Code Section Section (Subdivision)	Commenter	Comment	Response
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 language could be clarified. Staff are offering language to address comment.
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 as the regulation text. Staff notes that there are mulitple grades of water referenced in USP depending on the intended use. Staff note that section 1735.4(b) further identify the types of water.
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 clinican's professional judgment.
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 definition allows for better compliance and understanding of the term.	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 clinicans professional judgment.
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 clinicans professional judgment.

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 clinicans 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.
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. 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. Continued to Next Line:	Board staff have reviewed the comment and do not recommend any changes based on the comment. The example provide 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 knowledgable of current practice standards and legal requirements of the industry when exercising their professional judgment.
1735(d)	Melanie Horn Sutter Health Also Provided at Reg Hearing	Continued from Previous Line: 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)), same, similar, or an easily substitutable dosage strength, same dosage form, and the same route of administration as the commercially available drug product, except that it does not include any preparation in which there has been a change made for an identified individual patient that produces for that patient a clinically significant difference, as determined by the prescribing practitioner between that compounded preparation and the comparable commercially available drug product.	Board staff have reviewed the comment and do not recommend any changes based on the comment. The example provide 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 knowledgable of current practice standards and legal requirements of the industry when exercising their professional judgment.

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 at the time of dispensing 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.
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, as an example a facial cream that contains the patient's own blood.
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 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.	Staff believe the commenter is referring to proposed section 1735.5(a) as opposed to section 1735.1(a) referenced in the comment. Staff have reviewed the comment and do not recommend any change to the 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 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.
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 direct supervision and control 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.
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 logical. Recommend to move away from this guidance and to not use chapters over 1000 as regulation.	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 non sterile compounding to removing a dangerous drug from a manufacturer's bottle and placing it in a prescription vial.

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> 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?	After consideration of comments, staff recommend removing 1735.1(b), because it is appropriately addressed within the USP Chapter.
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 nonsubtantive 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)
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.

1735.1(e)(2)	Michael Blaire	Commenter expressed concern about veternariarn compounding to 7 days as the standard course of antibiotics in 10 to 14 days. He indicates an animal will show impovement after 5 days, so the animal owner will not fill the prescription for the remaining days and lead to reinfections. Some states allow in office use with no restrictions and others allow 14 days. Commenter requests an increase to 14 days.	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.
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 tables whole. The prescriber orders to give the medication as a suspension by mouth. The suspension of clobazam, which is commercially available, is out of stock. Under this statute [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 language to “In addition to prohibitions and requirements for compounding established in federal law, no CNSP <u>should</u> ~~shall~~ be prepared that”.	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.
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 the that 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.
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. Additonal information related to this issue is found in reponses 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.

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~~ should be prepared that: (1) Is essentially a copy of one or more commercially available drug products, unless: (A) that drug product is not available by the manufacturer or wholesaler, appears on an ASHP (American Society of Health- System Pharmacists), or FDA list of drugs at the time of compounding and at the time of dispense, or	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.
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 knowledgable 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.

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 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>	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.

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 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) that drug product is not available by the manufacturer or wholesaler, appears on an ASHP (American Society of Health- System Pharmacists), or FDA list of drugs at the time of compounding and at the time of dispense, or	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).

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 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	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).
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 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 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. **Continued Comment to Next Line**	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.

1735.1(f)(1)(A)	Melanie Horn Sutter Health	**Continued Comment from Previous Line** 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 (B) the drug product is not commercially available due to inability to supply by the manufacturer or wholesaler. (C) the drug product is unavailable to dispense and the CNSP is not compounded regularly or in inordinate amounts. (D) the compounding produces a clinically significant difference for the medical need of an identified individual patient, as determined by the prescribing practitioner. If such determination has not been documented on the prescription by the prescriber, the (ii) the compounding pharmacist, and or (iii) the dispensing pharmacist(s) Shall ensure that the determination is documented on the prescription. (C) Documentation describing the conditions in (1)(A) , (1)(B), (1)(C) and 1 (D) is maintained in a readily retrievable format	Contination from line 25. staff's recommended response is included in line 26.
1735.1(f)(1)(A)	Wendy Waldman Torrance Memorial Medical Center	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 requirements for compounding established in federal law, no CNSP shall be prepared that: (1) Is essentially a copy of one or more commercially available drug products, unless: (A) that drug product is not available by the manufacturer or wholesaler, appears on an ASHP (American Society of Health- System Pharmacists), or FDA list of drugs at the time of compounding and at the time of dispense, or...	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).
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.	Staff have reviewed the comment and do not recommend changes to the proposed regulation text. 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. Staff notes further that the commenter is asking a question regarding documentation requirements. Documentation requirements will be pharmacy specific.

