Three Cases and Literature Review. <i>Antibiotics</i>. 2022; 11(7):912. https://doi.org/10.3390/antibiotics11070912 https://www.mdpi.com/2079-6382/11/7/912/html Horowitz, R.I.; Freeman, P.R. Efficacy of Double-Dose Dapsone Combination Therapy in the Treatment of Chronic Lyme Disease/Post-Treatment Lyme Disease Syndrome (PTLDS) and Associated Co-infections: A Report of Three Cases and Retrospective Chart Review. <i>Antibiotics</i> 2020, 9, 725. https://doi.org/10.3390/antibiotics9110725 Horowitz, R.I., Murali, K., Gaur, G. et al. Effect of dapsone alone and in combination with intracellular antibiotics against the biofilm form of <i>B. burgdorferi</i>. <i>BMC Res Notes</i> 13, 455 (2020). https://doi.org/10.1186/s13104-020-05298-6 https://bmcrsnotes.biomedcentral.com/articles/10.1186/s13104-020-05298-6	

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19	General	R. Smith	Regarding potential new hurdles or restrictions to safe and effective compounds such as NAD+, Glutathione, and B-12. These compounds (using trusted compounding pharmacies like Infuserve) have proven a critical leg in the care of loved ones. Please do not restrict them further as many Californians/Americans will suffer even more than they are under a complex and frustrating system.	The Board believes that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk substances. After further consideration of the issue, the Board determined an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
20	General	S. Gevorkian	The commenter is writing to express strong opposition to the proposed ban on the compounding of NAD, glutathione, B12, and other essential compounds. This proposal is an unnecessary and harmful restriction that will have serious consequences for patients, healthcare providers, and the advancement of medical treatment. Compounded therapies are a critical component of individualized patient care, offering solutions that cannot be met by standard pharmaceuticals. NAD, glutathione, and B12 are used in a variety of medical applications, including neurological support, immune function, metabolic health, and chronic disease management. Banning these compounds from compounding pharmacies will deprive patients of access to safe, effective, and often life-changing treatments. The proposed ban undermines the medical autonomy of licensed healthcare professionals who rely on compounding to provide personalized treatment plans for their patients. Many individuals depend on compounded formulations because commercially available alternatives are inadequate, inaccessible, or do not meet their specific	The Board believes that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk substances. After further consideration of the issue, the Board determined an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.

			medical needs. Without these options, patients will be left with fewer choices, leading to worsened health outcomes, increased healthcare costs, and the potential need to seek care outside of California. There is no substantial evidence that compounding these substances poses a widespread public health risk when performed by licensed professionals following appropriate guidelines. Instead of imposing an outright ban, the Board should focus on maintaining high standards for compounding safety, ensuring that patients continue to have access to these vital compounds while upholding quality and regulatory oversight. This ban does not serve the best interests of the public or the medical community. It disregards the scientific basis for these treatments, the needs of thousands of patients, and the role of physicians, naturopathic doctors, and other licensed providers who prescribe these compounds responsibly. The Board should consider the real-world impact of such a decision and recognize that compounding is an essential practice that supports patient health in ways that standard pharmaceuticals cannot. I urge you to reject this proposal and work toward policies that protect patient access to necessary treatments without imposing blanket prohibitions that will do more harm than good. Patients and healthcare providers should not have to fight for access to well-established and beneficial therapies. I strongly encourage the Board to reconsider this approach and prioritize solutions that enhance safety without eliminating access to vital medical care.	
21	General	S. Shah	I am urging you to please keep Category 1 steriles such as glutathione, B12, NAD+, etc., allowable in the state. Being able to use this detoxification compounds has been life saving to me and my family and others that have genes that do not allow normal detoxification.	The Board believes that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk substances. After further consideration of the issue, the Board determined an approach that relies on a

				pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
22	General	W. Freitag	The restrictions you are proposing on natural compound treatments like Vitamin B12 and Glutathione is a slap in the face to our heroic firefighters and first responders. They selflessly expose themselves not just to physical harm but to the toxic chemicals that leech from devastating wildfires like the ones experienced in LA last month. Firefighters and first responders rely on these simple, affordable and effective compounds to detoxify so they can keep doing the critical work to keep all Californians safe. Another group at risk from these proposed regulations are those suffering from Lyme Disease and other ailments like Cystic Fibrosis, where the simple, affordable treatments have shown true efficacy. My good friend is one such person, and she relies on glutathione to treat her Lyme illness. Another angle to consider here is that the banning of such compounds is a violation of the interstate commerce clause of the United States Constitution, and that any attempt to regulate the sale and distribution of these compounds can (and will) be challenged in federal court. Meanwhile, no other state is considering such a ban. All you are doing here is burdening the people of our great state with the requirement to cross state lines to seek these vital treatments. Save yourselves the humiliation. Back down now.	The Board believes that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk substances. After further consideration of the issue, the Board determined an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
23	General	S. Johnson	I am submitting this comment in strong opposition to the proposed regulations on sterile compounding, particularly those that would severely limit access to critical compounded medications, including nebulized glutathione, methylcobalamin, NAD+, and other necessary treatments. These treatments are essential for thousands of patients	The Board believes that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk substances.

		across the state—especially those suffering from chronic conditions such as ME/CFS, Long COVID, and for firefighters exposed to toxins in the line of duty. The key issue with the proposed regulations is the financial burden they place on pharmacies, making the continued availability of these life-saving medications effectively unsustainable. Stability studies, which are required by these new regulations, are costing between \$10,000 and \$30,000 per formulation, with some common combinations potentially costing upwards of \$90,000 to comply. These costs are prohibitively expensive for many pharmacies, especially smaller ones that rely on compounding customized medications for their patients. To be clear, these stability studies are not required under current FDA or USP guidelines for many of the substances in question. As Maria Serpa correctly noted in her statement, the FDA's Category 1 list of approved bulk substances already ensures these treatments are safe and can be compounded without the need for additional studies. However, the proposed regulations introduce additional stability study requirements and documentation, making compliance financially unfeasible for many compounding pharmacies. Serpa's assertion that these regulations merely reflect federal and USP guidelines is misleading. She stated that "nothing in here says that each and every pharmacy needs to test all of these things for each and every compound," but this does not reflect the reality of the regulations as they are written. These rules will require many pharmacies to perform tests they are not currently required to under federal standards. This will raise the cost of these medications, making them inaccessible to patients who rely on them, despite the FDA and USP guidelines already providing a clear pathway for their safe use without such additional regulatory burdens. For example, Section 1736.9 of the proposed regulations introduces requirements for stability testing that exceed USP <797> standards. The FDA 503A guidelines permit the use of	After further consideration of the issue, the Board determined an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.

			published, reputable stability data from manufacturers or other sources, and USP <797> similarly does not mandate in-house stability studies for substances like glutathione and NAD+. These proposed additional testing requirements create a financial barrier that will result in reduced availability of these medications, despite their long-established safety in compounded formulations. The Board has failed to provide compelling evidence to justify the proposed regulations. The November 2024 education session was biased and misleading, with none of the examples presented being relevant to the current circumstances. Despite clear objections from the public, including on the day of the presentation, the Board continues to reference this session as a necessary source of information for the public and fellow Board members to shape and justify these proposed regulations. This ongoing reliance on inaccurate and unsubstantiated information undermines the credibility of the regulatory process. I also want to address the impact this will have on public health, particularly during California's ongoing wildfire crisis. As we know, toxic smoke and particulate matter released by wildfires severely impact respiratory health, especially for vulnerable individuals. Research has shown that nebulized glutathione has a protective effect against harmful toxins like hydrogen cyanide, benzene, and polycyclic aromatic hydrocarbons released by wildfires. This is especially relevant as many individuals who are already battling the health impacts of long-term exposure to environmental toxins—such as first responders and people with compromised respiratory health—rely on treatments like nebulized glutathione to protect their lungs and reduce exposure to harmful substances. Denying access to treatments like this will undoubtedly harm those most at risk. Moreover, the recent decision by the National Institutes of Health (NIH) to limit indirect costs for research institutions—capping them at just 15%—has serious implications for the future of medical research. These cuts reduce the ability of universities and	

			research organizations, including those in California, to conduct critical research that could lead to FDA-approved treatments for conditions like ME/CFS, Long COVID, and other chronic illnesses. NIH cuts threaten the infrastructure that supports studies on vital treatments, and without FDA-approved therapies for these conditions, compounded treatments remain one of the few viable options. The proposed regulatory burdens on pharmacies add further barriers to accessing these treatments, exacerbating the risk for patients who have no other options. Indirect costs are essential for covering the basic infrastructure of research—everything from lab space and equipment to the salaries of the support staff who make these studies possible. By limiting this funding, NIH is essentially cutting the financial foundation necessary to conduct any significant research, including the kind of research that could lead to FDA-approved treatments for conditions like ME/CFS, Long COVID, and others that are currently underserved by existing treatments. In the absence of FDA-approved treatments for these conditions, researchers in California and across the nation have been working tirelessly to explore alternatives, including compounded medications like nebulized glutathione, methylcobalamin, and NAD+. However, with these severe cuts to research funding and regulatory barriers created by the proposed California regulations, these treatments—often essential for patients with chronic illnesses—will become increasingly difficult to access. This is a direct threat to patient health, particularly as more people with conditions like ME/CFS and Long COVID struggle to find effective care. These cuts and proposed regulatory hurdles are a public health crisis in the making. Research into these critical treatments, especially as California faces the ongoing risk of wildfire smoke and the environmental toxins that accompany it, is essential for safeguarding vulnerable populations. The increasing financial burden on pharmacies due to unnecessary regulatory requirements only further	

		exacerbates the issue, making it less likely that patients will have access to the compounded treatments they need. On a personal note, my own experience underscores the urgency of this issue, the restriction of doctor-patient autonomy, and limiting interference in healthcare options. My primary care doctor, an osteopathic family medicine specialist at a large, multi-site practice, has been administering IVs with NAD+, glutathione, and Vitamin C with significant improvement in my symptoms. Given the severity of my medical condition, it is extremely difficult for me to leave the house to receive treatments in-office twice a week. The post-exertional malaise (PEM) I experience from such physical exertion makes it necessary for me to manage my energy very carefully and within a restricted “energy envelope.” These trips, which require dressing, bathing, and traveling to the office, contribute to my symptom flare-ups and are simply unsustainable. My doctor has agreed that continuing this therapy at home with compounded medications would be the most practical solution, yet it is exceedingly difficult to find a pharmacy that will provide or ship these compounded treatments due to the burdensome and overly restrictive regulatory environment. It seems that pharmacies are already being forced to adhere to requirements that go beyond federal guidelines—requirements that appear to be both unnecessary and damaging. These limits patients like me from accessing treatments that provide tangible benefits, despite the widespread medical need for these therapies. In addition to the challenges facing patients like me, I want to highlight an issue that has been exacerbated by the current regulatory environment in California. AgelessRx, a well-known telemedicine provider, has been forced to stop shipping vials of NAD+ and glutathione to California patients due to these underground regulations. AgelessRx had previously provided these treatments to patients in California without issue, but as the harmful nature of these regulations and the punitive actions taken against compounding	

		pharmacies have gained wider recognition, they ceased shipping these life-saving medications to the state. This is a clear example of how these regulations are not only overreach but are actively harming patient access to therapies that many of us rely on. Patients in California, including those with ME/CFS, Long COVID, and other chronic conditions, are now left without a viable option for obtaining these essential treatments. Furthermore, Simmaron Research, a prestigious ME/CFS research clinic, has partnered with AgelessRx to advance a groundbreaking clinical trial investigating the efficacy of Low-Dose Rapamycin in treating ME/CFS, Long COVID, and other infection-associated chronic conditions. This collaboration aims to leverage AgelessRx's expertise in decentralized clinical trials to enhance patient access and streamline the study process. Early trials suggest that Low-Dose Rapamycin has the potential to induce remission in ME/CFS patients, with significant improvement in symptoms such as post-exertional malaise (PEM) and fatigue. According to a study by Dr. Montoya and others published on Health Rising (2022), Rapamycin shows significant promise in improving chronic fatigue symptoms. Furthermore, PolyBio.org's ongoing Long COVID clinical trial on Low-Dose Rapamycin points to substantial potential for symptom relief in long-term COVID patients, showcasing the drug's capacity to modify immune response and treat chronic fatigue-related conditions. However, the restrictive and punitive regulations in California have created an environment where compounding pharmacies are unable to provide these essential treatments. The increasing recognition of the damaging nature of these regulations has led to limited access to life-saving therapies for Californians. This restriction creates a clear and dangerous gap in the availability of treatments for patients who are already struggling to find effective care.	

			I applaud and highlight the statements made by Members Trevor Chandler, Jeff Hughes, and Dr. Nicole Thibeu, who have intelligently, thoughtfully, compassionately, and appropriately expressed support for expanding patient access to these critical treatments. Member Chandler demonstrated wisdom and applied his insight from years of grassroots advocacy, "Responses like this are not false; they are not to be disregarded. The voices we have heard deserve to be taken seriously, and they deserve to be given the respect of showing that the effort they did to have their voices heard at this meeting and advocate to us are taken as seriously as possible." Member Hughes demonstrated compassionate and forward-thinking advocacy on behalf of disabled individuals, firefighters, first responders, and those impacted by urban-wildland fires. Jeff Hughes' remarks, "There are hundreds, if not thousands, of people using these compounded medications across the state", reflect the reality of the wide-reaching need for these treatments. His comments underscore the urgent need for thoughtful, immediate action as this crisis intensifies in Los Angeles and across California. The world is watching how public health bodies will respond to this growing climate and environmental emergency. Additionally, Dr. Nicole Thibeu demonstrated vulnerability and the unmatched wisdom of lived experience. She highlighted the potential harm these regulations could cause. Her pointed question (whether these regulations could inadvertently create greater risks by limiting access to necessary treatments) reminds us that people will find ways to access critical medical care, whether it's for abortion or for treating conditions like Long COVID and ME/CFS, which currently lack FDA-approved treatments. And let's not forget that 5% of all ME/CFS patients complete suicide due to the unbearable suffering of the condition. Access to sterile compounds like GLP-1s, especially in times of shortage, saves lives and has been demonstrated to reduce risk and ideation of suicide.	

			In July, Dr. Nicole Thibeu was moved by the outpouring of personal pleas from people with Long Covid and ME/CFS and urged, "People with chronic illnesses and disabilities are always an afterthought. And I'm encouraging us to reposition that as being one of our main focuses." She also very clearly said, "We're causing more harm if we take away treatments from people who have diseases that don't have any approved treatment." She reminded the entire board and the public that, "And if we take away tools that are helping them and protecting them, I can't feel like we're meeting our mission." These are the voices that must guide this decision-making process. Shockingly, today we're fighting to maintain our very existence. Seeing the severe, unconstitutional, and bigoted ongoing federal efforts to undermine existing hard-won protections under Section 504 of the Rehabilitation Act, California must once again lead the way. Section 504 of the Rehabilitation Act, established in 1973, was a direct result of activism in California, where disability rights activists in San Francisco led the historic 504 Sit-in, demanding equal access and protection for people with disabilities. This incredible movement was a turning point in the fight for disability justice, and California's leadership in this fight remains a point of pride. The recent federal complaint filed by Texas threatens to dismantle our precious healthcare and disability access protections. This is going to be the first of many deliberate efforts to erase basic human rights for people with disabilities, if not eliminate us completely. Given California's legacy of advocating for the disabled, the state must continue to take deliberate and incisive action to protect the chronically ill and disabled community, including those suffering from conditions like ME/CFS and Long COVID. The federal government's planned strategy to eliminate our rights makes it even more critical for the California Board of Pharmacy to ensure that residents have expanded access to lifesaving compounded treatments. These therapies are	

		essential for individuals who have no FDA-approved alternatives. Without them, many will continue to suffer. California must preserve its role as a leader in disability rights by making access to these therapies not just a priority but a guarantee for its most vulnerable residents. The proposed sterile compounding regulations would place substantial financial burdens on pharmacies, effectively blocking access to essential treatments. At a time when federal protections are under attack, California cannot afford to restrict access to these life-saving therapies. Instead, the state must prioritize safeguarding healthcare access for its most vulnerable residents, ensuring that they receive the critical treatments they need to survive and thrive. In contrast, the Board's failure to engage meaningfully with stakeholders and their refusal to amend the proposed regulations in response to the overwhelming public opposition—which includes over 11,000 petition signatures and hundreds of written and in-person comments—raises serious concerns about the adequacy of the Board's regulatory process. By stating that the public “does not understand federal or state laws,” the Board continues to dismiss well-informed, thoughtful concerns from patients, healthcare professionals, and advocates who rely on these treatments. No meaningful collaboration has been demonstrated between the Board and healthcare providers, including doctors, pharmacists, and naturopaths, to ensure that patient needs are met and that the regulations support, rather than hinder, effective medical care. I urge the Board to align these proposed regulations with the federal FDA and USP guidelines, which already provide a safe, well-established framework for compounding these essential medications. Further, I ask the Board to focus on creating a regulatory environment that makes these life-saving treatments more accessible and affordable, not less. (Refer to comment for supplied references)	

24	General	P. Pitts	My name is Peter Pitts. I am the President of the Center for Medicine in the Public Interest (www.cmpi.org) and a former Associate Commissioner at the FDA. I write to you to weigh in on the issue of drug compounding — and particularly the compounding of GLP-1 agonist products. I know you are likely to be inundated with comments on this issue, so I will be as consist possible. A few key points: * These products are illegal and unregulated. Caveat emptor is bad healthcare policy. * The advertising and marketing of these products are also illegal. * There is a difference between drug compounders and companies running illegal pharmaceutical manufacturing operations. * Not stridently working to stop these illegal drug manufacturers is an open invitation to counterfeiters. * Playing Russian Roulette with the lives of Californians is unacceptable. Below are a few articles (by me) that support all of the above statements — and more. https://www.washingtontimes.com/news/2024/sep/5/compounders-of-drugs-that-fight-diabetes-obesity-s/ https://www.washingtontimes.com/news/2024/sep/19/weight-loss-confusion-lets-not-compound-problem/ https://www.washingtontimes.com/news/2024/feb/12/redlining-americas-girth-new-medicines-help-battle/	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board agrees with the public safety concerns raised by the commenter. The Board's proposed regulations generally seek to align with federal law and guidance and USP standard. The Board continues to monitor for information released from the FDA and evaluate for insanitary conditions during inspections.
25	General	Unknown Mailed Comment	A commenter states that if pharmacies can sell harmful tobacco and uppers, the Board can allow compounding pharmacy treatments. The commenter adds that Walgreens sells cigarettes, and CVS sells "uppers" caffeine pills that send college kids to the ER. Firefighters have given their lives to protect the state and are asking that the Board stop trying to block nebulized glutathione.	The Board believes that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk substances. After further consideration of the issue, the Board determined an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate.

				Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
26	General	B. Go	Issue #2: Given the BOP's previous claim in published administrative cases that the FDA requires the existence of a USP DRUG monograph in order to allow sterile compounding of any substance, not exempting 503a bulk drug category 1 substances, with the claim that the substance could not be determined to be pharmaceutical grade without such a monograph, I'd like you to explicitly clarify, by responding to this comment, whether the proposed regulations, as currently worded, would allow for the STERILE compounding of bulk drugs under the 503a bulk category 1 list, EVEN IF THERE DOES NOT EXIST A USP DRUG MONOGRAPH for the substance (though there might exist a non-US drug monograph OR a US dietary supplement monograph), and as long as stability study requirements, quality testing requirements and proper compounding procedures as delineated in the BOP's regulations are met. Issue #3: Question: On day one of the February 5th meeting, one of the board members stated that a 503b Outsourcing facility is able to make patient-specific medications. This is not consistent with what I have been told by the outsourcing facilities themselves, as well as by my medical peers. Can you please confirm if that board member's statement was correct?	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board agrees with the commenter that the Board's proposed regulation text allows for the compounding using an active pharmaceutical ingredient that does have a USP drug monograph under specified conditions. Further, the Board believes that its recommended changes to the language in sections 1736.9 and 1739.17 (please refer to Addendum 1 for the recommended text) continue to provide a legal pathway to compound with Category 1 bulk drugs substances. The Board also directs the commenter to Business and Provisions Code Section 4129(e), which establishes the authority for an outsourcing facility licensed by the Board to dispense patient-specific compounded preparations under specified conditions.
27	General	Kaiser	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. The end result was the updated USP compounding chapters, which were designed to provide comprehensive evidence-based best practices for the	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board previously considered the comments, most recently during its January 8, 2025 Board meeting. The Board does not believe a delay in effective date is appropriate

		compounding of all compounded drug preparations in all compounding environments. Throughout the rulemaking process, the Board has assumed that adding what it views to be omissions from the USP compounding chapters to its own regulations will improve the safety of compounding and compounded products for California consumers. This is a faulty assumption; in fact, excessive regulations in healthcare, particularly those not supported by empirical evidence, can significantly increase complexity in the healthcare system and lead to an increased risk of errors. According to the American Hospital Association, regulatory overload not only raises costs to the healthcare system but also reduces the time healthcare professionals can dedicate to direct patient care, thereby increasing the likelihood of errors.² As such, we believe that the Board's decision to promulgate additional requirements on top of the USP standards, particularly regulations without supporting evidence, will increase the complexity that pharmacy licensees must navigate and is just as likely to introduce new sources of error as it is to protect California patients. Given these factors, Kaiser Permanente continues to support the following alternative approach: 1. The Board should accept the proposal to repeal sections 1708.3, 1708.4, and 1708.5 of Title 16, Division 17, Article 2 of the California Code of Regulations and to repeal 1735 et seq of Title 16, Division 17, Article 4.5 of the California Code of Regulations and to repeal 1751 et seq of Title 16, Division 17, Article 7 of the California Code of Regulations. 2. The Board should reject the proposal to add new sections 1735 et seq of Title 16, Division 17, Article 4.5 of the California Code of Regulations, and to add new sections/Article 1736 et seq of Title 16, Division 17, Article 4.6 of the California Code of Regulations, and to add new sections/Article 1737 et seq of Title 16, Division 17, Article 4.7 of the California Code of Regulations, and to add new sections/Article 1738 et seq of Title 16, Division 17, Article 4.8 of the California Code of Regulations. 3. The Board should enforce the provisions of the USP compounding chapters as required by California Business and Professions Code section 4126.8.	except were identified in the proposed regulation text. It has been common practice for the Board to focus on education of new requirements to facilitate compliance when immediate public harm is not at stake and where the licensee is making a good faith effort to come into compliance with new requirements.

			If the Board elects to finalize the proposed regulations, we continue to encourage the Board to establish a rational effective date for these regulations that will provide the regulated public with ample time to come into compliance with these new requirements. Given the nature of the changes that have been made during previous public comment periods, we believe that a period of nine months—rather than the one-year period we were previously requesting—from the date that the regulation is filed with the Secretary of State would be a reasonable effective date. If the proposed regulation is finalized as written, Kaiser Permanente will need to make extensive updates to our policies and standard operating procedures and enhancements to our pharmacy information systems. These tasks are time-consuming, costly, or both and, as such, the Board should establish a delayed effective date for organizations to do the work needed to meet these requirements.	
28	General	National Consumers League	Especially as our work relates to nutrition and health, NCL is deeply concerned about the growing epidemic of obesity, which now affects 41.9 percent of US adults – more than 100 million people – as well as 27.7 percent of Californians. Besides being a serious chronic disease that negatively impacts almost every aspect of health and well-being, obesity worsens the outcomes of over 230 obesity-related chronic diseases, is linked to approximately 400,000 premature deaths each year and costs the U.S. economy an estimated \$1.72 trillion annually. While these facts should disturb all Americans, the reality is that obesity is still not viewed as a serious disease and health plans routinely exclude coverage for FDA-approved anti-obesity medications. Thus, too many Americans opt for unauthorized or counterfeit versions of weight loss drugs, and especially injectable glucagon-like peptide-1 receptor agonists (GLP-1s) used to treat diabetes and obesity. It is because of issues like this that NCL worked with the National Council on Aging and leading obesity experts to issue the first Obesity Bill of Rights for the nation so people with obesity will be screened,	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board agrees with the public safety concerns raised by the commenter. The Board's proposed regulations generally seek to align with federal law and guidance and USP standard. The Board continues to monitor for information released from the FDA and evaluate for insanitary conditions during inspections.

		diagnosed, counseled, and treated according to medical guidelines. First among these rights is having accurate, clear, trusted and accessible information about obesity, which must include being warned about fake GLP-1s and the potential health consequences. The bill of rights also establishes the right to person-centered care, which necessitates that GLP-1s are produced safely and responsibly under the supervision of a qualified health provider and supplied by a licensed manufacturer or pharmacist. In furtherance of these rights, on February 5, NCL issued a national alert calling on consumers and health professionals to heed the warnings from the Food and Drug Administration⁶ that compounded versions of GLP-1 drugs now widely promoted on television and online are not FDA approved and may cause serious health problems. As the alert makes clear, an unregulated marketplace now exists where online telehealth companies and pharmacies are marketing untested compounded GLP-1 drugs or actual counterfeits that, according to the FDA, may contain incorrect dosages, the wrong ingredients, too much, too little or none of the active ingredients, and possibly bacteria. Even more worrying, a 2024 report from the National Association of Boards of Pharmacy⁷ warns that illegal online pharmacies are selling substandard or falsified GLP-1 agonists without holding the required pharmacy licensure and without requiring a valid prescription. Due to the serious health consequences associated with unapproved compounded weight loss drugs, a number of medical organizations and state Attorneys General have joined with NCL in issuing warnings that urge consumers to obtain prescriptions for GLP-1 medications from a trusted health provider and to fill the prescription at an appropriately licensed pharmacy. At the same time, several state boards of pharmacy have issued public alerts and/or released policy statements directing compounders to comply with federal regulations. This is to ensure that compounding does not	

			become a loophole for marketing knockoffs of available FDA-approved GLP-1 drugs. Recently, we learned that the California State Board of Pharmacy is considering modifications to its rules related to compounded drug preparations that we believe are inconsistent with federal law and may compromise patient safety. Thus, we encourage the Board to consider the existing fraud and patient harm from the lax controls over compounded GLP-1 drugs when finalizing its rulemaking. While the amended rules govern compounded drugs generally, the situation regarding untested, widely promoted and widely available compounded and counterfeit GLP-1s should be guidepost for determining the circumstances under which drugs should be compounded during a shortage and the requirements for reporting adverse reactions. Accordingly, NCL urges the Board to maintain federal requirements that spell out when compounding drug products is allowed as essentially copies of FDA-approved, commercially available drugs. Additionally, we believe that mandating compounding facilities to report adverse events associated with sterile and nonsterile compounded products is essential to identify potential quality issues and safety problems.	
29	General	Obesity Action Coalition	Among the patient community, we fear the growth of compounded GLP-1 products will endanger patients and create a sub-standard of care. Compounded GLP-1 drugs were never intended to be widely marketed and distributed to treat chronic disease. It is difficult to name another disease state or therapeutic area with widespread compounding and outsourcing combined with predatory marketing strategies for treatments. For example, we don't see these practices with cancer patients, where someone can purchase chemotherapy at the local medi-spa or by filling out a form with an online telehealth vendor. It's also not acceptable for the treatment of obesity. People living with obesity have a right to FDA-approved medications and should not be subject to sub-standard	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board agrees with the public safety concerns raised by the commenter. The Board's proposed regulations generally seek to align with federal law and guidance and USP standard. The Board continues to monitor for information released from the FDA and evaluate for insanitary conditions during inspections.

			healthcare. Policy reforms to address ongoing supply shortages and affordability barriers is critical to improve equitable access to safe, effective obesity care for all people living with obesity. The OAC appreciates the opportunity to comment on Division 17 of Title 16 of the California Code of Regulations - Board of Pharmacy to ensure limited availability of quality compounded GLP-1 products and strict standards for adverse event reporting. As a voice for people living with obesity, OAC looks forward to working with the state of California to ensure Californians have access to safe and FDA-approved treatments for this complex and chronic disease.	
30	General	Partnership For Safe Medicines	Compounded medications fill an important niche role in our drug supply chain. We have long appreciated the key role that compounding pharmacies play in servicing rare and unmet needs in our drug supply. Helping to fill in the gaps for temporary shortages and providing unique formulations for patients who cannot tolerate the FDA-approved manufactured drug products help fill critical, albeit niche, gaps in America's pharmaceutical supply chain. Compounded medicines represent a tradeoff of safety versus patient need in our drug supply. As the FDA states, [These] unapproved versions do not undergo FDA's review for safety, effectiveness and quality before they are marketed. .. A compounded drug might be appropriate if a patient's medical need cannot be met by an FDA-approved drug, or the FDA-approved drug is not commercially available. However, compounded drugs are not FDA approved. This means the agency does not review compounded drugs for safety, effectiveness or quality before they are marketed. From FDA alert, "FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss" (12/18/2024) Public misconceptions and patient safety risks in taking compounded medications...	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board agrees with the public safety concerns raised by the commenter. The Board's proposed regulations generally seek to align with federal law and guidance and USP standard. The Board continues to monitor for information released from the FDA and evaluate for insanitary conditions during inspections.

		While PSM endorses use of compounded medicine as a last resort to fill patient need, in recent years we have seen compounding facilities, medspas, and telehealth companies market compounded medicines to patients even when a commercially-available product was available. Many providers and patients misunderstand that having poor or no insurance is not a qualifying reason to access a compound medication. Concerned about the lack of knowledge in this area, in September 2024, PSM commissioned one of the only public opinion surveys about Americans' understanding of compounded medications. The findings are an excellent guide for policymakers: ● 90% of Americans are unfamiliar with compounding pharmacies and the differences between compounded and FDA-approved drugs. ● 75% of Americans mistakenly believe that compounded medications undergo rigorous FDA scrutiny for safety and effectiveness ● 93% of Americans express concern upon learning that compounded weight-loss drugs are not FDA-reviewed. Consumers might not be getting the drug they expect. ● Support for FDA oversight and regulation has strong bi-partisan backing amongst Democrats (94%), Independents (88%), and Republicans (88%) ...and some providers exploit that lack of knowledge. We're seeing an unprecedented amount of compounded medication made right now, and much of it is being pitched to Americans without adequate disclosure of the risks. The most egregious example is the recent ad by hims&hers for their compounded GLP-1 medications that ran during the Super Bowl that was viewed by 127 million Americans. While compounded medications occupy an important niche in our drug supply, some compounders are attempting to expand it beyond this niche. However expanding the role occupied by compounded medications without	

		acknowledging the lower safety profile is devolving the overall safety of our drug supply and endangering Americans. This standard would be inconsistent with federal law, and endanger patients by placing compounded medicines unapproved by the FDA and with lower safety standards, on the same level as medicines that have been through FDA scrutiny. Lack of serialization of compounded medicines All medicines, except compounded medications, must be part of the U.S.'s track and trace system. The expansion of the use of compounded medications will create a large untraceable supply of medicines in our drug supply, and create an opening for criminal behavior. The California Board Of Pharmacy should reject this rule. In 2013, after a series of major drug counterfeiting incidents that harmed American patients emanated from Florida's drug supply chain, Congress passed the Drug Supply Chain Security Act. The lesson of Florida's endangerment of the U.S. supply chain was that the supply chain required electronic traceability or criminals could easily infiltrate it, as they had shown repeatedly. At the time, compounded medications were excluded from track-and-trace requirements because the argument was that there was no supply chain and the quantity of compounded medicine in the drug supply was small and rare. That reality is no longer true. Compounding, particularly outsourcing facilities, have their own trade association, their own funded litigation initiatives to protect their interests, and their products are marketed to the public as a first line therapy. The revenue in this space is now enough to fund Super Bowl ads.	

			Lack of traceability of compounded medicines is a growing danger to patients.	
31	General	E. Seibert	I am writing to you as just one person, disabled by Long COVID, fighting for continued survival in a city that has just faced a historic natural disaster. As you know, the wildfires in Los Angeles have been unprecedented for the State of California - upwards of 56,000 acres have burned, including homes, cars and industrial spaces. In addition to the direct damages caused by the fires, Angelenos continue to reckon with the health implications of poor air quality. While we are grateful that the fires have been contained, we are only just at the beginning. As we know from 9/11, continuing to live, work and play in close proximity to cleanup efforts has devastating long term effects on health with many survivors being diagnosed with short latency cancers due to poor air quality. It is a known fact that more people died from health complications relating to the air quality post-9/11 than on the day of the attacks. What is less known is that there are over 113,000 people registered on the World Trade Center Registry for longitudinal research into the long term health effects of exposure to 9/11 air. This cohort is not purely comprised of first responders - it includes ordinary people of all ages who just happened to live in proximity to the attacks taking place on 9/11. According to the Coalition for Clean Air webinars on General Safety Practices during this time, the clean up efforts will take 6-8 months at the very least. As efforts to move and safely store an unprecedented volume of ash takes place, hazardous air pollutants and carcinogens are being released into the air we breathe. Despite this, there is a tragic dearth of information on risk and mitigation being provided by the current administration - many Angelenos are not aware of the risks we take on by resuming "life as usual" just because the fires no longer burn. Unlike in 9/11, we have the tools - but the past actions of the Board have put those tools at risk. Thanks to the groundbreaking research taking place at Volunteer Fire Foundation, we know that nebulized glutathione reduces levels of high range environmental toxins, mycotoxins and	The Board believes that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk substances. After further consideration of the issue, the Board determined an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.

			PFAS ("forever chemicals") in first responders. Thanks to the work of 9/11 activists like Lila Nordstrom, we know that people of all ages -- including children -- living in close proximity to clean up sites are at risk of developing serious long term health complications due to worsening air quality related to the transportation and storage of ash from burn sites. I said it at last month's board meeting and I will say it again: Angelenos deserve access to nebulized glutathione too. We deserve to survive and thrive in the midst of natural disaster. We deserve to survive and thrive in the midst of a pandemic. We deserve to survive and thrive, period. But access to critical therapies like nebulized glutathione is at risk during a time when we need them the most. The vote taking place in March presents an opportunity, not only to learn from the events of 9/11, but to do better. So, do better. Listen to your stakeholders. Send these regulations back to committee. Align with USP standards. Re-build these regulations from the ground up in partnership with the people most affected. Center the needs of the most marginalized.	
32	General	Integrative Healers	I want to express my deep concerns regarding the proposed amendments to Title 16, Sections 1735-1738, and their real-world impact on access to essential compounded medications, specifically glutathione. While the Board has stated in hearings that these regulations do not limit access to necessary medications, our firsthand experience tells a different story. Previously, our medical providers were able to send firefighters home with their own nebulizers and prescriptions for compounded glutathione so they could nebulize daily or multiple times a week as part of their recovery from toxic smoke exposure. This is no longer possible due to restrictions resulting from Board actions. This change directly compromises our ability to provide life-saving care to the first responders who risk their lives to protect our communities. Furthermore, only one pharmacy is currently dispensing compounded glutathione due to the legal actions brought forth by the Board of Pharmacy. Over the last six weeks, we have treated more than 1,200 first	The Board believes that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk substances. After further consideration of the issue, the Board determined an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.

		responders in Los Angeles, and every single week, we struggle to secure enough glutathione for our clinics. All of our clinics are provided free of charge to firefighters—we do this not to generate revenue but to offer essential, life-saving care. In the last six weeks alone, we have treated firefighters who were first on the line for the Eaton and Palisades fires. Many of them are experiencing severe respiratory issues and are deeply concerned about their long-term health risks, particularly the potential for developing cancer. Firefighters have started calling this their "9/11," as they fear the long-term consequences of their exposure to toxic smoke and chemicals. After even a single treatment with nebulized glutathione, these first responders report noticeable improvements—they cough less, sleep better, and breathe more easily. These treatments are working, and we simply cannot afford to have our access restricted any further. The Board claims that these regulations will not limit access, but in practice, they already have. The cost of compliance with the proposed stability testing and documentation requirements will place an insurmountable burden on compounding pharmacies, effectively making these medications unavailable. These regulations are far stricter than those of any of the other 49 states. While the Board insists that these changes align with FDA standards, that is simply not true. We are working alongside cancer research foundations and medical professionals to ensure that firefighters have the best possible chance of preventing serious health conditions caused by toxic smoke exposure. Many of them have hope for the first time that they may not have to die in the line of duty—not from fire, but from the long-term consequences of their exposure. This is an urgent public health issue, and we need you to listen to the communities most affected by your decisions. I have attended the hearings, and there has been no support from the public for these changes. None. The public overwhelmingly opposes these amendments. As public	Further, the Board has responded to comments related to item previously. As included in those prior responses, <i>"As the Board has previously noted and the commenter suggests, USP provides, "Although it is possible for FDA or another government authority in the U.S. or elsewhere to require the use a USP General Chapter numbered 1000 to 1999, the authority in question would need to make this requirement expressly applicable under law, regulation, or another appropriate vehicle that prescribes enforceable requirements. The Board's proposed regulation text is consistent with this approach and the Board, in some instances, is explicitly adopting a Chapter."</i> Specifically related to comment four, the Board notes that the Board has previously considered this issue and respectfully refers the commenter to row 34 of this document for the Board's response.

