Code Section Section (Subdivision)	Commenter	Comment	Response
1736(a)	John Gray Kaiser Permanente	The term “compounding process” is not defined in the Pharmacy Law or the USP 797 Chapter. The term “compounding” is defined in the USP 797 Chapter. We recommend using the defined term “compounding” rather than the potentially ambiguous term “compounding process” in the definition of the term “compounding personnel.”	Board staff have reviewed the comment and offer a recommendation to address the comment reflecting text more in line with the language used in the Chapter.
1736(b)	CSHP	It must be noted that the expert panel involved in the creation of the revised USP 797 received feedback nationally and recognized that the previous revision’s requirement for emergency situations was inadequate in caring for patients. They acted and removed the emergency requirement for immediate use CSPs based on research evidence that has shown an observed lag phase of bacterial growth once the microorganism is introduced in a suitable growth medium. Allen et al illustrate a batch culture growth experiment where a small number of bacteria are inoculated into a well-shaken container filled with liquid nutrient medium. During the measurement time period, the density of bacteria is measured, and the results are plotted as a function of time. Bacterial growth is characterized by and initial period in which no growth is detected, known as the lag phase. This is followed by a period of exponential growth, known as the exponential phase. This is then followed by a slowing down and eventual cessation of net growth, known as the stationary phase. It is believed that the lag phase occurs because the bacteria need time to adjust to the liquid medium after having been stored under different conditions. Similarly, it is thought that the stationary phase occurs when the population exhausts its nutrient supply or builds up waste products. In the instance of a code blue in a hospital, the requirement for additional documentation goes against the very purpose of making a drip to prevent a loss of life. The burden of completing additional documentation while attempting to save a life, could work to the detriment of a patient in an emergent situation. It must be noted that there are differences in pharmacist practices and code blue team expectations across different hospitals and health systems. **Comments Continued on Next Line**	Staff believes commenter is referring to 1736.1(b). Staff have considered the comment and note that the language in the proposed text is similar to existing regulation CCR Section 1751.8(e), including the current requirement to document the circumstances causing the immediate need. Staff note that to align with USP, the Board has removed the current one hour start time and will instead allow the four hour start time provided for in the revised USP Chapter. Further, staff note that the proposed regulation text makes clear that separate documentation is not required, rather, the patient's medical record documenting will comply with the regulation. Staff also note that maintaining complete administration records are required for many regulators, not just the Board. Staff recommend that the Board update Section 1736.17(b) to expand beyond classified area failure to include any equipment failure. SOPs should have redundancy included.

1736(b)	CSHP	**Comments Continued from Previous Line** In one instance the pharmacist may have a supportive role and only hand over medications during a code blue, in another setting pharmacists may have high engagement and assist with chest compressions. It is unreasonable to expect a pharmacist to perform the additional documentations required in this proposed regulation while a life is in peril. While patient safety is always important and we wholeheartedly agree that high standards are needed to assist in keeping patients safe, this proposed rule will be a barrier for pharmacists who are assisting in code blue teams.We recommend the board to remove language requiring documentation due to patient safety concerns. Concern 2: Additionally, this section, seen in the context of 1736.4 (f) which specifies that 'no CSP shall be compounded if the compounding environment fails to meet criteria specified in the law or the facilities SOPs,' has a significant potential to limit access to life saving medications for patients in hospitals. For example, if the PEC malfunctions in a rural hospital, the pharmacy will not be able to prepare CSP's with an immediate use BUD and the hospital will be unable to care for acutely ill patients. The hospital may be forced to close the hospital and emergently transfer patients out or turn to nursing staff to compounding medications on care units which can lead to a safety risk as well as risk of medication errors. Additionally, consideration must be given that the state of California is prone to natural disasters such as fire storms, earthquakes and flooding which heightens the potential for engineering control failures even in the presence of redundant backup systems. **Comments Continued on Next Line**	See response above
1736(b)	CSHP Also submitted at Reg Hearing	**Comments Continued from Previous Line** Engineering control failures and malfunctions have been occurring in the state of California and the Board elected to discipline the licenses of pharmacies and licensed professionals for attempting to safely provide continuity of patient care by assigning immediate use beyond use dating to CSP's. We ask that if the Board of Pharmacy wishes to keep this proposed regulation it must then proactively provide an avenue via regulation for pharmacies to have continuity of CSP compounding service during this scenario potentially dangerous situation. Recommendation: We recommend the board consider removal of language requiring documentation due to patient safety and public health concerns. 1736.1 Sterile Compounding Scope. Subsection (b) (b) CSPs for direct and immediate administration as provided in the Chapter shall only be done in those limited situations where the failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need. Documentation for each such CSP shall include identification of the CSP, compounded date and time, number of units, the patient's name and patient's unique identifier and the circumstance causing the immediate need. Such documentation may be available in the patient's medical record and need not be redocumented by the compounding staff if already available.	See response above

1736(g)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	Refer to 1735(f)	Staff have considered the comment and do not recommend a change based on the comment. Staff note that the comment appears general in nature and does not provide any recommended changes to the section.
1736.1	Paul Lofholm	If a shortage occurs and is not on the ASHP list, what does the pharmacist do? There should be other sources to document or the pharmacist documents the shortage in their Facility.	Staff have considered the change and do not recommend changes to the proposed regulation text. Staff note that referring to nationally recognized sources for drug shortages is necessary to ensure members of the regulated public have clear guidance on authorized sources. The sources specified in the proposed regulation text are consistent with current industry practice. Staff notes further that the proposed regulation text is consistent with the Board's current regulation, CCR Section 1735(d)(3).
1736.1(a)	John Gray Kaiser Permanente	"Direct supervision and control," is a defined term in the Pharmacy Law, while "supervision" is not. To provide clarity to the regulated public on the nature of pharmacist supervision that is required for pharmacy technicians compounding CSPs, we recommend using the defined term. For the purposes of this article, sterile compounding occurs, by or under the 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 confirm the Board's expectation that the level of supervisions encompasses direct supervision and control.
1736.1(b)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	There are many other times that CSPs should be compounded for direct and immediate administration other than loss of life or intense suffering. USP removed the emergency situation requirement for immediate-use CSPs. An example of when this might be required is during the shortage of lidocaine with epinephrine. Clinics could use available ingredients (lidocaine vials, epinephrine vials) to compound multiple syringes for use in multiple patients over a 4- hour period. This medication is often needed for infiltration and nerve block. Immediate use CSPs are often prepared from components stored in automated dispensing cabinets in hospitals, for situations which are not considered risking loss of life or intense suffering.	Staff have considered the comment and note that the language in the proposed text is similar to existing regulation CCR Section 1751.8(e), including the current requirement to document the circumstances causing the immediate need. Staff note that to align with USP, the Board has removed the current one hour start time and will instead allow the four hour start time provided for in the revised USP Chapter. Further, staff note that the proposed regulation text makes clear that separate documentation is not required, rather, the patient's medical record documenting will comply with the regulation. Staff also note that maintaining complete administration records are required for many regulators, not just the Board. Staff recommend that the Board update Section 1736.17(b) to expand beyond classified area failure to include any equipment failure. SOPs should have redundancy included.

1736.1(b)	John Gray Kaiser Permanente	The USP 797 Chapter provides sufficient guidance on the preparation of immediate use CSPs. We are very concerned that this proposed regulation will lead to delays in the preparation and administration of potentially lifesaving medications during urgent and emergent situations (e.g. Code Blues in the hospital setting). The additional requirements in the proposed regulation—some of which are in the Board's current compounding regulations—are likely to have a chilling effect on the preparation of immediate use CSPs out of fear that the Board will take disciplinary or administrative action against licensees. Furthermore, we believe that very few Board inspectors have completed the specialized training (e.g. a post-graduate hospital pharmacy residency) related to the treatment of critically ill hospital patients that would be required to make a well-reasoned assessment of whether the failure to administer a CSP could result in the loss of life or intense suffering. Finally, by including medical record documentation requirements for immediate use CSPs in the regulation, we believe that a pharmacist whose attention should be fully devoted to preparing an urgently needed CSP will likely be distracted by the comparably mundane task of ensuring that the documentation in the medical record meets the Board's requirements. ~~CSPs for direct and immediate administration as provided in the Chapter shall only be compounded in those limited situations where the failure to administer such CSP could result in loss of life or intense suffering of an identifiable patient. Any such compounding shall be only in such quantity as is necessary to meet the immediate need of the patient. Documentation for each such CSP shall include identification of the CSP, compounded date and time, number of units compounded, the patient's name and patient's unique identifier and the circumstance causing the immediate need of the patient. Such documentation may be available in the patient's medical record and need not be redocumented by the compounding staff if already available.~~	Staff have considered the comment and note that the language in the proposed text is similar to existing regulation CCR Section 1751.8(e), including the current requirement to document the circumstances causing the immediate need. Staff note that to align with USP, the Board has removed the current one hour start time and will instead allow the four hour start time provided for in the revised USP Chapter. Further, staff note that the proposed regulation text makes clear that separate documentation is not required, rather, the patient's medical record documenting will comply with the regulation. Staff also note that maintaining complete administration records are required for many regulators, not just the Board. Staff recommend that the Board update Section 1736.17(b) to expand beyond classified area failure to include any equipment failure. SOPs should have redundancy included.
1736.1(b)	Tommy Mai Huntington Health	Rationale: In the instance of a patient emergency such as a code blue or a rapid resuscitation event in a hospital, the requirement for additional documentation will result in a delay in providing immediately needed medication to prevent loss of life. Existing language could lead to significant unintended consequences such as organizational decisions to have nursing staff compound medications due to risk delays in drug administration which could be life-threatening. Recommendation: We recommend the board consider removal of language requiring documentation due to patient safety concerns. 1736.1 Sterile Compounding Scope. Subsection (b) (b) CSPs for direct and immediate administration as provided in the Chapter shall only be done in those limited situations where the failure to administer could result in patient harm ~~loss of life or intense suffering~~. Any such compounding shall be only in such quantity as is necessary to meet the immediate need. ~~Documentation for each such CSP shall include identification of the CSP, compounded date and time, number of units, the patient's name and patient's unique identifier and the circumstance causing the immediate need. Such documentation may be available in the patient's medical record and need not be redocumented by the compounding staff if already available.~~	Staff have considered the comment and note that the language in the proposed text is similar to existing regulation CCR Section 1751.8(e), including the current requirement to document the circumstances causing the immediate need. Staff note that to align with USP, the Board has removed the current one hour start time and will instead allow the four hour start time provided for in the revised USP Chapter. Further, staff note that the proposed regulation text makes clear that separate documentation is not required, rather, the patient's medical record documenting will comply with the regulation. Staff also note that maintaining complete administration records are required for many regulators, not just the Board. Staff recommend that the Board update Section 1736.17(b) to expand beyond classified area failure to include any equipment failure. SOPs should have redundancy included.

1736.1(b)	Rita Shane Cedars-Sinai Also provided at Reg Hearing	Rationale: • In the instance of a patient emergency such as a code blue or a rapid resuscitation event in a hospital, the requirement for additional documentation will result in a delay in providing immediately needed medication to prevent loss of life. • Existing language could lead to significant unintended consequences such as organizational decisions to have nursing staff compound medications due to risk of delays in drug administration which could be life-threatening. Recommendation: We recommend the board consider removal of language requiring documentation due to patient safety concerns. 1736.1 Sterile Compounding Scope. Subsection (b) (b) CSPs for direct and immediate administration as provided in the Chapter shall only be done in those limited situations where the failure to administer could result in patient harm ~~loss of life or intense suffering~~. Any such compounding shall be only in such quantity as is necessary to meet ~~the~~ immediate <u>needs of patients</u> ~~need~~. ~~Documentation for each such CSP shall include identification of the CSP, compounded date and time, number of units, the patient's name and patient's unique identifier and the circumstance causing the immediate need. Such documentation may be available in the patient's medical record and need not be redocumented by the compounding staff if already available.~~	Staff have considered the comment and note that the language in the proposed text is similar to existing regulation CCR Section 1751.8(e), including the current requirement to document the circumstances causing the immediate need. Staff note that to align with USP, the Board has removed the current one hour start time and will instead allow the four hour start time provided for in the revised USP Chapter. Further, staff note that the proposed regulation text makes clear that separate documentation is not required, rather, the patient's medical record documenting will comply with the regulation. Staff also note that maintaining complete administration records are required for many regulators, not just the Board. Staff recommend that the Board update Section 1736.17(b) to expand beyond classified area failure to include any equipment failure. SOPs should have redundancy included.
1736.1(b)	Keck Medicine of USC Also Provided at Reg Hearing	Comment: In most cases, compounding of CSPs for immediate use occurs in instances of bedside compounding by a pharmacist in cases of a "code blue" to meet an urgent patient care need. A "code blue" is a situation where patient who is in cardiac arrest or otherwise in a life-threatening condition is being resuscitated by a trained medical team. The requirement to document identification of the CSP, compounded date and time, number of units, the patient's name and patient's unique identifier and the circumstance causing the immediate need, will go against the very core of the need to have an allowance for immediate use compounding. It would be a threat to patient safety to introduce the requirement for documentation in a situation where every second counts and the pharmacist's full attention and focus is required. Additionally, the proposed documentation requirements pose questionable benefit, if any. Furthermore, the prohibition on immediate use compounding outside of the very narrow exception of "situations where the failure to administer could result in loss of life or intense suffering" may adversely impact the ability of hospital pharmacies to adequately meet patient care needs in cases of inadvertent failure of standard engineering controls. For example, in the case of sudden HVAC system failure in a small hospital with only a single cleanroom, the hospital pharmacy will have no alternatives to provide critical medications to the hospitalized patients. Compounding with an immediate use BUD could be a short-term plan while the HVAC issue is addressed or a long-term plan is determined. However, this proposed regulation would prohibit that option, and patients would face delays in care that can cause harm in the long term or adversely impact care outcomes. Recommendation: In light of significant safety concerns and barriers for access to care in unexpected downtime situations, the Board is urged to remove this section completely and follow USP 797	Staff have considered the comment and note that the language in the proposed text is similar to existing regulation CCR Section 1751.8(e), including the current requirement to document the circumstances causing the immediate need. Staff note that to align with USP, the Board has removed the current one hour start time and will instead allow the four hour start time provided for in the revised USP Chapter. Further, staff note that the proposed regulation text make clear that separate documentation is not required, rather, the patient's medical record documenting will comply wih the regulation. Staff also note that maintaining complete administration records are required for many regulators, not just the Board. Staff Recommend that the Board update Section 1736.17(b) to expand to include all equipment failure. SOPs should have redundancy included.

1736.1(b)	Philip Smyth Medisca	There are many other times that CSPs should be compounded for direct and immediate administration other than loss of life or intense suffering. USP removed the emergency situation requirement for immediate-use CSPs. An example of when this might be required is during the shortage of lidocaine with epinephrine. Clinics could use available ingredients (lidocaine vials, epinephrine vials) to compound multiple syringes for single use in multiple patients over a 4-hour period. This medication is often needed for infiltration and nerve block.	Board staff have reviewed the comment and do not recommend a change to the language. Staff note that should a pharmacist need to compound in such a situation, the current proposed regulation language provides such authority by recognizing the need to avoid situations that would result in extreme pain and suffering to a patient. Immediate use CSP provisions allow for the practice.
1736.1(b)	Scripps Health	Proposed 1736 1B regarding immediate use can cost the hospital 1.5 million each time an engineering control presents a challenge	This generic statement is not sufficiently specific for the Board to evaluate. Immediate use provisions proposed in the regulation text come from existing regulation language in CCR 1751.8(e). Existing law however requires that the administration begin within one hour. Under the proposed regulation text, the administration time is extended to four hours, to align with the immediate use provisions in USP Chapter 797 section 1.3. The proposed regulation text provides greater flexibility than current regulations and should result in cost savings. The commenter suggested a cost of $1.5, those costs, if accurate would be occurred now under the existing immediate use provisions. Board staff understands that at times primary engineering controls (PEC) may fail. Compounding in a PEC is a requirements of the Chapter, not a function of the Board's regulation. The Chapter established provisions for immediate use that allow for compounding outside of a PEC under specified conditions. The Board's proposed (and current) regulations allow for this process as well. As included in the Board's current regulation (CCR 1751.8(e) immediate use is allowed to prevent loss of life or intense suffering. Staff notes that the recommended inclusion of (1) will provide impacted facilities flexibility to continue to take care of patients in the event of an equipment failure for 24 hours while the facility implements its required "corrective action plan" that is required in response to any out-of-range results as established in Chapter 797, Section 5. This is a current flexibility is not allowed with the Board's current requirements but is included to allow for continuity of patient care while the facility implements its required "corrective action plan." Staff understand that there are requirements from other regulators for all hospitals to have emergency plans. The Board would anticipate that equipment failure would be included in such plans in compliance with these other regulator requirements. Staff are recommending changes to the proposed text to clarify that a facility can rely on documentation that already exists in a patient's medical record.
1736.1(b)	Melanie Horn Sutter Health Also Provided at Reg Hearing	Sutter Health recognizes the Board intent to maintain the current restrictions for applying the USP 797 immediate use provision by the pharmacy but request revising the immediate use to align with other enforcing regulatory agencies. Revising the patient condition allows pharmacies the ability to serve the needs of patients through owning compounding in immediate use scenarios related to identification of patient harm. Creating a standard that forces immediate use compounding to other professions outside of the Board jurisdiction does not support California consumer protections. Recommend removing documentation from immediate use CSPs to prevent care delay. CSPs for direct and immediate administration as provided in the Chapter shall only be done in those limited situations where the failure to administer could result in <u>patient harm</u> ~~loss of life or intense suffering~~. Any such compounding shall be only in such quantity as is necessary to meet the immediate need. ~~Documentation for each such CSP shall include identification of the CSP, compounded date and time, number of units, the patient's name and patient's unique identifier and the circumstance causing the immediate need. Such documentation may be available in the patient's medical record and need not be redocumented by the compounding staff if already available~~	Staff have considered the comment and note that the language in the proposed text is similar to existing regulation CCR Section 1751.8(e), including the current requirement to document the circumstances causing the immediate need. Staff note that to align with USP, the Board has removed the current one hour start time and will instead allow the four hour start time provided for in the revised USP Chapter. Further, staff note that the proposed regulation text make clear that separate documentation is not required, rather, the patient's medical record documenting will comply wih the regulation. Staff also note that maintaining complete administration records are required for many regulators, not just the Board. Staff Recommend that the Board update Section 1736.17(b) to expand to include all equipment failure. SOPs should have redundancy included.

1736.1(b)	Wendy Waldman Torrance Memorial Medical Center	Rationale: During a patient emergency like a code blue or rapid resuscitation event in a hospital, the need for additional documentation will cause a delay in providing urgently required medication to prevent loss of life. The current language may lead to substantial unintended consequences, such as organizational decisions to have nursing staff compound medications to avoid the risk of delays in drug administration, which could pose life-threatening situations. Recommendation We suggest the board consider removing the documentation requirement due to concerns regarding patient safety. 1736.1 Sterile Compounding Scope. Subsection (b) (b) CSPs for direct and immediate administration as provided in the Chapter shall only be done in those limited situations where the failure to administer could result in patient harm ~~loss of life or intense suffering~~. Any such compounding shall be only in such quantity as is necessary to meet the immediate need. ~~Documentation for each such CSP shall include identification of the CSP, compounded date and time, number of units, the patient's name and patient's unique identifier and the circumstance causing the immediate need. Such documentation may be available in the patient's medical record and need not be redocumented by the compounding staff if already available.~~	Staff have considered the comment and note that the language in the proposed text is similar to existing regulation CCR Section 1751.8(e), including the current requirement to document the circumstances causing the immediate need. Staff note that to align with USP, the Board has removed the current one hour start time and will instead allow the four hour start time provided for in the revised USP Chapter. Further, staff note that the proposed regulation text make clear that separate documentation is not required, rather, the patient's medical record documenting will comply wih the regulation. Staff also note that maintaining complete administration records are required for many regulators, not just the Board. Staff Recommend that the Board update Section 1736.17(b) to expand to include all equipment failure. SOPs should have redundancy included.
1736.1(b)	UCSD	There's a lot of documentation that's been proposed and most things are an electronic medical record so as long as it's available to the board in a timely fashion that should be sufficient.	Staff have considered the comment and note that the language in the proposed text is similar to existing regulation CCR Section 1751.8(e), including the current requirement to document the circumstances causing the immediate need. Staff note that to align with USP, the Board has removed the current one hour start time and will instead allow the four hour start time provided for in the revised USP Chapter. Further, staff note that the proposed regulation text make clear that separate documentation is not required, rather, the patient's medical record documenting will comply wih the regulation. Staff also note that maintaining complete administration records are required for many regulators, not just the Board.

1736.1(b)	UCSF	Comment: • Immediate-use compounding is frequently required in the Emergency Department and during hospital code situations. The proposed documentation requirements seem unlikely to enhance patient care or safety immediately and may introduce delays in an already high-stress, high-risk environment. As currently written, the regulations add another layer of complexity for participating pharmacists, potentially diverting their attention from triaging, participating in the code, and providing patient care. Recommendation: • We recommend the board consider modifying the language to accommodate administration documentation. 1736.1 Sterile Compounding Scope. Subsection (b) (b) CSPs for direct and immediate administration as provided in the Chapter shall only be done in those limited situations where the failure to administer could result in patient harm ~~loss of life or intense suffering~~. Any such compounding shall be only in such quantity as is necessary to meet the immediate need. Documentation of administration of CSP shall be recorded in patent's medical record if given. ~~Documentation for each such CSP shall include identification of the CSP, compounded date and time, number of units, the patient's name and patient's unique identifier and the circumstance causing the immediate need. Such documentation may be available in the patient's medical record and need not be redocumented by the compounding staff if already available~~	Staff have considered the comment and note that the language in the proposed text is similar to existing regulation CCR Section 1751.8(e), including the current requirement to document the circumstances causing the immediate need. Staff note that to align with USP, the Board has removed the current one hour start time and will instead allow the four hour start time provided for in the revised USP Chapter. Further, staff note that the proposed regulation text make clear that separate documentation is not required, rather, the patient's medical record documenting will comply wih the regulation. Staff also note that maintaining complete administration records are required for many regulators, not just the Board.
1736.1(b) **should be 1735.1(b)**	Rheta Silvas Kaweah Health	Recommend: clarify the following – 1. applicability of the proposed language. Are the documentation requirements outlined specific to sterile compounding personnel employed by the pharmacy or any healthcare professional (within the bounds of their scope)? 2. if the proposed language would limit the "repackaging" of a sterile product immediately prior to administration to the situations outlined in the proposed language (loss of life or intense suffering). For example, straight draw of insulin from the vial into a syringe by the nurse just prior to administration. Concerns: pharmacy oversight and assuring compliance of non-pharmacy personnel with the documentation requirements would be challenging given the emergency circumstances that prompt the need. Meeting the critical needs of the patient is the focus of the healthcare team; the documentation would be apt to be overlooked.	staff believes commenter is referring to section 1735.1(b) Staff have considered the comment and recommend a change to the language. Specifically staff recommend removing 1735.1(b) to avoid the potential overexpansion of the definition of compounding to encompass the strictly removing a dangerous drug from a manufacturer's bottle and placing it in a prescription vial.
1736.1(d)	Rheta Silvas Kaweah Health	Recommend: strike "compounded drug preparation". Rationale: this verbiage is preceded by the abbreviation CSP and is redundant.	Board staff have considered the comment and in response to the comment are offering a change to the proposed regulation text to address the comment and to make a conforming change to the language to reiterate the provisions related to patient-specific furnishing.

