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

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		Likewise, the pharmacist is not the one that makes the determination that the medication is required, but does document the determination on the prescription.	
1736.1	Assoc of NorCal Oncologists and Medical Oncology Assoc. California Rheumatology Alliance CA Medical Association CalDerm	We are concerned that the proposed regulations will require a pharmacist to be present during these types of activities, which would be an onerous burden on community sites of care, particularly those in rural settings. ANCO and MOASC are concerned that these proposed regulations, if adopted, would result in cancer patients being forced to obtain their chemotherapy at a hospital or infusion center, which would place new burdens on patients who are already fighting for their lives. 1736.1: In addition to the standards set forth in USP Chapter 797 and Food Drug Cosmetic Act (FDCA) section 503a (21 U.S.C. §353a) the following requirements apply throughout this article. This article shall not apply to compounding by or under the direct supervision of a licensed physician and surgeon.	Board staff have reviewed the comment and do not recommend a change to the proposed text based on the comment. Staff note the Board's jurisdiction are individuals and businesses within its practice act. Board staff read the comment as suggesting that the Board's proposed regulations would apply to a physician. Business and Professions Code section 4170(c) makes provides clear statutory reference that the Medical Board of California is specifically charged with the enforcement of Pharmacy Law (Chapter 9, Division 2) with respect to its licensees. Further, Business and Professions section 4111generally establishes prohibitions on individuals that can own a pharmacy. Specifically, 4111(a)(1) prohibits a person or persons authorized to prescribe or write a prescription from owning a pharmacy. It may be appropriate for the commenter to confer with their licensing board to determine in the practice described if the scenario described their comment is allowable. Board staff note that the Medical Board of California has previously provided a written response to individuals inquiring about the applicability of the Board of Pharmacy's regulations to individuals and practices that operate under the jurisdiction of the Medical Board of California. Below is the information provided from the Medical Board - - Dear Ms. Sodergren: I understand that some concerns have been raised by stakeholders about the applicability of the Board of Pharmacy's pending compounding regulations to licensees of the Medical Board of California (MBC). Existing statute (see Business and Professions Code (BPC) section 2220.5) makes it clear that only the MBC can discipline its physician licensees.

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			Whenever a physician is engaging in compounding (or any other action that their medical license authorizes them to perform) they must always do so consistent with the standard of care. For the purposes of MBC's enforcement program, the standard of care is established by expert testimony in the context of the facts and circumstances of a specific case. It is certainly possible that whatever regulations that are implemented by the Board of Pharmacy may influence the standard of care for physicians who are compounding, especially since some of the proposed regulations reflect what is already required for physician compounding under federal law, including, but not limited to, Section 503A of the Federal Food, Drug, and Cosmetic Act (BPC section 2225(b) allows MBC to investigate violations of federal law related to the practice of medicine). Feel free to share this message with others as you see fit who might also be concerned about the applicability of their pending regulations to the physician community. Please contact me if you have any further questions. Sincerely, Reji Varghese
1736.1(b)	John Gray Kaiser Keck/USC	~~*(b) (1) Except as allowed in paragraph (2), CSPs for direct and immediate administration as provided in the Chapter shall only be compounded in those limited situations where the failure to administer such CSP could result in loss of life or intense suffering of an identifiable patient. Any such compounding shall be only in such quantity as is necessary to meet the immediate need of the patient. If not already documented in the patient's medical record, documentation for each such CSP shall also include identification of the CSP, the compounded 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 BUD provisions, the Board has removed the current one hour start time and will instead allow the four-hour start time provided for in the revised USP Chapter. Staff note that the Board's regulations focus on patient safety in all compounding environments. Investigations have revealed that some entities have defaulted to immediate use provisions for all compounded preparations. Staff believe that there are times when, for patient safety, the use of immediate use compounding is appropriate; however, such occurrences should not be a standard practice.

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		~~(2) If the sterile compounding equipment or environment fail(s) to meet any required specification, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering of an identifiable patient. This provision may only be used for 24 hours after such failure(s). All such failures must be documented in accordance with facility's SOP and shall be reported to the BOP within 72 hours.~~ While we acknowledge that this proposed regulation is similar to the existing requirements for immediate use compounding in 16 CCR 1751.8(e), we continue to assert that neither the current regulation nor the proposed regulation are necessary. First, the USP 797 Chapter provides sufficient guidance on the preparation of immediate use CSPs. More importantly, continuing to enforce these requirements will incentivize organizations to shift compounding to non-pharmacy personnel in situations in which immediate use compounding is necessary, Kaiser encourages the Board to delete this proposed regulation and enforce the USP standards for immediate use compounding.	
1736.1(b)(1)	Bobgo1970@gmail.com	Only allows immediate use compounding if "failure to administer such CSP could result in loss of life or intense suffering of an identifiable patient." and in the case of equipment/environment failure. The USP797 has no such requirement. Please remove this requirement.	Staff have considered the comment and note that the language in the proposed text is similar to existing regulation CCR Section 1751.8(e), including the current requirement to document the circumstances causing the immediate need. Staff note that to align with USP BUD provisions, the Board has removed the current one hour start time and will instead allow the four-hour start time provided for in the revised USP Chapter. Staff note that the Board's regulations focus on patient safety in all compounding environments. Investigations have revealed that some entities have defaulted to immediate use provisions for all compounded preparations. Staff believe that there are times when, for patient safety, the use of immediate use compounding is appropriate;