			officials, it is your duty to listen to the voices of those you serve. This is a democracy, and we need our regulatory bodies to act in alignment with the needs and realities of the people. Our asks are simple: 1. Align California's regulations with federal standards to ensure patients have access to essential Category 1 sterile compounded medications. 2. Adhere to USP by allowing Category 2 compounding without requiring full stability studies, provided sterility and endotoxin testing is performed and a reasonable beyond-use-date (e.g., 45 days refrigerated) is applied. 3. Eliminate adherence to USP Chapters above 1000, which are not enforceable requirements and are meant for informational purposes only. 4. Amend the language to specify that Title 16 sterile comp	
33	General	C. Frost	On February 5, 2025, Member Maria Serpa asserted that the proposed updates to Title 16 are the only way to ensure Category 1 sterile compounds do not contain endotoxins. This is incorrect. Current USP standards already address and require measures to ensure sterile compounded medications meet endotoxin limits: ● USP <797> (Sterile Compounding): Requires endotoxin testing for certain high-risk compounded sterile products (CSPs). ● USP <85> (Bacterial Endotoxins Test): Establishes testing methods and specific endotoxin limits based on dosage form. ● USP <71> (Sterility Testing): Verifies that CSPs are free of microbial contamination which are the usual cause of endotoxins. The FDA Is Not to Blame for Glutathione's Inaccessibility in California If the FDA were truly preventing the use of glutathione, glutathione would not be readily available in 49 other states.* Member Serpa claimed the FDA is responsible for glutathione's inaccessibility in California, but this is false. In fact, the FDA's interim policy places glutathione on its Category 1 list—meaning it is among the bulk drug	The Board believes that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk substances. After further consideration of the issue, the Board determined an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text. Further, the Board has responded to comments related to item previously. As included in those prior responses, <i>"As the Board has previously noted and the commenter suggests, USP provides, "Although it</i>

		substances FDA has not objected to during the list's development. As the FDA states: "Patients' care should not be disrupted while the [503A bulks] list is under development... FDA seeks to avoid unnecessary disruption to patient treatment while the Agency considers the bulk drug substances that were nominated with sufficient support to permit FDA to evaluate them." Sterile compounded glutathione is not available in California for one reason only: the underground enforcement actions of this very Board. *StopTheBOP has contacted dozens of compounding pharmacies across the country and has not identified another state that prohibits Category 1 sterile compounds. Pharmacies offering Category 1 sterile products—such as methylcobalamin and glutathione—continue to provide them everywhere except California. At the January 8 board meeting, Member Maria Serpa claimed these regulations do not exceed USP and FDA requirements, but this is patently false. The proposed regulations exceed USP Standards in the following ways: • USP does not require full stability studies for Category 1 or 2 sterile compounding. These requirements only apply to Category 3 compounding. For the Board to mandate such studies—which can cost \$10,000 to \$30,000 per formulation—imposes an insurmountable financial burden on pharmacies. This will force them to limit offerings to the most generic formulations, eliminating the ability to create customized treatments based on individual prescriber orders. • The additional documentation of clinical circumstances for APIs on the FDA's interim Category 1 list far exceeds FDA requirements. These APIs are already treated like any other active ingredient under FDA guidelines, with no such documentation mandate. • The requirement to perform multiple tests on APIs, including tests listed in USP Chapters above 1000 (informational-only chapters), is both excessive and unprecedented. California	<i>is possible for FDA or another government authority in the U.S. or elsewhere to require the use a USP General Chapter numbered 1000 to 1999, the authority in question would need to make this requirement expressly applicable under law, regulation, or another appropriate vehicle that prescribes enforceable requirements. The Board's proposed regulation text is consistent with this approach and the Board, in some instances, is explicitly adopting a Chapter."</i> Specifically related to comment four, the Board notes that the Board has previously considered this issue and respectfully refers the commenter to row 34 of this document for the Board's response.

		would be the only state enforcing such standards on 503As, further restricting access without improving safety. I am deeply disturbed by the repeated false claims certain Board members and staff continue to make about federal standards. At best, these misrepresentations reflect negligence and incompetence, calling into question whether these proposed regulations are ready to be enacted. At worst, they suggest a deliberate effort to mislead both the public and fellow Board members—potentially serving hidden interests that seek to curtail patient access to safe, effective alternative medications. This troubling pattern raises serious concerns about the motivations behind these regulations and we hope other board members investigate these false statements as well and choose to act in the best interest of the public. These burdensome regulations will have devastating consequences, especially for patients needing compounded treatments tailored to their specific health needs which is the entire purpose of 503A compounding pharmacies. While pharmacies may justify the cost of stability studies for a generic glutathione multiple-dose vial, they will not be able to produce more individualized options such as essential preservative-free formulations or combinations. In essence, these regulations force 503A pharmacies to function as 503Bs which is effectively eliminating patient-specific sterile compounding. Doctors, organizations, patients, and firefighters have repeatedly told you that they do not want these regulations. The Alliance for Pharmacy Compounding and numerous individual pharmacists have also voiced strong opposition. And yet, you continue to move forward, closing your ears to the outcry from those directly affected by your decisions. As California faces an unprecedented public health crisis due to widespread toxic smoke exposure, including asbestos, lead, microplastics, and potentially thallium, this Board has a moral and ethical obligation to protect the public. Instead of actively making it harder for Californians to	

			access critical treatments, preserve access by fixing this proposal. Our asks are simple: 1. Align California's regulations with federal standards to ensure patients have access to essential Category 1 sterile compounded medications. 2. Adhere to USP by allowing Category 2 compounding without requiring full stability studies, provided sterility and endotoxin testing is performed and a reasonable beyond-use-date (e.g., 45 days refrigerated) is applied. 3. Eliminate adherence to USP Chapters above 1000, which are not enforceable requirements and are meant for informational purposes only. 4. Amend the language to specify that Title 16 sterile compounding regulations apply specifically to pharmacists and not to doctors.	
34	General	CMA	CMA is disappointed by the Board's continued refusal to revise its proposed language to clarify that the regulations do not apply to physicians. In its response to public comment requesting clarification on whether the regulations apply to physicians and other licensed practitioners, the Board effectively stated the regulations do not apply to licensees of other healing arts boards, noting: "[...] [the] Board's regulations apply to licensees within the Board's jurisdiction. The Board's jurisdiction is limited to those businesses and individuals within its practice act." The language of the proposed regulations, however, is written in a manner that could be construed to apply to compounding in any setting and by any individual, because their scope is not expressly limited to pharmacists and pharmacies, unlike the current regulation. Thus, the Board's proposed regulations continue to violate the clarity standard of the Administrative Procedure Act because the language of the regulations plainly conflicts with the Board's description of the effect of the regulations. CMA reiterates its request from CMA's prior comment letter dated December 9, 2024, to revise the proposed regulations	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board has considered this issue on several occasions most recently during its January 8, 2025, Board meeting. The Board respectfully refers the commenter to the Board's prior response. As was previously shared, the Board only has jurisdiction over individuals and businesses within its practice act. The Board reads the comment as suggesting that the Board's proposed regulations would apply to a physician. Business and Professions Code section 4170(c) makes clear that the Medical Board of California is specifically charged with the enforcement of Pharmacy Law (Chapter 9, Division 2 of the Business and Profession Code) with respect to its licensees. It may be appropriate for the commenter to confer with their licensing board to discuss their concerns. The Board notes that the Medical Board of California has previously provided a written response

		to clarify they do not apply to compounding performed by physicians outside of a pharmacy setting, so that the proposed language of the regulations aligns with the Board's description of the effect of the regulations.	to individuals inquiring about the applicability of the Board of Pharmacy's regulations to individuals and practices that operate under the jurisdiction of the Medical Board of California. Below is the information provided from the Medical Board - - <i>Dear Ms. Sodergren:</i> <i>I understand that some concerns have been raised by stakeholders about the applicability of the Board of Pharmacy's pending compounding regulations to licensees of the Medical Board of California (MBC). Existing statute (see Business and Professions Code (BPC) section 2220.5) makes it clear that only the MBC can discipline its physician licensees. Whenever a physician is engaging in compounding (or any other action that their medical license authorizes them to perform) they must always do so consistent with the standard of care. For the purposes of MBC's enforcement program, the standard of care is established by expert testimony in the context of the facts and circumstances of a specific case.</i> <i>It is certainly possible that whatever regulations that are implemented by the Board of Pharmacy may influence the standard of care for physicians who are compounding, especially since some of the proposed regulations reflect what is already required for physician compounding under federal law, including, but not limited to, Section 503A of the Federal Food, Drug, and Cosmetic Act (BPC section 2225(b) allows MBC to investigate violations of federal law related to the practice of medicine). Feel free to share this message with others as you see fit who might also be concerned about the applicability of their pending regulations to the physician community.</i> <i>Please contact me if you have any further questions.</i> <i>Sincerely,</i> <i>Reji Varghese</i>

				Reji Varghese is the Executive Director for the Medical Board of California. The Medical Board is charged with evaluating compounding practices and the standard of care relevant to its licensees.
35	General	Alliance of PHY Compounding	The Alliance for Pharmacy Compounding asks that the California State Board of Pharmacy not to pass the proposed compounding regulations as currently written. As stakeholder feedback has indicated, these regulations are just not ready for implementation and there is no buy-in from the healthcare community. A broad coalition of hospital pharmacists, compounding pharmacies, physicians, academic medical centers, and healthcare institutions have consistently raised concerns about the unintended consequences of these rules. Yet, the Board appears poised to move forward without addressing these concerns meaningfully. We do appreciate the many hours this Board has taken to review iterations of the proposed compounding regulations. Unfortunately, they are still filled with ambiguities and unnecessary obstacles to patient access. We understand the desire to finally pass these regulations and “move on.” However, it is of the utmost importance to get these regulations right, as the lives of Californians will be affected. The Board must not – as it appears to be doing – put the expediency of the process ahead of patient access to necessary medications, particularly when the Board has not shown a justification for some of the new rules or indicated how the rules make patients safer. Additionally, we are troubled that it appears that no written responses to the final round of public comments will be provided before the vote, as has been customary in the past. Instead, the Board intends to include responses in the Final Statement of Reasons, which suggests that the third modified text is functionally the final version—leaving no room for substantive changes before adoption. If that is the case, the Board is prioritizing expediency over stakeholder input and may be violating state administrative procedures rules. This rulemaking process has not provided a true opportunity for public engagement. The two-minute time slots for public	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received; however, notes that recommended changes will address some of the comments. The Board respectfully refers the commenter to Addendum 1 for the recommended changes related to Category 1 bulk drug substances. The Board notes that the Board is complying the with legal requirements established for promulgating regulations and consistent with those provisions, will be considering comments received during the most recent 15-day comment period at the March 6, 2025 Board Meeting. During the meeting members will consider the comments received and determine what action is appropriate based on the comments received. The Board believe it is important to highlight the Board's public meetings that provided opportunity to participate in the development of the proposed regulation text. These efforts began in 2019, where suspended while appeals were underway related to USP revisions, and resumed following finalization of related USP Chapters. The Board respectfully referred the commenter the underlying data referenced in the public rulemaking document that include information from several public meetings that occurred during the regulation development process in 2023 and note that information about the Board's public meetings in 2019 are also available on the Board's website.

		comment, without the ability for follow-up or meaningful discussion, have shut down dialogue and prevented pharmacists from responding to Board members' misunderstandings about the real-world impact of these regulations. A fundamental misunderstanding persists among some Board members regarding USP general chapters and the high standards those chapters already set for patient safety. Members of the Board also have made statements falsely suggesting the availability of stability studies for the specialized formulations of nebulized medications that are needed by Californians. The consequences of passing these regulations as written will be harmful to public health. Patients will lose access to critical medications and the care of pharmacists due to overly restrictive and duplicative requirements that go beyond USP standards without improving safety. Critical concerns that remain unresolved include: • Restrictions on immediate-use compounding that exceed USP standards, unnecessarily limiting access to time-sensitive medications. • Additional bulk drug testing requirements for Category 1 drugs, which duplicate testing already performed under USP standards, adding unnecessary costs and delays. • Requiring adherence to guidelines set in USP Chapters above 1000, even though those chapters are not intended for enforcement by USP. Before finalizing any new rules, we strongly urge the Board to form a task force of pharmacists from community hospitals, academic medical centers, rural hospitals, community pharmacies, and compounding pharmacies to share their expertise. This task force should include USP committee members to provide accurate, real-world insight. This approach would ensure the Board is fully informed before implementing regulations that could disrupt patient care. The Board must also acknowledge that California's approach to compounding regulation is outdated. USP standards have now set the national benchmark for patient safety while balancing medication access. Rather than layering unnecessary and conflicting state regulations on top of USP	The Board has previously responded to comment regarding USP Chapters over 1,000. The Board's previous response included in part, <i>"USP provides, 'Although it is possible for FDA or another government authority in the U.S. or elsewhere to require the use a USP General Chapter numbered 1000 to 1999, the authority in question would need to make this requirement expressly applicable under law, regulation, or another appropriate vehicle that prescribes enforceable requirements. The Board's proposed regulation text is consistent with this approach and the Board, in some instances, is explicitly adopting a Chapter"</i>

			standards, the Board should listen to the pharmacists in the profession—who have overwhelmingly opposed these proposed regulations precisely because they go too far and do not make patients safer. Given these concerns, we urge the Board to enforce existing USP standards in the interim while taking the necessary time to become better informed on the realities of compounding practice. Patients' ability to receive care is at stake, and it is simply too important to rush forward with misguided regulations. Please heed the hundreds of people who have spoken up at previous meetings who have overwhelmingly opposed these regulations.	
36	General	M. Cottman	I believe that this rule making has failed to meet the intent of the process as described in Chapter 3.5- Administrative Regulations and Rulemaking, ARTICLE 1 - General, Sections 11340 and 11340.1. If you are not familiar with it, you can find the full text here (https://law.justia.com/codes/california/code-gov/title-2/division-3/part-1/chapter-3-5/article-1/section-11340/). In addition to creating a more transparent process that included public participation, Section 11340 enumerates why our rule making process exists. In the 1994, the California Legislature recognized the following (paraphrased) facts: a) There had been an unprecedented growth of administrative regulations, b) Law language created unclear and unnecessarily complex regulations, c) Substantial time and public funds were spent to adopt regulations that may not be necessary, d) The imposition of prescriptive standards on entities through regulations that place an unnecessary burden and discourage innovation, research, and development and e) The complexity and lack of clarity of regulations put small businesses at a distinct disadvantage. THUS the Legislature established the Office of Administrative Law (OAL) to 1. Review adopted regulations 2. Reduce the number of administrative regulations and 3. Improve the quality of those regulations. With the INTENT that Agencies shall actively seek to reduce the regulatory burden on private entities by substituting performance standards for prescriptive	The Board has reviewed the comments and did not make any changes to the proposed text based on the comments received. The Board has appropriately followed the rulemaking process. The Board has provided information throughout the rulemaking process and the rulemaking record to support the proposed regulation text, including information from the FDA and USP. The Board respectfully refers the commenters to the Modified Initial Statement of Reasons, underlying data and documents added to the rulemaking.

		standards wherever performance standards can be reasonably expected to be as effective and less burdensome, and that this substitution shall be considered during the course of the agency rulemaking process. a) This rule making process is creating more rules than it is repealing. b) As evidenced by the volume of comments that you have received and the number of revisions you have had to publish, these rules remain unclear and unnecessarily complex. Page 1 of 9 c) This rule making process started 3 years ago on January 28, 2022. The number of hours spent on this rule making by Board Members, Board Staff, Attorneys, and all the stakeholders is clearly substantial... all in an effort to adopt regulations that may not be necessary (as USP is an adequate performance standard). NOTE: Throughout the rule making process, several commenters have asked for the Board to provide evidence or data to support that these proposed rules will improve patient safety and to my knowledge, no valid data or evidence has been provided. The comment responses continue to be "Board Staff have reviewed the comment and do not recommend any changes..." or similar to this. If facts or data are not presented to justify the staff's rationale, then it must just be an opinion. What credentials do the staff have to rank them as experts in the topic of pharmaceutical compounding? Certainly, they must be at least equally qualified as the members of the USP committee, no? d) I can guarantee that these rules and regulations will discourage innovation, research, and development of custom compounded medication solutions for patients in need. Additionally, these regulations will increase costs which will further impede access to necessary therapies for the California public. e) Most of your licensed compounders are small businesses, like mine. I have 10 employees. We provide unique services to 1,500 patients per month. Without a doubt, my business, and	

		much more importantly, my patients, will be adversely affected by these proposed rules. Summatively, over the last three years, the Board Staff have neglected to answer the most important question: How do these “in addition to USP Chapters” requirements ACTUALLY improve patient safety beyond the full adoption of the USP Compounding Chapters? There has been no evidence presented in the comment replies or at the hearings that these proposed prescriptive standards will, in fact, improve patient safety. Rather, I would argue that the performance standards provided throughout the USP Chapters are sufficient guidance for your licensees to result in safe compounds. Additionally, the regulatory burden of these proposed prescriptive requirements can be reasonably expected to be MORE burdensome and MORE expensive, but NOT result in safer compounds. As evidence of this, I remind you that the Board Staff stated in the last Comment Responses “Board staff notes that a variety of nonpharmacy personnel have authority to compound including for example physicians and veterinarians.” And compound they will, if these regulations go through! Their regulatory bodies will allow them to compound in compliance with the standards of USP which will be more cost effective for patients, who will elect NOT to have a pharmacist prepare their compound. I implore you to REJECT the Recommended Third Modified Text of Compounded Drug Products dated January 30, 2025. After three years of discussions and revisions, this text does not meet your mandate of Protecting the Public any better than if your licensees comply with the USP Chapters as written by the expert committees over a 12 year period from 2010-2022. As an alternative, I RECOMMEND that you move forward with a repeal of sections 1735-1735.8 of Article 4.5 and repeal sections 1751-1751.12 of Article 7 without any additional revision or adoption of rules. All of the USP compounding chapters are codified in BPC Section 4126.8 and can stand on their own until such time as rulemaking for requirements proven to improve patient safety can commence	

37	General	111 Commenters + L. Mendelovich	The commenters express strong opposition to the proposed regulations that would severely limit access to critical sterile compounded medications like injected and nebulized glutathione, methylcobalamin, NAD+, and others. These medications are essential for many, including firefighters and chronic illness patients. Commenters state that the regulations would create unnecessary barriers that harm the healthcare system, businesses, and people of California. Commenters state that during the February 5, 2025 meeting, board members misrepresented federal guidelines, claiming the FDA has recommended restricting glutathione. However, glutathione remains on the FDA's Category 1 bulk compounds list and is legal under their current policy. USP guidelines also do not mandate stability testing for these compounds. Despite this, the proposal introduces extreme testing requirements far exceeding federal standards without adequate safety-based justification. The unfeasible financial burden these regulations would place on pharmacies is a critical concern. Member Serpa's cost estimates—\$16.10 per glutathione vial and \$8.06 per methylcobalamin vial—dramatically understated the actual costs of stability testing. These tests actually range from \$10,000 to \$30,000 per API. These prohibitively expensive tests would force pharmacies to discontinue offering most, if not all, formulations of these treatments, eliminating access to life-saving medications. The need for treatments like nebulized glutathione is more urgent than ever since southern California's severe Urban Wildfires released record levels of harmful toxins like lead and asbestos into the environment. Nebulized glutathione has demonstrated efficacy in reducing these harmful substances in the body. Restricting access to these treatments would escalate health risks, including fatal cancers, for first responders, vulnerable residents, and future generations.	The Board believes that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk substances. After further consideration of the issue, the Board determined an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.