1736.1(e)	Scripps Health	Proposed 1736.1(e) regarding drug shortages will cost the hospital 120,000 to over a million dollar per year	This generic statement is not sufficiently specific for the Board to evaluate. The Board is unclear how the proposed regulation will result in the costs represented by the commenter as the regulation of drug manufacturers falls under the jurisdiction of FDA. The Board has also reached this conclusion for several other reasons. First, the proposed text referenced by the commenter is similar to the conditions in existing law, CCR Section 1735.2(d)(3). Further, federal law establishes the provisions for when compounding (FDCA section 503A can occur and provides authority to compound "essentially a copy" only under very limited circumstances. Federal law defines "essentially a copy" in FDCA 503A (b)(2). As included in the FDA's guidance document, " The restrictions on making drugs that are essentially copies ensure that pharmacists and physicians do not compound drug products under the exemptions for patients who could use a commercially available drug product. Such a practice would create significant public health risk because patients would be unnecessarily exposed to drug products that have not been shown to be safe and effective and that may have been prepared under substandard manufacturing conditions. FDA has investigated serious adverse events in patients who received contaminated compounded drugs when a comparable approved drug, made in a facility subject to CGMP requirements, was available. Restrictions in section 503A prevent compounders from producing drugs without having to comply with monograph standards, or CGMP requirements." Staff note that as written, the language provides flexibility for a clinician to use their professional judgment when determining if a compound is essentially a copy. https://www.fda.gov/files/drugs/published/Compounded-Drug-Products-That-Are-Essentially-Copies-of-a-Commercially-Available-Drug-Product-Under-Section-503A-of-the-Federal-Food--Drug--and-Cosmetic-Act-Guidance-for-Industry.pdf.
1736.1(e)	Melanie Horn Sutter Health	ASHP and FDA drug shortage lists can have a lag between the posted shortage and a disruption in supply. In 2023, the Akorn recall was posted after the State Board notification of the company shut down with multiple unlisted drug shortages already impacting supply. Wholesalers frequently cannot supply critical medications, especially in a pre-shortage situation. California code restrictions in place prevent compounding during these supply disruptions and contribute to heightened risk and safety concerns for patients unable to access medication therapies. Documentation of inability to 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**	Response to comment is below

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

1736.1(e)	Philip Smyth Medisca	We ask that California align its definition of "essential copy" with the FDA's definition. The FDA defines an “essential copy” as the same API, same route of administration, and same, similar, or easily substitutable strength, and same characteristics as two or more commercially available drug products. Aligning the California definition with the FDA definition allows for better compliance and understanding of the term.	The proposed regulation text referenced by the commenter is similar to the conditions in existing law, CCR Section 1735.2(d)(3). Further, federal law establishes the provisions for when compounding (FDCA section 503A can occur and provides authority to compound “essentially a copy” only under very limited circumstances. Federal law defines “essentially a copy” in FDCA 503A (b)(2). As included in the FDA’s guidance document, “ The restrictions on making drugs that are essentially copies ensure that pharmacists and physicians do not compound drug products under the exemptions for patients who could use a commercially available drug product. Such a practice would create significant public health risk because patients would be unnecessarily exposed to drug products that have not been shown to be safe and effective and that may have been prepared under substandard manufacturing conditions. FDA has investigated serious adverse events in patients who received contaminated compounded drugs when a comparable approved drug, made in a facility subject to CGMP requirements, was available. Restrictions in section 503A prevent compounders from producing drugs without having to comply with monograph standards, or CGMP requirements.” Staff note that as written, the language provides flexibility for a clinician to use their professional judgment when determining if a compound is essentially a copy.
1736.1(e)(1)(A-C)	Philip Smyth Medisca	The FDA defines an “essential copy” as the same API, same route of administration, and same, similar, or easily substitutable strength, and same characteristics as two or more commercially available drug products. Aligning the California with the FDA definition allows for better compliance and understanding of the definition.	The proposed regulation text referenced by the commenter is similar to the conditions in existing law, CCR Section 1735.2(d)(3). Further, federal law establishes the provisions for when compounding (FDCA section 503A can occur and provides authority to compound “essentially a copy” only under very limited circumstances. Federal law defines “essentially a copy” in FDCA 503A (b)(2). As included in the FDA’s guidance document, “ The restrictions on making drugs that are essentially copies ensure that pharmacists and physicians do not compound drug products under the exemptions for patients who could use a commercially available drug product. Such a practice would create significant public health risk because patients would be unnecessarily exposed to drug products that have not been shown to be safe and effective and that may have been prepared under substandard manufacturing conditions. FDA has investigated serious adverse events in patients who received contaminated compounded drugs when a comparable approved drug, made in a facility subject to CGMP requirements, was available. Restrictions in section 503A prevent compounders from producing drugs without having to comply with monograph standards, or CGMP requirements.” Staff note that that the proposed text provides flexibility for a clinician to use their professional judgment when determining if a compound is essentially a copy. https://www.fda.gov/files/drugs/published/Compounded-Drug-Products-That-Are-Essentially-Copies-of-a-Commercially-Available-Drug-Product-Under-Section-503A-of-the-Federal-Food--Drug--and-Cosmetic-Act-Guidance-for-Industry.pdf.

1736.1(e)(1)(A)	Wendy Waldman Torrance Memorial Medical Center	Rationale: The ASHP and FDA drug shortage lists may not consistently reflect real-time shortages. For instance, the 2023 Akorn recall was announced after the State Board notification of the company shutdown, leading to multiple drug shortages. Health systems employ monitoring strategies to track these shortages in real-time directly from drug manufacturers or wholesalers, preempting the inclusion of these shortage drugs on the ASHP and FDA drug shortage lists. Additionally, wholesalers themselves often run out of supply of critical medications (pre-shortage situations). Inability to procure medications or restrictions to compound in these events would have contribute to heightened risk and safety concerns for patients. With the growing number of medications going on shortage2 and recent manufacturer bankruptcies (i.e., Akorn, Apotex) it is becoming more challenging for Health-Systems to obtain commercially available products. Recommendation: Suggest the board include language addressing recent drug shortages not captured on the ASHP and FDA lists, along with unavailability from wholesalers, to ensure health systems adhere to requirements. (e) In addition to prohibitions established in federal law, no licensed pharmacy personnel shall compound a CSP that: (1) Is essentially a copy of one or more commercially available drug products, unless: (A) That drug product is not available (cannot be purchased) by the manufacturer or wholesaler, appears on an ASHP (American Society of Health- System Pharmacists), or FDA list of drugs at the time of compounding ~~and at the time of dispense~~, or...	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. 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.

1736.1(e)(1)(A)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP	Rationale: The ASHP and FDA drug shortage lists do not always reflect real-time real time drug shortages. As an example, the 2023 Akorn recall was posted after the State Board notification of the company shut down which resulted in multiple drug shortages. (see attached) 1 Health systems have monitoring strategies in place to track these drug shortages real-time from drug manufacturers or wholesalers before these shortage drugs get added to the ASHP and FDA drug shortage lists. Additionally, wholesalers themselves often run out of supply of critical medications (pre-shortage situations). Inability to procure medications or restrictions to compound in these events would have contribute to heightened risk and safety concerns for patients. With the growing number of medications going on shortage2 and recent manufacturer bankruptcies (i.e. Akorn, Apotex) it is becoming more challenging for Health-Systems to obtain commercially available products. Recommendation: Recommend the board to add language regarding recent drug shortages that may not be reflected on the ASHP and FDA lists as well as unavailability from wholesalers to ensure that health systems are compliant with requirements. 1736.1 Sterile Compounding Scope. Subsection (e) (1) (A): (e) In addition to prohibitions established in federal law, no licensed pharmacy personnel shall compound a CSP that: (1) Is essentially a copy of one or more commercially available drug products, unless: (A) <u>That drug product is not available (cannot be purchased) by the manufacturer or wholesaler</u>, appears on an ASHP (American Society of Health- System Pharmacists), or FDA list of drugs at the time of compounding ~~and at the time of dispense~~, or	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. 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.
1736.1(e)(1)(A)	UCSF	Comment: The ASHP and FDA Drug Shortages Database is not always a timely source for detecting fluctuations in the drug supply chain. Drug supply shortages often impact community or hospital pharmacies before being reported on the ASHP/FDA Drug Shortages list. Shortages and allocations can also be specific to a wholesaler rather than occurring on a national scale. Current regulations, as they stand, could prohibit pharmacies from compounding products in these instances, potentially causing delays in patient care, particularly in acute care settings. Recommendation: It is recommended that the board add language allowing pharmacies to compound products when there is evidence of drug allocation or shortages at the wholesaler or supplier level. Please see proposed revision below. 1735.1. Introduction and Scope. Subsection (e)(1)(A) that drug product appears in an American Society of Health-System Pharmacists (ASHP) or FDA Drug Shortages Database that are in short supply at the time of compounding and at the time of dispensing, or <u>the pharmacy can provide evidence of interruption in inventory supply (such as invoices to show allocation or back order from wholesaler) at the time of compounding or</u>	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. 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.

1736.1(e)(1)(A,B,C)	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.	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.
1736.1(e)(1)(A)	Marie Cottman Pacific Compounding	COMMENT: The FDA requirement is simply on the shortage list. Adding additional language may create confusion. RATIONALE: California language should be precisely the same as FDA language on this topic to prevent confusion of discrepancies in enforcement. The text of the 503A exemption only states you cannot compound essentially a copy of a commercially available drug product. The text of 503A does not reference the drug shortage list. FDA guidance does not consider a drug to be commercially available if it appears on the "FDA drug shortage list." The FDA defines "appears on the list" as being if the drug is on the drug shortages database list and shows its status as "currently in shortage". RECOMMENDATION: (1) Is essentially a copy of one or more commercially available drug products, unless: (A) that drug product appears in an American Society of Health-System Pharmacists (ASHP) or FDA Drug Shortages Database that are in short supply and the drug status is "currently in shortage" at the time of compounding and at the time of dispensing, or	Staff have considered the change and do not recommend changes to the proposed regulation text. Board staff believe the current regulation text is clear and is consistent with current regulations, CCR Section 1735(d)(3).
1736.1(e)(1)(B)	Marie Cottman Pacific Compounding	COMMENT: It is already established in Federal Guidelines and the proposed definition 1736(e) that the prescriber makes the determination of what is "essentially a copy." But if that is not sufficient, then "clinically significant difference" needs to be defined. Concern to consider: if the prescriber, compounding RPh and dispensing RPh all agree, but an inspector doesn't, who is right and for what reason? 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.

1736.1(e)(1)(B)	Jasmine Parker Pacific Compounding	COMMENT: There is no definition of "clinically significant" that can be applied RECOMMENDATION: Allow Federal statute 503A of the FD&C Act to stand on its own	Staff have considered the change and do not recommend changes. Staff note that FDA guidance documents establish the standard of practice for compounders. It is encumbant on licensed professionals to remain current on guidances issued to ensure compliance with provisions established. 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.
1736.1(e)(1)(B)(i-iii)	Rheta Silvas Kaweah Health	Recommend: strike 1736.1(e)(1)(B)(ii) and (B)(iii) to keep consistent with Title 21 Chapter 9 Subchapter V Part A § 353a definition of the term "essentially a copy of a commercially available drug product". The definition is as follows: For purposes of paragraph (1)(D), the term "essentially a copy of a commercially available drug product" does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product. Recommend: clarify the following: 1. if the expectation would be that the "determination" as referenced in the proposed language would be made for each time the preparation was compounded or for the initial prescription 2. If the expectation would be that the compounding pharmacist AND the dispensing pharmacist contact the prescriber to confirm the prescriber has determined the compounding produces a clinically significant difference for the medical need of an identified individual or the determination by the prescriber is assumed based on the generation of the prescription Concerns: Without complete medical information necessary for the pharmacist (compounding and/or dispensing pharmacist) to make the determination as proposed in 1736.1(e)(1)(B)(ii) and (iii), there could be unnecessary delays and/or barriers to the patient receiving a medication that is vital to their care. Rationale: the determination "the compounding produces a clinically significant difference for the medical need" is best made by the prescriber. The compounding pharmacist and dispensing pharmacist may not have complete medical information necessary to make this determination	Staff have considered the comment and do not recommend changes. 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 suggested by the commenter, the Board would be limiting this flexibility and a clinicans professional judgment.
1736.1(e)(2)	Scott Brunner Alliance for Pharmacy Compounding	As written, this eliminates the compounding of drugs for animals from API because AMDUCA does not address this. The statement says that it must be specifically allowed under AMDUCA, and AMDUCA does not address this topic. California should align with FDA GFI 256 in their approach to animal compounding to maintain patient access.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. Pharmacists must remain 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.
1736.1(e)(2)	National Community Pharmacists Association (NCPA)	Reference to AMDUCA is vague, compounded preparations are not covered under AMDUCA. Pharmacists should determine suitability of ingredients.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. Pharmacists must remain 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.

1736.1(e)(2)	Marie Cottman Pacific Compounding	COMMENT: Based on your statement of reasons, it appears clear that this is only intended for vet patients, however, as written, this statement applies to all CSP compounding (including human). Also, there is no definition for “component not suitable for use in a CSP” creating great vagueness and opportunity for multiple interpretations that can range from issues related to ingredient quality to how a prescriber intends to use it, clinically. RATIONALE: As proposed, a pharmacist, or an inspector, determining that a component is “not suitable” for the intended population is infringing on a prescribers prerogative to decide what they want to use to treat their patient. Other language exists to ensure ingredient quality, potency, and integrity of the CSP. This language creates confusion, lack of specificity, and opportunity for vague interpretations and should be stricken or reworded to achieve the specific regulatory oversight desired. RECOMMENDATION: Remove or clarify this applied to animal compounding. Clarify this is for animal/veterinary CNSPs by modifying the language: (2) Is made with any component not suitable for use in a CNSP for the intended ~~patient~~ animal population, unless allowable under the Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA).	Staff have reviewed the comment and recommend changes to the proposed regulation text to address the comment and provide clarity regarding applicability to veterinary patients.
1736.1(e)(3)	Marie Cottman Pacific Compounding	COMMENT: This says that one cannot use bulk-powder for CSP if a manufactured sterile component is appropriate. However, there is no definition of “appropriate” to provide clarity for a PIC to know if they are compliant with this regulation. RATIONALE: There may be instances where the package size available for a commercial product is so ridiculously large (e.g. needing only 1 ml out of a 250ml IV infusion bag) or so the packaging is so small (0.5ml vials) that it would requiring 10’s of vials to get sufficient volume for the preparation. The PIC should have discretion to choose if a bulk ingredient is “acceptable.” RECOMMENDATION: Remove.	Board staff have considered the comment and are offering a recommended change to the proposed regulation text. The proposed text offered by staff does not prevent nonsterile to sterile compounding and will ensure that appropriate safeguards are in place to protect patients, including stability testing which ensures the product is stable throughout the established beyond use date. Pharmacists must remain knowledgeable of current practice standards and legal requirements of the industry while exercising their professional judgment to determine when it is appropriate or not.
1736.1(e)(3)	Rheta Silvas Kaweah Health	COMMENT: There is no definition of "appropriate" that can be applied, this is based on pharmacist judgment. RECOMMENDATION: Remove.	Staff have reviewed the comment and do not recommend changes to the proposed regulation text. Pharmacists must remain knowledgable of current practice standards and legal requirements of the industry while exercising their professional judgment
1736.1(e)(3)	Rick Rhoads University Compounding Also Provided at Reg Hearing	Strike (e)(3). Reason: This language could become unnecessarily problematic for Category 3 compounders. It is unclear how inspectors will determine when commercially available products are mandated to use as components. This is very challenging for compounders to predict, especially when significant financial and time investments are put into stability studies (Approx $30-$50k and 6-12 months per formula). Also, the availability of each manufactured product changes, which can result in different excipients, concentrations, and pHs. This can change the stability and compatibility of the formulation. Lastly, the benefit to quality would be unclear when using a commercially available product along with other nonsterile API and excipients. I believe the newest revision of USP <797> adequately addresses the risk associated with utilizing nonsterile ingredients.	Board staff have considered the comment and are offering a recommended change to the proposed regulation text. The proposed text offered by staff does not prevent nonsterile to sterile compounding and will ensure that appropriate safeguards are in place to protect patients, including stability testing which ensures the product is stable throughout the beyond use date.

1736.1(e)(3)	Lauren Honda Valor Compounding Also Submitted in Reg Hearning	Commenter disagrees with the proposed law mandating compounding with a conventionally manufactured component when it is available as it fails to account for the nuanced considerations regarding beyond use dates and continuity of care for patients in need of sterile compounds. "Currently, with the stability study that our facility has invested in we are able to offer our patients atropine ophthalmic drops with a 60 day BUD at room temperature. After factoring in approximately 2 weeks for sterility testing our patients can get a prescription that is stable at room temperature with at least 45 days left on it's beyond use date. However, with the proposed regulation which would require compounding with the sterile commercially available atropine ophthalmic drops our beyond use date would drop to 30 days at room temperature. After factoring in the time it takes to complete sterility testing our patients would only be able to receive the product with approximately 2 weeks left on the beyond use date. Needing to refill a chronic prescription every 14 days is a challenging barrier to overcome with patients which may lead them to using a product past it's beyond use date putting them at a greater risk. Another option would be for us to assign a 45 day beyond use date with refrigerated storage requirements. Although this would allow our patients approximately 30 days left on the beyond use date after sterility testing, the need to maintain refrigerated storage conditions can be challenging for families who need to safely transport their medication when traveling. Instead of imposing a blanket regulation, I urge you to take into consideration the effects this may have on patients and their ability to readily and continuously access sterile compounded products."	Board staff have considered the comment and are offering a recommended change to the proposed regulation text. The proposed text offered by staff does not prevent nonsterile to sterile comounidng and will ensure that appropriate safeguards are in place to protect patients, including stability testing which ensures the product is stable throughout the beyond use date.
1736.1(e)(3)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	In some cases, starting with the non-sterile component would be more appropriate (excipients in the conventionally manufactured product, tonicity, concentration). Depending on batch size and compounding set-up, using a conventionally manufactured sterile product as opposed to bulk ingredients could cause more sterility issues and potency variability among units prepared (e.g., exponentially increased manual manipulations by repetitively entering vials or bags to transfer a portion of liquid to the finished preparation increases the potential for contamination and variability as these processes are primarily manual.) Additionally, starting with non- sterile ingredients already shortens the BUD of the final product. Does “conventionally manufactured” mean commercially available?	Board staff have considered the comment and are offering a recommended change to the proposed regulation text. The proposed text offered by staff does not prevent nonsterile to sterile compounding and will ensure that appropriate safeguards are in place to protect patients, including stability testing which ensures the product is stable throughout the beyond use date.
1736.1(e)(4)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	This would prevent the use of e- beam or gamma-irradiation sterilization methods, which are performed off-site at validated facilities. Can the board demonstrate the harm caused to patient care by offsite sterilization?	Staff have reviewed the comment and do not recommend any changes to the proposed regulation text. Staff note that on September 25, 2019, this issue was raised. At that time, counsel advised members that "provided based on her research of 503A subdivision (a) (1), the federal exemption applies to a state licensed pharmacy that exempts the pharmacy for the manufacturer requirements when compounding. Business and Professions Code sections 4127 and 4127.1 specifically reference the compounding has to occur in a sterile compounding pharmacy – a singular pharmacy – and the license is not transferable thereby emphasizing all compounding exempted under the federal law that occur can in a compounding pharmacy has to occur in a single licensed facility. Board counsel added at that time there are no statutory exemptions and would expect all aspects of compounding to occur in the single regulated unit.

1736.1(e)(4)	Philip Smyth Medisca	This would limit the ability to produce products relying on e-beam or gamma-irradiation for validated terminal sterilization as they cannot be performed onsite. Can we have additional clarity on how this would make an end product safer?	Staff have reviewed the comment and do not recommend any changes to the proposed regulation text. Staff note that on September 25, 2019, this issue was raised. At that time, counsel advised members that "provided based on her research of 503A subdivision (a) (1), the federal exemption applies to a state licensed pharmacy that exempts the pharmacy for the manufacturer requirements when compounding. Business and Professions Code sections 4127 and 4127.1 specifically reference the compounding has to occur in a sterile compounding pharmacy – a singular pharmacy – and the license is not transferable thereby emphasizing all compounding exempted under the federal law that occur can in a compounding pharmacy has to occur in a single licensed facility. Board counsel added at that time there are no statutory exemptions and would expect all aspects of compounding to occur in the single regulated unit.
1736.1(e)(4)	Mike Pavlovich Westcliff Compounding	Commenter states he employs electron beam to sterilize naltrexone pellets, the only sterile product we currently compound. This dosage form is in demand in the opiate/alcohol addiction and rehabilitation community. If these regulations were to be adopted, it would prohibit us from continuing to compound it as we have since early 2016 would be a great loss to patients with problems of dependence and there are very few providers anywhere. Oral naltrexone has a very poor track record of compliance for opiate addiction and Vivitrol is comparatively expensive (AWP of nearly $1600/dose), has a duration of action between only 21-28 days, and compliance is also not great. Having a dosage form that can be administered in a minor surgery, even under local anesthesia, that can provide serum levels for between 3 to 6 months is a significant therapeutic advantage. an implantable pellet is an anhydrous formulation, is highly stable, and is not suitable for sterilization by any means available in the pharmacy - wet methods such as steam would degrade the product and not generate sufficient heat (despite the fact Pfizer has sterilized their Testopel product by autoclave for many years) and dry heat methods would destroy these dosage forms. Irradiation (gamma, electron beam or X-ray) provides distinct advantages. However, these methods are neither practical or suitable for occurring in the licensed pharmacy. Herein lies the conflict with the proposed language. **Comment Continued on Next Line**	Staff have reviewed the comment and do not recommend any changes to the proposed regulation text. Staff note that on September 25, 2019, this issue was raised. At that time, counsel advised members that "provided based on her research of 503A subdivision (a) (1), the federal exemption applies to a state licensed pharmacy that exempts the pharmacy for the manufacturer requirements when compounding. Business and Professions Code sections 4127 and 4127.1 specifically reference the compounding has to occur in a sterile compounding pharmacy – a singular pharmacy – and the license is not transferable thereby emphasizing all compounding exempted under the federal law that occur can in a compounding pharmacy has to occur in a single licensed facility. Board counsel added at that time there are no statutory exemptions and would expect all aspects of compounding to occur in the single regulated unit.

1736.1(e)(4)	Mike Pavlovich Westcliff Compounding	**Comment Continued from Previous Line** Commenter states he selected eBeam for terminal sterilization, after considerable research, the cost, convenience and speed of the process appeared to suit my practice best. A "dry" method that could be used to sterilize the final product in its ultimate container without need for further manipulation, would not degrade the product, and was relatively inexpensive. USP <797> essentially advocates for the use of terminal sterilization since its potential SAL is 1000 times greater than other methods that can be performed in the pharmacy. The chain of custody for products is well-documented and the facility is licensed by multiple entities, state and federal, and tamper-evident measures are applied to all packages. There would be no interest on the facility's part to either contaminate or divert. Aside from testosterone, commenter knows of no other controlled substance that is prepared in a pellet form. Our compounds are not controlled substances but are accounted for similarly. Without the availability of terminal sterilization, we would not be able to function and patients would suffer. We have worked extremely hard and for a very long time to produce a consistent and safe sterile product. We have never failed a sterility, endotoxin or potency test. Commenter urges the Board to reconsideration this important regulation and ask that it be struck down entirely as stated.	Response to comment is above
1736.1(g) **-should be 1735.1(h)**	Melanie Horn Sutter Health	Harmonize the terminology used in 1735.1(i) and 1736.1 (h). Refer to comment above for 1735.1(i) (i) ~~CSPs with~~ Human whole blood or human whole blood derivatives used in CSPs shall be produced in compliance with Health and Safety Code section 1602.5 or supplied as a commercial biologic product licensed as a Fractionated Plasma Products.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. Staff notes that federal law does not allow for pharmacy compounding of biologic products.Staff note that the FDA has released guidance in this area. Staff note that FDA guidance documents help establish the standard of practice for compounders. It is incumbant on licensed professions to remain current on guidances 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
1736.1(g)	Wendy Waldman Torrance Memorial Medical Center	Rationale: Section 1707.2 (b)(2) does not mandate consultation for inpatients of a healthcare facility licensed under section 1250 of the Health and Safety Code. Nevertheless, there are outpatient ambulatory infusion centers where compounded sterile preparations (CSPs) are administered by healthcare professionals. Recommendation: Suggest that the BOP offer clarification for CCR 1736.1 subsection (g), specifying that the regulation does not apply to compounded sterile preparations (CSPs) administered and dispensed to patients by a healthcare professional. Proposed Exemption Language: (g) In addition to the provisions provided in Section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning proper use, storage, handling and disposal of the CSP and related supplies furnished. (i) Excluded from this requirement are health facilities, as defined in Section 1250 of the Health and Safety Code, provided that the prescriptions are administered by a licensed healthcare professional.	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.

1736.1(g)	Mark Johnston CVS Health	Commenter indicates that section 1702.2(c), Duty to Consult, only lists two categories of mandatory counseling and the pending regulations would create a third. Additionally, 1707.2(d) lists seven additional categories of consultation for which a pharmacist may use professional judgment to decide when to utilize such counseling components. Commenter states that CVS believes that patients may become concerned about ingesting a drug that is termed hazardous, potentially discontinuing therapy. Therefore, we believe that counseling on hazardous drug disposal should be left to the professional judgment of the pharmacist; otherwise, we fear that this pending 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: (g) In addition to the provisions in Section 1707.2, whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral consultation shall be provided to the patient and/or patient's agent concerning proper use, storage, and handling ~~and disposal~~ of the CSP and related supplies furnished.	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.
1736.1(g)	Tommy Mai Huntington Health, CSHP	Rationale: Section 1707.2 (b)(2) does not require consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, however there are outpatient ambulatory infusions centers where CSP is being administered by a healthcare professional. Recommendation: Would recommend the BOP to provide clarification for CCR 1736.1 subsection (g), in an FAQ to state that the regulation does not apply to CSPs administered and dispensed to patients by a healthcare professional. Proposed Exemption Language: (g) In addition to the provisions provided in Section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning proper use, storage, handling and disposal of the CSP and related supplies furnished (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.	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.
1736.1(g)	Rheta Silvas Kaweah Health	Recommend: add this language to 1707.2 or add language to clarify settings in which it is applicable. Rationale: adding this language to 1736.1 expands compliance requirements relevant to oral patient consultation to include pharmacies that are compounding CSPs that are not dispensed to a patient as is the case in the hospital setting where drugs are furnished by the hospital pharmacy to be administered to the patient.	Staff have reviewed the comment and agree that additional clarification to the language is appropriate to more specifically describe when patient consultation is required. Staff is offering recommended language.