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			however, such occurrences should not be a standard practice.
1736.1(b)(2)	UC San Diego CSHP Cedars-Sinai Torrance Memorial UC Health Alliance for PHY Compounding Kaweah Health	Requiring health-system pharmacies to remedy equipment failures within 24 hours may not be feasible due to a variety of reasons why there could have been equipment failures. Often times, it may take more than 24 hours to remedy. To use outside facility or vendor to provide compounding preparations would still pose a safety risk as they may not be following the health-systems processes and procedures. Given the concerns about potential audits, institutions may hesitate to report issues to the Board of Pharmacy. We urge the Board to embrace a 'Just Culture' framework, which emphasizes accountability and learning over punitive measures. To remove the requirement for immediate use compounding under this provision to be used for 24 hours after such failure(s), and requiring such failures must be documented in accordance with facility's SOP and shall be reported to the BOP within 72 hours. Or (2) If the sterile compounding equipment or environment fail(s) to meet any required specification, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering of an identifiable patient. This provision may only be used for **~~24~~ ~~hours~~ 7 business days after such failure(s). All such failures must be documented in accordance with facility's SOP and shall be available for inspection**. **~~reported to the BOP within 72 hours.~~**	Board staff have reviewed the comment and recommend a change to the proposed text. Board staff note that the proposed text currently would provide a pharmacy (or hospital pharmacy) 24-hours to implement their action plan in the event of an equipment failure. (**Note**: Existing regulations do not include such an allowance.) The intent of the proposed regulation text provides the opportunity to implement a facility's backup plan (as opposed to developing and implementing a backup plan at the time failure). After further consideration of the comment, staff are recommending additional amendment to clarify the provision and extend the allotted time for immediate use compounding to 48-hours. 1736.1(b)(2) If the sterile compounding equipment or environment fail(s) to meet any required specification, **~~after attempts to remediate pursuant to the facility's SOPs are unsuccessful,~~** an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering of an identifiable patient. This provision may only be used for **~~24~~ 48** hours after such failure(s). All such failures must be documented in accordance with facility's SOP and shall be reported to the BOP within 72 hours.
1736.1(d)	Wedgewood Pharmacy	Change terminology "veterinary office" to "veterinary practice". Mobile veterinarians practice in the field, not an office. Eliminate the words "Reasonable quantity". Clauses 1 and 2 of this provision and the phrase "estimated by the prescriber" establish clear	Board staff have conferred with a veterinary expert who indicated that the Board's reference to "veterinary office" is appropriate and consistent with language used in the VMB regulations and GFI #256. Further staff have reviewed the comment related to the day supply included in the proposed text. Staff

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		criteria for the amount of office stock drugs that can be ordered and sold. The prescriber is in the best position to determine based on their practice the amount of drugs that are appropriate. A pharmacy has no reasonable basis to determine what a particular practice may need particularly when the practice is permitted to both administer drugs in office and dispense. Align sterile and non-sterile to the 7-day supply standard. Current language in 1736.1 (d)(2) lists 120 hours.	recommend that the Board extend the provision to the 7-day supply as requested. The following language could be used: 1736.1(d)(2) for furnishing of not more than a 120-hour **7-day** supply for an individual patient, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing;
1736.1(d)(2)	Donald Cottman	As written, it limits the provision of compounds for a vet to furnish to "an individual patient… and documented…prior to furnishing." The furnishing to the office for an individual patient prevents the office from having products available for immediate furnishing, when needed. The "for an individual patient" requirement requires the office to provide a name, then the pharmacy can send it to the office, who could then furnish it to the patient. This is the same as the pharmacy dispensing it themselves to an individual patient. Pharmacy law already allows a pharmacy to send a patient's prescription to the office for the office to then furnish to the patient. This regulation, if that is the intent, would be redundant of existing regulation.	Board staff have reviewed the comment and do not recommend any change to the proposed text based on the comment. Staff note that provisions for office use relate only to veterinary office provisions as specified.
1736.1(e)(1)	Alliance for PHY Compounding Wedgewood Pharmacy	There is no accommodation for veterinary compounds, which are regulated under different provisions of federal law. A reference should be made to the appropriate guidance, and a section should be added to allow for compounded preparations being sold for veterinary office use where the API appears on the lists of approved or under consideration APIs for veterinary use. The final compounding regulations should reference GFI #256 where it applies to animal drug compounders.	Board staff have reviewed the comment and do not recommend a change to the proposed text based on the comment received. Board staff note that the provisions related to veterinary compounding are provided in 1736.1(e)(2). Staff note a recommendation to include reference to the GFI in section 1736.1(e)(2). (See below)