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, ~~and~~ ~~(iii) the dispensing pharmacist(s).~~	Staff have reviewed the comment and recommend no changes. 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.
1735.1(f)(1)(B)	Marci Bencomo Pacifica Compounding	Commenter disagrees with the requirement for two pharmacists to make the determination that a compound produces a clinically signigicant difference for the patient as it is redundent and federal guidelines require the prescribing practitioner to make the determination.	Staff have reviewed the comment and recommend no changes. 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.
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 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.	Staff have reviewed the comment and recommend no changes. 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. Staff notes that the commenter's rationale highlights the need for both pharmacists to use their professional judgment when compounding and dispensing the compounded product.

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. RECOMMENDATION: Allow Federal statute 503A of the FD&C Act to stand on its own.	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 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.
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.	Staff have reviewed the comment and do not recommend changes to the proposed regulation text. 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.

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 are providing a lower concentration of APAP than any of the commercially available products with good pain control. b) It would prevent compounding plavix for a 4 year old when the UCSF Pediatric Cardiologist feels it is the best solution for her medical issues because plavix is not intended for use in pediatrics (only approved for adult use). c) Anything compounded for “off-label use” could be construed as not suitable for that patient. RECOMMENDATION: Clarify this is for animal/veterinary CNSPs by modifying the language: (2) Is made with any component not suitable for use in a CNSP for the intended ~~patient~~ animal population, unless allowable under the Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA).	Board staff have reviewed the comment and agree that additional clarification of the proposed regulation language is appropriate.
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 knowledgable of current practice standards and legal requirements while exercising their professional judgment.
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. When a CNSP is furnished to a patient or patient’s agent, ~~i~~in addition to the provisions provided in section 1707.2, consultation shall be provided to the patient and/or patient’s agent concerning proper use, storage, handling, and disposal of the CNSP and related supplies furnished.	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.

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.
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 healthcare professional. Proposed Exemption Language: A pharmacist is not required by this subsection to provide consultation to a patient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code or where the compounded product will be administered by a licensed healthcare professional, except upon the patient's discharge with the compounded product.	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.
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: 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.	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.

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 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.	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.
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. When a CNSP is dispensed to a patient or patient's agent, 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.
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.

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 the are not well educated. Commenter requests the following edit: (h) In addition to the provisions provided in section 1707.2, whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral consultation shall be provided to the patient and/or patient's agent concerning proper use, storage, and handling~~, and disposal~~ of the CNSP and related supplies furnished.	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."
1735.1(i)	Melanie Horn Sutter Health Also Provided at Reg Hearing	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., 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~~ produced in compliance with Health and Safety Code section 1602.5 or supplied as a commercial biologic product licensed as a Fractionated Plasma Products. Reference: https://www.fda.gov/vaccines-blood-biologics/approved-blood-products/fractionated-plasma-products	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 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

1735.2	Paul Lofholm	Quality Control and quality assurance OK Container closure for CNSP- are you saying the existing pharmaceutical supplies are not meeting the compounding standards when it comes to CNSP? Data? likewise criteria for equipment selection, basis? How does one clean non-disposable garb before re-use?	Staff have reviewed the comments and do not recommend changes to the proposed language. Staff note that the commenter appears to be asking questions 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.
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 removal of the requirement for training by individuals that are just handling the completed compounded preparation.
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 on solely 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.
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 removal of the requirement for training by individuals that are just handling the completed compounded preparation.
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: 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.	Staff have considered the comment and agree with the commenter that section 1735.2(b) can be removed from the proposed text.
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.