1736.1(g)	John Gray Kaiser Permanente	To avoid confusion about the situations in which consultation is required, the regulation should specify that consultation is only required when the CSP is furnished to the patient or patient's agent. When a CSP is furnished to a patient or patient's agent, In addition to the provisions in Section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning proper use, storage, handling and disposal of the CSP and related supplies furnished.	Staff have reviewed the comment and agree that additional clarification to the language is appropriate to more specifically describe when patient consultation is required. Staff is offering recommended language.
1736.1(g)	Marie Cottman Pacific Compounding	COMMENT: This is repetitive of other regulations already in place. Further, consultation regulations should be consistent across all medications dispensed, not limited to compounded preparations and thus Section 1707.2 should be modified rather than creating new regulations limited only to CSPs. RATIONALE: Regarding "...proper use, storage…" the referenced Section 1707.2 subsections (c) and (d) both require consultation that includes proper use and storage. Disposal is not currently a consultation requirement, but CNSPs are not that different from capsules, creams, troches, and liquids that are dispensed by non-compounding pharmacies. If this is a true patient safety issue, then it should be addressed in ALL consultations, not just CNSPs. RECOMMENDATION: Remove section 1735.1 (h) and 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. Staff are offering langauge to address other comments received regarding the provisions in this section.
1736.1(h)	Marie Cottman Pacific Compounding	COMMENT: HSC 1602.5 requires biologic licensure which is granted by CA DPH Laboratory Field Services to provide blood products. However, their regulations do not include compliance with USP <797> and thus they do not require their licensed entities to comply with 797. This creates a completely uneven playing field that ensures that patients will get substandard less expensive preparations from individuals not regulated by the board of pharmacy. RATIONALE: Entities licensed under HSC 1602.5 are actively making drug products (autologous serum eye drops) when they are not licensed pharmacies. They fill prescriptions, compound preparations; dispense these to patients, and bill insurers for their services. They do not comply with USP<797> and offer eye drops with 6-month expiration dates for unpreserved, blood components.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. Staff note that the FDA has released a guidance in this area. Staff note that FDA guidance documents establish the standard of practice for compounders. It is encumbant on licensed professions to remain current on guidanances 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

1736.1(h)	Tommy Mai Huntington Health, CSHP	Rationale: The current health and safety code section 1602.5 states the following: (a) No person shall engage in the production of human whole blood or human whole blood derivatives unless the person is licensed under this chapter and the human whole blood or human whole blood derivative is collected, prepared, labeled, and stored in accordance with both of the following:" The proposed regulation in its current state would cause confusion as it would enforce a law that is not applicable to any human whole blood or human whole blood derivative that is already manufactured by a pharmaceutical company (e.g. Albumin, Factor products, IVIG etc.) Recommendation: Would recommend the board to revise the proposed language to provide clarification to state that the regulation does not apply to CSPs made with human blood/derivative that is manufactured by pharmaceutical companies. (h) CSPs with patient's own whole blood or human whole blood derivatives from the patient shall be produced in compliance with Health and Safety Code section 1602.5.	Board staff have reviewed the comment and do not recomment a change to the proposed regulation text. Staff note that the language is to ensure any blood handled from any patient is in compliance with the provision.
1736.1(h)	Wendy Waldman Torrance Memorial Medical Center	Rationale: The existing Health and Safety Code section 1602.5 states: (a) "No person shall engage in the production of human whole blood or human whole blood derivatives unless the person is licensed under this chapter and the human whole blood or human whole blood derivative is collected, prepared, labeled, and stored in accordance with both of the following:" The proposed regulation, as it stands, may create confusion by enforcing a law that does not apply to any human whole blood or human whole blood derivative already manufactured by a pharmaceutical company (e.g., Albumin, Factor products, IVIG, etc.). Recommendation: Recommend that the board revise the proposed language to clarify that the regulation does not apply to compounded sterile preparations (CSPs) made with human blood or derivatives manufactured by pharmaceutical companies. (h) CSPs with patient's own whole blood or human whole blood derivatives from the patient shall be produced in compliance with Health and Safety Code section 1602.5.	Board staff have reviewed the comment and do not recomment a change to the proposed regulation text. Staff note that the language is to ensure any blood handled from any patient is in compliance with the provision.

1736.2(b)	Wendy Waldman Torrance Memorial Medical Center	Rationale: The current USP 797 chapter does not require the PEC unique identifier to be documented for personnel training. Requiring a PEC unique identifier only adds to the additional documentation burden. Recommendation: Recommend that the Board of Pharmacy consider eliminating the requirement for the "PEC unique identifier." Proposed Regulation Revision: Initial and ongoing aseptic manipulation training and competency documentation shall include the Primary Engineering Control (PEC) type ~~and PEC unique identifier~~ used during the evaluation.	Staff staff have reviewed the comment and do not recommend a change to the proposed regulation text. Staff note that the requirement to document would occur once every three to six months. Further, the documentation ensures that a compounding personnel need only complete a single training and can leverage that training in other compounding environments with the same equipment. The unique identifier is necessary to identify where the competency was performed.
1736.2(b)	Tommy Mai Huntington Health, CSHP	Rationale: The current USP 797 chapter does not require the PEC unique identifier to be documented for personnel training. Requiring a PEC unique identifier only adds to the additional documentation burden. Recommendation: Recommend the Board of Pharmacy to consider removing the requirement of "PEC unique identifier" Proposed Regulation Revision: Initial and ongoing aseptic manipulation training and competency documentation shall include the Primary Engineering Control (PEC) type ~~and PEC unique identifier~~ used during the evaluation.	Staff staff have reviewed the comment and do not recommend a change to the proposed regulation text. Staff note that the requirement to document would occur once every three to six months. Further, the documentation ensures that a compounding personnel need only complete a single training and can leverage that training in other compounding environments with the same equipment. The unique identifier is necessary to identify where the competency was performed.
1736.2(b)	Rheta Silvas Kaweah Health	Recommend: clarify the term "materials" by adding to the sterile compounding definitions (CCR 1736). Rationale: the term "materials" is ambiguous.	Board staff have reviewed the comment and do not recommend changes to the proposed text. Staff note that the language of the regulation must be broad and flexible to allow for facilities to make site specific determinations in operationalizing the requirements.

1736.2(d)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP	Multiple factors can contribute to failure of staff in aseptic technique training and competency evaluation including environmental testing failure and engineering control failure. Prohibiting compounding personnel from compounding without an evaluation of contributing factors and timeframe would significantly disrupt patient treatment and jeopardize the ability of health-systems to provide CSPs for critically ill patients. Recommendation: Recommend adoption of facility's SOP for an action plan that specifies compounding personnel failing any aspect of aseptic manipulation ongoing training and competency evaluation. Proposed Regulation Revision: (d) ~~Compounding personnel or persons with direct oversight over compounding personnel who fail any aspect of the aseptic manipulation ongoing training and competency evaluation shall not be involved in compounding or oversight of the preparation of a CSP until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs. A person with only direct oversight over personnel who fails any aspect of the aseptic manipulation ongoing training and competency evaluation may continue to provide only direct oversight for no more than 14 days after a failure of any aspect while applicable aseptic manipulation ongoing training and competency evaluation results are pending~~ Facility's SOP shall include an action plan addressing evaluation follow up and timeframe to mitigate risk when compounding personnel or persons with direct oversight over compounding fail any aspect of the aseptic manipulation ongoing training and competency evaluation.	Board staff have considered the comment and do not recommend changes based solely on this comment. Staff note that an individual that fails any aseptic manipulation for example can compromise the integrity of the product. Staff have significant patient safety concerns with an individual that fails any aspect of the core competencies established in the Chapter be involved in compounding of sterile compounding preparations. Compounding of CSPs is a highrisk function that if not done appropriate can have dire impacts on patients. Regrettable there too many instances of patient death and harm attributed to lack of training and staff. Staff note that in adverse event reports it is common that the contributing factor was the training of the staff. Staff highlight that a person with direct oversight over personnel who fail any aspect competency assessment may contine to provide such oversight for 14 days.
1736.2(d)	Rheta Silvas Kaweah Health	Recommend: reconsider strict removal of compounder personnel from compounding duties until such time as they successfully pass training and competency in the deficient area(s). Recommend extending the 14 day grace for personnel that provide only direct oversight of compounding. Rationale: concern about ability to meet sterile compounding needs of patients in the acute care setting given the impact this requirement could have on staffing levels. If the failed competency was a media fill test, 14 days is the minimum time needed for incubation of a media fill test though the lab results may take longer to obtain. Should the failure be a media fill test, a 14 day grace may allow for results of media fill test if the test was done on the day the failed results are received. It is not always possible to complete a retest that timely as personnel may be on paid time off, on leave of absence at the time the failed results are received.	Board staff have considered the comment and do not recommend changes based solely on this comment. Staff note that an individual that fails any aseptic manipulation for example can compromise the integrity of the product. Staff have significant patient safety concerns with an individual who fails any aspect of the core competencies established in the Chapter be involved in compounding of sterile compounding preparations. Compounding of CSPs is a high risk function that if not done appropriate can have dire impacts on patients. Regrettably there too many instances of patient deaths and harm attributed to lack of training and staff. Staff note that in adverse event reports it is common that the contributing factor was the training of the staff. Staff highlight that a person with direct oversight over personnel who fail any aspect competency assessment may contine to provide such oversight for 14 days.
1736.2(d)	Narinder Singh Santa Clara Valley Healthcare (SCVH) Also Provided at Reg Hearing	The proposed language is very restrictive and will have significant impacts on smaller hospitals with limited staffing. We recommend allowing compounding personnel to continue with sterile compounding with a limitation of immediate use expiration dating pending results of the aseptic manipulation and competency evaluation	Board staff have considered the comment and recommend changes, although not based solely on this comment. Staff note that an individual that fails any aseptic manipulation for example can compromise the integrity of the product. Staff have significant patient safety concerns with an individual who fails any aspect of the core competencies established in the Chapter be involved in compounding of sterile compounding preparations. Compounding of CSPs is a high risk function that if not done appropriately can have dire impacts on patients. Regrettably there too many instances of patient deaths and harm attributed to lack of training and staff. Staff note that in adverse event reports it is common that the contributing factor was the training of the staff. Staff highlight that a person with direct oversight over personnel who fails any aspect competency assessment may contine to provide such oversight for 14 days.

1736.2(d)	Muno Bholat Providence	In agreement with the initial statement of reasons' justification of no more than a 14-day period to allow for a transition if necessary to avoid disruption in compounding while training and evaluation are still pending, this same concern for patient safety while the facility has a chance to make other arrangements, should also be applied to compounding personnel upon the failure of ongoing training and competency evaluation. Since this section reflects an immediate repeat of training and competency evaluation upon receiving results indicating a failure, it acknowledges that this would likely be the initial action taken for a failure. We recommend that compounding personnel be allowed to continue compounding during the same 14-day period allowed those with direct oversight only. Then, in the event that this initial repeat evaluation also fails, both compounding personnel and those with direct oversight will be restricted from performing any compounding or direct oversight until after successfully passing training and competency in the deficient area(s). Keeping patient safety in mind, disrupting the ability for an acute care hospital pharmacy to provide continuity of sterile compounding to patients 24 hours a day could delay delivery of care to critically ill patients. Workload, workflow, and staffing coverage would be negatively impacted and may take time to arrange without disrupting compounding and patient care. **Comment Continued on Next Line**	Board staff have considered the comment and do not recommend changes based solely on this comment. Staff note that an individual that fails any aseptic manipulation for example can compromise the integrity of the product. Staff have significant patient safety concerns with an individual who fails any aspect of the core competencies established in the Chapter be involved in compounding of sterile compounding preparations. Compounding of CSPs is a high risk function that if not done appropriate can have dire impacts on patients. Regrettably there too many instances of patient deaths and harm attributed to lack of training and staff. Staff note that in adverse event reports it is common that the contributing factor was the training of the staff. Staff highlight that a person with direct oversight over personnel who fail any aspect competency assessment may contine to provide such oversight for 14 days.
1736.2(d)	Muno Bholat Providence	**Comment Continued from Previous Line** Allowing a transition period for compounding personnel with their initial failure of ongoing training and competency will minimize the negative impact on patient safety. Recommend modifying the wording to: "(d) Compounding personnel or persons with direct oversight over compounding personnel who fail any aspect of the aseptic manipulation ongoing training and competency evaluation shall have no more than 14 days after a failure to successfully pass ~~not be involved in compounding or oversight of the preparation of a CSP until after successfully passing~~ training and competency in the deficient area(s) as detailed in the facility's SOPs. If training and competency are not passed after the 14 days, personnel shall not be involved in compounding or direct oversight of the preparation of a CSP, until successfully passing applicable aseptic manipulation ongoing training and competency as detailed in the facility's SOPs. ~~A person with only direct oversight over personnel who fails any aspect of the aseptic manipulation ongoing training and competency evaluation may continue to provide only direct oversight for no more than 14 days after a failure of any aspect while applicable aseptic manipulation ongoing training and competency evaluation results are pending.~~	see above

1736.2(d)	Melanie Horn Sutter Health	Failure of the aseptic technique competency evaluation can include contamination by the designated competency evaluator, an environmental testing failure and/or engineering control failure. Prohibiting compounding personnel from compounding without an evaluation of contributing factors and timeframe would significantly disrupt patient treatment and for jeopardize health-systems ability to operate. Recommendation: Establish requirement for facility's SOP for an investigation and corrective action plan that specifies compounding personnel failing any aspect of aseptic manipulation requirements specific to ongoing training and competency evaluation. (d) Compounding personnel or persons with direct oversight over compounding personnel who fail any aspect of the aseptic manipulation ongoing training and competency evaluation shall have a documented investigation of failure and remediation that demonstrates not be involved in compounding or oversight of the preparation of a CSP until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs. A person with only direct oversight over personnel who fails any aspect of the aseptic manipulation ongoing training and competency evaluation may continue to provide only direct oversight for no more than 14 business days after a failure of any aspect while applicable aseptic manipulation ongoing training and competency evaluation results are pending	Board staff have considered the comment and do not recommend changes based solely on this comment. Staff note that an individual who fails any aseptic manipulation for example can compromise the integrity of the product. Staff have significant patient safety concerns with an individual who fails any aspect of the core competencies established in the Chapter be involved in compounding of sterile compounding preparations. Compounding of CSPs is a high risk function that if not done appropriate can have dire impacts on patients. Regrettably there too many instances of patient death and harm attributed to lack of training and staff. Staff note that in adverse event reports it is common that the contributing factor was the training of the staff. Staff highlight that a person with direct oversight over personnel who fail any aspect competency assessment may contine to provide such oversight for 14 days.
1736.2(d)	Wendy Waldman Torrance Memorial Medical Center	Rationale: Several factors may contribute to the failure of staff in aseptic technique training and competency evaluation, such as environmental testing failure and engineering control failure. Prohibiting compounding personnel from compounding without an assessment of these contributing factors and timeframe could significantly disrupt patient treatment and jeopardize the health system's ability to operate. Recommendation: Recommend adopting the facility's Standard Operating Procedure (SOP) for an action plan that outlines the steps to be taken when compounding personnel fail any aspect of aseptic manipulation during ongoing training and competency evaluation. Proposed Regulation Revision: (d) ~~Compounding personnel or persons with direct oversight over compounding personnel who fail any aspect of the aseptic manipulation ongoing training and competency evaluation shall not be involved in compounding or oversight of the preparation of a CSP until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs. A person with only direct oversight over personnel who fails any aspect of the aseptic manipulation ongoing training and competency evaluation may continue to provide only direct oversight for no more than 14 days after a failure of any aspect while applicable aseptic manipulation ongoing training and competency evaluation results are pending~~ The facility's Standard Operating Procedure (SOP) shall incorporate an action plan that addresses compounding personnel or individuals with direct oversight over compounding who fail any aspect of the ongoing training and competency evaluation for aseptic manipulation.	Board staff have considered the comment and do not recommend changes based solely on this comment. Staff note that an individual that fails any aseptic manipulation for example can compromise the integrity of the product. Staff have significant patient safety concerns with an individual that fails any aspect of the core competencies established in the Chapter be involved in compounding of sterile compounding preparations. Compounding of CSPs is a highrisk function that if not done appropriate can have dire impacts on patients. Regrettable there too many instances of patient death and harm attributed to lack of training and staff. Staff note that in adverse event reports it is common that the contributing factor was the training of the staff. Staff note that in adverse event reports it is common that the contributing factor was the training of the staff. Staff highlight that a person with direct oversight over personnel who fail any aspect competency assessment may contine to provide such oversight for 14 days.

1736.2(d)	John Gray Kaiser Permanente	To more clearly delineate the difference in approach to a failed evaluation between compounding personnel and persons with only direct oversight of compounding personnel, we recommend deleting the reference to "persons with direct oversight over compounding personnel" from the first sentence. There might be situations in which a compounding personnel fails their competency evaluation for preparing CSPs in the hazardous drug compounding suite but passes their evaluation for compounding non-hazardous drugs. The regulation should clearly indicate that, in such a case, the individual could continue to compound in the non-hazardous drug compounding suite. Finally, to accommodate for shortages and shipping delays (e.g. due to inclement weather) of compounding testing supplies, we suggest increasing the time period that a person with only direct oversight over compounding personnel can continue to provide direct oversight to 21 days. Compounding personnel ~~or persons with direct oversight over compounding personnel~~ who fail any aspect of the aseptic manipulation ongoing training and competency evaluation shall not be involved in the compounding ~~or oversight of the preparation~~ of a CSP using the procedures and type of equipment associated with the failed evaluation until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs. A person with only direct oversight over <u>compounding</u> personnel who fails any aspect of the aseptic manipulation ongoing training and competency evaluation may continue to provide only direct oversight for no more than ~~14~~ <u>21</u> days after a failure of any aspect while applicable aseptic manipulation ongoing training and competency evaluation results are pending.	Board staff have considered the comment and do not recommend changes based solely on this comment. Staff note that an individual that fails any aseptic manipulation for example can compromise the integrity of the product. Staff have significant patient safety concerns with an individual that fails any aspect of the core competencies established in the Chapter be involved in compounding of sterile compounding preparations. Compounding of CSPs is a highrisk function that if not done appropriate can have dire impacts on patients. Regrettable there too many instances of patient death and harm attributed to lack of training and staff. Staff note that in adverse event reports it is common that the contributing factor was the training of the staff. Staff note that in adverse event reports it is common that the contributing factor was the training of the staff. Staff highlight that a person with direct oversight over personnel who fail any aspect competency assessment may contine to provide such oversight for 14 days.
1736.2(d)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	The person with only direct oversight who fails will need more than 14 days after the failure if this involves a media-fill failure. The incubation of a media-fill takes 14 days at a minimum per 797. Unless the person can do a media-fill on the same day that their media-fill failure is known they will not be able to continue to provide that direct oversight for some number of days. Recommend that this time be extended to 21 days. Similar to the comment in nonsterile compounding, removing people from performing all compounding due to a failure in any training area is not appropriate. A more nuanced approach should be used. If a person fails in their use of an autoclave they could still compound solutions that are prepared aseptically or by filtration assuming that they passed all training and competency for those processes. The supervising pharmacist needs to be able to determine areas of training and competency that would cause the compounder to be completely removed from all compounding of CSPs.	Board staff have considered the comment and do not recommend changes based solely on this comment. Staff note that an individual that fails any aseptic manipulation for example can compromise the integrity of the product. Staff have significant patient safety concerns with an individual that fails any aspect of the core competencies established in the Chapter be involved in compounding of sterile compounding preparations. Compounding of CSPs is a highrisk function that if not done appropriate can have dire impacts on patients. Regrettable there too many instances of patient death and harm attributed to lack of training and staff. Staff note that in adverse event reports it is common that the contributing factor was the training of the staff. Staff note that in adverse event reports it is common that the contributing factor was the training of the staff. Staff highlight that a person with direct oversight over personnel who fail any aspect competency assessment may contine to provide such oversight for 14 days.
1736.2(e)	Rheta Silvas Kaweah Health	Recommend: include a record retention requirement for maintenance of competency documentation or refer to applicable regulation. Alternatively, strike the language "documentation demonstrating compliance with training and competency must be maintained" as this is covered in CCR 1751.1.	Board staff have considered the comment and do not recommend changes to the proposed text. Staff note that documentation requirements are established in proposed section 1736.20.

1736.2 and 1736.3	Sam Kim USC	Personnel training requirements lack any evidence that this training is necessary. The cost to provide training would be substantial.	This generic statement is not sufficiently specific for the Board to evaluate. Training is so critical to sterile compounding USP 797 has an entire section, Section 2, dedicated to personnel training and evaluation. The Chapter details out the core competencies of training that must be completed at least every 12 months. Any costs incurred for these trainings is a function of compliance with the Chapter, not the Board's proposed regulation. The Board's proposed regulations do require training in four additional areas not specified in the chapter - - quality assurance and quality control; container closure and equipment selection; component selection and handling; and sterilization techniques (only when applicable). As noted in the ISOR, these additional components ensure that personnel are adequately training in all aspects of compounding including for example quality assurance which ensure an individual has knowledge to perform a root cause analysis if an issue arises with product quality or a medication error, or an understanding of a particular component selection when making a compounded preparation that could occur in a number of circumstances, including for example under extreme pressure such as for immediate use. Staff note that current regulations, CCR 1751.6 requiring training in these areas - - 1751.8(e)(1)(J) container, equipment, and closure system selection; 1751.8(e)(1)(D) quality assurance procedures, 1751.8(e)(I) sterilization technique for compounding. These costs would already be incurred so the staff is unclear how this would be a new cost. Staff note that Section 9.3 of the Chapter requires an SOP on component selection. An SOP without completing training on the provisions undermines the value of the SOP. Section 18 of Chapter 797 requires compliance with the training and assessment requirements. The need for proper training is highlighted in a number of areas, including in the USP 797 Commentary document which include " Personnel are the biggest source of contamination, and this frequency of personnel monitoring helps ensure continued, consistent, and proper performance." Elsewhere in the commentary, in response to another comment the USP includes, "The (training) standards are based on a combination of available evidence, expertise of the Compounding Expert Committee, and input from stakeholders, and take into consideration stability and sterility data, the compounding environment, and the financial impact on compounders and patients. Personnel are the main source of contaminants, and a frequency of every 6 months for the garbing competency for compounders helps assure continued proper hand hygiene and garbing procedures. The text was changed to allow designated person(s) and personnel who oversee compounding personnel to perform the competency every 12 months."
1736.3	Paul Lofholm	Garbing Donning and doffing garb shall not occur in the anteroom at the same time, seems problematic to me, install traffic lights? Is the location of the sink need clarification?	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff believe the comment is related to proposed text in CCR 1736.3(c). Staff note that the language provides flexibility to allow for SOPs to allow for the practice is a safe manner and how it is monitored. Staff note that garbing needs to occur outside of compounding space to decrease the risk of the introduction of contaminants.
1736.3	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	Refer to 1735.3(a) above	Staff reviewed the comment and do not recommend changes to the language. The USP Expert committee identified the risk and as such included provisions in the Chapter. The Board believes a brighline rule is necessary ensure the environment is not compromised. Staff note that as an example, an individual with an active respiratory illness can release airborn pathogens into the compounding environment thus compromising the environment.