			The public opposition to these regulations is overwhelming, with over 11,000 signatures on a petition—with an estimated 1,000+ from California firefighters—and hundreds of pages of comments submitted in writing and in person over the past year. Yet, the Board has failed to meaningfully respond to meaningful input from dozens of medical experts, consistently ignoring their expertise. The Board has repeatedly suggested that the public doesn't understand federal and state laws or their application, dismissing the well-informed concerns raised by patients, healthcare professionals, and advocates. The failure to engage meaningfully with stakeholders undermines the credibility of the Board's engagement process and has raised serious concerns about regulatory overreach. As written, the proposal creates unnecessary barriers severely limiting access to life-saving treatments. These barriers create an unjustifiable financial burden on patients and pharmacies and fail to reflect the true costs and needs of the community. Commenters strongly urge the Board to either (a) withdraw the proposal entirely from consideration or (b) send these proposed regulations back to the committee and re-write them to align them with and not exceed federal and Pharmacopeia standards by making the following changes: * Adhere to USP by allowing Category 2 compounding without requiring full stability studies, provided sterility and endotoxin testing is performed and a reasonable beyond-use-date (e.g., 45 days refrigerated) is applied. * Eliminate adherence to USP Chapters above 1000, which are not enforceable requirements and are meant for informational purposes only. * Amend the language to specify that Title 16 compounding regulations apply only to pharmacists. As written, this board appears to begin regulating medical practices which is regulatory overreach. * Remove the requirement of additional documentation of "clinical circumstances" which is not required by the FDA.	

Addendum 1

Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances)

The Board believed that the commenters may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's [guidance](#) related to bulk drug substances. The Board has confirmed the continued availability of compounded glutathione and methylcobalamin for California patients. These findings are consistent with public comment that suggests that treatments using compounded glutathione continue in California.

After further consideration of the issue, the Board determined that an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Following is the recommended text, the Board's response provides additional information in response to this and other comments on the same topic.

Recommended changes as follows:

1736.9(e) and (f)

~~(e)(1) Except as provided in (2), when 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 in 21 CFR section 216, or unless authorized by a public health official in an emergency use situation for a patient-specific compounded sterile preparation.~~

~~(2) A bulk drug substance nominated for inclusion in 21 CFR section 216.23(a) and for which the FDA determined that the nomination included adequate information for the FDA to evaluate the substance and that the substance does not appear to present significant safety risks, and accordingly included in the published 503A Category 1 bulk drug substances list, may be used in compounding in accordance with this article if all of the following conditions are satisfied:~~

~~(A) Any facility using a bulk drug substance permitted by this subdivision shall:~~

~~(i) Assign a beyond use date, supported by stability data obtained using stability-indicating analytical methods consistent with the provisions established in USP 797 Section 14.4.3, or stability information for a patient enrolled in a clinical trial that is approved by a U.S. Department of Health and Human Services (HHS) registered Institutional Review Board (IRB). The stability data or information is required regardless of the USP Category of CSP.~~

~~(ii) Dispense pursuant to a patient-specific prescription that documents the clinical circumstances that require the use of a bulk drug substance currently on the 503A Category 1 bulk drug substance list.~~

~~(iii) Failure to compound pursuant to this subdivision and the facility's SOPs constitutes unprofessional conduct and shall be deemed as posing an immediate threat to the public health as established subject to the provisions in Business and Professions Code section 4127.3~~

(e) All APIs and other components used must be evaluated for suitability for use in sterile drug preparations, as provided in USP 797, Section 9.3 Components, and follow the USP drug monograph if one exists. Components labeled with "not for pharmaceutical use", "not for injectable use", "not for human use" or an equivalent statement must not be used to compound for these purposes.

(f) If a component included on the published 503A Category 1 interim bulk drug substances list is used, it must be found suitable for sterile drug preparations following USP Chapter 797, Section 9.3 Components. The facility's SOPs must establish a process to determine the quality of the API.

1736.17(a)(2)(C), (E), and (F)

(C) The methods ~~a pharmacist will~~ used to determine and approve the ~~ingredients~~ **components** and the compounding process for each preparation before compounding begins; **including components referenced in section 1736.9(f)**; and

(D) The method for complying with all other requirements specifically defined in the SOPs.

~~(E) The methods by which the pharmacist compounding or supervising the compounding pursuant to section 1736.9(f) (e)(2) related to use of a bulk drug substance published in the section 503A Category 1 bulk substances list, will ensure each lot of the bulk drug substance is representatively sampled per USP Chapter 1097 (bulk powder sampling procedures), tested, and found to be in compliance with at least:~~

~~(i) USP Chapter 1, Injections and Implanted Drug Products (Parenterals) – Product Quality Tests~~

~~(ii) USP Chapters 232 and 233 related to Elemental Impurities;~~

~~(iii) USP Chapter 467 – Residual Solvents;~~

~~(iv) USP Chapter 85 – Bacterial Endotoxins; and~~

~~(v) any other USP Chapters deemed appropriate based on the clinical judgment of the pharmacist developing the SOPs;~~

~~(F) Nothing in paragraph (E) requires the facility to perform this testing when it is performed by the manufacturer, repackager, or wholesaler and appropriate documentation~~

The Board noted that in response to previous comments, the Board has been discussing this issue throughout the formal rulemaking process and has made significant changes to the proposed text to provide a legal pathway in California to compound using bulk drug substances included on the FDA Category 1 bulk drug substances list that meets the requirements of federal law, federal guidance and national standards.

The Board respectfully refers the commenter to the Board's response to prior similar comments that include the provisions of federal law established in section 503A of the federal Food, Drug, and Cosmetic Act (FDCA), relevant FDA guidance documents, and relevant sections of the

national standards, especially those sections related to components. The Board notes that contrary to what some public comment has stated, the FDA has not approved or authorized the compounding of Category 1 bulk drug substances, nor has the FDA stated that compounding with these substances is safe in every instance. Rather, the FDA has released [guidance \(https://www.fda.gov/media/174456/download\)](https://www.fda.gov/media/174456/download) that articulates an interim enforcement discretion policy that applies if an authorized facility or individual compounds using certain unapproved bulk drug substances, such as glutathione or methylcobalamin, but only under very specific conditions. Such conditions include that the original manufacturer and all subsequent manufacturers of the bulk drug substance are establishments that are registered under section 510 of the FDCA; that the bulk drug substance is accompanied by a valid Certificate of Analysis; and that the drug product compounded using the bulk drug substance is compounded in compliance with all other conditions of section 503A (including, for example, that the compound has not been produced or held under insanitary conditions). As the Board has noted previously, until the FDA formally makes a determination of approval of these bulk drug substances nominated for inclusion in 21 CFR 216.23, a pathway to allow for such compounding and continue access to these substances is needed.

The Board respectfully also refers the commenters to USP Chapter 797, Section 9.3 Components, which specifically provides: "All APIs and other components used must be evaluated for suitability for use in sterile drug preparations. Components labeled with "not for pharmaceutical use", "not for injectable use", "not for human use" or an equivalent statement must not be used to compound for these purposes." The Chapter continues: "Any component found to be of unacceptable quality must be promptly rejected, clearly labeled as rejected, and segregated...Any other lots of that component from that vendor must be examined to determine whether other lots have the same defect."

Further, the FDA Guidance Document, Insanitary Conditions at Compounding Facilities (dated November 2020) provides examples of insanitary conditions that the FDA has observed. The following is an example of an insanitary condition: "Using active ingredients, inactive ingredients, or processing aides, that have or may have higher levels of impurities compared to compendial or pharmaceutical grade equivalents (e.g., ingredients with potentially harmful impurities, ingredients labeled with "not for pharmaceutical use" or an equivalent statement)."

The Board's underlying data included in the Modified Initial Statement of Reasons contains additional information specifically related to this issue, including, as an example, item 21, "FDA highlights concerns with using dietary ingredient glutathione to compound sterile injectables."

The Board continues to monitor information released from the FDA and evaluate compounding facilities during inspections for insanitary conditions and compliance with state and federal law and national standards.

#	Section	Commenter	Comment	Board Response
1	1735(d)	CA Medical Association	Requirement to Verify a Preparation Produces a Clinically Significant Difference Interferes with Exercise of Professional Judgment and Exceeds Federal Law (§§ 1735(d), 1735.1(e)(1)(B), 1736(d), 1736.1(e)(1)(B)) CMA reiterates its concern regarding the Board's proposed requirement for pharmacists to "verify" that a compounded drug produces a clinically significant difference for a patient. This proposed requirement creates an undue burden and restricts the professional judgment the Board intended to preserve. Mandating verification for every instance of compounding a commercially available drug that is not on a shortage list establishes a rigid, prescriptive standard. This contradicts the Board's stated goal of maintaining flexibility, and, as such, the language violates the clarity standard because it conflicts with the Board's description of the effect of the regulations in its formal response to members of the public regarding this issue.⁸ We refer you to our comment letters dated January 27 and February 21, 2025, for detailed discussions of this issue. To enhance clarity and ensure patients maintain timely access to medications, CMA reiterates its request from our prior comment letter, dated January 27, 2025, to remove "verify and" from proposed sections 1735(d), 1735.1(e)(1)(B), 1736(d), and 1736.1(e)(1)(B) of the third modified text.	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Board staff note that the comment is outside the scope of the proposed changes in the fourth modified text. The Board has previously considered these comments. The Board respectfully refers the commenter to the Board's prior responses.
2	1735(d)	Wedgewood	Please clarify that this language applies to compounds intended for human patients. Guidance For Industry 256 provides a different definition of "Essentially a Copy" as it pertains to veterinary medicine that includes route of administration as a factor for consideration. Please consider the addition of language to align this definition with the federal standard as it relates to animal medicine. We do not recommend a direct reference to GFI 256 for the reasons outlined below (1735.1(e)(2)).	Board staff have reviewed the comment and do not recommend a change to the proposed text based on the comment received. Board staff note that the comment is outside the scope of the proposed changes in the fourth modified text. Further, this comment has been previously considered by the Board. The Board respectfully refers the commenter to the Board's prior response. In addition to the Board's prior comments, the Board highlights that it's essentially a copy definition relies heavily on a pharmacist's professional judgement in making a

				determination if a compounded preparation would provide a clinically significant difference for the patient, which would include an animal patient.
3	1735(d)	CSHP	We once more emphasize that us and others who commented on this section remain concerned with the wording of this section. We appreciate the board's position that the intent is to rely on the professional judgement of the pharmacist. At the same time, we object to the wording of the regulation and wish to point out that this section has the potential to be misinterpreted as written, both currently and in the future. It is important to get this right so that the intent is clear and does not cause confusion. The wording of ""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," could be interpreted to mean that ANY compound being made is defined as essentially a copy of a commercially available drug product. The trouble here is that any compounded drug that has the same API as a commercially available drug product will violate this regulation. Using the example of a hospital pharmacy that compounds a batch of 20 doses of "GI Cocktail" for use in the Emergency Department. To make this compound, the pharmacy mixes together Donnatal®, Viscous Lidocaine and an antacid such as Maalox®. By the definition above copied from the proposed regulation, it will be a violation of this proposed regulation since these doses are compounded and will be seen as including the same API as the commercially available products from which they are compounded. To further explain, since the compounded product contains lidocaine, it violates the proposed regulation since it contains the same API (lidocaine as the commercially available viscous lidocaine. Additionally, since the compounded product contains Donnatal®, it violates the proposed regulation since it contains the same API as the commercially available Donnatal®. Additionally, since the compounded product contains Maalox®, it violates the proposed regulation since it contains the same API as the commercially available Maalox®. These products are being used routinely in the ER for abdominal conditions. This proposed regulation, if it is read simply for the way it is stated, will imply that the pharmacist verifying the order will need to go through a	Board staff have reviewed the comment and do not recommend a change to the proposed text based on the comment received. Board staff note that comment is outside the scope of the proposed changes in the fourth modified text. Further, this comment has been previously considered by the Board. The Board respectfully refers the commenter to the Board's prior response. In addition to the Board's prior comments, the Board highlights that it's essentially a copy definition relies heavily on a pharmacist's professional judgement in making a determination if a compounded preparation would provide a clinically significant difference for the patient. There is nothing in the proposed regulation text that would prevent the batch compounding process described in the comment from occurring. Rather, the proposed regulations would provide that prior to administration of the compounded product, a pharmacist, using their professional judgement, has made a determination that the compounded product is appropriate and produces a clinically significant difference for the patient.

			process of verifying with the prescriber and then documenting each and every order for GI Cocktail that the change from the 3 commercially available products to a compounded GI Cocktail produces a clinically significant difference for each individual patient. This unintended consequence of altering the work of pharmacists and physicians in the ER was not explained in the ISOR. We are deeply concerned that the language as written, will cause additional communication and documentation of the communications for both physicians and pharmacists. We are concerned that board staff's previous response to this concern did not demonstrate their understanding of our concern. In the ISOR, the board states that the FDA guidance document is being utilized to provide guidance regarding this definition: It is important to note that the definition taken from the FDA guidance document and used in this proposed regulation, is only one part of three of the definition in the guidance document. Herewith the guidance document section on "Essentially a Copy" for reference: FDA intends to consider a compounded drug product to be essentially a copy of a commercially available drug product if: • the compounded drug product has the same active pharmaceutical ingredient(s) (API) as the commercially available drug product; • the API(s) have the same, similar, or an easily substitutable dosage strength; and • the commercially available drug product can be used by the same route of administration as prescribed for the compounded drug, unless, as provided by section 503A(b)(2), a prescriber determines that there is a change, made for an identified individual patient, which produces, for that patient, a significant difference from the commercially available drug product. The proposed regulation definition crucially leaves out the requirements for a same or similar dosage strength and route. By leaving out these clarifying terms, the definition is now so broad that it is inclusive of every single non-sterile and sterile compound being compounded by a pharmacy in the state of California. From our example above, it is open to interpretation by both the regulated public and board staff of what "essentially a copy" is because it will be everything with the same API. By the proposed	

		definition, since diazepam tablets are commercially available, a pharmacy may not compound a diazepam drip from IV vials since the tablets contains an API that is commercially available (even though it is available in a completely different non-sterile dosage form). According to the definition, a hospital making a batch of oral suspension from tablets on a regular basis for its neonatal of pediatric unit, will be making essentially copies of the API in the tablets and will have to call and verify with the prescriber and then document the self-evident information that the change was made for each and every identified individual patient that produces for that patient a clinically significant difference. We are sure that we can all agree that this is not the intent of the regulation. By adding the crucial elements of strength and route it narrows the definition and it is much clearer and is aligned with both the FDA and board's intent. This addition of language provides clarification while still allowing flexibility for the pharmacist to use professional judgement. By adding the components that aligns with FDA guidance, it becomes clear that it will be the same as federal statute and guidance, and we recommend that this regulation be deleted. We are concerned that Board staff's previous response to this concern did not demonstrate their understanding of our concern. While all involved currently in the creation and comments for the definition of "essentially a copy" may have a grasp and understanding of the intent of this proposed regulation, we must take the multiple comments from all stakeholders as an indicator that there will be future misunderstanding and misinterpretations of this language. It is of the utmost importance to recognize that ten to fifteen years from now these interpretations and intent will be forgotten, and the only guidance left to enforce are the words as written. We are sure that the current board would not want future board members and staff to enforce this rule under the misunderstandings that we and others took great pains to point out at this moment in time. We are concerned that Board staff's previous response to this concern did not demonstrate their understanding of our concern. Recommendation: (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, the API(s) have the same, similar, or an easily substitutable dosage strength; and the commercially available drug product can be used by the same route of administration as prescribed for the compounded drug 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 verified and documented by the pharmacist , between that compounded preparation and the comparable commercially available drug product.	
4	1735.1	FLAVORx	As you know from my previous comments, the language is a dealbreaker for pharmacies since it ties flavoring regs to other activities a pharmacy may need to perform. I realize that previous suggested fixes to the language created a potential loophole where pharmacies could argue they would be exempt from the new, modified non-sterile compounding requirements for practices unrelated to flavoring. That was not our intention, and I apologize if it came across as such. We are only concerned with flavoring. As you'll see from the suggested edits to the text below, you can avoid all confusion by focusing solely on the act of flavoring, instead of the facility that performs it. The language I'm proposing allows flavoring to stand alone, independent of other activities performed in the pharmacy, making it highly likely you will achieve the goal of getting flavoring back in California's pharmacies. The issue is the mention of "facility" so let's focus on the "act" instead. Here's an easy fix that ensures the exemptions only apply to flavoring medications: (i) <u>A facility that limits its compounding to the sole act of combining a flavoring agent with a prescribed FDA approved drug in an oral liquid dosage form at the request of a prescriber, patient, or patient's agent shall be exempt from the requirements established in subdivision (f) and Sections 1735.2 – 1735.13. A facility that performs any other form of nonsterile compounding at any time is not exempt as provided in this subdivision. The performance of any other form of nonsterile compounding is not exempt from the requirements established in subdivision (f) and Sections 1735.2-1735.13.</u>	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Board staff note that the comment is outside the scope of the proposed changes in the fourth modified text. Board staff note that the recommended text could create confusion regarding the requirement for pharmacies that engage in nonsterile compounding. The Board's proposed regulation text is appropriate and provides clarity on the requirements.