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 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. Staff are offering recommended changes to the section, to focus on the core competencies established in the USP Chapter.
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. Continued on Next Line	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.
1735.2(c)	Marie Cottman Pacific Compounding	Continued from Previous Line: This regulation may also force Compounding Pharmacy owners (who are willing to stay in the compounding business) to over-hire staff, for the “just in case” situation where a competent tech is removed from workflow for a specific failed competency; this will also raise prices for patients and continue to impede access. Further, if this regulation passes, it will encourage DPs to do only minimal assessments of staff to meet the letter of the law because it will be too costly (dollars, stress, patient dissatisfaction) to remove compounders from the daily work flow. Lastly, In USP 795, section 14, paragraph 2, the USP clearly requires that the DP create a policy to address “Personnel training, competency assessments, and qualification 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.	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.

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 related to the sections failed until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs. Reason: Nonsterile compounding personnel are often trained on each dosage form in addition to the core competencies required by USP <795>. Based on this wording, if an employee fails a new dosage form (eg. they are currently trained on compounding creams and then later begin to learn compounding capsules), they would be barred from compounding creams. I think this could have a negative unintended consequence of pharmacies choosing less stringent training with fewer domains for fear of employees becoming disqualified from doing any compounding at all.	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.
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.
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 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.	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.

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. ~~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.~~	Staff reviewed the and do not recommend changes to the language. Good policy dictates that determining if a contaminating condition exists requires professional judgment and must be done by a pharmacist. Staff note for example that an individual with an active respiratory illness can release airborn pathogens into the compounding environment thus compromising the environment. The USP Expert committee already identified the risk and as such included provisions in the Chapter.
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.	Staff reviewed the comment and do not recommend changes to the language. Staff note that where professional judgement is used, including determining if a contaiminating condition exists, it must be done so by a pharmacist. Staff note that an individaul with an active respiratory illness can release airborn pathogens into the compounding environment thus compromising the environment. The USP Expert committee already identified the rsisk and as such included provisions in the Chapter.
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 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.	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.

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 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.	Board staff have reviewed the change and do not recommend changes based solely on this comment. Staff are offering changes to this subdivision. Staff note that any potential compromise to the compounding environment must be evaluated to reduce the potential harm to patients.
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 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 injection) 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.	Board staff have considered the comment and do not recommend changes to the language based solely on the comment. Staff note that USP has identifed the list of conditions included in the proposed text including the flexibility to allow a pharmacist to identify other conditions beyond the list articulated in the text.

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 process. Using general language as proposed, that applies to all types of compounding practices, is problematic and may cause unintended consequences. Recommended language: ~~A gown and face mask~~ Appropriate PPE shall be used whenever a closed system processing device is required.	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.
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.
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 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. ~~All~~ Disposable garb removed and stored for reuse during a shift must remain in the designated 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.

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.
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.
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. Continued on Next Line.	Board staff have considered the comment and recommend changes to the language, although not based solely on these comments.

1735.3(e)	Marie Cottman Pacific Compounding	Continued from Previous Line: As a pharmacist compounder, my compounding day is interrupted frequently for phone calls, consultations, and overseeing other compounding staff. I may need to leave the compounding lab, and thus remove non-disposable garb many times in 1 day. I am concerned for the health of my skin if I have to clean the goggles every time I remove them and “re-use” them. Further, I’m concerned that it will take up as much as 3-5 minutes to do the cleaning process correctly and that workflow and patient access will ultimately be delayed. RECOMMENDATION: Remove this and let it stand that each facility MUST have this in their SOPs as required by USP 795, Section 3.3. If you really think that the DPs cannot write appropriate SOPs, then completely re-word this to provide a guideline for what you want in the SOP: “The facility's SOPs must describe cleaning and sanitization procedures and frequency for reusing goggles, respirators, and other reusable equipment that includes at least a germicidal cleaning agent and 70% IPA.	Board staff have considered the comment and recommend changes to the language, although not based solely on these comments.
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.
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.
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.
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.
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 referenced 1735.4(b). Staff are recommending changes to 1735.4(b); however not based on these comments.

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 propoer 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.
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 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."	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.
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 incluing 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, bateria, and other elements that could contaminate the equipment used in the preparation of CNSPs.
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.
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, distilled water, or reverse osmosis water shall be used for rinsing equipment and utensils.~~	Board staff have reviewed the comment and do not recommend changes based on this comment. Staff note that USP identifies various grades of water incluing 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, bateria, and other elements that could contaminate the equipment used in the preparation of CNSPs.