1736.3(a)	Marie Cottman Pacific Compounding	COMMENT: The term “potentially contaminating” condition is not defined and is open to broad interpretation. RATIONALE: Without clarity, a PIC cannot be compliant with a “shall” term unless the conditions for compliance are clear. Absent such clarity, it is appropriate that the regulation language be a “should” statement to provide the necessary latitude for PIC discretion. RECOMMENDATION: (a) The pharmacist overseeing compounding ~~shall not allow~~ should use their judgement to prevent personnel with potentially contaminating conditions to enter the designated compounding area.	Staff reviewed the comment and do not recommend changes to the language. The USP Expert committee identified the risk and as such included provisions in the Chapter. The Board believes a brighline rule is necessary ensure the environment is not compromised. Staff note that as an example, an individual with an active respiratory illness can release airborn pathogens into the compounding environment thus compromising the environment.
1736.3(b)	Narinder Singh Santa Clara Valley Healthcare (SCVH)	Covering the non-removeable piercings with PPE eliminated the risk of contamination of CSP. Add the following language to this section. “The personnel may be allowed to enter the compounding area if the non-removable piercings is covered with PPE.”	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. Staff believes that the provisions in CCR 1736.3(e) relating to provisions for granting an accommodation are sufficient to address this issue.
1736.3(c)	Rheta Silvas Kaweah Health	Recommend: Strike the language “garb shall be donned in an anteroom or immediately outside the segregated compounding area”. Recommend: revise language to …..”or in the SCA” to be consistent with USP Chapter <797> section 3.2 in the paragraph below Box 3 (this glove requirement is a little hidden gem). Rationale: allow compounding pharmacies to determine the best location for donning of gloves based on their facility design as long as they are donned in a classified space (not in a C-PEC/PEC) or in the SCA. Note: USP Chapter <797> requires that gloves be donned in a classified room or SCA. The proposed language specifies “immediately outside the SCA”.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. Staff note that the current proposed regulation text provides for flexibility in where gloving can occur by stating that the facilities SOPs may define specific processes.
1736.3(c)	Sam Kim USC	Donning and Doffing in the anti room is a should in USP; however, a shall with the regulations and there is not evidence that this impacts contamination or evironmental growth.	Board staff have considered the comment and do not recommend any changes to the proposed regulation text. Board staff disagree with the commenter. The Chapter notes the need for it, but is providing flexibility through its discretionary language. The Board’s proposed regulation language establishes a minimum threshold but allows flexibility for a facility to develop an SOP where it chooses not to meet the minimum threshold. Both the Chapter and the Board’s proposed regulations provide flexibility for the facility to determine how best to handle donning and doffing. Staff note that in 2015 USP 797 Pharmaceutical Compounding briefing the language prohibited donning and doffing from occurring at the same time in an ante-room or SCA. As part of the USP commentary, a change was made to provide flexibility because not all facility designs are the same. The Board’s proposed regulation text provides flexibility through the option of facility SOPs. Further, staff notes that FDA includes as an example of insanitary conditions applicable to the production of Sterile drugs as “putting on gowning apparel in a way that may cause the gowning apparel to become contaminated.”

1736.4(a)	Rheta Silvas Kaweah Health	Recommend: revise proposed language as follows – A sink used for cleaning of any equipment used in sterile compounding, hand hygiene when entering the sterile compounding area for the purpose of compounding, or compounding shall not be part of a restroom or 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 changesto the proposed text. Staff note that compounding personnel washing their hands after using the restroom does not meet the standards for hand hygiece prior to compounding. As an example, the compounding leaving the restroom would then be touching a door knob to open the door, creating the potential to contaminate their hands.
1736.4(c)	Wendy Waldman Torrance Memorial Medical Center	Rationale: According to USP Chapter 797, it is recommended to maintain a temperature of 20° Celsius or cooler for staff comfort within the classified compounding areas where multiple layers of PPE are worn. The term "designed compounding area" is defined by CCR 1736 as a restricted location within a facility that limits access, where only activities and items related to compounding are present. This definition encompasses both classified compounding areas and segregated compounding areas. If the language remains unchanged, stating "shall typically," it could have significant consequences for many health systems. Many would need to make substantial changes to their Heating, Ventilation, and Air Conditioning (HVAC) systems to comply with this requirement. Additionally, numerous classified compounding rooms and segregated compounding areas store medication at room temperature, which must adhere to the temperature range defined in USP Chapter 659 as 20°–25°C (68°–77°F). Recommendation: Recommend removing this requirement and have pharmacies follow USP 797 standards for temperature requirement. Recommend the Board of Pharmacy consider removing the requirement of CCR. 1736.4 subsection (c).	Staff note that CCR 1751.4(k) currently requires that the sterile compounding area in the pharmacy shall have a comfortable and well-lighted working environment, which typically includes a room temperature of 20 degrees Celsius or cooler to maintain comfortable conditions. Board staff are unclear how continuation of existing regulation requirements would result in a change in HVAC systems. Further, The USP Chapter 797, Section 4.2 discusses facility design and environmental controls and notes that in addition to minimizing airborne contamination, sterile compounding facilities must be designed and controlled to provide a well-lighted and comfortable working environment. The Chapter provides that the cleanroom suite should be maintained at a temperature of 20 degrees or cooler and a relative humidity of 60% to below to minimize the risk of microbial proliferation. The Board's current regulation and its proposed language provides flexibility by providing the temperature must typically meet the requirements. This allows for some minor fluctuations, while addressing the necessity established in the Chapter. The Chapter also provides that the temperature and humidity in the cleanroom suite must be controlled through an HVAC system. The Chapter thus establishes the requirements for the temperature and humidity control. Staff also note provisions in California Code of Regulations, Title 24 and other legal provisions also establish temperature requires for which licenses must comply.
1736.4(c)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP Also submitted at Reg Hearing	Rationale: The USP chapter 797 recommends rather than requires maintaining a temperature of 20° Celsius or cooler for staff comfort within the classified compounding areas where multiple layers of PPE are worn and states that classified compounding rooms and segregated compounding areas maintain room temperature medication which must be stored in temperatures defined in USP Chapter 659 as 20°–25° (68°–77° F). Requiring the temperature to be 20 degrees Celsius of lower is highly dependent on the health-systems' Heating, Ventilation, and Air Conditioning (HVAC) systems and may not always be feasible, especially in older buildings. In these situations, if the temperature is required, health-systems would not be able to compound CSPs for patients. Recommendation: Recommend this requirement be removed and pharmacies follow USP 797 standards for temperature requirement. Recommend the Board of Pharmacy to consider removing the requirement of CCR. 1736.4 subsection (c).	Staff note that CCR 1751.4(k) currently requires that the sterile compounding area in the pharmacy shall have a comfortable and well-lighted working environment, which typically includes a room temperature of 20 degrees Celsius or cooler to maintain comfortable conditions. Board staff are unclear how continuation of existing regulation requirements would result in a change in HVAC systems. Further, The USP Chapter 797, Section 4.2 discusses facility design and environmental controls and notes that in addition to minimizing airborne contamination, sterile compounding facilities must be designed and controlled to provide a well-lighted and comfortable working environment. The Chapter provides that the cleanroom suite should be maintained at a temperature of 20 degrees or cooler and a relative humidity of 60% to below to minimize the risk of microbial proliferation. The Board's current regulation and its proposed language provides flexibility by providing the temperature must typically meet the requirements. This allows for some minor fluctuations, while addressing the necessity established in the Chapter. The Chapter also provides that the temperature and humidity in the cleanroom suite must be controlled through an HVAC system. The Chapter thus establishes the requirements for the temperature and humidity control. Staff also note provisions in California Code of Regulations, Title 24 and other legal provisions also establish temperature requires for which licenses must comply.

1736.4(c)	John Gray Kaiser Permanente	The proposed regulation, which says, “compounding areas shall typically be maintained at a temperature of 20° Celsius or cooler,” and the USP 797 Chapter, which says “the cleanroom suite should be maintained at a temperature of 20° or cooler,” have the same meaning. The phrase “shall typically” in the Board’s proposed regulation allows for situations in which the compounding area is not at a temperature of 20° Celsius or cooler just as the phrase “should be” in the USP 797 Chapter does. Given the fact that USP and the proposed regulation are functionally the same, we recommend deleting the proposed regulation.	Staff note that CCR 1751.4(k) currently requires that the sterile compounding area in the pharmacy shall have a comfortable and well-lighted working environment, which typically includes a room temperature of 20 degrees Celsius or cooler to maintain comfortable conditions. Board staff are unclear how continuation of existing regulation requirements would result in a change in HVAC systems. Further, The USP Chapter 797, Section 4.2 discusses facility design and environmental controls and notes that in addition to minimizing airborne contamination, sterile compounding facilities must be designed and controlled to provide a well-lighted and comfortable working environment. The Chapter provides that the cleanroom suite should be maintained at a temperature of 20 degrees or cooler and a relative humidity of 60% to below to minimize the risk of microbial proliferation. The Board's current regulation and its proposed language provides flexibility by providing the temperature must typically meet the requirements. This allows for some minor fluctuations, while addressing the necessity established in the Chapter. The Chapter also provides that the temperature and humidity in the cleanroom suite must be controlled through an HVAC system. The Chapter thus establishes the requirements for the temperature and humidity control. Staff also note provisions in California Code of Regulations, Title 24 and other legal provisions also establish temperature requires for which licenses must comply.
1736.4(c)	Marie Cottman Pacific Compounding	COMMENT: Having “shall” and “typically” in the same sentence is contradictory. RATIONALE: A PIC cannot be compliant with something “typically” and have it state that it “shall” be a certain temperature. RECOMMENDATION: (c)(1) Designated compounding area(s) ~~shall~~ should typically be maintained at a temperature of 20° Celsius or cooler. (2) The temperature shall be monitored in each room of the designated compounding area each day that compounding is performed, either manually or by a continuous recording device.	Staff note that CCR 1751.4(k) currently requires that the sterile compounding area in the pharmacy shall have a comfortable and well-lighted working environment, which typically includes a room temperature of 20 degrees Celsius or cooler to maintain comfortable conditions. Board staff are unclear how continuation of existing regulation requirements would result in a change in HVAC systems. Further, The USP Chapter 797, Section 4.2 discusses facility design and environmental controls and notes that in addition to minimizing airborne contamination, sterile compounding facilities must be designed and controlled to provide a well-lighted and comfortable working environment. The Chapter provides that the cleanroom suite should be maintained at a temperature of 20 degrees or cooler and a relative humidity of 60% to below to minimize the risk of microbial proliferation. The Board's current regulation and its proposed language provides flexibility by providing the temperature must typically meet the requirements. This allows for some minor fluctuations, while addressing the necessity established in the Chapter. The Chapter also provides that the temperature and humidity in the cleanroom suite must be controlled through an HVAC system. The Chapter thus establishes the requirements for the temperature and humidity control.

1736.4(c)(1)	Melanie Horn Sutter Health	USP 797 Chapter, states “the cleanroom suite should be maintained at a temperature of 20° or cooler.” The term “designated compounding area(s)” definition encompasses SCA and Cleanroom suites to maintain a temperature lower than 20 C. SCA areas are often contiguous with general pharmacy areas and controlled room temperature medication storage requirements of USP Chapter 650 between 20°–25° C. These SCAs typically are present in smaller, critical access hospitals that do not have dedicated HVAC systems and a typical temperature at or below 20° Celsius lend to discomfort of the general work area and drug storage. When a SCA temperature is maintained at 70 F and 21.1 C this would require no CSP to be compounded as the facility with either a SCA or a Cleanroom suite would be ineligible to compound ANY CSP as directed in 1736.4(f). Additionally, the Board language proposal relevant to temperature standards in ACEAs for allergenic extract compounding could be harmonized since the allergenic compounding maintains the same compounding PPE requirements. Recommend removing CCR. 1736.4 subsection (c) and default to USP 797 standard. If added oversite for temperature required, recommend the Board of Pharmacy to add language to align with temperature monitoring harmonized with ACEA in allergenic extract compounding. (c)(1) <u>The cleanroom suite</u> ~~Designated compounding area(s)~~ shall typically be maintained at a temperature of 20° Celsius or cooler.	Staff note that CCR 1751.4(k) currently requires that the sterile compounding area in the pharmacy shall have a comfortable and well-lighted working environment, which typically includes a room temperature of 20 degrees Celsius or cooler to maintain comfortable conditions. Further, The USP Chapter 797, Section 4.2 discussed facility design and environmental controls and notes that in addition to minimizing airborne contamination, sterile compounding facilities must be designed and controlled to provide a well-lighted and comfortable working environment. The Chapter provides that the cleanroom suite should be maintained at a temperature of 20 degrees Celsius or cooler and a relative humidity of 60% to below to minimize the risk of microbial proliferation. The Board proposed language provides flexibility by providing the temperature must typically meet the requirements. This allows for some minor fluctuations, while addressing the necessity established in the Chapter. The Chapter also provides that the temperature and humidity in the cleanroom suite must be controlled through an HVAC system. The Chapter thus establishes the parameters for the temperature and humidity control. Critical access hospitals that do not have a dedicated HVAC system would be in violation of the Chapter.
1736.4(e)	Marie Cottman Pacific Compounding	COMMENT: Passive airflow connections between classified areas is required based on the physics of airflow and HVAC system operation. RATIONALE: The movement of air from one classified space to another must include passive movement between spaces, as the HVAC system can only directly affect airflow in the ductwork. Once air enters a wide open space, properties of fluid dynamics, gravity, and air-pressure differentials affect where air moves and how. The connections between rooms does not include powered vents, and gaps in door ways prevent complete separation of air from one room to another. By definition, passive air flow occurs whenever a door opens between the rooms. RECOMMENDATION: (e) Except as provided in subsection (d), dynamic interactions between areas and rooms with classified air shall be controlled through a heating, ventilation, and air condition (HVAC) system and <u>passive air exchange vents of appropriate design</u>.	Board staff have reviewed and comment and recommend a change to the language to address the comment. As noted in the Chapter, due to the interdependence of the various rooms or areas that make up a sterile compounding facility, it is essential to carefully desing and control the dynamic interactions permitted between areas and rooms. Staff note that passive air vents are uncontrolled.

1736.4(f)	John Gray Kaiser Permanente	There can be cases in which deviations in the performance of the compounding environment would not support the assignment of a Category 2 BUD but would support a Category 1 BUD. For example, there might be fluctuations in the pressures of the containment secondary engineering control with no impact on the functioning of the primary engineering control(s). The regulation should be clear that if all requirements in the law and the facility's SOPs are met, it would not be prohibited to continue to use the compounding environment and assign shorter (i.e. Category 1) BUDs. No CSP shall be compounded if the compounding environment fails to meet criteria specified in law or the facility's SOPs. This paragraph does not prohibit a pharmacy from treating a compounding environment that is typically USP classified space as a segregated compounding area if all applicable criteria specified in law and the facility's SOPs are met.	Board staff have reviewed the proposed comment and do not recommend a change to the proposed text. Board staff note that the proposed language is consistent with existing law, CCR section 1751.4(a). SOPs should have redundancy included should a failure occur.
1736.4(f)	Marie Cottman Pacific Compounding	COMMENT: This is so general, it does not allow for potential monitoring deviations that are corrected to enable ongoing operations. RATIONALE: For example, if surface testing indicates excessive CFU in an ante area, this would then stop all activity in the compounding suite. The intent in monitoring is to identify an excursion (aka "failure to meet criteria") then take remediation actions and continue to monitor for ongoing excursions. As written, one excursion in temperature, monitoring, pressure, humidity, missed floor cleaning, would trigger a stoppage of all compounding, even if the excursion was deemed not a substantial risk by the PIC. There are numerous regulations around identifying and mitigating these excursions, and discretion if given to the PIC to evaluate these and decide accordingly if compounding should be performed. This regulation is vague and redundant. RECOMMENDATION: Remove.	Board staff have reviewed the proposed comment and do not recommend a change to the proposed text. Board staff note that the proposed language is consistent with existing law, CCR section 1751.4(a). Staff also note that the language provides flexibility through the use of an SOPs. SOPs should have redundancy included should a failure occur.
1736.4(f)	Narinder Singh Santa Clara Valley Healthcare (SCVH)	When an environment fails to meet criteria specified in the law or the facility's SOPs, the BUD of the CSP should change. Not allowing any compounding will negatively impact patient care. We recommend the following language: "Only CSP with BUD of Segregated Compounding Area (SCA) or Immediate Use shall be compounded if the compounding environment fails to meet criteria specified in law or the facility's SOPs."	Board staff have reviewed the proposed comment and do not recommend a change to the proposed text. Board staff note that the proposed language is consistent with existing law, CCR section 1751.4(a). Staff also note that the language provides flexibility through the use of an SOPs. SOPs should have redundancy included should a failure occur. Staff also refer commenter to proposed changes in CCR 1736.1 being recommended by staff related to immediate use provisions.
1736.4(f)	Rheta Silvas Kaweah Health	Recommend: strike the proposed language. Rationale: There are many circumstances where CSPs can continue to be safely compounded until such time as the compounding environment achieves the criteria specified in law or the facilities SOP. For example, a HEPA filter in the buffer room ceiling requires replacement. BUD assignments can be reduced to the maximum allowed for a SCA in the interim to allow continuation of compounding operations without jeopardizing the health and safety of patients. Ceasing compounding in some cases would be counter to consumer protection.	Board staff have reviewed the proposed comment and do not recommend a change to the proposed text. Board staff note that the proposed language is consistent with existing law, CCR section 1751.4(a). Staff also note that the language provides flexibility through the use of an SOPs. SOPs should have redundancy included should a failure occur.

1736.4(f)	Tommy Mai Huntington Health, CSHP	Rationale: In smaller rural hospitals, this proposed law in combination with CCR 1736.1 Introduction and Scope. Subsection (b) would lead to severe consequences for patients. For example, if a designated compounding area fails to meet the criteria specified in the law, and hospitals are unable to compound for immediate use, they would have to cease operations as they would not be able to provide appropriate patient care. Recommendation: Recommend the Board of Pharmacy to consider removing the requirement of CCR. 1736.4 subsection (f) and defer to USP 797.	Board staff have reviewed the proposed comment and do not recommend a change to the proposed text. Board staff note that the proposed language is consistent with existing law, CCR section 1751.4(a). Staff also note that the language provides flexibility through the use of an SOPs. SOPs should have redundancy included should a failure occur.
1736.5(a) and (b)	Narinder Singh Santa Clara Valley Healthcare (SCVH)	Recommending removing CETA requirement for certification as updated USP 797 chapter doesn't require.	Board staff have reviewed the comment and do not recommend any change to the proposed language. Staff note that the proposed language is similar to existing provisions in CCR 1751.4(d). The proposed text updates the reference to the current CETA guidelines revised in 2022.
1736.5(a)	John Gray Kaiser Permanente	To promote the durability of the regulation and reduce the need for future rulemaking to reference revised CETA standards, we recommend amending the regulation such that it references the most recent version of the CETA Certification Guide for Sterile Compounding Facilities. Testing and certification of all ISO classified areas shall be completed by a qualified technician knowledgeable with certification methods and procedures outlined in the Controlled Environment Testing Association (CETA)'s Certification Guide for Sterile Compounding Facilities as specified in this section. Testing shall be performed in accordance with the most recent version of the CETA Certification Guide for Sterile Compounding Facilities (~~CAG003, Revised 2022~~), which is hereby incorporated by reference.	Board staff have reviewed the comment and do not recommend changes to the proposed regulations. Staff note that the proposed language suggested by the commenter may not meet the clarity standards of the Administrative Proceedures Act because it would incorporate a changing standard.
1736.6(a)	John Gray Kaiser Permanente	Kaiser Permanente performed a literature review (see Appendix A for search terms and results) to assess whether there are data to support the practice of speciating isolated microbes to the genus level when the USP action level is not exceeded. Based on our literature review, we found no relevant peer reviewed studies; therefore, we conclude that there is no compelling evidence to support adopting this practice. Additionally, the Board has failed to provide any concrete evidence to support the notion that speciating all microbes found during air and surface sampling that do not exceed action levels will improve safety or prevent untoward events; therefore, this requirement should be removed from the proposed regulation. ~~At a minimum of every 6 months, air and surface sampling results shall be identified to at least the genus level, regardless of the CFU count to trend for growth of microorganisms.~~ Investigation of air and surface sampling results that exceed action levels must be consistent with the deviation and must include evaluation of trends.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text not based on this comment. As indicated in the ASHP release "Pharmacy Environmental Monitoring (EM) Implementation Toolkit- "A hallmark of a strong EM program is the measurement of progress in order to continuously program compounding conditions, and effectively correct excursions." This document further provides metrics to consider during tracking efforts and descriptions of the benefits of the trending. Staff note that the ASHP document recommends monitoring monthly; however, the Board's proposed regulation text only requires trending every six months. Further as noted in USP Chapter 1161, "Particulate counts as well as microbial counts within controlled environments vary with the sampling locations and the activities being conducted during sampling. Monitoring the environment for nonviable particulates and microorganisms is an important control function because they both are important in achieving product compendial requirements for Foreign and Particulate Matter and Sterility in Injections and Implanted Drug Products." Also included in Chapter 1161, "Environmental microbial monitoring and analysis of data by qualified personnel can assist in ensuring that a suitable state of control is maintained." And the Chapter further provides, "Since the advent of comprehensive environmental monitoring programs, their applications in capturing adverse trends or drifts has been emphasized."

1736.6(a)	Marie Cottman Pacific Compounding	COMMENT: This is just not always possible, I believe that is why USP 797 States "an attempt must be made to identify any microorganisms recovered to the genus level" RATIONALE: Is there a scientific basis for requiring this? Why is the language of 797 insufficient when it calls for "an attempt MUST be made"? Growing microorganisms can be tricky and identification may only be to the Class Level, not Genus depending on the conditions. It is out of the PICs control as to if the organism CAN be identified to the Genus level. Holding the PIC/DP accountable to this requirement of "shall be identified" is unreasonable. As stated in 797, an attempt must be made, is reasonable. RECOMMENDATION: Remove. Allow 797 to stand as is.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text not based on this comment. As indicated in the ASHP release "Pharmacy Environmental Monitoring (EM) Implementation Toolkit- "A hallmark of a strong EM program is the measurement of progress in order to continuously program compounding conditions, and effectively correct excursions." This document further provides metrics to consider during tracking efforts and descriptions of the benefits of the trending. Staff note that the ASHP document recommends monitoring monthly; however, the Board's proposed regulation text only requires trending every six months. Further as noted in USP Chapter 1161, "Particulate counts as well as microbial counts within controlled environments vary with the sampling locations and the activities being conducted during sampling. Monitoring the environment for nonviable particulates and microorganisms is an important control function because they both are important in achieving product compendial requirements for Foreign and Particulate Matter and Sterility in Injections and Implanted Drug Products." Also included in Chapter 1161, "Environmental microbial monitoring and analysis of data by qualified personnel can assist in ensuring that a suitable state of control is maintained." And the Chapter further provides, "Since the advent of comprehensive environmental monitoring programs, their applications in capturing adverse trends or drifts has been emphasized."
1736.6(a)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	The second sentence is not clear. What deviation is this referring to? Is there an assumption that the sampling will result in a deviation or there will be results exceeding the action limits?	Board staff have reviewed the comment and are recommending a change to the proposed text based on the comment received. Staff note that the Chapter already requires the investigation and evaluation. As recommended by staff, the sentence highlighted by the commenter would be removed.
1736.6(a)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP	Rationale: USP 797 recommends identifying sampling results on a genus level for actionable CFUs (CFUs exceeding action levels). Infection Control and current evidence does not support that trending genus level below actionable levels will yield data that will reduce patient risks; however, this will result in increase in costs and workload. Recommendation: (a) At a minimum every 6 months, air and surface sampling results shall be identified to at least the genus level, ~~regardless of~~ when the CFU count exceeds action level to trend for growth of microorganisms. Investigation must be consistent with the deviation and must include evaluation of trends.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text not based on this comment. As indicated in the ASHP release "Pharmacy Environmental Monitoring (EM) Implementation Toolkit- "A hallmark of a strong EM program is the measurement of progress in order to continuously program compounding conditions, and effectively correct excursions." This document further provides metrics to consider during tracking efforts and descriptions of the benefits of the trending. Staff note that the ASHP document recommends monitoring monthly; however, the Board's proposed regulation text only requires trending every six months. Further as noted in USP Chapter 1161, "Particulate counts as well as microbial counts within controlled environments vary with the sampling locations and the activities being conducted during sampling. Monitoring the environment for nonviable particulates and microorganisms is an important control function because they both are important in achieving product compendial requirements for Foreign and Particulate Matter and Sterility in Injections and Implanted Drug Products." Also included in Chapter 1161, "Environmental microbial monitoring and analysis of data by qualified personnel can assist in ensuring that a suitable state of control is maintained." And the Chapter further provides, "Since the advent of comprehensive environmental monitoring programs, their applications in capturing adverse trends or drifts has been emphasized."
1736.6(a)	Walgreens	As written, we feel that microorganism testing would be required even in the event of negative sampling results. We ask that the board provide clarity that additional testing would not be required to be performed on samples with no growth. Recommended Language: (a) At a minimum of every 6 months, air and surface sampling result shall be completed and if growth has been observed it shall identified to at least the genus level, regardless of the CFU count ~~to trend for growth of microorganisms~~. Investigation must be consistent with the deviation and must include evaluation of trends.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text based solely on this comment. Staff note that where results occur (e.g. there is evidence that something has grown) identification is necessary. However, if no results are provided, no further action is required.