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1736.1(e)(2)	Alliance for PHY Compounding Wedgewood Pharmacy	As written, this eliminates the compounding of drugs for animals from API because AMDUCA does not address this. The statement says that it must be specifically allowed under AMDUCA, and AMDUCA does not address this topic. California should align with FDA GFI 256 in their approach to animal compounding to maintain patient access. The phrase "not suitable for use in the intended veterinary population" is ambiguous and unnecessary. If a drug or excipient is toxic to a specific animal population, professional judgment and existing pharmacy practice standards already preclude its use. The reference to AMDUCA in this context is also problematic. AMDUCA permits the off-label use of FDA-approved human and animal drugs in veterinary patients but does not address compounding or bulk drug substances. The law neither explicitly allows nor prohibits compounding from bulk drug substances, and its inclusion in the regulation creates unnecessary confusion. FDA's Guidance for Industry 256 allows for the use of bulk drug substances in compounded animal medications when there is a clinical rationale, but this guidance is not a law or regulation restricting such practices. Recommend removing the reference to AMDUCA or revising the regulation to explicitly protect the ability to compound using bulk drug substances.	Staff note that the suggestion to incorporate GFI #256 was reviewed by staff and an external expert. Board staff are recommending the following change to the proposed regulation text to incorporate reference to GFI #256. 1736.1(e)(2) Is made with any component not suitable for use in a CNSP for the intended veterinary population, unless allowable under the Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA). **When a veterinarian, acting within a valid veterinarian-client-patient relationship (VCPR), determines there is no medically appropriate human or animal drug that is FDA-approved, conditionally approved, or indexed to treat the animal a pharmacy may use a bulk drug substance to compound an animal drug. This compounding shall be done in compliance with the Center for Veterinary Medicine Guidance for Industry #256 – Compounding Animal Drugs from Bulk Drug Substances issued August 2022.**
1736.1(e)(3)	Alliance for PHY Compounding	In some cases, starting with the non-sterile component would be more appropriate (excipients in the conventionally manufactured product, tonicity, concentration). Depending on batch size and compounding set-up, using a conventionally manufactured sterile product as opposed to bulk ingredients could cause more sterility issues and potency variability among units prepared (e.g., exponentially increased manual manipulations by repetitively entering vials or bags to transfer a portion of liquid to the finished preparation increases the potential for contamination and variability as these processes	Board staff have reviewed the comment and recommend a change to the proposed regulation text to provide flexibility for a pharmacist to use their clinical judgment to determine which USP Category the CSP must be prepared under. A pharmacist, using their professional clinical judgment will be responsible for determining the USP category. The below text could be used.

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		are primarily manual.) Additionally, starting with nonsterile ingredients already shortens the BUD of the final product. Does "conventionally manufactured" mean commercially available? APC recommends allowing for compounding with non-sterile starting ingredients outside of full Category 3 requirements or shortages when it makes more sense for the product to be compounded with API rather than finished form injectable products.	1736.1(e)(3) Is made with a non-sterile component for which a conventionally manufactured sterile component is available ~~and appropriate for the intended CSP~~, unless the CSP master formula supports such use and is appropriate for the intended CSP ~~is compounded in full compliance with USP 797 Category 3 requirements, or the conventionally manufactured sterile component appears in an American Society of Health-System Pharmacists (ASHP) or FDA Drug Shortages Database.~~
1736.1(e)(3)	Donald Cottman	This regulation will completely exclude licensed pharmacies, typically smaller ones, from the ability to provide compounding in an environment that have been accepted as a standard of practice, have been implemented in compliance with those standards, and have established patient populations dependent on access to their services. To suddenly have these pharmacies and their compounds be excluded from serving patients is a grave injustice to pharmacy owners, California prescribers, and California patients. Additionally, to state that a non-sterile to sterile preparation can be made as a category 2 if it is in shortage, but not at other times is illogical with respect to protecting the public. If it is not safe for a licensed pharmacy to prepare a particular non-sterile to sterile product in a Category 2 environment on a routine basis, why is it suddenly acceptable for the public to get it from them during a shortage? The Board should decide that it is either appropriate, or not appropriate, for non-sterile to sterile compounding to be performed under USP Category 2 conditions. Commenter cannot understate the extreme hardship this regulation would impose on licensed pharmacies to the detriment it represents to California patient access to medications.	Board staff have reviewed the comment and recommend a change to the proposed regulation text to provide flexibility for a pharmacist to use their clinical judgment to determine which USP Category the CSP must be prepared under. A pharmacist, using their professional clinical judgment will be responsible for determining the USP category. The below text could be used. 1736.1(e)(3) Is made with a non-sterile component for which a conventionally manufactured sterile component is available ~~and appropriate for the intended CSP~~, unless the CSP master formula supports such use and is appropriate for the intended CSP ~~is compounded in full compliance with USP 797 Category 3 requirements, or the conventionally manufactured sterile component appears in an American Society of Health-System Pharmacists (ASHP) or FDA Drug Shortages Database.~~
1736.1(e)(4)	Alliance for PHY Compounding Wedgewood Pharmacy	This would prevent the use of e-beam or gamma-irradiation sterilization methods, which are performed off-site at validated facilities. Can the board demonstrate the harm caused to patient care by offsite sterilization?	Staff have reviewed the comment and do not recommend any changes to the proposed regulation text. Staff note that on September 25, 2019, this issue was raised. At that time, counsel advised members that "based on her research of