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 be 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 note 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.
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.
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 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.
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 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.

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 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 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~~.	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. Staff performing the cleaning could then document the date, time, and place a check box or other indication next to the products used.
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 compounding evironment. 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.
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.
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 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.~~	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. Further, storing components inappropriately can compromise the component and thereby create a risk to the safety and efficacy of the CNSP. As an example, a component that is not stored in appropriate temperature conditions could result in an adulterated product under state and federal law.
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 knowledgable of current practice standards and legal requirements while exercising their professional judgment. This extends to knowledge of appropriate industry standards.

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. RECOMMENDATION: Remove.	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.
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 completed,"	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.
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 available upon request prior to compounding ~~readily retrievable at the time of compounding~~ and shall be retrievable ~~maintained~~ for three years from the date each CNSP is dispensed.	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.
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 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.	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 the Chapter 797. The Board's proposed regulation text ensures consistency between CNSPs and CSPs, standardizing the process for pharmacies.

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) shall be retrievable and contains the required information developed in compliance with USP Chapter 795, and includes the following additional elements:	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.
1735.7(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 these systems/software to ensure compliance, recommend the board consider amending this section to make the allow pharmacies to make compounding records readily retrievable. Recommendation: Recommend the Board consider modify the language to: (c) Compounding record requirements shall be readily retrievable to comply with USP Chapter 795 and includes the following additional elements:	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.
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: (c) Compounding record requirements shall be readily retrievable to comply with USP Chapter 795 and includes the following additional elements:	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.

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 document” and how it will be interpreted. Recommended language: c) A compounding record (CR) shall be ~~a single document~~ developed in compliance with USP Chapter 795, maintained in a retrievable manner, and includes the following additional elements:	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.
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~~ pharmacist 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.
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 the Chapter 797. The Board's proposed regulation text ensures consistency between CNSPs and CSPs, standardizing the process for pharmacies.
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 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.	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.
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 the Chapter 797. The Board's proposed regulation text ensures consistency between CNSPs and CSPs, standardizing the process for pharmacies.
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.

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 date or date and time of compounding, if the BUD is listed in hours. The time of preparation is ~~which is the time~~ when compounding of the CNSP started, and which determines when the assigned BUD starts. (2) The manufacturer, lot number, and expiration date for each component. (3) The assigned internal identification number, which shall be unique for each CR. (4) The total quantity compounded, which shall include the number of units made and the volume or weight of each unit, if immediately packaged into the final dispensing container. Reason: This language is helpful to clarify that the date and/or time of compounding refers to when the compounding process started. However, this language may be confused to mean that the BUD must specify a day and time (eg. Discard after 06/15/2023 at 1PM). However, most BUDs are assigned in days only, which would make the start time irrelevant. The time compounded would only be applicable when the BUD is listed in hours, which is very rare for CNSPs. Reason: It is common to package bulk CNSPs into multiple containers at the time of dispensing. This language could inadvertently create a new requirement to package into the final containers only at the time of compounding. This would dramatically change the practice of compounding and dispensing CNSPs.	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.
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 (l) shall apply. (i) Exempt from the requirements in this paragraph (1735.3(a)(2)(F)) are sterile preparations compounded in a single lot for administration within seventy-two (72) hours to a patient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for “Redispensed CSPs” found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference. Recommendation: To prevent delays in care to acutely ill patients, recommend the board consider including the same exemption language to the 1735.7 Master Formulation and Compounding Records, subsection (c)(2): The manufacturer, lot number, and expiration date for each component. (i) Exempt from the requirements in this paragraph are non-sterile preparations compounded in a single lot for administration within seventy-two (72) hours to a patient in a health care facility licensed under section 1250 of the Health and Safety Code.	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.)

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: (F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply. (i) Exempt from the requirements in this paragraph (1735.3(a)(2)(F)) are sterile preparations compounded in a single lot for administration within seventy-two (72) hours to a patient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for "Redispensed CSPs" found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference. Recommendation: In order to avoid disruptions in care for acutely ill patients, it is suggested that the board contemplate incorporating similar exemption language into subsection (c)(2) of 1735.7 Master Formulation and Compounding Records., subsection (c)(2): The manufacturer, lot number, and expiration date for each component.(i) <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>	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.)
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.
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)."