1736.6(a)	UCSF	Comment: There is concern regarding the feasibility of the proposed language, if identification is needed down to any CFU level it could potentially overwhelm current lab/resource capacity, especially with surface sampling requirement changing to every month. The proposed language also does not provide clear action on what to do with this information. Recommendation: Recommend the Board to consider adopting USP 797 standard and use the USP797 proposed action levels for surface sampling as cut off for genus level identification. Recommend modified language below. 1736.6 Microbiological Air and Surface monitoring. Subsection (a) At a minimum of every 6 months, air and surface sampling results shall be identified to at least the genus level <u>based on facility SOP action level</u>, r~~egardless of the CFU count~~ to trend for growth of microorganisms. Investigation must be consistent with the deviation and must include evaluation of trends.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text not based on this comment. As indicated in the ASHP release "Pharmacy Environmental Monitoring (EM) Implementation Toolkit- "A hallmark of a strong EM program is the measurement of progress in order to continuously program compounding conditions, and effectively correct excursions." This document further provides metrics to consider during tracking efforts and descriptions of the benefits of the trending. Staff note that the ASHP document recommends monitoring monthly; however, the Board's proposed regulation text only requires trending every six months. Further as noted in USP Chapter 1161, "Particulate counts as well as microbial counts within controlled environments vary with the sampling locations and the activities being conducted during sampling. Monitoring the environment for nonviable particulates and microorganisms is an important control function because they both are important in achieving product compendial requirements for Foreign and Particulate Matter and Sterility in Injections and Implanted Drug Products." Also included in Chapter 1161, "Environmental microbial monitoring and analysis of data by qualified personnel can assist in ensuring that a suitable state of control is maintained." And the Chapter further provides, "Since the advent of comprehensive environmental monitoring programs, their applications in capturing adverse trends or drifts has been emphasized."
1736.6(a)	Narinder Singh Santa Clara Valley Healthcare (SCVH)	Identifying genus levels "regardless of CFU counts" is burdensome and adds no value to the safety of CSP. Recommend that genus level identification only occur if CFU count exceeds actionable level per USP 797. "At a minimum of every 6 months, air and surface sampling results shall be identified to at least the genus level, if CFU count exceeds actionable level per USP 797. Investigation must be consistent with the deviation and must include evaluation of trends."	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text based on this comment. Board staff note that it is necessary to determine at least to the genus level, regardless of the CFU count to trend for growth of miccroorganism. CFU fungus tend (e.g. aspergillus) to be more harmful than a CFU of enviornmental bacteria (e.g. bacillus). Absent a determination to at least the genus level, compounding personnel would be unable to determine if action steps such as a change in cleaning practices or products. The commenters recommended text is the current requirement of the USP Chapter which is not sufficient for reasons stated. Staff further note, that existing CCR Section 1751.4(j) requires identification of the CFUs at least to the genus level when environmental monitoring action levels are exceeded. Further, board staff have reviewed the comment and do not recommend a change to the proposed regulation text not based on this comment. As indicated in the ASHP release "Pharmacy Environmental Monitoring (EM) Implementation Toolkit- "A hallmark of a strong EM program is the measurement of progress in order to continuously program compounding conditions, and effectively correct excursions." This document further provides metrics to consider during tracking efforts and descriptions of the benefits of the trending. Staff note that the ASHP document recommends monitoring monthly; however, the Board's proposed regulation text only requires trending every six months. Further as noted in USP Chapter 1161, "Particulate counts as well as microbial counts within controlled environments vary with the sampling locations and the activities being conducted during sampling. Monitoring the environment for nonviable particulates and microorganisms is an important control function because they both are important in achieving product compendial requirements for Foreign and Particulate Matter and Sterility in Injections and Implanted Drug Products." Also included in Chapter 1161, "Environmental microbial monitoring and analysis of data by qualified personnel can assist in ensuring that a suitable state of control is maintained." And the Chapter further provides, "Since the advent of comprehensive environmental monitoring programs, their applications in capturing adverse trends or drifts has been emphasized."

1736.6(b)	Marie Cottman Pacific Compounding	COMMENT: This requires licensees to obtain membership with a private entity ($295/yr) just to view the documents (CETA membership). The entity openly states they are intended only as guidance documents. As such, they are not appropriate for use as regulatory compliance documents. Also, the current CAG-009 document available for viewing was revised in 2020. The item referenced is not even available to determine if compliance can be achieved. RATIONALE: Having "shall" language being used on documents that are guidance and suggestive in nature creates vague language that makes it impossible for a PIC to determine if they are in compliance, or not, with CA BOP regulations. RECOMMENDATION: (b) Environmental sampling ~~shall~~ should be done in compliance with Controlled Environment Testing Association's Certification Application Guide USP <797> Viable Environmental Sampling & Gowning Evaluation (CAG-009, Revised October 2022), which is hereby incorporated by reference.	Board staff have reviewed the comment and recommend a change to the proposed text to reflect the current revision date of 2020. Board staff do not believe additional changes to the language are appropriate. As indicated in the Initial Statement of Reasons, a standard is necessary to ensure consistent and repeatable testing at facilities.
1736.4(f)	Wendy Waldman Torrance Memorial Medical Center	Rationale: The proposed law, coupled with CCR 1736.1 Introduction and Scope, Subsection (b), could have grave implications for patients. For instance, if a designated compounding area fails to meet the criteria specified in the law, hospitals might be unable to compound medications for immediate use. Consequently, this could force them to cease operations, unable to deliver the necessary level of patient care. Recommendation: Recommend that the Board of Pharmacy consider eliminating CCR 1736.4 subsection (f) and instead adhere to the standards outlined in USP 797.	Board staff have reviewed the proposed comment and do not recommend a change to the proposed text. Board staff note that the proposed language is consistent with existing law, CCR section 1751.4(a). Staff also note that the language provides flexibility through the use of an SOP.
1736.6(a)	Melanie Horn Sutter Health	The USP 797 standard identifies on a genus level for above threshold CFUs only. The tracking and trending genus level below action levels has no identified impact on risk to CSPs and patients. Consider if genus level sought, that requirement be based on repeated and consecutive growth to trend, regardless of CFU count for investigation of the source at sample locations in classified areas. Random every 6 months genus level identification of low-level growth will not establish actionable trends. Alternative wording: Investigation of air and surface sampling results that exceed action levels must be consistent with the deviation and must include evaluation of trends. At a minimum of every 6 months, ~~air and~~ surface sampling results shall be identified to at least the genus level, regardless of the CFU count to trend for growth of microorganisms. Investigation must be consistent with the deviation and must include evaluation of trends.	Board staff have reviewed the comment and do not recommend changes to the proposed text based on the comment. Board staff note that air sampling is extremely important in ensuring safe CSPs. Staff highligths that an issue with the HVAC for example could create a contaminated compounding environment, which would not be identified without air sampling. Further, staff note that air sampling is a requirement of the Chapter and accepted the recommend text would contrary to the Chapter.

1736.6(a)	Wendy Waldman Torrance Memorial Medical Center	Rationale: USP 797 recommends identifying sampling results on a genus level for actionable Colony Forming Units (CFUs) that exceed action levels. However, current evidence and infection control practices do not support the idea that tracking genus level below actionable levels will yield data that reduces patient risks. Nonetheless, this approach will lead to increased costs and workload. Recommendation: (a) At a minimum, every 6 months, air and surface sampling results shall be identified to at least the genus level, ~~regardless of~~ when the CFU count exceeds action level to trend for growth of microorganisms. Investigation must be consistent with the deviation and must include evaluation of trends.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text not based on this comment. As indicated in the ASHP release "Pharmacy Environmental Monitoring (EM) Implementation Toolkit- "A hallmark of a strong EM program is the measurement of progress in order to continuously program compounding conditions, and effectively correct excursions." This document further provides metrics to consider during tracking efforts and descriptions of the benefits of the trending. Staff note that the ASHP document recommends monitoring monthly; however, the Board's proposed regulation text only requires trending every six months. Further as noted in USP Chapter 1161, "Particulate counts as well as microbial counts within controlled environments vary with the sampling locations and the activities being conducted during sampling. Monitoring the environment for nonviable particulates and microorganisms is an important control function because they both are important in achieving product compendial requirements for Foreign and Particulate Matter and Sterility in Injections and Implanted Drug Products." Also included in Chapter 1161, "Environmental microbial monitoring and analysis of data by qualified personnel can assist in ensuring that a suitable state of control is maintained." And the Chapter further provides, "Since the advent of comprehensive environmental monitoring programs, their applications in capturing adverse trends or drifts has been emphasized."
1736.6(a)	Mark Johnston CVS Health Also provided at Reg Hearing	Commenter indicates that 1736.6 does not account for the fact that people will introduce an acceptable amount of airborne particulate, as determined by USP experts, and this is especially true in the anti-room and the buffer room (ISO 8 and 7). Commenter states according to USP 797, based upon scientific expert review, ISO 7 and 8 areas are expected to have a CFU count > 1CFU. Commenter requests the following edit: (a) At a minimum of every 6 months, air and surface sampling shall occur and results shall be identified to at least the genus level when surface sampling exceeds >1 CFU in an ISO Class 5 area, >5 CFU in an ISO Class 7 area, and >50 CFU in an ISO Class 8 area and when air sampling exceeds >1 CFU in an ISO Class 5 area >5 CFU in an ISO Class 7 area, and >50 CFU in an ISO Class 8 area ~~regardless of the CFU count to trend for growth of microorganisms~~. Investigation must be consistent with the deviation and must include evaluation of trends.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. Board staff note that it is necessary to determine at least to the genus level, regardless of the CFU count to trend for growth of miccroorganism. CFU fungus tend (e.g. aspergillus) to be more harmful than a CFU of environmental bacteria (e.g. bacillus). Absent a determination to at least the genus level, compounding personnel would be unable to determine if action steps such as a change in cleaning practices or products. Board staff have reviewed the comment and do not recommend a change to the proposed regulation text not based on this comment. As indicated in the ASHP release "Pharmacy Environmental Monitoring (EM) Implementation Toolkit- "A hallmark of a strong EM program is the measurement of progress in order to continuously program compounding conditions, and effectively correct excursions." This document further provides metrics to consider during tracking efforts and descriptions of the benefits of the trending. Staff note that the ASHP document recommends monitoring monthly; however, the Board's proposed regulation text only requires trending every six months. Further as noted in USP Chapter 1161, "Particulate counts as well as microbial counts within controlled environments vary with the sampling locations and the activities being conducted during sampling. Monitoring the environment for nonviable particulates and microorganisms is an important control function because they both are important in achieving product compendial requirements for Foreign and Particulate Matter and Sterility in Injections and Implanted Drug Products." Also included in Chapter 1161, "Environmental microbial monitoring and analysis of data by qualified personnel can assist in ensuring that a suitable state of control is maintained." And the Chapter further provides, "Since the advent of comprehensive environmental monitoring programs, their applications in capturing adverse trends or drifts has been emphasized."
1736.6(a-b) **should be 1737.6(a-b)**	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	There are no standards for contamination action levels for HD drugs. Wipe sampling is recommended in USP 800 but not required, as there is no consensus on what to do with the results.	Board staff have reviewed the comment and believe the commenter is referring to CCR 1737.6(a-b) related to hazardous compounding staff. Staff note that the requirements in hazardous compounding in article 4.7 does not establish a requirement as suggested by the commenter.

1736.7(a)	Melanie Horn Sutter Health	USP 797 states, "The frequency, method(s), and location(s) of cleaning, disinfecting, and applying sporicidal disinfectants must be established in written SOPs, in accordance with the manufacturer's instructions and must be followed by all cleaning personnel. The manufacturer's directions or published data for the minimum contact time must be followed for each of the cleaning, disinfecting, and sporicidal disinfectants used." Recommend removing duplicate requirements. ~~Any cleaning, disinfecting, and sporicidal disinfectants used by the facility to meet the requirements in this article shall be used in accordance with manufacturers' specifications.~~	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments. Staff note that the Board's regulatory text requires a licensee to follow a manufacturer's instructions. The USP Chapter only requires the SOPs to address the issue. The Board's language is more direct and specific.
1736.7(b)	Melanie Horn Sutter Health	Request Board to consider that storage directly along the back wall of an ISO-5 LAFW has no impact on PEC. Consider revision to opening or 1 meter from the DCA of a PEC.	Board staff have considered the comment and do not recommend a change to the proposed regulation text. Board staff note that the proposed regulation text establish a 1 meter perimeter around the PEC which appears to be what the commenter is also suggesting.
1736.7(c)	Melanie Horn Sutter Health	Cleaning Logs include each occurrence with identity of individual and detail the cleaning agent(s) and when used. The Board proposed language places additional burden of added documentation of listing multiple cleaning agents used every day. Each occurrence to document a fixed rotation of cleaning agents adds burden that does not introduce added compliance to performing a thorough and detailed cleaning task. The facility's documentation of each occurrence of the cleaning and sanitizing of the compounding area shall include <u>the product name(s) of the cleaning and sanitizing agents used. The documentation for each cleaning occurrence</u> shall identify ~~the identity of~~ the person completing the cleaning and sanitizing~~, as well as the product name(s) of the cleaning and sanitizing agent(s) used~~.	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.
1736.8	Marie Cottman Pacific Compounding	COMMENT: This is redundant of the language in 1736.17(d) RATIONALE: Redundant of proposed 1736.17(d), which says "(d) The SOPs shall specify the process and products to be used on any equipment and other items entering from an unclassified area into the clean side of the anteroom, entering a PEC, and entering the SCA." RECOMMENDATION: Remove regulation.	Board staff have reviewed the comment and do not recommend a change to the proposed language. Board staff note that 1736.8 requires the compounding personnel to comply with the SOPs that are required to be developed in CCR 1736.17(d)
1736.9	Paul Lofholm	Equipment, Supplies and Components What to do is the API is manufactured in a non-FDA facility or one not registered by CA BOP, is there room of a COA requirements or other?	Board staff have reviewed the comment and believe the comment is related to 1736.9(d). Board staff do not recommend a change to the proposed text based on the comment. Staff note that provisions in 503A require all API to be manufactured by a drug establishment registered with the FDA. Board staff note that federal law establishes the requirements for APIs, and FDA issued guidance provides further clarification. Staff note that FDA guidance documents establish the standard of practice for compounders. It is incumbant on licensed professionals to remain current on guidances issued to ensure compliance with provisions established.

1736.9(b)	Melanie Horn Sutter Health Also Provided at Reg Hearing	Recommend aligning to match USP 825 California proposed section 1738.6 (e), "(e) Incubators must be calibrated and operated in accordance with the manufacturer's specifications. Temperatures must be monitored either manually or by a continuous recording device during incubation, and the results must be reviewed and documented as described in the facility's SOPs." Incubators require regular cleaning and maintenance per manufacturer specifications, but are not maintained in a controlled environment to establish a required interval of every 30 days. Incubators used by the facility ~~shall be cleaned, maintained,~~ must be calibrated, and operated in accordance with manufacturers' specifications. ~~For incubators without specific manufacturers' specifications, cleaning shall take place at least every 30 days and temperature calibration shall take place at least every 12 months.~~ Temperatures must be monitored either manually or by a continuous recording device during incubation, and the results must be reviewed and documented as described in the facility's SOPs.	Board staff have reviewed the comment and are offering recommended language to ensure consistency between article 4.6 and article 4.8 related to the use of incubators.
1736.9(b)	John Gray Kaiser Permanente	Some organizations might choose to use a continuous temperature monitoring system to monitor incubator temperatures. The regulation should be amended to clarify that practice is permitted if the temperature monitoring device is calibrated according to the manufacturer's specifications. (b) Incubators used by the facility shall be cleaned, maintained, calibrated, and operated in accordance with manufacturers' specifications. (1) For incubators without specific manufacturers' specifications, cleaning shall take place at least every 30 days and calibration shall take place at least every 12 months. (2) If an external temperature monitoring device is used to monitor the temperature of an incubator, then the temperature monitoring device shall be calibrated in accordance with the manufacturer's specifications.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation language. Board staff note that the Board's text ensures the monitoring device is functioning as specified by the manufacture at least every 12 months.
1736.9(c)	Rheta Silvas Kaweah Health	Recommend: revise the proposed language deleting the word "used". Rationale: it may be acceptable to use a component for sterile compounding in a manner that is not consistent with the manufactures' specifications as is the case of a literature supported unlabeled use of a medication. Unclear what was intended when using this term in the language.	Board staff have reviewed the comment and do not recommend changes to the proposed regulatory text. Board staff believe the commenter may be conflating the use of a component versus the indication of a prescription.

1736.9(d)	Rick Rhoads University Compounding Also provided at Reg Hearing	(d) All API and excipient components used to compound a CSP shall be manufactured by an FDA-registered facility, be accompanied by a Certificate of Analysis (COA), and suitable for use in sterile pharmaceuticals. A COA that includes the compendial name, the grade of the material, and the applicable compendial designations on the COA, must be received and evaluated prior to use, unless components are commercially available drug products. When the COA is received from a supplier, it must provide the name and address of the manufacturer. API and excipient components provided with a COA without this data shall not be used in a CSP, unless the manufacturer name and address are retrieved from the supplier and documented on the COA. Reason: It would helpful to allow compounders to obtain this information from the supplier, if missing from the COA. In my experience, this information is not usually printed on the COA.	Board staff have reviewed the comment and recommend a change to the proposed text to clarify that the proposed regulation text only applies to APIs, not excipient components. Pharmacists must remain knowledgable of current practice standards and legal requirements of the industry while exercising their professional judgment. Staff note that included in guidance provided by the FDA, improper repackaging or lack of supply change transparency regarding API or excipients can cause serious vulneratbillities in the supply chain and may lead to patient safety issues. Source: FDA to Compounders: Know Your Bulks and Excipients Suppliers.
1736.9(d)	Jasmine Parker Pacific Compounding	COMMENT: There is no definition of what constitutes "suitable for use in sterile pharmaceuticals" RECOMMENDATION:(d) All AP/ and excipient components used to compound a CSP shall be manufactured by an FDA-registered facility, be accompanied by a Certificate of Analysis (GOA), and suitable for use in sterile pharmaceuticals. A GOA that includes the compendia/ name, the grade of the material, and the applicable compendia/ designations on the GOA, must be received and evaluated prior to use, unless components are commercially available drug products. When the GOA is received from a supplier, it must provide the name and address of the manufacturer. AP/ and excipient components provided with a GOA without this data shall not be used in a CSP	Pharmacists must remain knowledgable of current practice standards and legal requirements of the industry while exercising their professional judgment. Staff note that included in guidance provided by the FDA, improper repackaging or lack of supply change transparency regarding API or excipients can cause serious vulneratbillities in the supply chain and may lead to patient safety issues. Source: FDA to Compounders: Know Your Bulks and Excipients Suppliers.
1736.9(d)	Philip Smyth Medisca	Excipients are different than APIs. USP explored this topic extensively through a panel and workshop with industry experts on the topic of excipient quality. They decided on the below language. We ask that the same language be used: [excipients] should be manufactured by an FDA- registered facility If a component cannot be obtained from an FDA- registered facility, the designated person(s) must select an acceptable and reliable source (see Good Distribution Practices for Bulk Pharmaceutical Excipients 1197). The compounding facility must establish the identity, strength, purity, and quality of the ingredients obtained from that supplier by reasonable means. Reasonable means may include but are not limited to visual inspections, evaluation of a COA supplied by the manufacturer, and/or verification by analytically testing a sample to determine conformance with the COA or other specifications.	Board staff have reviewed the comment and recommend a change to the proposed text to clarify that the proposed regulation text only applies to APIs, not excipient components. Pharmacists must remain knowledgable of current practice standards and legal requirements of the industry while exercising their professional judgment. Staff note that included in guidance provided by the FDA, improper repackaging or lack of supply change transparency regarding API or excipients can cause serious vulneratbillities in the supply chain and may lead to patient safety issues. Source: FDA to Compounders: Know Your Bulks and Excipients Suppliers.

1736.9(d)	Lauren Honda Valor Compounding Also Submitted in Reg Hearning	As a compounding pharmacist, I understand that vetting chemical suppliers is of the utmost importance to ensure the quality and safety of the final CSP that is delivered to patients. However, I would like to express that we have encountered challenges in obtaining the name and address of the manufacturer from several of our major chemical suppliers. Despite our efforts to request this information these suppliers have been unable to provide this information as they hold it to be proprietary information. In light of the difficulties our facility has had in obtaining the manufacturer name and address from some suppliers, we have put SOPs into place which state that when appropriate a supplier that is able to provide the manufacturer name and address will be considered a first-tier supplier and used over a manufacturer that is not able to provide that information. This allows us to consider best practices while still being able to source chemicals from alternative secondary suppliers when our first-tier suppliers are unable to source a chemical we need for compounding. I ask you to consider how this regulation might impact patients' access to CSPs, given that certain chemicals necessary for compounding are only available from suppliers that we have historically not been able to acquire the manufacturer name and address from.	Pharmacists must remain knowledgable of current practice standards and legal requirements of the industry while exercising their professional judgment. Staff note that included in guidance provided by the FDA, improper repackaging or lack of supply change transparency regarding API or excipients can cause serious vulneratbillities in the supply chaing and may lead to patient safety issues. Source: FDA to Compounders: Know Your Bulks and Excipients Suppliers. Board staff are recommending a change to allow flexibility for the PIC or designated person to include the manufacturer name an address on the COA provided by the supplier. Staff also note that the USP Chapter requires reasonable meants to establihs the identity, strength, purity and quality of the ingredients obtained from a supplier withic includes evaluation of a COA supplied by the manufacturer and/or verification by analystically testing a sample to determine conformance with the COA or other spefications. The Chapter further states: "All APIs and other components used must be evaluated forsuitability for use in sterile drug preparation. Components labeled with “not for pharmaceutical use”, “not for injectable use”, “not for humanuse” or an equivalent statement must not be used to compound for these purposes."
1736.9(d)	A.J. Day	Requires all excipient components to be manufactured by an FDA registered facility however the FDA does not equire registration for excipient manufacturers and therefore those manufactur generally do not register.	Board staff have reviewed the comment and recommend a change to the proposed text to clarify that the proposed regulation text only applies to APIs, not excipient components. Pharmacists must remain knowledgable of current practice standards and legal requirements of the industry while exercising their professional judgment. Staff note that included in guidance provided by the FDA, improper repackaging or lack of supply change transparency regarding API or excipients can cause serious vulneratbillities in the supply chaing and may lead to patient safety issues. Source: FDA to Compounders: Know Your Bulks and Excipients Suppliers. Board staff are recommending a change to allow flexibility for the PIC or designated person to include the manufacturer name an address on the COA provided by the supplier. Staff also note that the USP Chapter requires reasonable meants to establihs the identity, strength, purity and quality of the ingredients obtained from a supplier withic includes evaluation of a COA supplied by the manufacturer and/or verification by analystically testing a sample to determine conformance with the COA or other spefications. The Chapter further states: "All APIs and other components used must be evaluated forsuitability for use in sterile drug preparation. Components labeled with “not for pharmaceutical use”, “not for injectable use”, “not for humanuse” or an equivalent statement must not be used to compound for these purposes."

1736.9(d)	Scott Brunner Alliance for Pharmacy Compounding	Most excipient components are sold by FDA-registered wholesalers but are not manufactured by FDA-registered facilities. FDA registration is required of manufacturers of food, beverages, dietary supplements, cosmetics, animal and veterinary products, medical devices, drug products, tobacco products, radiation-emitting devices, and biologics. What is meant by "suitable for use in sterile pharmaceuticals?" Additionally, not all wholesalers or repackagers include the original manufacturer name or address on the COA, as they assert that is a trade secret. Trade secrets should be protected under California law.	Board staff have reviewed the comment and recommend a change to the proposed text to clarify that the proposed regulation text only applies to APIs, not excipient components. Pharmacists must remain knowledgeable of current practice standards and legal requirements of the industry while exercising their professional judgment. Staff note that the FDA has released compounding alerts and guidance related to this issue. Staff note that as stated in FDA guidance, improper repackaging or lack of supply chain transparency regarding API or excipients can cause serious vulnerabilities in the supply chain and may lead to patient safety issues. Source: FDA to Compounders: Know Your Bulks and Excipients Suppliers. Staff further note that section 503A(b)(1)(A)(ii) of the FDCA requires that APIs used in compounding be manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)) of the FDCA. To confirm compliance with this specific federal requirement, knowledge of the manufacturer is required. Further, USP Chapter 797 includes guidance related to the components used in CSPs. The Chapter requires that compounding personnel use reasonable means to establish the identity, strength, purity and quality of the ingredients obtained from a supplier, which includes evaluation of a COA supplied by the manufacturer and/or verification by testing a sample to determine conformance with the COA or other specifications. The Chapter further states: "All APIs and other components used must be evaluated for suitability for use in sterile drug preparation. Components labeled with "not for pharmaceutical use", "not for injectable use", "not for human use" or an equivalent statement must not be used to compound for these purposes." Lastly, simply identifying the manufacturer of a component without more does not appear to be requiring the disclosure of a trade secret under Civil Code section 3426.1(d)
1736.9(d)	Marie Cottman Pacific Compounding	COMMENT: There is no definition of what constitutes "suitable for use in sterile pharmaceuticals" RATIONALE: Without a definition of what "suitable for use in sterile compounding" means, a PIC cannot determine if they are compliant with this regulation. It is appropriate to have specifics about what kind of documentation is required, and the information that is required on the document. Including a "shall" statement for a subjective assessment to determine if something is "suitable" is too vague to be included in the compliance regulations and should be removed. RECOMMENDATION:(d) All API and excipient components used to compound a CSP shall be manufactured by an FDA-registered facility, be accompanied by a Certificate of Analysis (COA), ~~and suitable for use in sterile pharmaceuticals~~. A COA that includes the compendial name, the grade of the material, and the applicable compendial designations on the COA, must be received and evaluated prior to use, unless components are commercially available drug products. When the COA is received from a supplier, it must provide the name and address of the manufacturer. API and excipient components provided with a COA without this data shall not be used in a CSP.	Pharmacists must remain knowledgable of current practice standards and legal requirements of the industry while exercising their professional judgment. Staff note that the FDA has released compounding alerts and guidance related to this issue. Further the USP Chapter also includes guidance related to the components used in CSPs. The Chapter also states: "All APIs and other components used must be evaluated forsuitability for use in sterile drug preparation. Components labeled with "not for pharmaceutical use", "not for injectable use", "not for humanuse" or an equivalent statement must not be used to compound for these purposes."