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		Recommendation: E-beam sterilization is an FDA approved process. It is recognized and accepted by international standards organizations, and should be allowed.	503A subdivision (a) (1), the federal exemption applies to a state licensed pharmacy that exempts the pharmacy from the manufacturer requirements when compounding. Business and Professions Code sections 4127 and 4127.1 specifically reference the compounding has to occur in a sterile compounding pharmacy – a singular pharmacy – and the license is not transferable thereby emphasizing all compounding exempted under the federal law that can occur in a compounding pharmacy has to occur in a single licensed facility." Board counsel added at that time there are no statutory exemptions and would expect all aspects of compounding to occur in the single regulated unit.
1736.1(h)	UC San Diego CSHP UC Health	The current health and safety code section 1602.5 states the following: No person shall engage in the production of human whole blood or human whole blood derivatives unless the person is licensed under this chapter and the human whole blood or human whole blood derivative is collected, prepared, labeled, and stored in accordance with both of the following:" The proposed regulation in its current state would cause confusion as it would enforce a law that is not applicable to any human whole blood or human whole blood derivative that is already manufactured by a pharmaceutical company (e.g. Albumin, Factor products, IVIG etc.) Recommend the board to revise the proposed language to provide clarification to state that the regulation does not apply to CSPs made with human blood/derivative that is manufactured by pharmaceutical companies. (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. While Board staff believe the language is clear, submission of the comment suggests otherwise. Board staff are offering language that could further clarify the Board's policy. 1736.1(h) CSPs with human whole blood or human whole blood derivatives shall be produced in compliance with Health and Safety Code section 1602.5. **This shall not apply to the compounding of an FDA- approved human whole blood or human whole blood derivative product.**

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1736.2(b)	Stanford Health Care	**Comment**: It is unclear whether "aseptic qualifications" include hand hygiene and garbing competencies (observational competency and gloved fingertip and thumb sampling) or if it pertains to aseptic technique competencies only. **Recommendation:** To avoid confusion, be more specific with what sterile compounding competencies are transferrable between pharmacy locations or define "aseptic qualifications."	Board staff have reviewed the comment and agree with the commenter that clarification of the language may be appropriate. 1736.2(b) Initial and ongoing aseptic manipulation training and competency documentation shall include the Primary Engineering Control (PEC) type and PEC unique identifier used during the evaluation. Aseptic manipulation competency evaluation and requalification shall be performed using the same procedures, type of equipment, and materials used in aseptic compounding. **Garbing and hand hygiene competencies and A**aseptic ~~**qualifications**~~ **manipulation competencies** from one premises may be used for another premises if all of the following conditions are met: (1) The Standard Operating Procedures (SOPs) required by section 1736.17 related to compounding are identical. (2) The Secondary Engineering Control (SEC) facility designs are sufficiently similar to accommodate the use of the same SOPs. (3) The PECs are of the same type and sufficiently similar to accommodate the use of the same SOPs describing use and cleaning.
1736.2(b)	CSHP	The current USP 797 chapter does not require the PEC unique identifier to be documented for personnel training. Requiring a PEC unique identifier only adds to the additional documentation burden. Recommend the Board consider removing the requirement of "PEC unique identifier". P**roposed Revision:** Initial and ongoing aseptic manipulation training and competency documentation shall include the Primary Engineering Control (PEC) type **and PEC unique identifier** used during the evaluation.	Staff have reviewed the comment. Staff note that the requirement to document would occur once every three to six months. Staff note that the unique identifier is necessary to identify where the competency was performed. Staff note that maintaining the PEC unique identifier provides the facility with the location of the equipment and is consistent with the standard of practice. The language provides flexibility for each facility to determine the PEC unique identifier, e.g. hood 2.
1736.2(d)	UC San Diego Cedars-Sinai Torrance Memorial	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	Board staff have considered the comment and do not recommend changes based on this comment. Staff note that an individual that fails any aseptic manipulation for example can compromise the integrity of the product. Staff note that with the recent changes in the proposed regulation text that