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 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 providingtheir 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. **Comments Continued on Next Line**	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)."
1735.7(c)(2)	National Community Pharmacists Association (NCPA)	**Comments Continued from Previous Line** 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 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.")	see above to response.

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)."
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)(I).
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. The identity of each person performing the compounding, the person ~~who has~~ exercising direct supervision and control over ~~oversight of~~ compounding, and the pharmacist verifying the final drug preparation.	Board staff have reviewed the comment and are recommending a change to the proposed text based on the comment received.
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. 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 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 recommend a change to the proposed regulation text based on the comment.

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).
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.
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 flexiblity.
1735.9(a) & (B)	Marie Cottman Pacific Compounding	COMMENT: These requirements should not be limited to CNPS, but rather applied to all medications dispensed to improve patient safety. RATIONALE: In the statement of reasons, “The board determined that the labeling requirements must be mandatory; adequate labeling is essential for dispensed medication to ensure patient safety.” However, by creating this new regulation specific to CNSPs, you are ONLY ‘ensuring the safety’ of patients receiving compounds (a very small percentage of the prescriptions dispensed in California). If this is deemed “mandatory” by the board, it should be included in section 4076, with all the other 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.	Board staff have reviewed the comment and do not recommend changes to the proposed text. Staff note that the comments exceed the scope of the proposed regulation.

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 language in the proposed language for HSC 1250 (a) licensed facilities. This exemption is justified as compounded medications administered to patients are conducted by healthcare personnel authorized to administer medications, rather than being dispensed for outpatient use. CCR 1735.9 Labeling subsection (c): (c) Any CNSP dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5. (i) Exempt from this requirement are health facilities, as defined in Section 1250 of the Health and Safety Code, if the prescriptions are administered by a licensed health care professional.	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.
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. (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.	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.
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.
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.

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 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 identied. 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.
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.
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. RATIONALE:USP 795 states in Section 10.2 paragraph 2 "When establishing a BUD for a CNSP, compounders must consider parameters that may affect quality, including but not limited to the following: Chemical and physical stability properties of the API and any added substances in the preparation (e.g., if the API and added substances in the preparation are known to rapidly degrade over time and/or under certain storage conditions, reduce the strength of the preparation, or produce harmful impurities). Compatibility of the container closure system with the finished preparation (e.g., leachables, interactions, adsorption, and storage conditions) Degradation of the container closure system, which can lead to a reduction in integrity of the CNSP".	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 identied. 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.

1735.10(b)	Marie Cottman Pacific Compounding	Continued from Previous Line 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.	see above to response.
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.
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.
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 (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.	Board staff have reviewed the comment and recommend changes to the language; however, not solely based on this comment.

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 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.	Board staff have reviewed the comment and recommend changes to the language; however, not solely based on this comment.
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.

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 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.	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.
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.
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 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	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 that have been established as appropriate for patient safety.
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 Assuance in Pharmaceutical Compounding. Business and Professions Code section 4126.8, establishes compliance with pharmacy compounding chapters.

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 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.~~	Staff note that existing CCR 1751.3 has several of these requirements as currrent 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
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 Assuance in Pharmaceutical Compounding. Business and Professions Code section 4126.8, establishes compliance with pharmacy compounding chapters

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 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.~~ ~~(~~B~~A) 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.	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 Assuance in Pharmaceutical Compounding. Business and Professions Code section 4126.8, establishes compliance with pharmacy compounding chapters
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! 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.	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 mulitple areas.

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</u> 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.	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 require where applicable.
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 proceedures 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.
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 additonal SOP may be necessary. When such a determination is made, an SOP must be developed.

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 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	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.
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 etablishing 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 clarify is needed.
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.
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 rational for the requirements are 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.

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 • Claim of lack if potency (which should not be reported until potency test are completed. I had a patient claim lack of potency, testing results showed the product to be within 3% of the labeled strength). • Claim of lack of effect. • Just to list a few.	Board staff believes commenter is refering 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.
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.