1736.9(d)	National Community Pharmacists Association (NCPA)	Refer to 1735.7(c)(2) above	Board staff have reviewed the comment and recommend a change to the proposed text to clarify that the proposed regulation text only applies to APIs, not excipient components. Pharmacists must remain knowledgeable of current practice standards and legal requirements of the industry while exercising their professional judgment. Staff note that the FDA has released compounding alerts and guidance related to this issue. Staff note that as stated in FDA guidance, improper repackaging or lack of supply chain transparency regarding API or excipients can cause serious vulnerabilities in the supply chain and may lead to patient safety issues. Source: FDA to Compounders: Know Your Bulks and Excipients Suppliers. Staff further note that section 503A(b)(1)(A)(ii) of the FDCA requires that APIs used in compounding be manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)) of the FDCA. To confirm compliance with this specific federal requirement, knowledge of the manufacturer is required. Further, USP Chapter 797 includes guidance related to the components used in CSPs. The Chapter requires that compounding personnel use reasonable means to establish the identity, strength, purity and quality of the ingredients obtained from a supplier, which includes evaluation of a COA supplied by the manufacturer and/or verification by testing a sample to determine conformance with the COA or other specifications. The Chapter further states: "All APIs and other components used must be evaluated for suitability for use in sterile drug preparation. Components labeled with “not for pharmaceutical use”, “not for injectable use”, “not for human use” or an equivalent statement must not be used to compound for these purposes." Lastly, simply identifying the manufacturer of a component without more does not appear to be requiring the disclosure of a trade secret under Civil Code section 3426.1(d)
1736.9(e)	Marie Cottman Pacific Compounding	COMMENT: There is a profound contradiction in assuring public safety with this regulation. It prevents compounding with drugs the FDA is allowing to be done while its expert committees make decisions about them. At the same time, it gives any public health official in CA the power to allow a compounding pharmacy to use any bulk ingredient it deems appropriate for a specific patient. RATIONALE: As worded, this prevents pharmacies from using on the FDA’s Category 1 Bulk drug substances under evaluation list (503A updated updated 5/2024). As a result, patients will go out of state or have things shipped-in from unlicensed out of state providers. This does little to improve the safety of California patients. At the same time, it allows a compounder to “get permission” from any public health official to use any bulk drug substance on a patient specific basis. One quick web search for what is a “public health official” showed “Public health official means a local health officer, the Director of the Bureau of Health, Department of Health and Human Services, or any designated employee or agent of the Department of Health and Human Services.” RECOMMENDATION: (e) When a bulk drug substance or API is used to compound a CSP, it shall comply with a USP drug monograph, be the active substance of an FDA approved drug, or be listed 21 CFR 216, on the FDA Category 1 Bulk Drug Substances list, unless authorized by a public health official in an emergency use situation for a patient-specific compounded sterile preparation.	In response to this and other comments, Board staff are recommending a change to the proposed text to, subject to specified conditions, allow for the compounding of a bulk drug substance that currently appears in 503A Category 1 on FDA’s website. Staff note that the "recommendation" appears to be consistent with the language in the proposed text.

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

1736.9(e)	Philip Smyth Medisca	This is in opposition to FDA guidance which allows for the compounding of products on the interim Bulks List (category 1). We ask that California align with federal guidance to avoid gaps in care.	Board staff have reviewed the comment. The proposed regulation text is not intended to create barriers to effective treatments, rather was intended to provide flexibility as practices evolve and research supports emerging treatments. However, in response to public comment, staff are recommending a proposed change to noticed text. The recommended text if approved would more directly allow for the compounding of a bulk drug substance that is included in the published 503A Category 1 bulk substance list under specified conditions. Staff remind all commenters that the FDA evaluates research studies to determine the safety and efficacy of drugs and establish the appropriate and approved use of medications including compounded preparations. The Board defers to the FDA judgment and notes that the FDA releases information, guidance documents, evaluation of research, etc. and that such FDA information establishes a standard of practice for which Board licensees must remain mindful of when evaluating prescriptions and exercising clinical judgment including the proposed provisions related to bulk drug substances. Pharmacists must remain knowledgable of current practice standards and legal requirements of the industry while exercising their professional judgment. Staff note that the FDA has released compounding alerts and guidance related to this issue. Further the USP Chapter also includes guidance related to the components used in CSPs. Staff note that included in guidance provided by the FDA, improper repackaging or lack of supply change transparency regarding API or excipients can cause serious vulneratbillities in the supply chaing and may lead to patient safety issues. Source: FDA to Compounders: Know Your Bulks and Excipients Suppliers. Board staff are recommending a change to allow flexibility for the PIC or designated person to include the manufacturer name an address on the COA provided by the supplier. The Chapter further states: "All APIs and other components used must be evaluated for suitability for use in sterile drug preparation. Components labeled with “not for pharmaceutical use”, “not for injectable use”, “not for human use” or an equivalent statement must not be used to compound for these purposes."
1736.10.	Paul Lofholm	Sterilization and Depyrogenation reference to 1228 is advisory, basically sterilization processes must be validated and meet SOP for sterilization	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Staff note that compliance with Chapter 1228 is necessary to ensure that sterile products are free from harmful pyrogens.
1736.10.	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	From USP's General Notices: "General chapters numbered 1000 to 1999 are for informational purposes only. They contain no mandatory tests, assays, or other requirements applicable to any official article, regardless of citation in a general chapter numbered below 1000, a monograph, or these General Notices"	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Staff note that the comment appears it is general in nature and does not provide recommendations for response.
1736.10(e)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	This would prevent the use of e- beam or gamma-irradiation sterilization methods, which are performed off-site at validated facilities.	Staff have reviewed the comment and do not recommend any changes to the proposed regulation text. Staff note that on September 25, 2019, this issue was raised. At that time, counsel advised members that "provided based on her research of 503A subdivision (a) (1), the federal exemption applies to a state licensed pharmacy that exempts the pharmacy for the manufacturer requirements when compounding. Business and Professions Code sections 4127 and 4127.1 specifically reference the compounding has to occur in a sterile compounding pharmacy – a singular pharmacy – and the license is not transferable thereby emphasizing all compounding exempted under the federal law that occur can in a compounding pharmacy has to occur in a single licensed facility. Board counsel added at that time there are no statutory exemptions and would expect all aspects of compounding to occur in the single regulated unit.

1736.10(e)	Philip Smyth Medisca	This would prevent the use of e-beam or gamma-irradiation sterilization methods, which are performed off-site at validated facilities. We ask that this be allowed for.	Staff have reviewed the comment and do not recommend any changes to the proposed regulation text. Staff note that on September 25, 2019, this issue was raised. At that time, counsel advised members that "provided based on her research of 503A subdivision (a) (1), the federal exemption applies to a state licensed pharmacy that exempts the pharmacy for the manufacturer requirements when compounding. Business and Professions Code sections 4127 and 4127.1 specifically reference the compounding has to occur in a sterile compounding pharmacy – a singular pharmacy – and the license is not transferable thereby emphasizing all compounding exempted under the federal law that occur can in a compounding pharmacy has to occur in a single licensed facility. Board counsel added at that time there are no statutory exemptions and would expect all aspects of compounding to occur in the single regulated unit.
1736.10(e)	Mike Pavlovich Westcliff Compounding	Recommendation/Comment Omit/delete all language in (e) or use relevant USP <1229> sections as were used for other sterilization methods. Since electron beam sterilization is a superior method that contributes to product and patient safety, prohibiting its use would be a serious step backwards. I suggest these proposed regulations be rescinded, or at the very least amended to include methods outlined in <797>, and <1229> or to establish criteria necessary for terminal sterilizers to qualify as approved by the Board. I respectfully disagree with the statement “the pharmacy would not be completing all steps of the compounding process”. Sterilization, particularly terminal sterilization, occurs once the compounding has been completed and the CSP is properly packaged in the final container. It is a distinctly separate process. I further disagree with the Economic Impact Assessments, as jobs and businesses may well be eliminated.	Staff have reviewed the comment and do not recommend any changes to the proposed regulation text. Staff note that on September 25, 2019, this issue was raised. At that time, counsel advised members that "provided based on her research of 503A subdivision (a) (1), the federal exemption applies to a state licensed pharmacy that exempts the pharmacy for the manufacturer requirements when compounding. Business and Professions Code sections 4127 and 4127.1 specifically reference the compounding has to occur in a sterile compounding pharmacy – a singular pharmacy – and the license is not transferable thereby emphasizing all compounding exempted under the federal law that occur can in a compounding pharmacy has to occur in a single licensed facility. Board counsel added at that time there are no statutory exemptions and would expect all aspects of compounding to occur in the single regulated unit.
1736.11(a)(1)	Walgreens	Our concerns with the Master Formulation and Compounding records remain the same as with non-sterile preparations. UPS monographs are widely referenced for beyond-use date assignments, however access to these monographs are often restricted. If requested due to concerns by the compounding pharmacists, requests can be made to receive a copy of the materials supporting the extended BUD. 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. Board staff note that the information may be stored in different locations and in various means (e.g., paper, electronic form, etc); however, when requested, the compounding record must be produced to the Board that includes the required information in a single document. Staff are offering a proposed change to the language to clarify.

1736.11(c)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP	Rationale: Electronic record keeping systems/software that enable documentation compliance to the compounding record requirements do not always have reporting capabilities to list all the elements in a single document. To allow pharmacies to continue to use this systems/software to ensure compliance, recommend the board consider amending this section to make the allow pharmacies to make compounding records readily retrievable. Recommendation: Recommend the Board consider modify the language to: (c) Compounding record requirements shall be readily retrievable to comply with USP Chapter 797 and includes the following additional elements:	Board staff have considered the comment. Board staff note that the information may be stored in different locations and in various means (e.g., paper, electronic form, etc); however, when requested, the compounding record must be produced to the Board that includes the required information in a single document. Staff are offering a proposed change to the language to clarify.
1736.11(c)	Walgreens	The requirement for a "single" document for the compounding record does not account for the use of digital systems that keep the documentation electronic and readily retrievable. When paper records are utilized, pharmacies often have multiple "documents" or pages of information for the full compounding record, and we are concerned with the use of the language "single document" and how it will be interpreted. Recommended language: c) A compounding record (CR) shall be a ~~single document~~ developed in compliance with USP Chapter 797, ~~maintained in a retrievable manner,~~ and includes the following additional elements:	Board staff have considered the comment. Board staff note that the information may be stored in different locations and in various means (e.g., paper, electronic form, etc); however, when requested, the compounding record must be produced to the Board that includes the required information in a single document. Staff are offering a proposed change to the language to clarify.
1736.11(c)	Rheta Silvas Kaweah Health	Recommend: revise the proposed language to "The compounding record shall satisfy the requirements of USP Chapter 797 and also contain the following"… Rationale: The proposed language is congruent with a paper-based recordkeeping process. As facilities are moving towards implementing IV workflow management systems, the information required for recordkeeping as described in 1735.3(a)(2)(A-J) is captured/stored electronically. The stored electronic information is readily retrievable in the pharmacy.	Board staff have considered the comment. Board staff note that the information may be stored in different locations and in various means (e.g., paper, electronic form, etc); however, when requested, the compounding record must be produced to the Board that includes the required information in a single document. Staff are offering a proposed change to the language to clarify.
1736.11(c)	Melanie Horn Sutter Health	USP 797 states, "If an ACD, workflow management system, or other similar equipment is used, the required information in the CR may be stored electronically as long as it is retrievable and contains the required information." Harmonize the CR requirement for USP 795 & USP 797 for clarity and support automated workflow solutions with forcing functions to capture and detail the required information readily. The current electronic health record and most other safety IV workflow technologies have some limitations in their ability to produce a single document, but all information is readily obtained and held 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. (c) A compounding record (CR) shall be ~~a single document.~~ readily retrievable and contain the required information~~. The document shall~~ to satisfy the requirements of USP Chapter 797, and ~~also contain~~ the following:	Board staff have considered the comment. Board staff note that the information may be stored in different locations and in various means (e.g., paper, electronic form, etc); however, when requested, the compounding record must be produced to the Board that includes the required information in a single document. Staff are offering a proposed change to the language to clarify.

1736.11(c)	Wendy Waldman Torrance Memorial Medical Center	Rationale: Health-system pharmacies currently rely on electronic record-keeping systems/software to fulfill compounding record requirements. However, this reliance on electronic systems may limit the ability to present all the necessary information in a single document. Recommendation: Recommend the Board consider modify the language to: (c) Compounding record requirements shall be readily retrievable to comply with USP Chapter 797 and includes the following additional elements:	Board staff have considered the comment. Board staff note that the information may be stored in different locations and in various means (e.g., paper, electronic form, etc); however, when requested, the compounding record must be produced to the Board that includes the required information in a single document. Staff are offering a proposed change to the language to clarify.
1736.11(c)(1)	Rick Rhoads University Compounding	(1) The date, or date and time of preparation, if the BUD is listed in hours. The time of preparation is the time when compounding the CSP started, which also determines when the assigned BUD starts. Reason: This language is helpful to clarify that the date and/or time of compounding refers to when the compounding process started. However, this language may be confused to mean that the BUD must specify a day and time (eg. Discard after 06/15/2023 at 1PM). However, most BUDs are assigned in days only, which would make the start time irrelevant. The time compounded would only be applicable when the BUD is listed in hours.	Board staff have reviewed the comment and do not recommend a change to the proposed language. Board staff note that the Chapter requires the compounding record to include the date and time. Further the Chapter provides that the BUD is determined from the date and time that the preparation of the CSP is initiated. Given the specificity in the Chapter, staff believe (c)(1) could be deleted from the proposed text if the Board believe such aciton is appropriate.
1736.11(c)(3)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP Also provided at Reg Hearing	Rationale: Current language in CCR 1735.3 below has a provision for CSPs compounded in health facilities to prevent delays in care to acutely ill patient, i.e. infections, cancer, critical care, etc. The current language states: (F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply. (i) Exempt from the requirements in this paragraph (1735.3(a)(2)(F)) are sterile preparations compounded in a single lot for administration within seventy-two (72) hours to a patient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for “Redispensed CSPs” found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference. Recommendation: Add back the language above: 1736.11 Master Formulation and Compounding Records, subsection (c)(3): (c)(3) The manufacturer, lot number, and expiration date shall be recorded for each component for CSPs. (i) Exempt from the requirements in this paragraph are sterile preparations compounded in a single lot for administration within seventy-two (72) hours to a patient in a health care facility licensed under section 1250 of the Health and Safety Code.	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments. Staff note that while existing law provides such an exemption, continuation of the current exemption is not appropriate as it hampers the ability of a facility to respond appropriately in the event of a product recall. Staff note that the Chapter requires either the recording of the manufacturers or vendor; however, in separate guidance issued by the FDA, the facility needs to have transparency into the supply chain and awareness of the manufacturer (where the manufacturer and vendor are different.) Staff note that the Chapter provides a limited exemption for CSPs prepared for a single patient for sterile to sterile compounding only.

1736.11(c)(3)	Wendy Waldman Torrance Memorial Medical Center	Rationale: Current language in CCR 1735.3 below has a provision for CSPs compounded in health facilities to prevent delays in care to acutely ill patient, i.e., infections, cancer, critical care, etc. The current language states: F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply. Recommendation: Add back the language above: 1736.11 Master Formulation and Compounding Records, subsection (c)(3): (c)(3) The manufacturer, lot number, and expiration date shall be recorded for each component for CSPs. (i) Exempt from the requirements in this paragraph are sterile preparations compounded in a single lot for administration within seventy-two (72) hours to a patient in a health care facility licensed under section 1250 of the Health and Safety Code.	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments. Staff note that while existing law provides such an exemption, continuation of the current exemption is not appropriate as it hampers the ability of a facility to respond appropriately in the event of a product recall. Staff note that the Chapter requires either the recording of the manufacturers or vendor; however, in separate guidance issued by the FDA, the facility needs to have transparency into the supply chain and awareness of the manufacturer (where the manufacturer and vendor are different.) Staff note that the Chapter provides a limited exemption for CSPs prepared for a single patient for sterile to sterile compounding only.
1736.11(c)(5)	Tommy Mai Huntington Health, CSHP	Rationale: Current compounding practices in Health-System pharmacies have the pharmacist that has direct oversight of compounding, also verifying the final drug preparation. Moreover, requirements needing three different individuals within the sterile compounding space will prove to be difficult for smaller hospitals within California with their limited number of staff. Recommendation: Recommend the Board of Pharmacy clarify the intent of this requirement or consider adding verbiage allowing one person to suffice the requirements of both direct oversight of compounding and verifying final drug preparations.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. Staff note that where the compounding personnel is a pharmacist, there would be no requirement to document a separate pharmacist providing direct oversight, as there is no requirement for a pharmacist to compound under the direct oversight of another pharmacist. Similarly where a pharmacist is performing the compounding, there is no requirement for another pharmacist to perform final verification of the drug preparation.
1736.11(c)(5)	Wendy Waldman Torrance Memorial Medical Center	Rationale: In current compounding practices at health-system pharmacies, the pharmacist overseeing compounding also verifies the final drug preparation. The requirement for three different individuals will present challenges for smaller hospitals in California due to their limited staff. This situation may lead to delays in patient care and have a negative impact on safety. Recommendation: recommend that the Board of Pharmacy clarify the intent of this requirement or consider adding language allowing one individual to fulfill both the requirements of direct oversight of compounding and verifying final drug preparations.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. Staff note that where the compounding personnel is a pharmacist, there would be no requirement to document a separate pharmacist providing direct oversight, as there is no requirement for a pharmacist to compounding under the direct oversight of another pharmacist. Similarly where a pharmacist is performing the compounding, there is no requirement for another pharmacist to perform final verification of the drug preparation.

1736.11(c)(5)	John Gray Kaiser Permanente	The term “direct oversight” is vague. Conversely, “Direct supervision and control,” is a defined term in the Pharmacy Law. In some facilities, there might be several pharmacists who are engaged in the compounding workflow. We recommend amending the regulation to use the term “direct supervision and control” to make it clear to the regulated public which individuals’ identities should be recorded in the compounding record. The identity of each person performing the compounding, the person ~~that has~~ exercising direct supervision and control over ~~oversight of~~ compounding, and the pharmacist verifying the final drug preparation.	Staff have reviewed the comment and recommend a change to clarify the language to confirm the Board's expectation that the level of supervisions encompasses direct supervision and control.
1736.11(c)(6)	Marie Cottman Pacific Compounding	COMMENT: I outsource endotoxin testing and the calculations are handled by the vendor. How do you define “when applicable”? How can I show calculations that I am not doing? RATIONALE: Vague definition of “when applicable” and the calculations and results are determined by the vendor of the service… Below a certain level is the current standard of practice, not provided the exact level measured or the corresponding calculations, which involve a variety of sample dilutions, measurement, then extrapolation of the levels. This is why labs are registered with the FDA, to ensure the services provided are compliant. As a client using those services, we have neither the expertise nor insight to their proprietary procedures to fully validate the results we are collecting. How far does the BOP expect an RPH to go to validate a vendor? Do we inspect FDA manufacture plants for tablet production? Or commercially available injections? RECOMMENDATION: (6) When applicable, endotoxin ~~level calculations and~~ testing results	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that not all compounding pharmacies use an outside vendor to perform endotoxin testing. In such instances where this is performed by the pharmacy, documentation of the endotoxin levels calculations are necessary. For a pharmacy that outsources the endotoxin testing, the levels calculations would not be applicable.
1736.12(b)	Melanie Horn Sutter Health	Per USP 797, sterility testing and thus validation of method suitability is required to be completed in certain cases for category 2 or 3 CSPs. Modify to indicate that this requirement needs to be met only when applicable to the CSP in question. If applicable, ~~A~~a pharmacist performing or supervising sterile compounding is responsible for ensuring validation of an alternative method for sterility testing is done in compliance with USP Chapter 1223, Validation of Alternative Microbiological Methods and shall receive and maintain documentation of the method-suitability for each CSP formulation for which the alternate method is used.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Staff note that the language applies only if the facility is using an alternate method for sterility testing.
1736.12(b)	John Gray Kaiser Permanente	Sterility testing is required for Category 3 and some Category 2, depending on the assigned Beyond Use Date, CSPs. Because the regulation does not apply to Category 1 and some Category 2 CSPs, we suggest that the regulation be modified to indicate that this requirement needs to be met only when applicable to the CSP in question.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Staff note they believe the commenter is reference Section 1736.12(c). Staff note that the proposed regulations require testing for endotoxins for all nonsterile to sterile testing. Such testing is necessary to ensure that the end product does not contain excessive bacterial endotoxins, which if present, place patients at risk.

1736.12(b)	Scott Brunner Alliance for Pharmacy Compounding	This places the burden of ensuring validation of an alternative method for sterility testing is done in compliance with USP Chapter 1223 on the pharmacist. Validation should be provided by the Analytical Laboratory performing the alternative method and maintained by the pharmacy as part of the compounding record.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Staff note that the language applies only if the facility is using an alternate method for sterility testing.
1736.12(c)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	For Category 2 CSPs that are not sterility tested, it is impractical and would hinder patient care to wait for endotoxin testing to release the CSP. In addition, CSPs that use nonsterile starting components and are not sterility tested only have a 4-day BUD. Typical endotoxin testing would not be available before the end of the BUD.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Staff note that this is currently required in CCR 1751.7(e)(1) for batch-testing. Staff note that endotoxin testing can be performed in house and completed within four hours. Staff note that the proposed regulations are limited to injectable CSPs made from nonsterile components. Staff note that harm has occurred to patients where nonsterile to sterile compounding from a single preparation including decreased blood pressure, shortness of breath, hospitalization, etc.,
1736.13(a)	Melanie Horn Sutter Health	The USP 797 requires that prescription "labeling" include instructions for administration. The labeling versus label is recommended as the requirement based on complexities of including specific administration instructions for sterile compounds directly onto the label. When CSPs are dispensed directly to patients the administration instructions readily available in the USP 797 labeling allows for more accurate and inclusive administration detail. Healthcare facilities labels have significant concern regarding ability to fit the detailed administration procedures. Administration instructions, titrations and medication details often require the additional support of the electronic health record (EHR) system due to complexity and required modification of administration detail. Labels produced cannot be replaced or updated for all corresponding changes to administration instructions. Consider revising a label requirement to reference where to refer to instructions for administration location. 503b provided CSPs from California licensed pharmacies cannot be labeled and furnished with specific instructions for administration beyond "See order" or "refer to electronic health record". **Comment Continued on Next Line.**	Board staff have reviewed the comment and recommend a change to the proposed language to address the comment, in part. Staff note that the route of administration is different then the instructions for administration. Staff further note that the instructions for administration (which the commenter is proposing to delete) is existing language in CCR 1751.2(b).