5	1735.1(e)(1))	Novo Nordisk	Comment: We reiterate our request that the Board update Section 1735.1(e)(1) to state only the prohibition on compounding of “essentially a copy of one or more commercially available drug products,” as defined at Section 1735(d), and to remove the exceptions to the copies restriction at (e)(1)(A) related to shortage lists and inability of a health care facility to obtain a drug. As explained in NNI’s comments on the Second and Third Modified Texts, the provisions relating to the ASHP Drug Shortage List and compounding when a health care facility cannot obtain a drug from the manufacturer or wholesaler are inconsistent with federal law and policy. These broad permissions for compounding copies create risks for patient safety and the public health, and undermine a key check on compounding of unapproved drug products. Recommended language revision: “(e) 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, as defined at Section 1735(d) of this article. Documentation by the pharmacist that the compounded drug product produces a clinically significant difference for the medical need of an identified individual patient, as provided for at Section 1735(d) of this Article, must be maintained in a readily retrievable format.”	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Board staff note that the comment is outside the scope of the proposed changes in the fourth modified text. The Board has previously responded to similar comments from this commenter, and the Board respectfully refers the commenter to this Board’s prior response. Further, the Board notes that it is seeking to align with federal law and federal guidance. The Board continues to monitor for information from the FDA. Licensees of the Board are required to maintain a strong understanding of federal law and guidance documents that have been released. It is the Board’s expectation that pharmacists, using professional judgment, will make appropriate decisions for patients that are consistent with their education and training, comply with all legal requirements, and meet the standard of care.
6	1735.1(e)(1)) (B)	CA Medical Association	Requirement to Verify a Preparation Produces a Clinically Significant Difference Interferes with Exercise of Professional Judgment and Exceeds Federal Law (§§ 1735(d), 1735.1(e)(1)(B), 1736(d), 1736.1(e)(1)(B)) CMA reiterates its concern regarding the Board’s proposed requirement for pharmacists to “verify” that a compounded drug produces a clinically significant difference for a patient. This proposed requirement creates an undue burden and restricts the professional judgment the Board intended to preserve. Mandating verification for every instance of compounding a commercially available drug that is not on a shortage list establishes a rigid, prescriptive standard. This contradicts the Board’s stated goal of maintaining flexibility, and, as such, the language violates the clarity standard because it conflicts with the Board’s description of the effect of the regulations in its formal response to members of	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Board staff note that the comment is outside the scope of the proposed changes in the fourth modified text. The Board has previously considered these comments. The Board respectfully refers the commenter to the Board’s prior responses.

			the public regarding this issue.⁸ We refer you to our comment letters dated January 27 and February 21, 2025, for detailed discussions of this issue. To enhance clarity and ensure patients maintain timely access to medications, CMA reiterates its request from our prior comment letter, dated January 27, 2025, to remove “verify and” from proposed sections 1735(d), 1735.1(e)(1)(B), 1736(d), and 1736.1(e)(1)(B) of the third modified text.	
7	1735.1(e)(2)	Wedgewood	We appreciate that the Board addressed our earlier concerns about the ambiguous reference to AMDUCA, but we continue to remain concerned about a direct reference to a Guidance Document that could be eliminated tomorrow by the current administration. What will compliance look like if the Agency rescinds or edits the guidance document making this reference irrelevant? We again make the following Recommendation: This compound shall be in compliance with current industry guidance. ~~the Center for Veterinary Medicine Guidance for Industry #256 – Compounding Animal Drugs from Bulk Drug Substances issued August 2022.~~	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Board staff note that the comment is outside the scope of the proposed changes in the fourth modified text. The Board has previously considered these comments. The Board respectfully refers the commenter to the Board’s prior responses.
8	1735.12(b)	CSHP	We are concerned that board staff's comments regarding our concern does not reflect the intent that board members verbalized during the full board meeting. We therefore request that board members review our concerns and indicate their agreement or disagreement with staff's response. We once more reiterate our previous concerns. The way that this regulation is worded could be misinterpreted. This proposed regulation was discussed by the board during the last board meeting, and it was mentioned that the intent is for complaints that indicate true quality problems be reported to the board. From the way that it is written, the understanding that one could derive from the language is that the board must be notified of all complaints that could potentially indicate a quality problem. For example, a patient given a compounded gel, could complain that from their recollection it appears to have a slightly different opacity from one dispensed previously. Since this could potentially indicate a quality problem, the pharmacist will then report the complaint of a potential quality problem to the board. The pharmacist then investigates and finds that the medication was	Board staff have reviewed the comment and do not recommend a change to the proposed text based on the comment received. Board staff note that the comment is outside the scope of the proposed changes in the fourth modified text. Board staff respectfully refer the commenter to prior responses that the Board has approved. Further, the Board notes that a pharmacist, using their professional judgment, would determine if reporting of a potential quality problem is necessary. The pharmacist, understanding the specific facts of potential quality problem, is best suited to make such a determination. As the Board seeks to transition to a more robust standard of care model, where pharmacists believe additional clarity is required, a pharmacist can include in

			compounded correctly but the master formula was changed to a different gel base due to a change in manufacturers. One of our members reported to CSHP that they started to report all complaints that could indicate a potential complaint to the board. They were instructed by board staff that they should only report it when there was an actual quality problem since they were inundating the board with reports. It shows that there has been confusion with the current regulations. It is important that we use this opportunity to make the language as clear as possible. We are concerned that Board staff's previous response to this concern did not demonstrate their understanding of our concern and did not explain why board staff instructed the health system to stop reporting all potential quality problems. While all involved currently in the creation and comments may have a grasp and understanding of the intent of this proposed regulation, we must take the multiple comments from all stakeholders as an indicator that there will be future misunderstanding and misinterpretations of this language. It is of the utmost importance to recognize that ten to fifteen years from now these interpretations and intent will be forgotten, and the only guidance left to enforce are the words as written. We are sure that the current board would not want future board members and staff to enforce this rule under the misunderstandings that we and others took great pains to point out at this moment in time. Recommendation: (b) The pharmacy shall report in writing a product quality issue for any compounded product to the board within 96 hours after the pharmacy receives notice of the product quality issue.	standard operating procedures criteria if determined appropriate.
9	1735.15	FLAVORx	For the same reasons stated above, this language will prevent pharmacies from flavoring medications. The fix is the same. Focus on the "act" and not the "facility". Here is what we suggest: (a) In addition to the standards in USP Chapter 795 and section 503a (21 U.S.C. §353a) the of the Federal Food, Drug, and Cosmetic Act (FDCA) section 503a (21 U.S.C. §353a) ~~a facility that limits its compounding as described in Section 1735.1(i) shall establish the following SOPs:~~	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Board staff note that the comment is outside the scope of the proposed changes in the fourth modified text. Board staff note that the recommended text would create confusion and conflict with the article governing nonsterile compounding.

			<u>facilities shall establish the following SOPs for the sole act of combining a flavoring agent with a prescribed FDA approved drug in an oral liquid dosage form:</u>	

#	Section	Commenter	Comment	Board Response
1	1736(d)	CA Medical Association	Requirement to Verify a Preparation Produces a Clinically Significant Difference Interferes with Exercise of Professional Judgment and Exceeds Federal Law (§§ 1735(d), 1735.1(e)(1)(B), 1736(d), 1736.1(e)(1)(B)) CMA reiterates its concern regarding the Board's proposed requirement for pharmacists to "verify" that a compounded drug produces a clinically significant difference for a patient. This proposed requirement creates an undue burden and restricts the professional judgment the Board intended to preserve. Mandating verification for every instance of compounding a commercially available drug that is not on a shortage list establishes a rigid, prescriptive standard. This contradicts the Board's stated goal of maintaining flexibility, and, as such, the language violates the clarity standard because it conflicts with the Board's description of the effect of the regulations in its formal response to members of the public regarding this issue. We refer you to our comment letters dated January 27 and February 21, 2025, for detailed discussions of this issue. To enhance clarity and ensure patients maintain timely access to medications, CMA reiterates its request from our prior comment letter, dated January 27, 2025, to remove "verify and" from proposed sections 1735(d), 1735.1(e)(1)(B), 1736(d), and 1736.1(e)(1)(B) of the third modified text.	Board staff have reviewed the comment and do not recommend a change in the proposed text. Board staff note that the comment is outside the scope of the proposed changes in the fourth modified text. Board staff note that the comment has been previously considered and a response provided. Board staff respectfully refer the commenter to the Board's prior response.
2	1736(e)	CSHP	We once more emphasize that us and others who commented on this section remain concerned with the wording of this section. We appreciate the board's position that the intent is to rely on the professional judgement of the pharmacist. At the same time, we object to the wording of the regulation and wish to point out that this section has the potential to be misinterpreted as written, both currently and in the future. It is important to get this right so that the intent is clear and does not cause confusion. The wording of ""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," could be interpreted to mean that ANY compound being made is defined as	Board staff have reviewed the comment and do not recommend a change to the proposed text based on the comment received. Board staff note that the comment is outside the scope of the fourth modified text. Board staff believe it is appropriate to note that licensed pharmacists are required by law to exercise professional judgement. The commenter appears to suggest that language in some areas lacks clarity. The Board disagrees. The regulation language is intended to provide flexibility for a pharmacist, using professional judgement to make the appropriate decision for the patient. The Board's regulations in

		essentially a copy of a commercially available drug product. The trouble here is that any compounded drug that has the same API as a commercially available drug product will violate this regulation. We are deeply concerned that the language as written, will cause additional communication and documentation of the communications for both physicians and pharmacists. We are concerned that board staff's previous response to this concern did not demonstrate their understanding of our concern. In the ISOR, the board states that the FDA guidance document is being utilized to provide guidance regarding this definition. It is important to note that the definition taken from the FDA guidance document and used in this proposed regulation, is only one part of three of the definition in the guidance document. Herewith the guidance document section on "Essentially a Copy" for reference: FDA intends to consider a compounded drug product to be essentially a copy of a commercially available drug product if: • the compounded drug product has the same active pharmaceutical ingredient(s) (API) as the commercially available drug product; • the API(s) have the same, similar, or an easily substitutable dosage strength; and • the commercially available drug product can be used by the same route of administration as prescribed for the compounded drug, unless, as provided by section 503A(b)(2), a prescriber determines that there is a change, made for an identified individual patient, which produces, for that patient, a significant difference from the commercially available drug product. The proposed regulation definition crucially leaves out the requirements for a same or similar dosage strength and route. By leaving out these clarifying terms, the definition is	several areas are also intended to provide facilities with flexibilities to implement the requirements as they believe is appropriate for their specific operations. As an example, the Board's essentially a copy definition relies heavily on a pharmacist's professional judgement in making a determination if a compounded preparation would provide a clinically significant difference for the patient. Note: The Board did not include the strikethrough (appears to be track changes) in a sentence in the CSHP comment in this area.

			now so broad that it is inclusive of every single non-sterile and sterile compound being compounded by a pharmacy in the state of California. From our example above, it is open to interpretation by both the regulated public and board staff of what "essentially a copy" is because it will be everything with the same API. By the proposed definition, since diazepam tablets are commercially available, a pharmacy may not compound a diazepam drip from IV vials since the tablets contains an API that is commercially available (even though it is available in a completely different non-sterile dosage form). According to the definition, a hospital making a batch of oral suspension from tablets on a regular basis for its neonatal of pediatric unit, will be making essentially copies of the API in the tablets and will have to call and verify with the prescriber and then document the self-evident information that the change was made for each and every identified individual patient that produces for that patient a clinically significant difference. We are sure that we can all agree that this is not the intent of the regulation. By adding the crucial elements of strength and route it narrows the definition and it is much clearer and is aligned with both the FDA and board's intent. This addition of language provides clarification while still allowing flexibility for the pharmacist to use professional judgement. By adding the components that aligns with FDA guidance, it becomes clear that it will be the same as federal statute and guidance, and we recommend that this regulation be deleted. We are concerned that Board staff's previous response to this concern did not demonstrate their understanding of our concern. While all involved currently in the creation and comments for the definition of "essentially a copy" may have a grasp and understanding of the intent of this proposed regulation, we must take the multiple comments from all stakeholders as an indicator that there will be future misunderstanding and misinterpretations of this language. It is of the utmost importance to recognize that ten to fifteen years from now these interpretations and intent will be forgotten, and the only guidance left to enforce are the words as written. We	

			are sure that the current board would not want future board members and staff to enforce this rule under the misunderstandings that we and others took great pains to point out at this moment in time. We are concerned that Board staff's previous response to this concern did not demonstrate their understanding of our concern. Recommendation: (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, the API(s) have the same, similar, or an easily substitutable dosage strength; and the commercially available drug product can be used by the same route of administration as prescribed for the compounded drug 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 verified and documented by the pharmacist, between that compounded preparation and the comparable commercially available drug product.	
3	1736.1(b)	CSHP	We would like to continue our objections to this proposed regulation for the reasons that we and others have pointed out both in writing and written comments up to this point. As stated before, we object to the proposed regulation since it would severely limit pharmacies' ability to utilize the immediate-use provision to only those limited situations where the failure to administer such CSP could result in loss of life or intense suffering of an identifiable patient. This continues to narrow the scope of application of the immediate use provisions of USP to a point where it is practically unusable. We and others continue to point out the unintended consequences that this rule has been responsible for in the past, such as shifting compounding to disciplines that do not fall under the jurisdiction of the board. We are concerned that the board's response to stated concerns negates the complexity of health system operations by implying our practices are inefficient and potentially inaccurate. . The Board's responses, at times, fails to provide evidence for the continued support of the	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments received. Board staff note that the comment is outside the scope of the fourth modified text. The Board notes that it has previously responded to this comment and respectfully refers the commenter to the Board's prior response. The Board also notes that the commenter appears to be speculating on unintended consequences. The Board has also previously responded to this speculation about shifting compounding to disciplines that do not fall under the Board's jurisdiction. The Board notes that its regulations cover a variety of different practices, and its regulations must address processes and use cases beyond health systems. The Board notes that it's approach to immediate use

		proposed regulations that have been identified by the regulated entities as potentially harmful to the patients we serve. We thank the board for clarifying our questions regarding the expectations for reporting utilization of the proposed immediate use during instances when the appropriate compounding environment is not available at the time. A review of the ISOR does not address the increase in direct and indirect costs to licensees and the board of the proposed rules associated with the expected increase in reporting. The changed text makes clear the expectations that every single instance of initiation of immediate use in this context be reported to the board, even in cases where routine maintenance of the engineering controls is scheduled and there is an emergent need for an immediate use compounded medication. We once more reiterate our concern that the board will not have adequate resources to manage the onslaught of additional reports that will be received from licensees. The subsequent increase in staffing will then be passed to licensees via increases in license fees. We are concerned that the board may underestimate the seriousness of challenges that many hospitals that are not designated critical access hospitals will experience in the state. Especially those that serve rural communities. We maintain our position that the board's proposal for immediate use in instances where there may be equipment and engineering control failures is egregiously inadequate. It does not account for both catastrophic failures of the equipment and environment or for catastrophes like natural disasters. We once more reiterate our stance that the additional allowance for critical access hospitals only addresses the problem partially. We object to this partial addressing of this problem and again recommend that the board recognize that there are many rural hospitals that are not designated as critical access hospitals. These hospitals can run into the exact same problems with equipment and engineering controls as critical access hospitals with equally devastating consequences. There are even standalone, single owner hospitals in metropolitan areas without the	provisions is consistent with its consumer protection mandate, focused on reducing the opportunity for compromise of the CSP. Immediate use compounding is inherently at higher risk for potential contamination. The Board notes that the commenter suggests potential cost impacts to the proposed requirements. Staff note that in existing regulation, immediate use preparations require administration to begin no later than one hour following the start of the compounding process. USP and the Board's proposed regulations allow for use of immediate use provisions for up to 4 hours with expanded opportunities for use. Staff note that current regulations do not allow for immediate use compounding in the event of equipment or environment failure. Under the proposed regulation text, reporting to the Board would be required when compounding equipment or environment fail, and the facility elects to use the expanded provisions for immediate use as allowed in the proposed regulation text. Note: The Board did not include the strikethrough words (appears to be track changes) in a sentence in the CSHP comment in this area.

		benefit of belonging to a health system that can be impacted. While we highly recommend that subsection (b) be changed to our recommendation below under the bolded heading of 'Recommendation", absent an acceptance of this recommendation, we recommend that the allowances of subsection (3) be changed to: 3) If the sterile compounding equipment or environment fail(s) to meet any required specification in a critical access hospital that are not within 40 road miles of a hospital of the same corporate ownership , ~~as defined in the Social Security Act 42 U.S.C. 1395i-4 section (c)(2)(B)~~, after attempts to remediate pursuant to the facility's SOPs are unsuccessful, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering or an identifiable patient. This provision may be used for 120 hours after such failure(s). All such failures shall be documented in accordance with facility's SOPs and shall be reported to the Board within 72 hours. To continue with the proposed requirement, in essence, means California pharmacists will be the only licensed professionals in the USA banned from utilizing the USP immediate-use allowance. It is concerning that other than stating that "this is existing language at section 1751.8(e)..." there are no reasons provided in the ISOR for the requirement that CSPs used for immediate administration be limited to situations where the failure to administer could result in loss of life or intense suffering. This requirement was created based on the old USP standards when there was limited understanding of the applicable microbiological principles and the wide clinical barriers it creates as it relates to immediate use. It is important that the board consider the negative impact on patient care that this antiquated rule creates. Since the ISOR does not address the objective and scientific reasons for the limitation on immediate use, we recommend that the regulation be deleted. We are concerned that the board has not demonstrated their understanding of our concern regarding this issue.	

		The expectation of an emergency plan to provide compounding services when the hospital's sterile compounding operations are down are ideal and hospitals are required by federal regulations to have emergency plans. However, the proposed regulations are implying the hospital must have a backup cleanroom. This is a multi-million dollar investment which is not possible for most hospitals and especially for rural and stand alone hospitals. . The impact of the proposed regulations will have significant impact on hospitals financial solvency with unintended consequences to patient care. Elimination of low complexity immediate use provision creates additional hurdles to acquiring the medication that might be insurmountable and therefore jeopardize patient safety. We wish to provide the following realistic example: when a rural non-critical access hospital pharmacy has a sterile compounding airflow hood malfunction, and the replacement hood must be ordered and shipped, they can use immediate use compounding for two days. After this they must stop compounding. What is a pharmacy supposed to do then? Think about it, a licensee has the drugs in their hands, but they cannot go through the simple process of mixing it together in a few seconds to treat a patient. . In the absence of a workable solution, we recommend that the immediate use regulation be deleted. We are concerned that the board has not demonstrated their understanding of our concern regarding this issue that has the potential to shut down rural hospitals to the significant detriment of patients and communities. We continue to object to the boards business impact numbers. The immediate use regulation alone will cause a loss in income totaling millions of dollars if a hospital must close their doors and ship patients out to a hospital with a working cleanroom. The Board failed to capture the economic impact to health systems in their ISOR. The board's response to the question of "Business Impact" in ISOR states; "the board anticipates minimal ongoing costs ranging from approximately \$5,700 to \$15,000 per year related to administrative and maintenance workload." This statement applies to the multiple proposed regulations requiring the	

		addition of new administrative procedures, reporting requirements, and enhanced testing. The amount stated is a gross underestimation of the true cost to health systems. Understandably the Board lacks the internal expertise to accurately reflect those anticipated costs associated with development of policies and procedures, monitoring implementation of those procedures, correctly reporting to the Board as proposed by this regulation and others, cost of monitoring visits by the Board, enhanced environmental and personnel testing requirements, purchase of additional inventory for PPE, implementation of technology to support the deployment of the policies and procedures and hiring of additional staff to support compliance with the proposed regulation. The Board further states in the ISOR under the header of "Business Impact" as it relates to the issue of cost the following: "This initial determination is based on the absence of testimony to that effect during the public discussion and development of the proposed regulation." The public meetings mandate testimony be limited to a few minutes and attendees tend to focus their input on the specific wording of the proposed regulation and not the cost. It is incumbent on the Board to actively pursue input from those that can accurately project the cost to health system of the proposed regulation. The Board should, during public meetings, or by other means seek input from experts who can inform the Board's ISOR development as it relates to both "Business Impact" and Economic Impact Assessment" to ensure the ISOR is an accurate reflection of the impact to health systems on cost and health care access. We ~~continue to wish to further~~ point out that the board has not responded to our comments regarding the economic impact of this proposed rule since they have not approached senior health system leaders who are best situated to assess and assist them with economic impact of this rule. Neither has the board shared their assessment of how this rule will increase their cost of enforcement of the proposed rule.	