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 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 facility's quality assurance program shall include ~~the following~~: (1) Aa 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.~~	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.
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.
1735.12(a)(2)	Marci Bencomo Pacifica Compounding	Requiring reporting of complaints within 72 hours would result in the Board being overloaded with complaints and should be limited to Quality complaints.	Board staff have reviewed the comment and believe the commenter is referring to CCR Section 1735.12(b). Board staff believes commenter is refering 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 etablishing 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.
1735.12(b)	Lauren Honda Valor Compounding Also Submitted in Reg Hearning	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 refering 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 etablishing 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.

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 has reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. Board staff note that the regulation will be etablishing 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. Staff are recommending a change to this paragraph to align with the federal definition of drug event.
1735.12(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 3 business days ~~72 hours~~ of the facility's receipt of a complaint of a potential quality problem or the occurrence of an adverse drug event involving a CNSP.	Board staff has reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. Board staff note that the regulation will be etablishing 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. Staff are recommending a change to this paragraph to align with the federal definition of drug event.
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 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.	Board staff has reviewed the comment and do not recommend changes to the proposed regulation text. Board staff note that the regulation will be etablishing 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.

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.’ 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.	Board staff has reviewed the comment and do not recommend changes to the proposed regulation text. 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. Staff are recommending a change to this paragraph to align with the federal definition of drug event.
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 3 business days ~~72 hours of the facility’s receipt of a complaint of a potential quality problem~~ after a potential quality problem is identified or the occurrence of an adverse drug event involving a CNSP.	Board staff have reviewed the comment and recomment a change to the proposed regulation text, however not solely based on this comment. Staff are recommending a change to this paragraph to align with the federal definition of drug event
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, and must notify the Board in writing with 15 days of the receipt of complaint.	Board staff has reviewed the comment and do not recommend changes to the proposed regulation text based on the comment. 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. The proposed notification timeframe requested in the comment is not approrpriate given the Board's consumer protection mandate. Staff are recommending a change to this paragraph to align with the federal definition of drug event
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 3 business days ~~72 hours~~ of the facility’s receipt of a complaint of a potential quality problem or the occurrence of an adverse drug event involving a CNSP.	Board staff have reviewed the comment and recomment a change to the proposed regulation text, however not solely based on this comment. Staff are recommending a change to this paragraph to align with the federal definition of drug experience.

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 3 business days after a potential quality problem is identified ~~72 hours of the facility’s receipt of a complaint of a potential quality problem~~ or the occurrence of an adverse drug event involving a CNSP. (c) All complaints related to a potential quality problem with a CNSP and all adverse events shall be reviewed by the pharmacist-in-charge 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.	Board staff believes commenter is refering 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.
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 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.
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.
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. 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 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.

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; 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.
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. Recommendation (c)All complaints related to a potential quality problem with a CNSP and all adverse events shall be reviewed by the pharmacist-in-charge, or licensed designee, within 3 business days ~~72 hours~~ of receipt of the complaint or occurrence of the adverse event. Such review shall be documented and dated as defined in the SOPs.	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.
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 proposed language and it only confuses the issue.	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.
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 etablishing 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.

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.
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.
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. Policies and procedures and SOPs required by USP Chapter 795 and this article ~~Records created~~ shall be created and maintained in a manner to provide an audit trail for revisions and updates ~~of each record document~~. Prior versions of each ~~record~~ policy and procedure and SOP must be maintained in a readily retrievable format and include the changes to the document, identification of individual who made the change, and the date of each change.	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.

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,...” doesn’t make sense. A prior (earlier) version will not have the current nor future changes recorded on it. And we need clarity on how long to keep this audit trail. RECOMMENDATION: (reword for clarity) (b) Records created shall be created and maintained in a manner to provide an audit trail for revisions and updates of each record document for at least 3 years from the date of the revision. Prior versions of each record must be maintained in a readily retrievable format. Each revision must include the changes to the document, identification of the individual who made the change, and the date of each change.	Board staff have reviewed the comment and do not recommend changes to the proposed text. Board staff note that the retention of records is established in paragraph a of the section and do not believe it needs to be restated again in paragraph b.
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	Boards staff belives the commenters is referanceing 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 dispened to the patient or patient's agent.