1736.13(a)	Melanie Horn Sutter Health	**Comment Continued from Previous Line** CCR 1735.4(3) referenced “admixed IV solutions” has been revised to “an admixed CSP”. Since CSPs are all admixed, recommend eliminating the duplicative terminology by removing “admixed.” The scope of the revised terminology is recommended for revision to clearly define the scope of the requirement is for CSPs administered by infusion requiring rates and durations. The broad scope of the required dosage forms sterile CSPs include body cavity irrigations, gravity instilled CSPS, inhaled medications for bronchial inhalation, eye drops, and intrathecal which would be imposed arbitrary or misleading mandatory durations for the CSP to be administered. (a) A CSP label shall include all of the following: (1) Route of intended administration; (2) The solution utilized, if applicable; ~~(3) Instructions for administration;~~ (A) ~~For an admixed CSP~~ For CSPs administered by infusion, the rate of infusion, or range of rates of infusion as prescribed, or the duration for the entire CSP to be administered.	see above.
1736.13(a)	Wendy Waldman Torrance Memorial Medical Center	Rationale: Most health-systems utilize electronic health record (EHR) system that can provide the required label components in readily retrievable format. Not all admixture CSPs are infused. Recommendations: Recommend modifying the language to include: (a) A CSP label shall include all of the following and <u>these can also be readily retrievable from the EHR</u>: (1) Route of intended administration; (2) The solution utilized, if applicable; (3) Instructions for administration; (A) For an admixed CSP <u>that are to be infused</u>, the rate of infusion, or range of rates of infusion as prescribed, or the duration for the entire CSP to be administered.	Board staff have reviewed the comment and recommend a change to the proposed language to address the comment, in part. There is nothing in the proposed regulation text that would prohibit the information from also being available in an EHR.

1736.13(a)	Tommy Mai Huntington Health, CSHP	Rationale: Most health-systems utilize electronic health record (EHR) system that can provide the required label components in readily retrievable format. Recommendations: Recommend updating the regulation to: (a) A CSP label shall include all of the following and <u>these can also be readily retrievable from the EHR</u>: (1) Route of intended administration; (2) The solution utilized, if applicable; (3) Instructions for administration; (A) For an admixed CSP <u>that are to be infused</u>, the rate of infusion, or range of rates of infusion as prescribed, or the duration for the entire CSP to be administered.	Board staff have reviewed the comment and recommend a change to the proposed language to address the comment, in part. There is nothing in the proposed regulation text that would prohibit the information from also being available in an EHR.
1736.13(a)	Rita Shane Cedars-Sinai Also provided at Reg Hearing	Rationale: Most health-systems utilize electronic health record (EHR) system which accurately provides the patient specific order rate, duration of infusion. Requiring a range of rates on the label could cause confusion and result in medication errors if nurses misinterpret the ranges. Rates are updated on an ongoing basis in response to changes in the patient's condition and the EHR is the source of truth for the current rate. The duration may not be specified at the time the CSP is initiated since duration will be based on the patient's response to therapy, e.g. blood pressure changes, determination of infection source, blood glucose, etc. Therefore, instructions for administration may reference the EHR when rate changes are anticipated. Additionally, due to changes in the patient's condition, the rate documented on the label may change by the time the CSP is hung on the pt Recommendations: Recommend updating the regulation to: (a) A CSP label shall include all of the following and <u>these can also be readily retrievable from the EHR</u>: (1) Route of intended administration; (2) The solution utilized, if applicable; (3) Instructions for administration will include the rate and/or reference the EHR which serves as the source of truth for the rate of drug to be infused based on the patient's condition. ~~(A) For an admixed CSP, the rate of infusion, or range of rates of infusion as prescribed, or the duration for the entire CSP to be administered.~~	Board staff have reviewed the comment and recommend a change to the proposed language to address the comment, in part. There is nothing in the proposed regulation text that would prohibit the information from also being available in an EHR. Staff note that the route of administration is different then the instructions for administration. Staff note that not all health care facilities have EHRs that are linked to infusion pump systems.
1736.13(a)(2)	Scott Brunner Alliance for Pharmacy Compounding	Clarify what this means.	Board staff have reviewed the comment and are recommending a change to the propsoed text to clarify the requirement if the CSP is administered by infusion.

1736.13(a)(2)	Marie Cottman Pacific Compounding	COMMENT: Having a “shall” requirement for the label to indicate the solution in the CSP may not be practical to achieve in some situations. RATIONALE: Not all CSPs are simple solutions that can be detailed on the label. IV admixtures are often simply D5 or NS and can be listed. However eyedrops can be complex mixtures of solvents, lubricants, stabilizers, salts, buffers, and pH adjustments. Often, these are labeled as “aqueous” for water based or “emulsion” for oil in water solutions, or “in oil”. This amount of detail on the label should be a point of discretion by the RPH to reflect, as practically as possible, information sufficient for the end user (patient, provider, etc). RECOMMENDATION: a) A CSP label ~~shall~~ should include all of the following: (1) Route of intended administration;(2) The solution utilized, if applicable;	Board staff have reviewed the comment and recommend a change to the proposed text to address the comment. Staff believe that the label only needs to include the solution if the compounded CSP is administered through infusion.
1736.13(a)(3)(A)	Keck Medicine of USC	Displaying “rate of infusion, or range of rates of infusion” is not feasible to accomplish in many contemporary electronic medical record (EMR) systems. Specifically, this would not be possible in cases where a CSP infusion intended to be titrated per institutional nursing protocol per provider order. For example, in Oracle Cerner EMR the required order elements include the initial rate, titratable units, titration frequency, subjective titration goal, and maximum rate of infusion. In these cases, the “rate” that is generated on the label states “As Directed”, and the order details are specified in the EMR. This practice meets patient safety recommendations outlined in The Joint Commission elements of performance (MM.04.01.02). It is a safer practice to maintain those elements in the EMR to make the most up-to-date information available to the administering nurse in real time. In acute care settings where provider orders frequently change, the source of truth regarding medication rates must remain as the EMR (not the printed label). This requirement will impose major operational challenges for health-system pharmacies to develop processes for manual modification of labels, and therefore increase risk of errors and adverse impact on patients. Recommendation: This new proposal is not aligned with CMS-approved accreditation agency standards for patient care and not feasible to achieve with some, of not all of the current EMR systems. It will likely result in higher risk of medication errors and adversely impact patient care. Recommend to revise as follows: “A) For an admixed CSP, the rate of infusion, or range of rates of infusion as prescribed (unless the infusion rate is specified in a shared electronic medical record system), or the duration for the entire CSP to be administered.”	Board staff have reviewed the comment and recommend a change to the proposed language to address the comment, in part. There is nothing in the proposed regulation text that would prohibit the information from also being available in an EHR. Staff note that the route of administration is different then the instructions for administration. Staff note that not all health care facilities have EHRs that are linked to infusion pump systems.
1736.13(a)(4)	Jasmine Parker Pacific Compounding	COMMENT: Having one pharmacy put another pharmacy's name on its product label can create confusion regarding accuracy and liability. RECOMMENDATION: (4) Name of compounding facility and dispensing facility (if different).	Board staff have reviewed the comment and do not recommend changes to the proposed regulations. Staff note that this requirement is existing language in CCR section 1735.4(a)(1).

1736.14(a)(1-3)	Jasmine Parker Pacific Compounding	COMMENT: This uses USP language for extended BUDs beyond and applies it to any compounded preparation. This will block the ability for any custom compounding, there is no way for there to be data regarding every possible formulation of CSP. RECOMMENDATION: Remove regulation.	Board staff have reviewed the comment and do not recommend changes to the proposed text. Staff note the distinction between USP requirements and the proposed regulation is merely that the BUD shall not extend beyond the literature. The Board's regulation text establishes a requirement for the professional to follow the limitations when documents in assigning a BUD as opposed to only considering the information as required in USP. Staff notes that the USP compounding already requires relianace upon studies.
1736.14(a)(2)	Rheta Silvas Kaweah Health	Recommend revise the proposed language as follows – A CSP's beyond-use date (BUD) shall not exceed: (2) The compatibility and degradation of the container-closure system with the finished preparation (e.g., possible leaching, interactions, and storage conditions), <u>where such information is available; and</u>. Rationale – a BUD limit based on the criteria included in the proposed language may be warranted in some sterile compounding settings. In the acute care setting, BUD considerations are largely driven by the reference that supports the sterile compounding process for a specific preparation. Specific information about compatibility and degradation of the container-closure system is not frequently described in the reference.	Board staff have reviewed the comment and do not recommend changes to the proposed text. Staff note the distinction between USP requirements and the proposed regulation is merely that the BUD shall not extend beyond the literature. The Board's regulation text establishes a requirement for the professional to follow the limitations when documents in assigning a BUD as opposed to only considering the information as required in USP. Staff notes that the USP compounding already requires relianace upon studies.
1736.13(a)(4)	Marie Cottman Pacific Compounding	COMMENT: Having one pharmacy put another pharmacy's name on its product has multiple issues regarding accuracy and liability. RATIONALE: Having one pharmacy put another pharmacy's identifying information on the label is problematic. Different registered names, spellings, specific location (basement or clinic). Maybe the compounding pharmacy doesn't know what facility it will ultimately be dispensed by, or what if it changes? Who updates the information? Is it mislabelled? Delays in care and mismatched records. If a pharmacy dispenses something made by another pharmacy, then require that pharmacy to also label the product with identifying information. The burden should be on the dispensing pharmacy, who acquires it, to label it with their information. RECOMMENDATION: (4) Name of compounding facility ~~and dispensing facility (if different)~~.	Board staff have reviewed the comment and do not recommend changes to the proposed regulations. Staff note that this requirement is existing language in CCR section 1735.4(a)(1).

1736.13(b)	Marie Cottman Pacific Compounding	COMMENT: It is Redundant to state they must comply with a regulation that is already required to be compliant with in another section. RATIONALE: It starts with "(a) A pharmacist shall not dispense a prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:" Since, by definition, a compound can only leave a pharmacy under order of a prescription (dispensed), not distributed, then 4076(a) automatically attached to every item made and dispensed. No need to restate the requirement. "Or ready to be dispensed" prevents preparation in anticipation of dispensing. Similarly, 1707.5 defines label requirements for items dispensed to patients. By definition, anything leaving the pharmacy must be dispensed (pursuant a prescription) and meet this requirement. It is unnecessarily redundant here. RECOMMENDATION: Remove regulation	Board staff have reviewed the comment and recommend a change to the proposed regulation text not based solely on this comment. Language recommended by staff would establish a more explicit exemption for a CSP that is administered as specified.
1736.13(b)	Tommy Mai Huntington Health, CSHP	Rationale: Currently, a health facility, as defined in Section 1250 of the Health and Safety Codes, are exempt from patient centered label requirements. Recommendations: To be consistent with current regulations, recommend adding exemption language to the current proposed language for HSC 1250 (a) licensed facilities as the administration of compounded medications to patients are done by health care personnel authorized to administer medications and not dispensed for outpatient use. CCR 1736.13 Labeling subsection (b): (b) Any CSP dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5. (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.	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.

1736.13(b)	Wendy Waldman Torrance Memorial Medical Center	Rationale: Currently, a health facility, as defined in Section 1250 of the Health and Safety Codes, are exempt from patient centered label requirements. Recommendations: To align with current regulations, it is recommended to include exemption language in the proposed language for HSC 1250 (a) licensed facilities. This is because compounded medications are administered to patients by authorized healthcare personnel and are not dispensed for outpatient use. CCR 1736.13 Labeling subsection (b): (b) Any CSP dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5. (i) Exempt from this requirement are health facilities, as defined in Section 1250 of the Health and Safety Code, if the prescriptions are administered by a licensed health care professional.	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.
1736.14 **not correct section**	Marie Cottman Pacific Compounding	COMMENT: Redundant of USP <1163> RATIONALE: As stated above in 1736.17(a)(1) requiring compliance with USP<1163> that also states Is the intent of this to be more restrictive than USP <1164> by excluding the option for "an extrapolation of above based on professional judgment"? RECOMMENDATION: Remove regulation.	Board staff have reviewed the comment and do not recommend change in the proposed regulation text. Staff note that the Chapter requires the information to be available in USP 1163. Staff does not believe there is any redundancy in the proposed regulation text and the referenced USP Chapter 1163.
1736.14(a)(1)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	Components such as pH adjusters should be excluded from impacting the BUD of the formulation. These are typically made fresh, used, and disposed of. If the pharmacy were to document a 1-day BUD for the pH adjuster then this language as written would cause the final preparation to have a 1 day BUD. Recommend aligning with USP's approach to exclude pH adjusters from the determination of the BUD.	Board staff have considered the comment and recommend a change to the proposed language as it is consistent with appropriate compounding practices.
1736.14(c)	Scott Brunner Alliance for Pharmacy Compounding	Sterility testing can take more than 2 weeks for results to be reported., and patients may need access to the compounded preparations before testing results are available. Restricting formulations to release after testing creates a situation where patients could be denied a medication if testing cannot be performed fast enough to prevent suffering or patient harm.	Board staff have reviewed the comment and do not recommend a change to the proposed language. Staff note that existing law, CCR 1751.7(e)(1) , generally establish a similar requirement. Staff note that the sterility testing is required in the Chapter as part of the establishment of a BUD for the compounded preparation
1736.14(c)	National Community Pharmacists Association (NCPA)	Sterility testing can take more than 2 weeks for results to be reported. USP removed the requirement for these results to be reviewed before the release of a CSP as long as proper recall procedures were in place. With the new BUDs being so short, patients would have very little time to use their CSPs before they would expire. In some situations patients will experience harm or suffering from delays in treatment. Hospitals cannot receive all endotoxin and sterility results before furnishing CSPs to patients in all situations.	Board staff have reviewed the comment and do not recommend a change to the proposed language. Staff note that existing law, CCR 1751.7(e)(1) , generally establish a similar requirement. Staff note that the sterility testing is required in the Chapter as part of the establishment of a BUD for the compounded preparation

1736.14(c)	John Gray Kaiser Permanente	Sterility and/or endotoxin testing are not required for all CSPs. Therefore, the regulation should be modified to indicate that this requirement needs to be met only when applicable to the CSP in question.	Board staff have reviewed the comment and recommend a change in the proposed text to clarify the requirement. Staff note that testing is not required in all situtation. Rather testing is required consistent with USP requirements and for nonsterile to sterile compounding. Board current regulations and the proposed text require test results be received and reviewed by to furnishing the CSP.
1736.14(c)	Marie Cottman Pacific Compounding	COMMENT: Are you intending for this to apply to ALL CSPs? Currently, not all CSPs require this testing. This is an impractical requirement that will prevent all hospital, home infusion, and retail compounding from happening in a timely manner. RATIONALE: This restricts all CSP compounding, even hospital IV Add mixtures and TPNs to performing sterility and endotoxin tests prior to dispensing. By definition, sterile to sterile do not require this in 797, but this would be more restrictive. If a result does not have an established acceptable limit, such as endotoxins for eye drops or for sterile topical applications, then one cannot even comply with this requirement. RECOMMENDATION: Delete and rewrite to achieve the desired regulatory oversight goals.	Board staff have reviewed the comment and recommend a change in the proposed text to clarify the requirement. Staff note that testing is not required in all situtation. Rather testing is required consistent with USP requirements and for nonsterile to sterile compounding. Board current regulations and the proposed text require test results be received and reviewed by to furnishing the CSP.
1736.14(c)	Philip Smyth Medisca	Sterility testing can take more than 2 weeks for results to be reported. USP removed the requirement for these results to be reviewed before the release of a CSP as long as proper recall procedures were in place. With the new BUDs being so short, patients would have very little time to use their CSPs before they would expire.	Board staff have reviewed the comment and recommend a change in the proposed text to clarify the requirement. Staff note that testing is not required in all situtation. Rather testing is required consistent with USP requirements and for nonsterile to sterile compounding. Board current regulations and the proposed text require test results be received and reviewed by to furnishing the CSP.
1736.14(c)	Melanie Horn Sutter Health	Per USP 797, endotoxin testing, and sterility testing are required to be completed in certain cases for category 2 or 3 CSPs. Modify to indicate that this requirement needs to be met only when applicable to the CSP in question If applicable, p~~P~~rior to furnishing a CSP, the pharmacist performing or supervising sterile compounding is responsible for ensuring that sterility and endotoxin testing for BUD determination is performed and has received and reviewed the results. Results must be within acceptable USP limits. Test results must be retained as part of the compounding record.	Board staff have reviewed the comment and recommend a change in the proposed text to clarify the requirement. Staff note that testing is not required in all situtation. Rather testing is required consistent with USP requirements and for nonsterile to sterile compounding. Board current regulations and the proposed text require test results be received and reviewed by to furnishing the CSP.
1736.14(c)	Wendy Waldman Torrance Memorial Medical Center	Rationale: According to USP 797, endotoxin and sterility testing must be performed in certain cases for category 2 or 3 compounded sterile preparations (CSPs). Recommendations: To align with the USP 797 recommendations, we suggest the following revision to this section: (c) Prior to furnishing a CSP, the pharmacist performing or supervising sterile compounding is responsible for ensuring that sterility and endotoxin testing (when applicable) for BUD determination is performed and has received and reviewed the results.	Board staff have reviewed the comment and recommend a change in the proposed text to clarify the requirement. Staff note that testing is not required in all situtation. Rather testing is required consistent with USP requirements and for nonsterile to sterile compounding. Board current regulations and the proposed text require test results be received and reviewed by to furnishing the CSP.

1736.14(c)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP	Rationale: Per USP 797, endotoxin testing, and sterility testing are required to be completed in certain cases for category 2 or 3 CSPs. Recommendations: To be consistent with the USP 797 recommendations, we recommend the following revision to this section: (c) Prior to furnishing a CSP, the pharmacist performing or supervising sterile compounding is responsible for ensuring that sterility and endotoxin testing (when applicable) for BUD determination is performed and has received and reviewed the results.	Board staff have reviewed the comment and recommend a change in the proposed text to clarify the requirement. Staff note that testing is not required in all situtation. Rather testing is required consistent with USP requirements and for nonsterile to sterile compounding. Board current regulations and the proposed text require test results be received and reviewed by to furnishing the CSP.
1736.14(c)	UCSF	Comment: • This section could be interpreted that there must be sterility and endotoxin testing done for any BUD determination. • Sterility and bacterial endotoxin testing is usually a send out test, contracted to an outside lab, the process could take up to a week. One example where such practice would cause delay in acute care setting is the compounding of formalin for treatment of persistent hemorrhagic cystitis. Recommendation: recommend modified language below 1736.14 Establishing Beyond-Use Dates. Subsection (c) (c) Prior to furnishing a CSP, the pharmacist performing or supervising sterile compounding is responsible for ensuring that applicable sterility and endotoxin testing for BUD determination is performed per USP and has received and reviewed the results. Results must be within acceptable USP limits. Test results must be retained as part of the compounding record.	Board staff have reviewed the comment and recommend a change in the proposed text to clarify the requirement. Staff note that testing is not required in all situtation. Rather testing is required consistent with USP requirements and for nonsterile to sterile compounding. Board current regulations and the proposed text require test results be received and reviewed by to furnishing the CSP.
1736.16(a)	Marie Cottman Pacific Compounding	COMMENT: Without a definition of “stock solution” it is unclear what provisions must be compliant with. RATIONALE: Does this mean prior to use? Does it have to be sterility testing prior to being used in the final CSP. It is vague and does not provide clarity of what it intended. There’s no definition of “stock solution” If a CSP is made in multiple steps, is each ingredient considered “stock solution”? This is clearly written to address some scenarios, but without being specific on the conditions, it leaves broad interpretation and discretion, which simply creates uncertainty for PICs, difficulty understanding when compliance has been obtained, and a business risk that will further drive owners away from practice and decrease patient access and increase costs. RECOMMENDATION: Discard and rewrite to achieve the desired regulatory oversight.	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that the USP Chapter provides a defintion of compounded stock solution.

1736.17	Scripps Health	Transferring and documentation of items in the ante room and PEC will cause pharmacies to double staffing to take care of this rule alone which will cost 200 to 1,000 to over a million dollar per year.	This generic statement is not sufficiently specific for the Board to evaluate. Board staff are unclear on the scope of the comment. The referenced section relates to the requirement to develop Standard Operating Procedures on their chosen workflow. Should the comment be referring to 1736.17(d), Board staff note that the proposed regulation text requires the facility to develop a policy, providing flexibility to the facility to determine how to operationalize their SOP. Absent additional information to support the claim, Board staff are unclear how the development of the SOP could result in a doubling of staff and a cost of over $1,000,000 per year. Chapter 797, Section 8, establishes the requirements for introducing items into the secondary engineering control and primary engineering control. The Board is not establishing any requirements above what the Chapter provides. It may be helpful for the commenter to describe how the development of an SOP could result in over a $1,000,000/annually and a doubling of staff. Of note, staff believe that in the prior version of Chapter 797, there was already a requirement to have a process in place, similar to what the Board's proposed regulation text is requiring.
1736.17(a)	John Gray Kaiser Permanente	We recommend that this SOP requirement be deleted because it is duplicative with the rest of the article and USP Chapter 797. Specifically, the methods by which the supervising pharmacist will ensure the quality of CSPs will be to comply with the requirements of the regulation and USP 797. Not all facilities that compound CSPs handle infectious materials. The facility's SOPs should only be required to address the handling, compounding, and disposal of infectious materials if the facility handles infectious materials. (a) Standard operating procedures (SOPs) for sterile compounding shall be followed and shall: ~~(1) Comply with USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding; and~~ ~~(2) Define the following:~~ ~~(A) Methods by which the pharmacist compounding or supervising the compounding will ensure the quality of compounded drug preparations;~~ ~~(B) If applicable,~~ the Pprocedures for handling, compounding, and disposal of infectious materials. The SOPs shall describe the facility protocols for cleanups and spills in conformity with local health jurisdictional standards;	Board staff have reviewed the comment and recommend changes to the proposed regulation text related to infection materials. Further, Board staff note that Initial Statement of Reasons documents the basis for inclusion of USP Chapter 1163, Quality Assuance in Pharmaceutical Compounding. Business and Professions Code section 4126.8, establishes compliance with pharmacy compounding chapters.

1736.17(a)(1)-(2)	Melanie Horn Sutter Health	The USP 797 chapter provides relevant quality assurance requirements, listing required Compounding SOPs and including referencing USP chapter 1163; therefore, including a requirement for facilities' Standard Operating Procedures (SOP) to comply with all elements of USP chapter 1163 is duplicative versus prescriptive as a standard. Recommend that this SOP requirement be deleted because it is duplicative with the rest of the article and USP Chapter 797. Specifically, the methods by which the supervising pharmacist will ensure the quality of CSPs will be to comply with the overall quality assurance and quality control standards outlined in the regulation and within the USP 797 chapter. Not all facilities that compound CSPs handle infectious materials. The facility's SOPs should only be required to address the handling, compounding, and disposal of infectious materials if the facility handles infectious materials. (a) Standard operating procedures (SOPs) for sterile compounding shall be followed and shall: ~~(1) Comply with USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding; and~~ (2) Define the following: ~~(A) Methods by which the pharmacist compounding or supervising the compounding will ensure the quality of compounded drug preparations;~~	Board staff have reviewed the comment and recommend changes to the proposed regulation text related to infection materials. Furhter, 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.
1736.17(a)(2)(C)	Melanie Horn Sutter Health	Automated workflow systems utilizes barcode scanning and often additional image capture to validate accurate ingredient components before allowing technicians to proceed with compounding without requiring pharmacist advance determination. Recommend revising the statute language to support automated workflows with technology and the pharmacist ability to determine and approve during the duration of the process can be captured, even after compounding has begun. The methods a pharmacist will use to determine and approve the ingredients and the compounding process for each preparation ~~before compounding begins~~;	Board staff have reviewed the comments and do not recommend a change to the proposed text. Staff note that this is consistent with the board's current regulation requirements in the SOP, CCR 1751.3(a)(22). The Board understands automation typically require some sort of confirmation step before compounding begins. These methods could be documented in the SOPs.
1736.17(a)(2)(C)	Wendy Waldman Torrance Memorial Medical Center	Rationale: Many health systems currently use IV room workflow systems with barcode scanning to verify components before allowing technicians to proceed with compounding. Additionally, due to pharmacy recruitment challenges, it would be difficult for health systems to conduct manual individual checks for a large number of CSPs before and after compounding. This adds an addition step that does not add any safety components. Recommendations: The methods a pharmacist will use to determine and approve the ingredients and the compounding process for each preparation before compounding begins; (i) A sterile compounding workflow system may be utilized for verification of correct components used for preparing a CSP.	Board staff have reviewed the comments and do not recommend a change to the proposed text. Staff note that this is consistent with the board's current regulation requirements in the SOP, CCR 1751.3(a)(22). Further, staff note that not all technology solutions are the same. The Board understands automation typically require some sort of confirmation step before compounding begins. These methods could be documented in the SOPs.