		USP 797 provides sufficient guidance in their improved and updated standards for immediate-use compounding, and we once more recommend that the board to require USP's standards and not engage in additional regulations that are not based on an articulated and proven evidence that such proposed regulations will enhance patient safety efforts beyond the national standards. We appreciate the complexities of regulating sterile compounding across the diversity of health system procedures and processes and we would like to invite board members and staff to consider doing site visits to gain a greater appreciation for how health systems promote patient safety and quality of compounded drug preparations. We would be happy to set up those site visits with our members. Specifically, we are inviting board members with limited background and experience in compounding. We once more are signaling our agreement that the routine utilization of immediate use in a hospital is an inappropriate practice. CSHP and our members have the same goals for patient safety as the board. It is unfortunate that some have engaged in this practice and now the majority of law-abiding facilities and pharmacy licensees must suffer the consequences. To account for the unfortunate choices of the few, whilst not punishing the majority we would recommend a more measured approach by limiting the time that an immediate use sterile compound can be used for up to 12 hours maximum from the time that compounding starts. This way the concerns for patient safety is addressed while it is also not so restrictive to the vast majority of ethical and law-abiding licensees. It also has the added benefit that it will not lock both licensees and board staff in a burden of reporting and administrative duties. Additionally, this problem does not have to be solved with multiple layers of regulation that attempts to solve for endless 'what-if' scenarios. As we have taken pains to point out in the aforementioned, these regulations will be creating insurmountable obstacles to patient care, which could in	

			practice only be overcome by licensees making immediate use sterile compounds which would be a violation of the regulations if enacted. Please see our recommendation below. Recommendation: Remove the requirement limiting the use of immediate-use CSP's to situations where failure to administer could result in loss of life or intense suffering due to this being deleted from the new USP 797 standards and the profound negative impact on patients. This will subsequently remove the need for reporting to the board. Recommended Text: (b) CSPs for direct and immediate administration shall only be compounded in such quantity as is necessary to meet the immediate need of the patient. A compound made for immediate use shall have a maximum beyond use date of 4 hours and shall expire after 12 hours. Note: We note that the board did not show understanding of this recommendation in their response. We therefore wish to clarify that our recommendation is aligned with USP in that it copies the requirement of a beyond use date of 4 hours for immediate use. It must be noted that USP does not assign expiration dates to compounds. Contrary to board staff's assertion that we expand immediate use provisions, we actually limit the life span of an immediate use compound. Board staff's previous comment relayed their concern for patient safety where it is observed that some licensees engaged in preparing epidural and intrathecal compounds that stays on the patient for 24 hours or longer. We mimic the boards approach of adding additional rules to limit USP standards by addressing the stated concern of the board. With this recommendation, we place an expiration date on the compound, implying that a drip or infusion may be started within 4 hours of compounding and use on the patient must then be discontinued by the 12-hour expiration date.	
4	1736.1(b)	Kaiser	At this juncture, we have nothing new to say about this regulation; however, we do not want to risk our silence on the matter being misconstrued as agreement. We continue	Board staff have reviewed the comment and do not recommend a change in the proposed text. The Board has previously considered this comment. The

			to believe that this regulation is not necessary because the USP standard on immediate use compounding strikes the appropriate balance between patient safety and timely access to compounded medications. This regulation will have a chilling effect on pharmacy personnel performing immediate use compounding, including in critical situations like Code Blue events in hospitals, and is likely to promote immediate use compounding by non-pharmacy personnel. ~~(b) (1) Except as allowed in paragraph (2), CSPs for direct and immediate administration as provided in USP Chapter 797 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. If not already documented in the patient's medical record, documentation for each such CSP shall also include the compounded date and time, the patient's name and patient's unique identifier and the circumstance causing the immediate need of the patient. Such documentation need not be redocumented by the compounding staff if already available.~~ ~~(2) If the sterile compounding equipment or environment fail(s) to meet any required specification, after attempts to remediate pursuant to the facility's SOPs are unsuccessful, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering of an identifiable patient. This provision may only be used for 48 hours after such failure(s). All such failures must be documented in accordance with facility's SOP and shall be reported to the Board within 72 hours.~~	Board respectfully refers the commenter to the Board's prior responses. Staff note that in existing regulation, immediate use preparations require administration to begin no later than one hour following the start of the compounding process. USP and the Board's proposed regulations allow for use of immediate use provisions for up to 4 hours with expanded opportunities for use. Staff note that current regulations do not allow for immediate use compounding in the event of equipment or environment failure. Under the proposed regulation text, reporting to the Board would be required when compounding equipment or environment fail, and the facility elects to use the expanded provisions for immediate use as allowed in the proposed regulation text.
5	1736.1(e)(1)	Novo Nordisk	Comment: We reiterate our request that the Board update Section 1736.1(e)(1) to state only the prohibition on compounding of "essentially a copy of one or more commercially available drug products," as defined at Section 1736(e), for the same reasons as described above in our comments regarding Section 1735.1(e)(1). Specifically, the provisions relating to the ASHP Drug Shortage List and compounding when a health care facility cannot obtain a drug from the manufacturer or wholesaler are inconsistent	Board staff have reviewed the comment and do not recommend a change to the proposed text. Board staff note that the comment is outside the scope of the proposed changes in the fourth modified text. The Board has previously considered this comment. The Board respectfully refers the commenter to the Board's prior response.

			with federal law and policy, create risks for patient safety and health, and undermine a key check on compounding unapproved drugs. Recommended language revision: “(e) In addition to prohibitions and requirements for compounding established in federal law, no CSP shall be prepared that: (1) Is essentially a copy of one or more commercially available drug products, as defined at Section 1736(e) of this article. Documentation by the pharmacist that the compounded drug product produces a clinically significant difference for the medical need of an identified individual patient, as provided for at Section 1736(e) of this Article, must be maintained in a readily retrievable format.”	
6	1736.1(e)(1)(B)	CA Medical Association	Requirement to Verify a Preparation Produces a Clinically Significant Difference Interferes with Exercise of Professional Judgment and Exceeds Federal Law (§§ 1735(d), 1735.1(e)(1)(B), 1736(d), 1736.1(e)(1)(B)) CMA reiterates its concern regarding the Board's proposed requirement for pharmacists to "verify" that a compounded drug produces a clinically significant difference for a patient. This proposed requirement creates an undue burden and restricts the professional judgment the Board intended to preserve. Mandating verification for every instance of compounding a commercially available drug that is not on a shortage list establishes a rigid, prescriptive standard. This contradicts the Board's stated goal of maintaining flexibility, and, as such, the language violates the clarity standard because it conflicts with the Board's description of the effect of the regulations in its formal response to members of the public regarding this issue. We refer you to our comment letters dated January 27 and February 21, 2025, for detailed discussions of this issue. To enhance clarity and ensure patients maintain timely access to medications, CMA reiterates its request from our prior comment letter, dated January 27, 2025, to remove "verify and" from proposed sections 1735(d), 1735.1(e)(1)(B), 1736(d), and 1736.1(e)(1)(B) of the third modified text.	Board staff have reviewed the comment and do not recommend a change in the proposed text. Board staff note that the comment is outside the scope of the proposed changes in the fourth modified text. Board staff note that the comment has been previously considered and a response provided. Board staff respectfully refer the commenter to the Board's prior response.

7	1736.1(e)(2)	Wedgewood	We appreciate that the Board addressed our earlier concerns about the ambiguous reference to AMDUCA, but we continue to remain concerned about a direct reference to a Guidance Document that could be eliminated tomorrow by the current administration. What will compliance look like if the Agency rescinds or edits the guidance document making this reference irrelevant? We again make the following Recommendation: This compound shall be in compliance with current industry guidance. ~~the Center for Veterinary Medicine Guidance for Industry #256 – Compounding Animal Drugs from Bulk Drug Substances issued August 2022.~~	Board staff have reviewed the comment and do not recommend a change in the proposed text. Board staff note that the comment is outside the scope of the proposed changes in the fourth modified text. The Board has previously considered these comments. The Board respectfully refers the commenter to the Board's responses
8	1736.9(e)	Novo Nordisk	We write to alert the Board to a new critical patient safety issue raised by the most recent changes to the Proposed Rule, notably by allowing compounding of untested fixed-dose combinations of a Category 1 bulk drug substance with a component of an FDA-approved drug. In addition, while we acknowledge the Staff Responses to NNI's comments to the Third Modified Text, we urge the Board to further consider the legal considerations raised in our prior comments and update the Proposed Rule to account for these important issues. Comment: The Proposed Rule's bulks provisions should be further revised to protect patients against harmful combinations of compounded drugs that have not been assessed for safety or effectiveness. The Board states that it intends to "provide a legal pathway in California to compounding using bulk drug substances included on the FDA Category 1 bulk drug substances list that meet the requirements of federal law, federal guidance and national standards." The Fourth Modified Text, however, goes far beyond the Board's stated intent by proposing to allow untested and unsafe compounding of Category 1 substances in combination with components of an FDA-approved drug. We strongly urge the Board to add our recommended text below to limit the scope of this	Board staff have reviewed the comment and do not recommend a change to the proposed text. Board staff appreciate the commenter raising patient safety concerns and agree with the potential for patient harm when using category 1 bulk drug substances. The Board has made a determination following significant public comment, that the Board's approach to allow for compounding using bulk drug substances included on the published 503A Category 1 bulk drug substances may be performed consistent with federal law, federal guidance and national standards, including for example that the component must be found suitable for the sterile drug preparation consistent with the requirements of the national standards. Board staff note that Section 503A requires compounding to be patient-specific prescription.

		allowance and protect patients from unknown harms associated with compounded combination products. As written, the Board's Fourth Modified Text would permit compounding of "semaglutide" with co-active ingredients. Combining ingredients that have not been studied with "semaglutide" heightens the complexity of compounded "semaglutide" formulations and introduces some known risks and, critically, a myriad of unknown risks. Developing a fixed-dose combination product is an extremely complex process and requires a careful assessment of the individual drugs alone and when used in combination. This is particularly true when the co-active ingredient is a Category 1 bulk drug substance that has not been evaluated by FDA for its own safety and effectiveness. FDA itself states that a fixed-dose combination "may present greater risk compared to clinical development of an individual drug" and "should ordinarily be reserved" for circumstances where there is a (a) combination intended to treat a serious disease or condition, (b) strong biological rationale for use of the combination, (c) full nonclinical characterization of the activity of both the combination and the individual drugs, or a short-term clinical study on an established biomarker that suggests the combination may provide a significant therapeutic advantage over an available therapy and is superior to the individual agents, and (d) compelling reason why the new drugs cannot be developed independently. These circumstances do not exist for the compounded fixed-dose combination products purporting to contain "semaglutide." Because fixed-dose combination products are more complicated than individually formulated drugs, extensive testing, which compounders do not conduct, is essential to ensure that all ingredients in the drug product work together to provide the expected safety and efficacy profile. Co-active ingredients in compounded "semaglutide" drugs that are not present in FDA-approved semaglutide products include Body Protection Compound-157 (BPC-157), L-Carnitine (levocarnitine), vitamin B-12 (cyanocobalamin or methylcobalamin), glycine, pyridoxine, chromium PIC,	

		tirzepatide, and nicotinamide adenine dinucleotide (NAD+). Testing conducted on some of these compounded samples with multiple APIs revealed impurities and degradants caused by the interactions between the semaglutide and the co-active ingredient, underscoring how complex it is to create such a formulation. For instance, testing revealed safety and efficacy concerns involving a compounded drug containing semaglutide and NAD+, an oxidized form of NAD. NAD and NAD+ "substantially degrade when exposed to light, moisture, alkaline pH, or standard room temperatures; therefore, [they] will not be stable under ordinary storage conditions." Testing results for the sample showed extremely high levels of oxidations and di-oxidations, likely due to the NAD+ reacting with the semaglutide peptide. These testing results indicated that the stability of semaglutide was compromised, which may adversely impact its effectiveness. In addition, the oxidation may result in the formation of aggregates with the potential to induce or enhance immune responses. Novo Nordisk received a complaint from a patient who took compounded "semaglutide" and NAD, was hospitalized, and was diagnosed with liver cirrhosis. The FDA Adverse Event Reporting System (FAERS) also includes one report associated with "semaglutide" and NAD+ where a patient suffered a liver injury, was hospitalized, and ultimately died. These adverse event reports (although limited in number and information) suggest that combinations of "semaglutide" with Category 1 substances may be dangerous. Compounders attempt to justify their compounding of "semaglutide" products based on supposed clinical needs of patients. No clinical justification supports the serious risks associated with compounding "semaglutide" with Category 1 co-actives. The FDA-approved semaglutide medicines come in a variety of strengths and dosage forms to meet the needs of many patients, and if an individual patient has a medical need for a compounded Category 1 substance, the physician can prescribe that drug for the patient. Instead of using this approach, some compounding	

		pharmacies offer prescribers options like the ability to “add Vitamin B6 or Vitamin B12 to semaglutide to prevent nausea or . . . request a formulation of the drug that is delivered under the tongue, . . . which is different from the injectables marketed by [Novo Nordisk]” However, in those cases where a prescriber determines that a patient needs another drug to complement their therapy, such as vitamin B-6 or B-12, the patient could easily be separately prescribed that vitamin B-6 or B-12 medication alongside an FDA-approved semaglutide medicine, rather than be prescribed an unapproved compounded “semaglutide” product in which the “semaglutide” is mixed with vitamin B-6 or B-12. There is no clinical evidence that using these products in a fixed-dose combination will improve patient outcomes; to the contrary, there are significant unknown risks to patient safety from patients taking such unapproved compounded fixed-dose combination products. FDA expressed some of these unknown risks at an Advisory Committee meeting on methylcobalamin. FDA recommended against adding methylcobalamin to the list of 503A Category 1 substances partly because the Agency had “a concern regarding lack of available safety data with methylcobalamin, particularly for intravenous injections and infusions.” An Advisory Committee member raised a specific concern that a published study “found cobalt levels following Vitamin B12 injections were significantly high” and multiple Advisory Committee members voted against adding methylcobalamin to Category 1 due to its unknown safety and effectiveness profile. As we note above, these unknown risks are amplified when methylcobalamin and other co-actives are compounded with “semaglutide.” For these reasons, we urge the Board to expressly state that a Category 1 substance should not be permitted to be used as a co-active in a fixed-dose combination product. Recommended language revision: “(f)(1) A component included in the published 503A Category 1 bulk drug substances list shall not be used as a co-active in a fixed-dose combination product.”	

			Comment: We also suggest that the Board reinsert the requirement that a compounded drug is dispensed pursuant to a patient-specific prescription that documents the clinical circumstances that require the use of a bulk drug substance currently on the 503A Category 1 bulk drug substance list. This requirement is consistent with the Federal Food, Drug, and Cosmetic Act section 503A.	

#	Section	Commenter	Comment	Board Response
1	1737.15(a)	Kaiser	We appreciate the Board's continued willingness to discuss this section of the regulation. In response to our comment letter dated February 20, 2025, Board staff responded, "the recommendation to add in a provision for the study to be 'peered reviewed' does not ensure an independent reviewer is involved." We find the Board's feedback perplexing as peer review is the gold standard process for independently evaluating the methodological rigor of a study. The University of California Office of Scholarly Communication describes peer review as the process by which "reviewers who are experts in the topic at hand... review new scholarship for relevance, accuracy, and importance to the field." Typically, during peer review, "the identities of the reviewers and authors are kept anonymous to mitigate the risk of bias." Therefore, we continue to recommend amending the regulation text to indicate that the study must be published in a peer-reviewed journal. Deactivating, decontaminating, cleaning, disinfecting, and sporicidal agents shall be used in accordance with manufacturers' specifications, or subsequent ~~manufacturer approved~~ studies <u>published in a peer-reviewed journal</u>, and shall be surface compatible.	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Board staff note that the comment is outside the scope of the proposed changes in the fourth modified text. Board staff note that the Board previously considered a similar comment from the commenter and determined that changes to the regulation text were not appropriate. In addition to the Board's prior comments, the Board notes that, while outside the scope of the Board's jurisdiction, it may be appropriate for the commenter to contact other regulators that oversee the approval of cleaning agents to discuss options to update the use of such agents-based manufacturer's specifications.

#	Section	Commenter	Comment	Board Response
1	General	CSHP	We continue with our concerns on several critical issues we have raised. Specifically, we have submitted feedback and voiced concerns regarding: 1. The Board's definition of what constitutes 'essentially a copy' of a manufactured product, which has significant implications for pharmacy practice and patient access to necessary medications. The unintended consequences and potential for misinterpretation continues to be a cause for concern. 2. The proposed regulation for immediate-use compounding, which, in its current form, presents operational challenges and potential unintended consequences that may impact patient care. 3. The proposed regulation requiring the reporting of potential quality problems, which lacks clarity and may lead to undue burdens on pharmacies without a clear framework for addressing genuine quality concerns. We appreciate that there is a looming deadline with Office of Administrative Law one year time frame and a general distaste for starting the process of regulatory rule making again. However, the development of compounding regulations that are universally implementable to the benefit of the patients we serve would benefit from a comprehensive and collaborative engagement from all interested stakeholders. The current process of submitting comments and a two-minute testimony at board of pharmacy hearings is unable to capture the complexities of compounding and its impact on multiple entities and individuals. We ask that the Board of Pharmacy consider, given the ongoing concerns, to pause the process and convene stakeholder meeting(s) that allows for a platform for substantive discussion on these issues.	Board staff have reviewed the comment and do not recommend a change to the proposed text based on the comment. Board staff note that the three issues raised have been previously submitted and considered by the Board. In addition to the prior responses, Board staff believe it is appropriate to note that licensed pharmacists are required by law to exercise professional judgement. The commenter appears to suggest that language in some areas lacks clarity. The Board disagrees. The proposed regulation language is intended to provide flexibility for a pharmacist, using professional judgement, to make the appropriate decision for the patient. The Board's regulations in several areas are also intended to provide facilities with flexibilities to implement the requirements as they believe is appropriate for their specific operations. As an example, the Board's essentially a copy definition relies heavily on a pharmacist's professional judgement in making a determination if a compounded preparation would provide a clinically significant difference for the patient. Similarly, a pharmacist using their professional judgement would determine if reporting of a potential quality problem. The pharmacist, understanding the specific facts of potential quality problem is best suited to make such a determination. As the Board seeks to transition to a more robust standard of care model, where pharmacists believe additional clarity is required, they can include in standard operating procedures or criteria as deemed appropriate. The Board also believes it is appropriate to respectfully refer the commenter to the Modified

				Initial Statement of Reasons and Underlying Data that include the significant opportunities afforded to stakeholders to participate in the development of the rulemaking process. Minutes from the meetings demonstrate the robust participation from a number of stakeholders from a cross-section of the Board's regulated public. As the formal rulemaking process began, the Board has followed the Administrative Procedures Act (APA). The Board respectfully refers the commenter to legal requirements for the rulemaking process established in the APA, Government Code section 11340 et seq.
2	General	CA Medical Association	Language of Proposed Text Conflicts with Board's Description of Its Effect (throughout all sections) CMA is disappointed by the Board's continued refusal to revise its proposed language to clarify that the regulations do not apply to physicians. In its response to public comment requesting clarification on whether the regulations apply to physicians and other licensed practitioners, the Board effectively stated the regulations do not apply to licensees of other healing arts boards, noting: "[...] [the] Board's regulations apply to licensees within the Board's jurisdiction. The Board's jurisdiction is limited to those businesses and individuals within its practice act." The language of the proposed regulations, however, is written in a manner that could be construed to apply to compounding in any setting and by any individual, because their scope is not expressly limited to pharmacists and pharmacies, unlike the current regulation. Thus, the Board's proposed regulations continue to violate the clarity standard of the with the Board's description of the effect of the regulations. CMA would also like to address comments made by Board staff at its most recent meeting held on March 6, 2025. Board counsel summarized section 4170(c) of the Business and Professions Code (BPC), stating "the	Board staff have reviewed the comment and do not recommend a change in the proposed text. Board staff note that the comment is outside the scope of the proposed changes in the fourth modified text. The Board respectfully refers the commenter to the Board's prior responses to these comments that have been considered several times during this rulemaking process.