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	UC Health	timeframe would significantly disrupt patient treatment and for jeopardize health-systems ability to operate. Recommendation: (d) Compounding personnel or persons with direct oversight over compounding personnel who fail any aspect of the aseptic manipulation ongoing training and competency evaluation shall not be involved in compounding or oversight of the preparation of a CSP until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs. A person with only direct oversight over personnel who fails any aspect of the aseptic manipulation ongoing training and competency evaluation <u>may continue to provide only direct oversight including performing in-process checks, final verification, and failure of any aspect while applicable aseptic manipulation ongoing training and competency evaluation results are pending</u>. Recommended revisions are underlined in italics for emphasis. While there is no modified text to provide public comment on in this section, public comment was submitted for the proposed changes to the current language with acknowledgment of review by staff but no recommended changes to the proposed text, noting that the current proposed text provides for flexibility in where gloving can occur by stating that the facilities SOPs may define specific processes. Respectfully disagree with staff response, the proposed text as it reads provides flexibility specific to simultaneous donning and doffing in the anteroom. Please reconsider. <u>Rationale:</u> Current language as proposed is in conflict with USP 797 in regards to donning of sterile gloves. See section 3.2 Hand Hygiene (last sentence above Box 4).	was released for the 30-day comment period, provisions were already extended to allow an individual that has failed aspects of aseptic manipulation to continue oversight of compounding for 30-days. This time period was established to allow for retraining and sufficient time to process the results of the retesting. Staff have significant patient safety concerns going beyond the 30-day timeframe for any individual that fails any aspect of the core competencies established in the Chapter to be involved in compounding of sterile compounding preparations. Compounding of CSPs is a high-risk function that if not done appropriately can have dire impacts on patients. Staff note that in adverse event reports it is common that a contributing factor was the training of the staff. Staff highlight that a person with direct oversight over personnel, who fail any aspect competency assessment may continue to provide such oversight for 30 days. Staff note that the comment related to donning and doffing is responded to below in the proposed responses to comments related to 1736.3(c).

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1736.3(a)	Donald Cottman	There is no definition of "potentially contaminating condition" and there is a "shall not allow" requirement. Without a definition, it cannot be determined if compliance has been achieved.	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that "potentially contaminating condition" is the term used in the chapter. A pharmacist, using their professional clinical judgment will be responsible to determine if such a condition exists as specified in the language.
1736.3(c)	Kaweah Health	Recommend: Revise language to read "*With the exception of sterile gloves*, garb shall be donned in an anteroom or immediately outside the segregated compounding area (SCA). *Sterile gloves must be donned in a classified room or SCA.* Donning and doffing garb shall not occur in the anteroom at the same time unless the facility's SOP define specific processes that must be followed to prevent contamination.	Board staff have reviewed the comment and agree with the commenter and that the proposed text should be clarified to avoid confusion. Below is text that could be used. 1736.3(c) **With the exception of sterile gloves, g~~G~~**arb shall be donned in an anteroom or immediately outside the segregated compounding area (SCA). **Sterile gloves must be donned in a classified room or SCA.** Donning and doffing garb shall not occur in the anteroom at the same time unless the facility's SOP define specific processes that must be followed to prevent contamination.
1736.3(d) and (e)	Donald Cottman	What is being affected by this regulation is the prevention of passive-air movement, typically though low in doors, from an ante-room and uncontrolled room air. This requirement would require the ante-room be sealed off from the room air so only the HVAC system would push air into the room (through HEPA filters) and remove air from the room through return ducting. This is contrary to basic design principles of HVAC systems. HVAC systems REQUIRE the ability to have air flow out of the area to accommodate normal variations between the air flowing in from supply and the air leaving by returns. Due to the fluid-dynamics of air flow, these are NEVER in perfect balance and need passive points of overflow. In addition, the point of overpressuring a room's supply relative to its return is so that when the door is opened, the positive pressure pushes air out of the room.	Board staff have reviewed the comment and believe the comments are related to 1736.4 (e). Board staff agree with the commenter that the proposed text requires modification. Board staff believe the subsection can be removed. Staff note that the Chapter addresses many of the different forms of penetration. **1736.4 ~~(e) Except as provided in subsection (d), dynamic interactions between areas and rooms with classified air and unclassified air shall be controlled through a heating, ventilation, and air condition (HVAC) system.~~**