1736.17(a)(2)(c)	Tommy Mai Huntington Health	Rationale: Many health-systems currently utilize IV room workflow system that utilizes barcode scanning to check for correct components before allowing technicians to proceed with compounding. Moreover, with pharmacy recruitment issues, it would become challenging for health-systems to provide manual individual checks for a large number of CSPs. Recommendations: The methods a pharmacist will use to determine and approve the ingredients and the compounding process for each preparation before compounding begins; (i) A sterile compounding workflow system may be utilized for verification of correct components used for preparing a CSP.	Board staff have reviewed the comments and do not recommend a change to the proposed text. Staff note that this is consistent with the board's current regulation requirements in the SOP, CCR 1751.3(a)(22). Further, staff note that not all technology solutions are the same. The Board understands automation typically require some sort of confirmation step before compounding begins. These methods could be documented in the SOPs.
1736.17(a)(2)(D)	Rheta Silvas Kaweah Health	Recommend: strike or clarify the proposed language so the intent is clear. Rationale – the language is ambiguous. SOPs have many requirements. It would be challenging to specify a method for complying with all the requirements of the SOP. Seeking to better understand the intent and expectation with practical examples.	Board staff have reviewed the comments and do not recommend changes to 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.
1736.17(d)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health	Rationale: Pharmacist/Health-systems have SOPs that define the product used, dwell time (based on manufacturer data), and how staff are monitoring and observations to determine compliance. Requiring documentation for the frequency and quantity of items entering a sterile compounding area in hospital settings or PEC, will adds a significant burden to the workload of sterile compounding staff which could increase the risk of causing an error in compounding. Recommendation: d) The SOPs shall specify the process and products to be used on any equipment and other items entering from an unclassified area into the clean side of the anteroom, entering a PEC and entering the SCA. These SOPs must define at a minimum what product is to be used, the dwell time required, and how dwell time will be monitored~~. and documented.~~	Board staff have reviewed the comments and do not recommend a change to the proposed text. Staff note that this is consistent with the board's current regulation requirements in the SOP, CCR 1751.3(a)(22). Further, staff note that not all technology solutions are the same. The Board understands automation typically require some sort of confirmation step before compounding begins. These methods could be documented in the SOPs.
1736.17(d)	Narinder Singh Santa Clara Valley Healthcare (SCVH)	Recommend language change to category of cleaning agents instead of what the product is	Board staff have reviewed the comment and do not recommend a change. Staff note that the SOP must be specific to ensure consistency amoung all staff perfoming the task.
1736.17(d)	Wendy Waldman Torrance Memorial Medical Center	Rationale: In many health systems, numerous items enter the sterile compounding spaces, including the PEC. Requiring documentation of monitoring dwell time adds a significant burden to the workload of sterile compounding staff, which could increase the risk of errors in compounding. Recommendation: d) The SOPs shall specify the process and products to be used on any equipment and other items entering from an unclassified area into the clean side of the anteroom, entering a PEC and entering the SCA. These SOPs must define at a minimum what product is to be used, the dwell time required, and how dwell time will be monitored~~. and documented.~~	Board staff have reviewed the comments and do not recommend a change to the proposed text. Staff note that this is consistent with the board's current regulation requirements in the SOP, CCR 1751.3(a)(22). Further, staff note that not all technology solutions are the same. The Board understands automation typically require some sort of confirmation step before compounding begins. These methods could be documented in the SOPs.

1736.17(d)	CSHP	Rationale: In many health-system pharmacies there are many items entering the sterile compounding spaces including into the SEC and PEC. Requiring monitoring and documentation of the monitoring of the dwell time for each individual item adds a significant burden to the workload of sterile compounding staff. It will take them away from performing the work of compounding medications for acutely ill patients and will further contribute to the potential for increased compounding while providing no demonstratable benefits. In practice, this requirement could be interpreted that the wiping and dwell time of medication and related sterile compounding items such as syringes, needles etc. sterile isopropyl alcohol be individually timed and documented when introduced to the PEC for sterile compounding. We suspect that the intent of this regulation is for SOPs to sufficiently address documentation and following manufacturer recommended dwell times as part of sterile compounding practice and wish to point out the potential for misinterpretation during enforcement inspections. Recommendation: d) The SOPs shall specify the process and products to be used on any equipment and other items entering from an unclassified area into the clean side of the anteroom, entering a PEC and entering the SCA. These SOPs must define at a minimum what product is to be used~~, the dwell time required, and how dwell time will be monitored. and documented.~~	Board staff have reviewed the comments and do not recommend a change to the proposed text. Staff note that this is consistent with the board's current regulation requirements in the SOP, CCR 1751.3(a)(22). Further, staff note that not all technology solutions are the same. The Board understands automation typically require some sort of confirmation step before compounding begins. These methods could be documented in the SOPs.
1736.17(g)	Scott Brunner Alliance for Pharmacy Compounding	The statement “validated processes” is unclear and undefined. What does the Board consider to be a validated process? Temperature mapping, thermal mapping, or must standardized tests be used (International Safe Transit Association standards 3A, 20, 7D and 7E or the ASTM International Standard D3103)?	Board staff have reviewed the comment and do not recommend any changes to the proposed regulations. Staff note that "validated processes" is not used in article 4.6.

1736.18(a)	Melanie Horn Sutter Health	In the Initial Statement of Reasons, the Board references pharmacies are required to meet the requirements of USP Chapter 1163 "per BPC 4126.8." Business and Professions Code section 4126.8 requires pharmacies to compound drug preparations in a manner consistent with "the pharmacy compounding chapters of USP including relevant testing and quality assurance [requirements]." The USP 797 chapter provides relevant quality assurance requirements, including referencing USP chapter 1163; therefore, including a requirement for pharmacies to meet all elements of USP chapter 1163 is unnecessary. The USP 797 chapter addresses temperature monitoring, documentation, and follow-up for areas where CSPs are stored in sufficient detail that requiring a written standard operating procedure would be duplicative. In the Initial Statement of Reasons, the Board claims that this regulation is necessary to "ensure appropriate action will be taken timely should it be needed to ensure patient safety." The Board fails to recognize that existing regulations (e.g. 16 CCR 1714(b)) require all pharmacies to ensure that medications are "safely and properly maintained and secured" and that existing law (e.g. BPC 4084 and 4086) prohibits pharmacies from trading in adulterated drugs. Because the USP 797 Chapter and existing law and regulation require pharmacies to store drugs at the appropriate temperature, the proposed regulation in 1736.18(a)(2) is unnecessary. (a) The quality assurance program shall comply with section 1711 ~~and the standards contained in USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding.~~ In addition, the facility's quality assurance program shall include the following: (1) Aa written procedure for scheduled action, such as a recall, in the event any CSP is discovered to be outside the expected standards for integrity, quality, or labeled strength. ~~(2) A written procedure for responding to out-of-range temperature variations within the medication storage areas where a furnished drug may be returned for furnishing to another patient~~.	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. Further, staff note that in the event of a temperature excursion, the facility has a plan to address the issue.
1736.18(a)	John Gray Kaiser Permanente	In the Initial Statement of Reasons, the Board contends that pharmacies are required to meet the requirements of USP Chapter 1163 "per BPC 4126.8."20 Business and Professions Code section 4126.8 requires pharmacies to compound drug preparations in a manner consistent with "the pharmacy compounding chapters of USP including relevant testing and quality assurance [requirements]."21 The USP 797 chapter already provides relevant quality assurance requirements, including referencing USP chapter 1163; therefore, including a requirement for pharmacies to meet all elements of USP chapter 1163 is unnecessary. The USP 797 chapter addresses temperature monitoring, documentation, and follow-up for areas where CSPs are stored in sufficient detail that requiring a written standard operating procedure would be duplicative. In the Initial Statement of Reasons, the Board claims that this regulation is necessary to "ensure appropriate action will be taken timely should it be needed to ensure patient safety."22 The Board fails to recognize that existing regulations (e.g. 16 CCR 1714(b)) require all pharmacies to ensure that medications are "safely and properly maintained and secured" and that existing law (e.g. BPC 4084 and 4086) prohibits pharmacies from trading in adulterated drugs. Because the USP 797 Chapter and existing law and regulation require pharmacies to store drugs at the appropriate temperature, the proposed regulation in 1736.18(a)(2) is unnecessary. (a) The quality assurance program shall comply with section 1711 ~~and the standards contained in USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding~~. In addition, the facility's quality assurance program shall include the following: ~~(1) A~~a written procedure for scheduled action, such as a recall, in the event any CSP is discovered to be outside the expected standards for integrity, quality, or labeled strength. ~~(2) A written procedure for responding to out-of-range temperature variations within the medication storage areas where a furnished drug may be returned for furnishing to another patient~~.	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. Further, staff note that in the event of a temperature excursion, the facility has a plan to address the issue.

1736.18(a)(1)	Marie Cottman Pacific Compounding	COMMENT: Recalls are not scheduled events. RATIONALE: Recalls are not scheduled actions. Remove “scheduled” and simply have “a written procedure for action in the event…” RECOMMENDATION: (a) The quality assurance program shall comply with section 1711 and the standards contained in USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. In addition, the program shall include the following: (1) A written procedure for scheduled action, such as a recall, actions in the event any CSP is discovered to be outside the expected standards for integrity, quality, or labeled strength.	Board staff have reviewed the language and recommend a change to the proposed text based on the comment received to clarify the language as suggested by the commenter.
1736.18(b)	Rheta Silvas Kaweah Health	Recommend: revise the proposed language to include the word “drug” after the word “adverse”. Add to the definition adverse drug event. Rationale: adverse event is a broader term and unlikely the intent of the language.	Board staff has reviewed the comment and 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.
1736.18(b)	Marie Cottman Pacific Compounding	COMMENT: Redundant of other regulations. RATIONALE: Redundant. No need for a regulation that states you must comply with another regulation? RECOMMENDATION: Remove regulation.	Board staff has reviewed the comment and 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.
1736.18(c)	CSHP	Rationale: A requirement of 72 hours may not provide sufficient time for health-systems to investigate and notify the necessary regulatory bodies in cases where it occurs over the holiday weekend. Recommendation: (c) In addition to subsection (b), all complaints made to the facility related to a potential quality problem with a CSP and all adverse events shall be reviewed by the pharmacist-in-charge, or licensed designee, within 3 business days ~~72 hours~~ of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs.	Board staff have reviewed the comment and do not recommend a change to the language based on the the comment related to 72 hours; however Board staff do recommend a change to the language to clarify that the PIC in the event the PIC is not available, another designated person must complete the review.
1736.18(c)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	Adverse events are expected as a potential occurrence with the use of a drug and may not represent a quality related problem with the compounded medication. As written the board will have to hear about every adverse effect related to a CSP whether or not it is related to the quality of the CSP. This type of reporting may drown out the times that the board needs to be aware of a CSP that has a quality problem. Suggest that this be changed to have the reporting occur when the adverse drug event is related to a quality problem and is not an adverse event that is generally expected to occur with the use of the drug. Pharmacies should investigate potential quality problems. We advise that the pharmacy must initiate an investigation with 72 hours of receipt of a complaint of a potential quality problem, and must notify the Board in writing with 15 days of the receipt of complaint.	Board staff have reviewed the comment and do not recommend a change to the language based on the the comment related to 72 hours; however Board staff do recommend a change to the language to clarify that the PIC in the event the PIC is not available, another designated person must complete the review.

1736.18(c)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health	Rationale: A requirement of 72 hours may not provide sufficient time for health-systems to investigate and notify the necessary regulatory bodies in cases where it occurs over the holiday weekend. Recommendation: (c) In addition to subsection (b), all complaints made to the facility related to a potential quality problem with a CSP and all adverse events shall be reviewed by the pharmacist-in-charge within 3 business days ~~72 hours~~ of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs.	Board staff have reviewed the comment and do not recommend a change to the language based on the the comment related to 72 hours; however Board staff do recommend a change to the language to clarify that the PIC in the event the PIC is not available, another designated person must complete the review.
1736.18(c)	Keck Medicine of USC	Comment: The requirement, as written, would not allow the PIC to be away from the pharmacy for more than a 72-hour period. This is not a reasonable standard, both from a patient safety and humanistic perspectives. Recommendation There should be an option for a designated pharmacist to perform the duty. For example: "(c) In addition to subsection (b), all complaints made to the facility related to a potential quality problem with a CSP and all adverse events shall be reviewed by the pharmacist-in-charge or designated pharmacist within 3 business days of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs."	Board staff have reviewed the comment and do not recommend a change to the language based on the the comment related to 72 hours; however Board staff do recommend a change to the language to clarify that the PIC in the event the PIC is not available, another designated person must complete the review.
1736.18(c)	Rheta Silvas Kaweah Health	Recommend: revise the proposed language to include the word "drug" after the word "adverse". Add to the definition adverse drug event. Rationale: adverse event is a broader term and unlikely the intent of the language.	Board staff has reviewed the comment and recommend changes to the proposed regulation text to align with the federal definition of "drug experience".
1736.18(c)	Wendy Waldman Torrance Memorial Medical Center	Rationale: A 72-hour requirement may not provide sufficient time for health systems to investigate and notify the necessary regulatory bodies if an incident occurs over a holiday weekend. Recommendation: (c) In addition to subsection (b), all complaints made to the facility related to a potential quality problem with a CSP and all adverse events shall be reviewed by the pharmacist-in-charge within 3 business days ~~72 hours~~ of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs.	Board staff have reviewed the comment and do not recommend a change to the language based on the the comment related to 72 hours; however Board staff do recommend a change to the language to clarify that the PIC in the event the PIC is not available, another designated person must complete the review.

1736.19	Marie Cottman Pacific Compounding	COMMENT: Issues of compound stability and container reactivity don't fit this section on transport integrity. RATIONALE: From Wikipedia: "Adsorption is the adhesion[1] of atoms, ions or molecules from a gas, liquid or dissolved solid to a surface.[2]" CSP transport packaging has no effect on the compound adsorption to the container it is in. This is part of container closure considerations. The word should be removed. Contamination and degradation are also components of container closure considerations and should not be included in this section on handling, storage and transportation. RECOMMENDATION: 1736.19 CSP Handling, Storage, Packaging, Shipping, and Transport. In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding. Packaging materials shall protect CSPs from damage, leakage, ~~contamination, degradation, and adsorption~~ while also preventing transportation personnel from inadvertent exposure.	Board staff have reviewed the comment and believe the change to the proposed language as proposed by the commenter is appropriate. Staff are offering recommended language.
1736.20(b)	John Gray Kaiser Permanente	As the proposed regulation is written, any and all records related to compounding CNSPs would be required to include a complete audit trail showing "all revisions and updates." Complying with this requirement would be administratively burdensome, would increase costs associated with document retention (whether electronic or hard copy records), and in some cases is likely to be impracticable based on the capabilities of the software system(s) used to generate and maintain the records. To more appropriately balance the recordkeeping burden with the Board's needs to understand when and by whom documents were edited, we recommend amending the proposed regulation to require pharmacies to maintain an audit trail of changes to policies and procedures and SOPs. Policies and procedures and SOPs required by this article ~~Records created~~ shall be created and maintained in a manner to provide an audit trail for revisions and updates ~~of each record document~~. Prior versions of each ~~record~~ policy and procedure and SOP must be maintained in a readily retrievable format and include the changes to the document, identification of individual who made the change, and the date of each change.	USP Chapter 797 Section 20 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. BPC 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 if a maintained in an electronic format. 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.
1736.21	Marie Cottman Pacific Compounding	COMMENT: As this section applies to Allergenic Extracts, the regulation should be specific in its language and not broadly applied to all sterile compounding. RECOMMENDATION: 1736.21 Compounding Allergenic Extracts. In addition to the requirements in USP Chapter 797, the following requirements apply to sterile allergen compounding.	Board staff have reviewed the comment and recommend changes to the proposed language to clearly indicate that the provisions of this section apply to the compounding of allergenic extracts.

1736.21(a)	Marie Cottman Pacific Compounding	COMMENT: Logically unsound, arbitrary and with no basis in scientific fact. This is nonsensical. To state that no other CSP can be made in a PEC suggests that there is contamination that happens that cannot be remediated. If this is the case, then having allergen extracts made in a horizontal laminar flow hood exposes the entire buffer room to allergen extracts that cannot be remediated, so one should not allow any compounding to happen in a room where any allergen is compounded. Likewise, if they are required to be made in a vertical flow biologic safety cabinet, then it would then presume to have the assumed contamination of garb that a hazardous chemo compound would, where gloves are assumed to be contaminated and changed between chemicals. Thus should not gloves also be changed between compounding. And since garb is presumed to be contaminated and discarded with every use, should not garb with allergens be similarly considered contaminated. And in this logic, if you cannot use a hood where allergens would have been compounded, and the buffer area and gowns are presumed contaminated in hazardous compounding, the same contamination should be assumed in allergen compounding. To prevent exposure to HD chemo patients, who are presumed immunocompromised, that should not the regulations say you cannot use a buffer room used for allergen compounding for any other compounding. And what about cross contamination between allergen patients. If I cannot decontaminate the PEC sufficiently to do compounding of non-allergens, then am I not exposing one allergen patient to another allergen patient's mixture? There is no scientific, measurable, quantifiable assay or data to justify this practice. And, when given that this kind of compounding is routinely done on the counter top in an allergies office, and just recently have they even begun to start training their office clerks on aseptic technique, to put such an onerous, unscientific regulation in practice is irresponsible of the BOP. RECOMMENDATION: Remove.	Board staff have reviewed the comment and do not recommend changes to the proposed text based solely on this comment. Board staff are offering recommended changes to the text as recommended by other comments received related to this section.
1736.21(a)	Wendy Waldman Torrance Memorial Medical Center	Rationale: The new USP 797 chapter mandates that allergenic extracts be compounded in either (1) an ISO Class 5 Primary Engineering Control chamber (PEC) or (2) a dedicated Allergenic Extracts Compounding Area (AECA). Requiring a dedicated PEC for allergenic extracts would result in significant operational and financial burdens. Recommendations: To align with the new USP 797 guidance, it is recommended to revise the language to permit the PEC to be used for other CSPs and not solely for allergenic extracts. CCR 1736.21 Compounding Allergenic Extracts subsection (a): (a) Any allergenic extract compounding shall take place in <u>either a dedicated Allergenic Extracts Compounding Area or a PEC. No other CSP may be made in this PEC at the same time allergenic extract compounding is occurring. Work surface of the PEC must be disinfected immediately after compounding.</u>	Board staff have reviewed the comment and do not recommend changes to the proposed text based solely on this comment. Board staff are offering recommended changes to the text consistent with comments received related to this section.

1736.21(a)	Melanie Horn Sutter Health	The new USP 797 chapter requires that allergenic extracts be compounded in either a 1) ISO Class 5 Primary Engineering Control chamber (PEC), or (2) in a dedicated Allergenic Extracts Compounding Area (AECA). Allergenic extracts are sterile liquids manufactured from natural substances and diluted using sterile preservatives that inhibit microbial growth for extended periods. The requirement to raise the standard for pharmacies by restricting compounding to a dedicated PEC for allergenic extracts would lead to inability for pharmacists to oversee this compounding. These additional requirements impose a significant variance to operational and financial burden for a pharmacy versus physician office compounding not regulated by the board in an AECA. There is no evidence that natural substances sterilized within vial dosage forms when extracted with sterile needles and supplies pose any risk to other nonallergenic extract CSPs. (a) Any allergenic extract compounding shall take place in a dedicated Allergenic Extracts Compounding Area ~~dedicated~~ PEC. No other CSP may be made in this PEC~~.~~ at the same time allergenic extract compounding is occurring. Work surface of the PEC must be cleaned disinfected immediately after compounding.	Board staff have reviewed the comment and do not recommend changes to the proposed text based solely on this comment. Board staff are offering recommended changes to the text consistent with comments received related to this section.
1736.21(a)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP	Rationale: USP 797 requires that allergenic extracts be compounded in either a (1) ISO Class 5 Primary Engineering Control chamber (PEC), or (2) in a dedicated Allergenic Extracts Compounding Area (AECA). To require a dedicated PEC for allergenic extracts may not be feasible for many organizations due to existing facility space constraints Recommendations: To be consistent with the new USP 797 guidance, recommend revising the language to allow the PEC to be used for other CSPs and not just allergenic extracts. CCR 1736.21 Compounding Allergenic Extracts subsection (a): (a) Any allergenic extract compounding shall take place in either a dedicated Allergenic Extracts Compounding Area or a PEC. No other CSP may be made in this PEC at the same time allergenic extract compounding is occurring. Work surface of the PEC must be disinfected immediately after compounding.	Board staff have reviewed the comment and do not recommend changes to the proposed text based solely on this comment. Board staff are offering recommended changes to the text consistent with comments received related to this section.
1736.21(a)	UCSF	Comments: • Requiring a dedicated PEC would potentially constrict pharmacy workflow and displace resources that could cause a delay in patient care where PEC is needed. We ask the board to consider adopting the USP 797 language as is and allow the use of Allergenic Extracts Compounding Area (AECA) for allergenic extracts and BUD determination. Recommendations: recommend modified language below (a). Any allergenic extract compounding shall take place in a dedicated PEC or be compounded in an Allergenic Extracts Compounding Area (AECA). No other CSP may be made in this PEC if allergenic extract is compounded until appropriate cleaning is conducted per regulation or facility SOP.	Board staff have reviewed the comment and do not recommend changes to the proposed text based solely on this comment. Board staff are offering recommended changes to the text consistent with comments received related to this section.

1736.21(a)	Jasmine Parker Pacific Compounding	COMMENT: No basis in scientific fact. RATIONALE: If you can clean a chemo hood and use it to compound other non-chemo products, why are allergens not handled in the same way? RECOMMENDATION: Remove.	Board staff have reviewed the comment and do not recommend changes to the proposed text based solely on this comment. Board staff are offering recommended changes to the text as recommended by other comments received related to this section.
1736.21(b)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP	Rationale: USP 797 requires that allergenic extracts be compounded in either a 1) ISO Class 5 Primary Engineering Control chamber (PEC), or (2) in a dedicated Allergenic Extracts Compounding Area (AECA). Limiting allergen extract compounding conditions to category I or 2 will have a significant financial impact on health-systems to design and construct an SCA or a classified area for allergenic extract compounding. In addition, this proposed law creates an ambiguity if allergen extract compounding will have to follow the BUD of category 1 or 2 which would significantly reduce the BUD that is allowed by USP 797. Recommendations: Recommend the Board of Pharmacy clarify the intent of this requirement or to remove the requirement and to align with USP 797.	Board staff have reviewed the comment and are recommending changes to the paragraph necessary to conform to the changes made in paragraph (a) of this section.
1736.21(a)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding Also provided at Reg Hearing	Compounding of allergenic extracts per USP may be done in a PEC or a dedicated Allergenic Extracts Compounding Area. The PEC is not required to be used only for allergenic extracts. This requirement is onerous and will restrict access of this vital medication therapy.	Board staff have reviewed the comment and do not recommend changes to the proposed text based solely on this comment. Board staff are offering recommended changes to the text consistent with comments received related to this section.
1736.21(b)	Marie Cottman Pacific Compounding	COMMENT: Inconsistent with environmental risk design of USP <797>. RATIONALE: What is the scientific basis for limiting the compounding of one kind of drug to a particular category? The categories are established based on the risk of contamination based on the intensity of environmental controls and monitoring activities, not the ingredients being used in the environment. RECOMMENDATION: Remove and rewrite to achieve desired regulatory oversight.	Board staff have reviewed the comment and are recommending changes to the paragraph necessary to conform to the changes made in paragraph (a) of this section.
1736.21(b)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	Allergenic extracts are in a category of their own, and USP allows up to a one-year BUD after preparation without sterility testing. If pharmacies have to treat them as a category 1 or 2 CSP, the short BUDs will prevent patient access. Additionally, this is more onerous than FDA's approach to compounding these preparations as discussed in their Biologics guidance document.	Board staff have reviewed the comment and are recommending changes to the paragraph necessary to conform to the changes made in paragraph (a) of this section.

1736.21(b)	Melanie Horn Sutter Health	Strike Language. Allergen extract compounding conditions are listed in USP 797 as exempt from the category 1 or 2 dating since they contain significant preservative and pose a limited infection risk in published literature to causing patient harm when kept for durations allowed with USP 797 up to 1 year as listed in allergenic extract package insert dating. Recommend remove the requirement and to align with USP 797.	Board staff have reviewed the comment and are recommending changes to the paragraph necessary to conform to the changes made in paragraph (a) of this section.
1736.21(c)	Marie Cottman Pacific Compounding	COMMENT: As this section applies to allergy extracts, the regulation should be specific in its language. RECOMMENDATION: (c) Any compounded stock allergy solution shall comply with the requirements established in USP Chapter 51, Antimicrobial Effectiveness Testing and the requirement established in USP Chapter 1207, Sterile Product Packaging – Integrity Evaluation related to container closure. A compounding record is required for any compounded stock solution.	Board staff have reviewed the comment and believe a change to the proposed text is appropriate to provide clarity in the regulation as recommended by the commenter.