		Medical Board of California and other healing arts boards are specifically charged with the enforcement of Pharmacy Law with respect to their respective licensees." CMA has never disputed this fact. In fact, our letter dated December 9, 2024, cited BPC 2220.5, acknowledging the Medical Board's authority. Further, BPC 2220.5 specifies this authority empowers the Medical Board to investigate or take disciplinary actions against physicians for violations "...of the Medical Practice Act and any other provision of this division," referring to the Healing Arts division (division 2 of the BPC, commencing with section 500), which contains the Pharmacy Law (chapter 9 of the BPC, commencing with section 4000), among other healing arts laws. (BPC 2220.5(b) (emphasis added).) Thus, BPC 2220.5 and BPC 4170(c) both authorize the Medical Board to enforce the Pharmacy Law on physicians. While these two statutes limit the Board of Pharmacy's authority to take enforcement action against a physician's license, they do not limit the scope of licensees to whom the Board's regulations may apply. Rather, they suggest the opposite. The Pharmacy Law may, at times, apply to physicians, and in those situations, the Medical Board is authorized to take enforcement action if a physician is acting in violation of the law. Through the regulatory process, the Board of Pharmacy is implementing, interpreting, and making specific the Pharmacy Law which, in this case, the Medical Board has confirmed "may influence the standard of care for physicians who are compounding." Allowing pharmacist-centric regulations to influence the physician standard of care is inappropriate and would harm patient care in California. CMA reiterates its request from our prior comment letter dated December 9, 2024, to revise the proposed regulations to clarify they do not apply to compounding performed by physicians outside of a pharmacy setting, so that the proposed language of the regulations aligns	

			with the Board's description of the effect of the regulations, as required by the APA.	
3	General	Kaiser	Myth: Many of the provisions in the proposed regulations have been in California pharmacy regulations for years and removing those longstanding requirements would be "taking a step back." Fact: It is true that some of the requirements in the proposed regulations have been in existing compounding regulations for many years. However, a great deal has changed since the last major update to the Board's compounding regulations in 2011. Most significantly, beginning in 2020, the Pharmacy Law has required pharmacies to comply with the United States Pharmacopeial Standard's (USP) compounding chapters. With the statutory requirement to meet the requirements of the USP compounding chapters, separate compounding regulations are no longer necessary. Myth: It is appropriate for the regulation to become effective based on the date the final regulation is filed with the Secretary of State. Fact: The Board should establish a rational delayed effective date—at least nine months—for these regulations to provide the regulated public with ample time to come into compliance with these new requirements. If the proposed regulation is finalized as written, organizations will need to make extensive changes to compounding workflows, which will need to be memorialized in organizations' policies and standard operating procedures. The policy-writing and approval process is not automatic and, in some settings such as General Acute Care Hospitals, the updated policies must be reviewed and approved by the organization's governing body, which is also time-consuming. Many organizations will also need additional time to upgrade their electronic pharmacy systems to meet the new requirement in the proposed regulations to maintain an audit trail of all prior versions of all compounding records.	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments received. The Board has appropriately considered all comments received and has made significant changes to the proposed regulation text based on comments received during the rulemaking process. Board staff disagree with the request from the commenter to repeal existing regulations. This issue was previously considered by the Board. The Board respectfully refers the commenter to the Board's prior response. Further, staff note the rulemaking record including the Modified Initial Statement of Reasons, Underlying Data, Documents Relied Upon and responses to comments articulates the basis for the proposed regulations and is consistent with the Board's consumer protection mandate. Board staff does believe it is appropriate to correct the comment regarding the applicability of USP national standards. Compliance with USP national standards was required before 2020. Board staff respectfully note that Section 503A has required compliance with USP national standards since at least 2013. Further several provisions of Pharmacy Law also referenced compliance with national standards prior to 2020. As an example, Business and Professions Code section 4342, passed in 1996, provided authority for the "Board to institute any action or actions... to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopeia or the National Formulary..."

		Myth: The public does not understand the proposed regulations and would benefit from “more education.” Fact: The vast majority of the feedback offered by the public has been rational and credible and should not be dismissed as ill-informed. The oral and written comments from both the regulated public and the lay public demonstrate a sophisticated understanding of pharmacy compounding, the proposed regulations, and the effects that the regulations are likely to precipitate. Myth: Pharmacies are resistant to the proposed regulations because they just don’t want to be regulated. Fact: Kaiser Permanente supports commonsense, evidence-based compounding standards that promote the preparation of safe and effective compounded drug products, which is the reason that we support the adoption of the USP compounding standards for non-sterile, sterile, and hazardous drug products. The Pharmacy Law already requires “the compounding of drug preparations by a pharmacy... be consistent with standards established in the pharmacy compounding chapters of... USP,” which provides an immediate path the Board could take to simply conform to the USP standards.¹ Myth: If this regulation is not finalized, the Board would have to start the rulemaking process over. Fact: The Board could move forward with enforcing the USP compounding standards and not promulgating new regulations without starting the rulemaking process over. The rulemaking package comprises a proposal to repeal the Board’s current compounding regulations and a proposal to adopt the new compounding regulations. To proceed with enforcing provisions of the USP compounding chapters as required by Business and Professions Code section 4126.8, the Board should move to:	Board staff note that the Board previously considered an extended effective date and determined that it was not appropriate. The Board respectfully refers the commenter to the Board’s prior response. Board staff further note that the revised USP compounding chapters became effective November 1, 2023. Consistent with the Board’s policy statement, most pharmacies have already transitioned to the updated chapters. The Board recognizes that compounding is a complex area of practice. As part of the regulation development process and through the rulemaking, the Board has sought to provide education to interested stakeholders serving as adjunct educational materials beyond those included in Modified Initial Statement of Reasons. This education has included presentations, FAQs and summary documents along with responses to public comments.

			1. Accept the proposal to repeal sections 1708.3, 1708.4, and 1708.5 of Title 16, Division 17, Article 2 of the California Code of Regulations and to repeal 1735 et seq of Title 16, Division 17, Article 4.5 of the California Code of Regulations and to repeal 1751 et seq of Title 16, Division 17, Article 7 of the California Code of Regulations. 2. Reject the proposal to add new sections 1735 et seq of Title 16, Division 17, Article 4.5 of the California Code of Regulations, and to add new sections/Article 1736 et seq of Title 16, Division 17, Article 4.6 of the California Code of Regulations, and to add new sections/Article 1737 et seq of Title 16, Division 17, Article 4.7 of the California Code of Regulations, and to add new sections/Article 1738 et seq of Title 16, Division 17, Article 4.8 of the California Code of Regulations.	
4	General	Alliance for PHY Compounding	The Alliance for Pharmacy Compounding again urges the California State Board of Pharmacy to reject the proposed compounding regulations in their current form. The feedback from a broad coalition of stakeholders—hospital pharmacists, compounding pharmacies, physicians, academic institutions, and healthcare organizations—has been clear: these regulations are unworkable, unnecessary, and detrimental to patient care. Yet, despite extensive opposition, the Board seems determined to move forward without making the meaningful revisions needed to align these regulations with patient needs and practical compounding practices. We acknowledge the significant time invested in this rulemaking process. However, that sunken cost does not justify pushing forward regulations that impose unclear, duplicative, and excessively burdensome requirements without clear evidence of benefit. The goal must be to ensure patient access to safe and necessary medications, not to create barriers that disrupt care without justification. Unfortunately, these regulations	Board staff have reviewed the comment and do not recommend a change to the proposed text based on the comment received. Board staff note that the commenter is not recommending any changes to the proposed regulation text. The rulemaking record including the Modified Initial Statement of Reasons, Underlying Data, Documents Relied Upon and responses to comments articulates the basis for the proposed regulations and is consistent with the Board's consumer protection mandate. These documents also demonstrate the significant opportunities for public engagement both during the regulation development process and through the formal rulemaking. Board staff respectfully refer the commenter to the Administrative Procedure Act (Government Code section 11340 et seq) to gain an understanding of the rulemaking process.

		prioritize procedural finality over patient well-being, and the Board has failed to demonstrate how the proposed rules enhance patient safety. The public comment process has been inadequate. Restricting pharmacists and other experts to two-minute speaking slots—without opportunities for meaningful discussion—has stifled necessary debate and left significant misunderstandings unaddressed. Several Board members have demonstrated a fundamental lack of knowledge regarding USP standards and their existing safeguards for patient safety. Moreover, some have incorrectly suggested that stability studies exist for certain compounded medications, such as nebulized formulations, when in reality, such studies are extremely limited or nonexistent. To ensure that any regulatory changes are based on expertise and real-world applicability, we strongly urge the Board to convene a task force of pharmacists from diverse practice settings—including hospitals, academic medical centers, rural facilities, and compounding pharmacies. This group should also include USP committee members to provide authoritative insight. A collaborative approach is essential to crafting regulations that truly enhance patient safety without unnecessary disruption. The Board must recognize that USP standards already set a rigorous, evidence-based national benchmark for compounding safety. Imposing additional, conflicting state-specific regulations serves only to create confusion and limit patient access to vital treatments. Rather than advancing these flawed regulations, the Board should commit to enforcing existing USP standards while taking the time necessary to engage in meaningful dialogue with healthcare professionals. These regulations are not supported by the very professionals responsible for patient care. Instead, they	

			appear to serve the interests of groups with financial incentives to limit compounding—a fact that has not gone unnoticed by the compounding and broader healthcare communities. The few public comments in support of these regulations have been made by Big Pharma and groups backed by pharmaceutical companies.	
5	General	M. Morgenstern	Please listen to the numerous Pharmacists, Medical Doctors, Naturopaths, Firefighters and Lyme Patients asking you by public and written comment to go by the Federal rules for compounding instead of creating stricter regulations for California. I am frustrated that this farce and abuse of power is allowed to drag on.	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comment received. The Board's proposed regulations in this area do not go beyond federal law, federal guidance and national standards. The Board respectfully refers the commenter to 1736.9(e) which explicitly refers to the FDA guidance and relevant national standards.
6	General	C. Uribe	I strongly oppose the proposed regulations that would severely limit access to essential compounded medications like injected and nebulized glutathione, methylcobalamin, and NAD+. These treatments are vital for patients with chronic illnesses, first responders, and many others who rely on them for their health and well-being. The Board's proposal goes beyond federal guidelines, imposing excessive testing requirements with no clear safety justification. The financial burden of these unnecessary regulations would make these treatments inaccessible, harming both patients and pharmacies. With over 11,000 signatures in opposition—including 1,000+ from firefighters—and strong concerns from medical experts, it's clear these restrictions are not in the public's best interest. The Board must reconsider and align regulations with federal and USP standards by: • Allowing Category 2 compounding without full stability studies, as long as sterility and endotoxin testing are performed. • Removing enforcement of non-mandatory USP	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments received. Board staff note that the proposed modified text does not ban the compounding using bulk substances such as glutathione, methylcobalamin and NAD+. The Board's proposed regulations in this area do not go beyond federal law, federal guidance and national standards. The Board respectfully refers the commenter to 1736.9(e) which explicitly refers to the FDA guidance and relevant national standards. Board staff note that the commenter may, at least in part, be referring to a prior version of the proposed regulation text. Staff note that the fourth modified text does not include a requirement for stability studies, sterility and endotoxin testing on the bulk ingredient. Board staff respectfully refer to commenters to the fourth modified text in 1736.9 which highlights removal of the requirements.

		Chapters above 1000. • Ensuring regulations apply only to pharmacists, not medical practitioners. • Eliminating unnecessary documentation requirements not mandated by the FDA. I urge you to either withdraw the proposal entirely or revise it to protect patient access to life-saving medications.	As the Board has previously noted, USP provides, “Although it is possible for FDA or another government authority in the U.S. or elsewhere to require the use a USP General Chapter numbered 1000 to 1999, the authority in question would need to make this requirement expressly applicable under law, regulation, or another appropriate vehicle that prescribes enforceable requirements. The Board’s proposed regulation text is consistent with this approach and the Board, in some instances, is explicitly adopting a Chapter. As was previously shared, staff note the Board only has jurisdiction over individuals and businesses within its practice act. Board staff read the comment as suggesting that the Board’s proposed regulations would apply to a physician. Business and Professions Code section 4170(c) makes clear that the Medical Board of California is specifically charged with the enforcement of Pharmacy Law (Chapter 9, Division 2 of the Business and Profession Code) with respect to its licensees. The Board believes it is appropriate to highlight information specifically related to compounding with bulk drug substances included on the 503A interim bulk drug substances. As the Board has previously stated in prior responses provisions of federal law established in Section 503A, relevant FDA guidance documents and relevant sections of the national standards, especially those sections related to components must all be considered when compounding with such substances. The FDA has not approved or authorized the compounding of these substances, nor has the FDA stated that compounding with these substances is safe in every instance. Rather, the FDA has released guidance that articulates an interim enforcement

				discretion policy that applies if an authorized facility or individual compounds using certain unapproved bulk drug substances, such as glutathione and methylcobalamin, but only under very specific conditions. Such conditions include that the original manufacturer and all subsequent manufacturers of the bulk drug substance are establishments that are registered under section 510 of the FDCA; that the bulk drug substance is accompanied by a valid Certificate of Analysis; and that the drug product compounded using the bulk drug substance is compounded in compliance with all other conditions of section 503A (including, for example, that the compound has not been produced or held under insanitary conditions). As the Board has noted previously, until the FDA formally makes a determination regarding bulk drugs substances nominated for inclusion in 21 CFR 216.23, the Board has determined that there is a need at the state level to provide a pathway to allow for such compounding. Board staff respectfully also refer the commenter to Chapter 797 Section 9.3 Components, which specifically provides that all APIs and components used must be evaluated for suitability for use in sterile drug preparations. "Components labeled with "not for pharmaceutical use", "not for injectable use", "not for human use" or equivalent statement must not be used to compound for these purposes. The Chapter continues that any component found to be of unacceptable quality must be promptly rejected, clearly labeled as rejected, and segregated...Any other lots of that component from that vendor must be examined to determine whether other lots have the same defect." Further, from the FDA Guidance Document, Insanitary Conditions are Compounding Facilities (dated November 2020) which provides examples

				of insanitary conditions including “Using active ingredients, inactive ingredients, or processing aides, that have or may have higher levels of impurities compared to compendial or pharmaceutical grade equivalents (e.g., ingredients with potentially harmful impurities, ingredients labeled with “not for pharmaceutical use” or an equivalent statement). The Board’s underlying data included in the Modified Initial Statement of Reasons contains additional information specifically related to this issue including as an example item 21, “FDA highlights concerns with using dietary ingredient glutathione to compound sterile injectables.” The Board continues to monitor for information released from the FDA and evaluate for insanitary conditions during inspections and compliance with national standards.
7	General	T. Sanor	Why is the Board trying to get rid of a treatment that helps patients and has research supporting its efficacy. It appears as an affront to patient-centered healthcare advocates. I sent links to research last time. If you need those again, contact me. Sick patients have been ignored too long. Chronic illnesses from infections is now very much in the limelight w RFK Jr whommay or may not be right. At least he puts patients above profits unlike most of gov't for the past decades by ignoring pain and suffering especially of Lyme, a spirochete like syphilis yet much worse than syphilis as there are 30 plasmids, biofilms, persists and there are no good early tests when it is treatable. Every known brain disordered pathway can be triggered by infections per IDSA researchers at "The Science of Infections & Dementia" 2024 conference and 9.15.24 J of Inf Dis microbial issue. NeuroImmune.org confirms mental illnesses from infections such as Lyme, Bartonella, strep grp A and Covid too. AlzPi.org consortium researchers include top univ and confirm Lyme, HSV, EBV, etc cause brain	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Board staff note that comments do not appear to be recommending any changes to the proposed text.

			disorders and Michal Tal lab showed Lyme spirochetes in uterus recently, too. Dr Neil Spector's "Lyme in the Era of Precision Med" 2019 before he died of complications of a heart transplant after Lyme shows connection with cancer as does Eva Sapi. MeghanBradshaw.com for joint degeneration and chronic pain from Lyme. Lymedisease.org for research and the largest patient database will show how tragic it is to ignore these patients, many thousands w children the most affected. PsychologyRedefined.com shows too that mental illnesses root causes can be infections including Lyme, Bartonella...having a cat w Bartonella causes 3x the chance of schizophrenia and it is a coinfection along w babesia that takes weeks to months to treat. A paradigm change to find root causes and not just treat symptoms will find cures. Now pharmacists just give lifelong meds for symptoms, not cures. BOP needs to be a leader in healing by listening yo patients who are dealing with preventable chronic pain, suffering. Physicians like myself are not taught that the test is <50% sensitive and often no tick or rash is seen so when a patient has migrating, fluctuating pain, it is not believed and they are sent to psych. It is a scandal thousands of times worse than Tuskegee when syphilis was untreated as it has been decades of medical denialism of what is probable starting in 1995 iron key brain studies showing plaques, lesions consistent w severe symptoms.	
8	General	T. Kitahata	It is my humble yet strong opinion that access to treatments that are beneficial to the health of Californians be protected. In addition to daily exposure at work, I was also a first responder to the attacks of 9-11, Hurricanes Katrina, Ike, Gustav, Irma, Harvey, the Malibu fires of 1992, the Camp Fire in Paradise (and other large-scale wildfires), the Montecito mudslides, the LA Riots, the Northridge earthquake, exposed to harmful toxins from it all. I	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments received. Board staff note that the proposed modified text does not ban the compounding using bulk substances such as glutathione. Board staff note that the Board has confirmed the continued availability of compounded glutathione.

			was also on duty 24/7 for 30 days during the Palisades fire, working the fire and then assigned to a command post to care for 2000 first responders from all over the nation, the National Guard, LAPD and law enforcement from multiple agencies, utility and essential workers, and the kind people who fed us. In short, my lungs and my entire body have recently, and over time, been compromised. I firmly believe my glutathione treatments have helped me get back to my baseline. I urge the Board of Pharmacy to allow access, to offer future protections to those who stand in harm's way and those who are sick and find relief from this natural compound.	
9	General	T. Delaney	Someone that I love depends on compounded glutathione and b vitamins to stay healthy. It has become a critical part of her daily struggle to be as healthy as possible despite a multitude of debilitating health problems that make one question the value of their own life. It is absolutely necessary to protect the ability of compounding pharmacies to make these compounds. The life giving medicine contained in glutathione and b vitamins are invaluable to my loved one and I urge you to do what's absolutely right and protect the ability by pharmacies to make these important compounds.	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments received. Board staff note that the proposed modified text does not ban compounding using bulk substances such as glutathione. Board staff note that the Board has confirmed the continued availability of compounded glutathione.
10	General	R. Smith	Regarding potential new hurdles or restrictions to safe and effective compounds such as NAD+, Glutathione, and B-12 These compounds (using trusted compounding pharmacies like Infuserve) have proven a critical leg in the care of loved ones. Please do not restrict them further as many Californians/Americans will suffer even more than they are under a complex and frustrating system.	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments received. Board staff note that the proposed modified text does not ban compounding using bulk substances such as glutathione. Board staff note that the Board has confirmed the continued availability of compounded glutathione.