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		The industry standard design, and long standing history of success, and the basic physics of HVAC design REQUIRE passive airflow connections between the cleanroom and the surrounding room air.	
1736.4(c)	John Gray Kaiser Stanford Health Care CSHP Cedars-Sinai Torrance Memorial	Because the proposed regulation is not clear, we suggest that this section of regulation be deleted and that the Board simply enforce the USP standard for the temperature of the compounding suite. USP defines room temperature storage as a temperature range of 20°C to 25°C.	Board staff have reviewed the comment and do not recommend any change to the proposed regulation text. Staff note that CCR 1751.4(k) currently requires that the sterile compounding area in the pharmacy shall have a comfortable and well lighted working environment, which typically includes a room temperature of 20 degrees Celsius or cooler to maintain comfortable conditions. Further, USP Chapter 797, Section 4.2 discusses facility design and environmental controls and notes that in addition to minimizing airborne contamination, sterile compounding facilities must be designed and controlled to provide a well-lighted and comfortable working environment. The Chapter provides that the cleanroom suite should be maintained at a temperature of 20 degrees or cooler and a relative humidity of 60% or below to minimize the risk of microbial proliferation. The Board's current regulation and its proposed language provides flexibility by providing the temperature must typically meet the requirements. This allows for some minor fluctuations, while addressing the necessity established in the Chapter.
1736.4(f)	Torrance Memorial	In smaller rural hospitals, this proposed law in combination with CCR 1736.1 Introduction and Scope. Subsection (b) would lead to severe consequences for patients. For example, if a designated compounding area fails to meet the criteria specified in the law, and hospitals are unable to compound for immediate use, they would have to cease operations as they would not be able to provide appropriate patient care. Recommend the Board of Pharmacy to consider removing the requirement of CCR. 1736.4 subsection (f) and defer to USP 797.	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that compounding facilities must have back-up plans in their SOPs so that in the event of a failure in the compounding environment, to ensure provisions for patient care can continue. This flexibility is established in another section of the proposed regulations allowing for transition to immediate use provisions while implementing the back-up plan. However, staff appreciate the reference to the unique challenges of rural hospitals and believe that

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			a change to 1736.1(b)(3) is appropriate to allow a longer duration of time for immediate use provisions for critical access hospitals. The following text could be used. Additional changes in 1736.1(b)(2) are recommended based on additional comments referenced elsewhere in this document. **1736.1(b)(3) If a critical access hospital, as defined in the Social Security Act 42 U.S.C. 1395i-4, section (c)(2)(B), experiences a sterile compounding equipment or environment failure to meet any required specification, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering of an identifiable patient. This provision may only be used for 120 hours after such failure(s). All such failures shall be documented in accordance with facility's SOP and shall be reported to the Board within 72 hours.**
1736.5(b)	Donald Cottman	The pharmacy cannot control the output of reports from vendors, so having a "shall be recorded on the report" is overly restrictive. It is reasonable to instruct that the PIC shall document what standard the vendor used in preparing the report.	Board staff have reviewed the comment do not recommend changes to the proposed text. Board staff note that a facility, if concerned about this requirement, can make this a condition of the contract with the vendor. Inspector staff have provided education to various vendors performing certifications to underscore the legal requirement to include this information in the report.
1736.6(a)	Kawea h Health	Recommend: modify the language to include the current versioning and application guide title. Allow the public an opportunity to comment after having had an opportunity to review the specific version of the application guide the regulated public will be expected to comply with. Rationale: Proposed language presented for public comment during the 45-day comment period April 19th, 2024 to June 3, 2024 and the modified changes to the proposed language presented for public comment during the 30-day comment period November 8, 2024 to December 9, 2024 did not include the correct versioning or title of CAG-009. CAG-009 version 2020 document	Board staff have reviewed the comment and recommend a change to the proposed text. Staff have confirmed that CAG 009 was most recently revised September 2020. As the proposed regulation text references the incorrect title and wrong month, staff are recommending a change to accurately reflect the title and revision date. 1736.6(a) Environmental sampling shall be done in compliance with Controlled Environment Testing Association's Certification Application Guide USP Viable Environmental **Monitoring for Sterile Compounding Facilities** ~~**Sampling & Gowning Evaluation**~~ (CAG-009, Revised **September** ~~**October 2022**~~ 2020), which is hereby incorporated by reference.

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		is not available for the regulated public to review to determine if compliance can be achieved. The most current version is 2023, the title of the current application guide is Viable Environmental Monitoring for Sterile Compounding Facilities.	
1736.8	Donald Cottman	Having a regulation stating that you must comply with another regulation is redundant. Delete.	recommend a change to the proposed regulation other regulation serves as an important reminder that SOPs are specifically required for introducing
1736.9(d)	Alliance for PHY Compounding	Most excipient components are sold by FDA-registered wholesalers but are not manufactured by FDA-registered facilities. FDA registration is required of manufacturers of food, beverages, dietary supplements, cosmetics, animal and veterinary products, medical devices, drug products, tobacco products, radiation-emiting devices, and biologics. What is meant by "suitable for use in sterile pharmaceuticals?" Additionally, not all wholesalers or repackagers include the original manufacturer name or address on the COA, as they assert that is a trade secret. Trade secrets should be protected under California law. Per the Civil Code, "Trade secret" means information, including a formula, pattern, compilation, program, device, method, technique or process that (1) derives independent economic value, actual or potential, from being generally known to the public or to other persons who can obtain economic value from its disclosure or use, and (2) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy. Some pharmacy vendors maintain that the manufacturers they source API from is a trade secret and disclosure would cause economic injury.	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments. Staff note that both the USP and the FDA have released information to assist pharmacists in determining what is suitable for use in sterile pharmaceuticals when the pharmacist is using professional judgment in making the decision. The FDA has at times released information about contacting the manufacturer of the API to determine its intended use. Pharmacists should similarly consider taking such action. Staff note that the Chapter requires either the recording of the manufacturer or vendor; however, in separate guidance issued by the FDA, it notes that a facility needs to have transparency into the supply chain and awareness of the manufacturer (where the manufacturer and vendor are different.) The FDA has released guidance in this area, including the importance of a compounders knowing your suppliers - - https://www.fda.gov/drugs/human-drug-compounding/fda-compounders-know-your-bulks-and-excipientssuppliers. Lastly, simply identifying the manufacturer of a component does not appear to be requiring the disclosure of a trade secret under Civil Code section 3426.1(d)."
1736.9(d)	Donald Cottman	FDA registered wholesalers consider source provide it directly to pharmacies. Language that	

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		wholesalers that they are willing to provide, under NDA, this information directly to the BOP upon request, would accomplish the same effect and be agreeable to wholesalers.	
1736.9(e)	Alliance for PHY Compounding	21 CFR 216 only includes items on the Final FDA bulks list, and not anything on the interim bulks list (category 1 items). Removal of the ability to use these agents in a CSP will harm California patients who require these medications, and who cannot get them otherwise. Items in FDA's Interim Bulks List 1 are allowed to be used in compounded drug products by the FDA and every other state. They should not have requirements that are different than any other API. Pharmacies must use a grade of API that is appropriate for sterile compounding. Stability studies are not required for other API compounded under Category 1 or 2, and will limit patient access to specialized therapies like inhaled glutathione. There is no point in endotoxin testing API and then also requiring endotoxin testing of the CSP.	Board staff have reviewed the comment and believe the comment is in relation to 1736.17(a)(2)(e). Board staff do not recommend a change to the proposed regulation text based on the comment. Staff believe that the commenter may be misunderstanding some of the language in the proposed regulation. The Board's proposed text will explicitly allow for compounding of certain bulk drug substance under specified conditions. In staff's view the commenter is not correctly characterizing the FDA's Interim Bulks List. The Board strongly encourages all individuals interested in FDA's Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act to read this guidance document in its totality to gain a full understanding of the provisions. The Board has been clear about its intentions to create a legal pathway in California to compound using bulk ingredients on the FDA's Category 1 list. Board staff believes that the language of the proposed text aligns the enforcement discretion articulated by the FDA and also meets the provisions of the USP 797 Chapter through the requirement to develop SOPs that establish provisions for additional testing and evaluation. The FDA has released information that explicitly states there is value in testing. The Board received a presentation that included information about an FDA warning specifically related to glutathione that demonstrated, through subsequent testing of the involved API, that endotoxins of the API caused harm to patients. Testing the API before the use of the API provides a pharmacist with information necessary to use their clinical judgment to determine if the API is in fact appropriate for use in