11	General	M. Morey	The current for-profit model of health care in the US allows many people to fall through the cracks, leading to bankruptcies and early demise. Sicker people cost much more to treat than the cost of preventative treatments. For instance, insurance stops paying for treatment of Lyme disease after roughly a month because "long term Lyme doesn't exist". This false statement leads to a (shortened) life of suffering if the tick bite isn't noticed or treated immediately, just to save money. Similarly, someone I love depends on compounded glutathione and b vitamins to stay healthy and so I am writing to protect the ability of compounding pharmacies to make these compounds. This is what she relies upon to maintain a bare minimal quality of life, paying out of pocket with money she doesn't have. THAT'S how important it is she receives these compounded drug preparations, and the protection of pharmacies' ability to make them.	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments received. Board staff note that the proposed modified text does not ban compounding using bulk substances such as glutathione. Board staff note that the Board has confirmed the continued availability of compounded glutathione and methylcobalamin.
12	General	J. Shea	Please DO NOT restrict access to IV glutathione and other alternative treatments.	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments received. Board staff note that the proposed modified text does not ban compounding using bulk substances such as glutathione. Board staff note that the Board has confirmed the continued availability of compounded glutathione and methylcobalamin.
13	General	S. Johnson	I am writing as a California resident and patient who relies on affordable, sterile compounded medications—including intravenous and injectable therapies compounded from Category 1 bulk drug substances—to maintain my quality of life. I strongly urge the Board to reconsider or revise the overly restrictive provisions outlined in Addendum 1 to the proposed regulations. Specifically, I am deeply concerned that the Board's new requirements for stability testing, extensive documentation of clinical circumstances, and strict adherence to USP chapters beyond federal mandates	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments received. Board staff note that the proposed modified text does not ban compounding using bulk substances such as glutathione, methylcobalamin and NAD+. The Board's proposed regulations in this area do not go beyond federal law, federal guidance and national standards. The Board respectfully refers the commenter to 1736.9(e) which explicitly refers

		will effectively eliminate or severely reduce access to essential sterile compounded medications, including but not limited to NAD+, glutathione, and methylcobalamin. As currently proposed, these new testing requirements (with costs estimated between \$10,000 to \$30,000 per API) would drastically raise pharmacy overhead, which will inevitably be passed on to patients or cause pharmacies to discontinue compounding these vital medications altogether. Such outcomes would place compounded therapies financially out of reach for many, including myself, directly threatening my health and quality of life. The Board's proposed regulations conflict with the existing FDA Policy. I am particularly troubled by the misleading assertion in the Board's meetings and addendum documents implying that these extensive stability tests are required by FDA policy or USP guidelines. The FDA's Interim Policy on Compounding Drugs Using Bulk Drug Substances explicitly states: "FDA does not intend to take action against an outsourcing facility for compounding drugs using bulk drug substances identified in category 1 provided that the conditions described in the guidance document are met." (FDA Interim Policy on Compounding) Additionally, the FDA has already outlined specific conditions for compounding with Category 1 bulk drug substances, stating that a bulk substance not on the drug shortage list may still be compounded if: • The bulk substance is included in Category 1 of FDA's list; • The manufacturers of the substance are all registered under Section 510 of the FDCA; • The bulk substance is accompanied by a valid Certificate of Analysis (COA); • If the bulk substance has a USP or NF monograph, it complies with that monograph; and • The bulk substance is compounded in compliance with all other provisions of Section 503B of the FDCA. (FDA Interim Policy Source)	to the FDA guidance and relevant national standards. Board staff note that the commenter may, at least in part, be referring to a prior version of the proposed regulation text. Staff note that the fourth modified text does not include a requirement for stability studies, sterility and endotoxin testing on the bulk ingredient. Board staff respectfully refer to commenters to the fourth modified text in 1736.9 which highlights removal of the requirements. Board staff note that specifically related to veterinary compounding, the Board through various comment periods, has updated proposed text to incorporate recommended changes made by the California Veterinary Medical Association. Staff believe the commenter may be referring to statements made during a legislative hearing. Board staff have confirmed the availability of products for equine patients from sources including outsourcing facilities that are licensed in California. The rulemaking record including the Modified Initial Statement of Reasons, Underlying Data, Documents Relied Upon and responses to comments articulates the basis for the proposed regulations and is consistent with the Board's consumer protection mandate. These documents also demonstrate the significant opportunities to public engagement both during the regulation development process and through the formal rulemaking. The Board believes it is appropriate to highlight information specifically related to compounding with bulk drug substances included on the 503A interim bulk drug substances. As the Board has

		The Board's proposed requirements exceed the scope of FDA guidance and create unnecessary regulatory burdens that are not aligned with federal policy. If the FDA has deemed these conditions sufficient for safety and oversight, why is the California Board imposing additional, unnecessary restrictions that will make it impossible for patients to access affordable compounded medications? This will cause unnecessary financial and public health consequences. The financial and administrative burdens imposed by this addendum will likely result in higher costs for compounded medications. For patients like me, who depend on these treatments to maintain health and manage chronic conditions, any increase in cost or reduction in supply could have devastating consequences. As a patient managing chronic illness, my consistent access to affordable NAD+ treatments has meaningfully improved symptoms where no other FDA approved drugs or treatments exist. Interruptions or prohibitive cost increases due to the Board's regulations would mean losing the stability these medications currently provide, potentially forcing me into greater disability, diminished independence, or worsening chronic symptoms. These aren't abstract risks—they're real, immediate threats to my health and well-being, and the Board must fully recognize the tangible consequences of its regulatory actions. Patients and animals are already suffering due to the board's overreach. The real-world consequences of these excessive regulations extend beyond human patients—they are already harming animals due to unnecessary restrictions on veterinary compounding. As Dr. Grant Miller, Director of Regulatory Affairs for the California Veterinary Medical Association, testified, "California is the only state in the country in which veterinarians are reporting that they do not have access to critical drugs to treat their patients. These drugs are	previously stated in prior responses provisions of federal law established in Section 503A, relevant FDA guidance documents and relevant sections of the national standards, especially those sections related to components must all be considered when compounding with such substances. The FDA has not approved or authorized the compounding of these substances, nor has the FDA stated that compounding with these substances is safe in every instance. Rather, the FDA has released guidance that articulates an interim enforcement discretion policy that applies if an authorized facility or individual compounds using certain unapproved bulk drug substances, such as glutathione and methylcobalamin, but only under very specific conditions. Such conditions include that the original manufacturer and all subsequent manufacturers of the bulk drug substance are establishments that are registered under section 510 of the FDCA; that the bulk drug substance is accompanied by a valid Certificate of Analysis; and that the drug product compounded using the bulk drug substance is compounded in compliance with all other conditions of section 503A (including, for example, that the compound has not been produced or held under insanitary conditions). As the Board has noted previously, until the FDA formally makes a determination regarding bulk drugs substances nominated for inclusion in 21 CFR 216.23, the Board has determined that there is a need at the state level to provide a pathway to allow for such compounding. Board staff respectfully also refer the commenter to Chapter 797 Section 9.3 Components, which specifically provides that all APIs and components used must be evaluated for suitability for use in sterile drug preparations. "Components labeled with "not for pharmaceutical use", "not for injectable use", "not for human use" or equivalent

		not available in FDA-approved formulations, and thus we may only obtain them through compounding pharmacies. However, excessively stringent Board of Pharmacy regulations have shrunk the number of California veterinary compounding pharmacies to just a few." "As a result, critical eye medications for horses and important medications for exotic animals such as birds and reptiles are nowhere to be found. Without drugs like ophthalmic diclofenac ointment, ophthalmic antifungal medications, and certain ophthalmic antibiotics, veterinarians have to watch helplessly as innocent horses and other animals lose their eyesight." This is an avoidable tragedy caused directly by the Board's restrictive policies, yet the Board continues to push even more severe restrictions under the proposed regulations in Addendum 1. Furthermore, a licensed pharmacist from an animal compounding pharmacy testified, "Ten years ago, we had over 100 compounding pharmacies throughout California. Now, only a handful remain to service the 40 million residents, the 20 million pets, and the 500,000 horses that live here. This is a dire situation." The Board's actions are actively reducing the availability of critical, life-sustaining medications, harming both human and animal patients alike. Serious legal and ethical concerns were raised during the Joint Hearing of the Senate Business, Professions and Economic Development Committee and the Assembly Business and Professions Committee – Joint Sunset Review Oversight Hearing on March 11, 2025. Testimony made it clear that the California Board of Pharmacy (CA BOP) is engaged in regulatory overreach, misinformation, and negligence, directly harming patients, healthcare providers, and even animals in need of critical care. The need for legal and administrative accountability has been made copiously evident.	statement must not be used to compound for these purposes. The Chapter continues that any component found to be of unacceptable quality must be promptly rejected, clearly labeled as rejected, and segregated...Any other lots of that component from that vendor must be examined to determine whether other lots have the same defect." Further, from the FDA Guidance Document, Insanitary Conditions are Compounding Facilities (dated November 2020) which provides examples of insanitary conditions including " Using active ingredients, inactive ingredients, or processing aides, that have or may have higher levels of impurities compared to compendial or pharmaceutical grade equivalents (e.g., ingredients with potentially harmful impurities, ingredients labeled with "not for pharmaceutical use" or an equivalent statement)". The Board's underlying data included in the Modified Initial Statement of Reasons contains additional information specifically related to this issue including as an example item 21, "FDA highlights concerns with using dietary ingredient glutathione to compound sterile injectables." The Board continues to monitor for information released from the FDA and evaluate for insanitary conditions during inspections and compliance with national standards.

			If the Board insists on passing these excessively burdensome regulations, established checks and balances remain available, including legislative oversight and judicial review under the Administrative Procedure Act (APA). Regulations that are arbitrary, capricious, or impose undue burdens without clear evidence of enhanced patient safety may be subject to legal challenge. Furthermore, if these financial burdens force pharmacies to discontinue these medications, patients—including myself—will inevitably suffer preventable declines in health, which directly contradicts the public health mission of this Board. The request for revision is made yet again. I urge the California Board of Pharmacy to withdraw or substantially revise this proposal to align strictly with FDA and USP standards and eliminate excessive regulatory requirements that lack justification. The Board should prioritize maintaining patient access to these medically necessary, safely compounded treatments rather than imposing excessive barriers that will remove them from the market.	
14	General	R. Horowitz	I am board-certified physician who published the first study on glutathione for COVID-19 in April 2020. Not one of my patients died during the pandemic. We also use glutathione regularly while doing dapsone combination therapy for chronic Lyme/PTLDS, as it helps reduce oxidative stress and methemoglobin, as well as Herxheimer reactions. This is an essential medication that patients must have! Commenter provided several references, which were also provided during the last comment period and are available for within the specific comment and here.	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments received. Board staff note that the proposed modified text does not ban compounding using bulk substances such as glutathione, methylcobalamin and NAD+. The Board's proposed regulations in this area do not go beyond federal law, federal guidance and national standards. The Board respectfully refers the commenter to 1736.9(e) which explicitly refers to the FDA guidance and relevant national standards.
14	General	33 Commenters	The commenters express strong opposition to the proposed regulations that would severely limit access to critical sterile compounded medications like injected and nebulized glutathione, methylcobalamin, NAD+,	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments received.

		and others. These medications are essential for many, including firefighters and chronic illness patients. Commenters state that the regulations would create unnecessary barriers that harm the healthcare system, businesses, and people of California. Commenters state that during the February 5, 2025 meeting, board members misrepresented federal guidelines, claiming the FDA has recommended restricting glutathione. However, glutathione remains on the FDA's Category 1 bulk compounds list and is legal under their current policy. USP guidelines also do not mandate stability testing for these compounds. Despite this, the proposal introduces extreme testing requirements far exceeding federal standards without adequate safety-based justification. Commenters state that the unfeasible financial burden these regulations would place on pharmacies is a critical concern. Member Serpa's cost estimates—\$16.10 per glutathione vial and \$8.06 per methylcobalamin vial—dramatically understated the actual costs of stability testing. These tests actually range from \$10,000 to \$30,000 per API. These prohibitively expensive tests would force pharmacies to discontinue offering most, if not all, formulations of these treatments, eliminating access to life-saving medications. Commenters add that the need for treatments like nebulized glutathione is more urgent than ever since southern California's severe Urban Wildfires released record levels of harmful toxins like lead and asbestos into the environment. Nebulized glutathione has demonstrated efficacy in reducing these harmful substances in the body. Restricting access to these treatments would escalate health risks, including fatal cancers, for first responders, vulnerable residents, and future generations.	Board staff note that the proposed modified text does not ban compounding using bulk substances such as glutathione, methylcobalamin and NAD+. The Board's proposed regulations in this area do not go beyond federal law, federal guidance and national standards. The Board respectfully refers the commenter to 1736.9(e) which explicitly refers to the FDA guidance and relevant national standards. Board staff note that the commenter may, at least in part, be referring to a prior version of the proposed regulation text. Staff note that the fourth modified text does not include a requirement for stability studies, sterility and endotoxin testing on the bulk ingredient. Board staff respectfully refer to commenters to the fourth modified text in 1736.9 which highlights removal of the requirements. As the Board has previously noted, USP provides, "Although it is possible for FDA or another government authority in the U.S. or elsewhere to require the use a USP General Chapter numbered 1000 to 1999, the authority in question would need to make this requirement expressly applicable under law, regulation, or another appropriate vehicle that prescribes enforceable requirements. The Board's proposed regulation text is consistent with this approach and the Board, in some instances, is explicitly adopting a Chapter." As was previously shared, staff note the Board only has jurisdiction over individuals and businesses within its practice act. Board staff read the comment as suggesting that the Board's proposed regulations would apply to a physician. Business and Professions Code section 4170(c) makes clear that the Medical Board of California is specifically

		Commenters indicate that public opposition to these regulations is overwhelming, with over 11,000 signatures on a petition—with an estimated 1,000+ from California firefighters—and hundreds of pages of comments submitted in writing and in person over the past year. Yet, the Board has failed to meaningfully respond to meaningful input from dozens of medical experts, consistently ignoring their expertise. The Board has repeatedly suggested that the public doesn't understand federal and state laws or their application, dismissing the well-informed concerns raised by patients, healthcare professionals, and advocates. The failure to engage meaningfully with stakeholders undermines the credibility of the Board's engagement process and has raised serious concerns about regulatory overreach. Commenters believe that the proposal creates unnecessary barriers severely limiting access to life-saving treatments. These barriers create an unjustifiable financial burden on patients and pharmacies and fail to reflect the true costs and needs of the community. Commenters strongly urge the Board to either (a) withdraw the proposal entirely from consideration or (b) send these proposed regulations back to the committee and re-write them to align them with and not exceed federal and Pharmacopeia standards by making the following changes: * Adhere to USP by allowing Category 2 compounding without requiring full stability studies, provided sterility and endotoxin testing is performed and a reasonable beyond-use-date (e.g., 45 days refrigerated) is applied. * Eliminate adherence to USP Chapters above 1000, which are not enforceable requirements and are meant for informational purposes only. * Amend the language to specify that Title 16 compounding regulations apply only to pharmacists. As written, this board appears to begin regulating medical practices which is regulatory overreach.	charged with the enforcement of Pharmacy Law (Chapter 9, Division 2 of the Business and Profession Code) with respect to its licensees. Board staff note that it has confirmed the continued availability and compounding of glutathione and methylcobalamin for California patients. The Board believes it is appropriate to highlight information specifically related to compounding with bulk drug substances included on the 503A interim bulk drug substances. As the Board has previously stated in prior responses provisions of federal law established in Section 503A, relevant FDA guidance documents and relevant sections of the national standards, especially those sections related to components must all be considered when compounding with such substances. The FDA has not approved or authorized the compounding of these substances, nor has the FDA stated that compounding with these substances is safe in every instance. Rather, the FDA has released guidance that articulates an interim enforcement discretion policy that applies if an authorized facility or individual compounds using certain unapproved bulk drug substances, such as glutathione and methylcobalamin, but only under very specific conditions. Such conditions include that the original manufacturer and all subsequent manufacturers of the bulk drug substance are establishments that are registered under section 510 of the FDCA; that the bulk drug substance is accompanied by a valid Certificate of Analysis; and that the drug product compounded using the bulk drug substance is compounded in compliance with all other conditions of section 503A (including, for example, that the compound has not been

			* Remove the requirement of additional documentation of "clinical circumstances" which is not required by the FDA.	produced or held under insanitary conditions). As the Board has noted previously, until the FDA formally makes a determination regarding bulk drugs substances nominated for inclusion in 21 CFR 216.23, the Board has determined that there is a need at the state level to provide a pathway to allow for such compounding. Board staff respectfully also refer the commenter to Chapter 797 Section 9.3 Components, which specifically provides that all APIs and components used must be evaluated for suitability for use in sterile drug preparations. "Components labeled with "not for pharmaceutical use", "not for injectable use", "not for human use" or equivalent statement must not be used to compound for these purposes. The Chapter continues that any component found to be of unacceptable quality must be promptly rejected, clearly labeled as rejected, and segregated...Any other lots of that component from that vendor must be examined to determine whether other lots have the same defect." Further, from the FDA Guidance Document, Insanitary Conditions are Compounding Facilities (dated November 2020) which provides examples of insanitary conditions including " Using active ingredients, inactive ingredients, or processing aides, that have or may have higher levels of impurities compared to compendial or pharmaceutical grade equivalents (e.g., ingredients with potentially harmful impurities, ingredients labeled with "not for pharmaceutical use" or an equivalent statement)". The Board's underlying data included in the Modified Initial Statement of Reasons contains additional information specifically related to this issue including as an example item 21, "FDA highlights concerns with using dietary ingredient glutathione to compound sterile injectables."

				The Board continues to monitor for information released from the FDA and evaluate for insanitary conditions during inspections and compliance with national standards.