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			the CSP to be compounded. Endotoxin testing of the API will enable the pharmacist to determine if the API is grossly contaminated and therefore rendered either safe or unsafe through the filtration process.
1736.9(e)(1)	Donald Cottman	There is no definition of what a "public health official" nor "emergency use situation". This allows that person to approve for use in compounding a drug without a monograph, nor having been FDA approved drug, not on on the bulks list… which means this allows a public health official can approve the compounding of an unapproved drug, for a specific patient, upon their definition of an emergency use situation. This does not seem to be in the public's best interest.	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Board staff note that while the regulation itself does not include a definition of "public health official," this term is commonly understood. Board staff further notes that although very rare, there was a prior instance where a child required a compound that was ordered by a public health official to prevent the death of the child. Inclusion of the language will provide assurances to a pharmacist facing such a scenario to provide the compounded medication should such a condition arise in the future.
1736.10	Alliance for PHY Compounding	From USP's General Notices: "General chapters numbered 1000 to 1999 are for informational purposes only. They contain no mandatory tests, assays, or other requirements applicable to any official article, regardless of citation in a general chapter numbered below 1000, a monograph, or these *General Notices.*" Recommendation: USP Chapters above 1000 are for informational purposes only. They **contain no mandatory tests, assays, or other requirements applicable to any article, regardless of citation in a general chapter below 1000**, a monograph or these General Notices. The Board's assertion that it is just listing out all the tests required on API (and other requirements in Chapters above 1000) is untrue. Per USP, these tests are not required, even if they are cited in chapters below 1000. We recommend removing all requirements for pharmacies outlined in the proposed regulations that reference USP chapters above 1000.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Board staff note that the Initial Statement of Reasons documents the basis for inclusion of USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. Business and Professions Code section 4126.8, establishes compliance with pharmacy compounding chapters. Staff further notes, USP provides, "Although it is possible for FDA or another government authority in the U.S. or elsewhere to require the use a USP General Chapter numbered 1000 to 1999, the authority in question would need to make this requirement expressly applicable under law, regulation, or another appropriate vehicle that prescribes enforceable requirements."
1736.10(e)	Alliance for PHY Compounding	This would prevent the use of e-beam or gamma-irradiation sterilization methods, which are performed off-site at validated facilities.	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

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			research of 503A subdivision (a) (1), the federal that exempts the pharmacy for the manufacturer requirements when compounding. Business and specifically reference the compounding has to occur in a sterile compounding pharmacy – a 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 expect all aspects of compounding to occur in the
1736.11(c)(2)	UC San Diego CSHP Cedars-Sinai Torrance Memorial UC Health	Current language in CCR 1735.3 below has a provision for CSPs compounded in health facilities to prevent delays in care to acutely ill patient, i.e. infections, cancer, critical care, etc. The current language states: (F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply. Add back the language above: 1736.11 Master Formulation and Compounding Records, subsection (c)(3) The manufacturer, lot number, and expiration date shall be recorded for each component for CSPs. *(i) 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 a change to proposed text. Staff note that current regulations provide an exemption to the compounding record requirement. Staff do not believe that the exemption is still appropriate. Staff note that inspections reveal that health systems and other facilities generally maintain this information within its electronic system or other documentation. Recalls can occur requiring action at the patient level. Maintenance of this information is essential to identify impacted patients. Collection of this information also allows facilities to maintain documentation of compliance with manufacturer approved labeling provisions. The recent proposed changes in the 30-day comment period provided further clarification that the information required in this subsection does not need to be maintained in a single document. Such an approach is providing flexibility in how a pharmacy maintains this information.
1736.11(c)(4)	Stanford Health Care	Comment: The pharmacist who has direct supervision and	Board staff have reviewed the comment. While staff believe the language is sufficiently clear, submission

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		control of compounding is often the pharmacist verifying the final drug preparation. Recommendation: Revise language to read: (4) The identity of personnel performing the compounding, the pharmacist verifying the final drug preparation, as well as the pharmacist who has direct supervision and control of compounding, <u>if different from the pharmacist verifying the final drug preparation</u>.	of the comment indicates otherwise. Board staff believe the additional language submitted by the commenter may provide additional clarity to the regulated public. 1736.11(c)(4) The identity of ~~each~~ <u>personnel</u> ~~person~~ performing the compounding, <u>pharmacist</u> ~~that~~ <u>who</u> has direct ~~oversight~~ <u>supervision and control</u> of compounding, and the pharmacist verifying the final drug preparation, **<u>if different</u>**.
1736.12(b)	Alliance for PHY Compounding	This places the burden of ensuring validation of an alternative method for sterility testing is done in compliance with USP Chapter 1223 on the pharmacist. Validation should be provided by the Analytical Laboratory performing the alternative method and maintained by the pharmacy as part of the compounding record. Recommendation: USP Chapters above 1000 are for informational purposes only. They **contain no mandatory tests, assays, or other requirements applicable to any article, regardless of citation in a general chapter below 1000**, a monograph or these General Notices. The Board's assertion that it is just listing out all the tests required on API (and other requirements in Chapters above 1000) is untrue. Per USP, these tests are not required, even if they are cited in chapters below 1000. We recommend removing all requirements for pharmacies outlined in the proposed regulations that reference USP chapters above 1000.	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that USP 797 Chapter references USP Chapter 1223 where it discusses alternative testing methods. The Board is not requiring a pharmacist to perform the testing required in USP Chapter 1223; however, the Board is explicitly stating that where an alternative method for sterility testing is used, a pharmacist must ensure the test used was compliant with Chapter 797 requirements. Staff further notes, USP provides, "Although it is possible for FDA or another government authority in the U.S. or elsewhere to require the use a USP General Chapter numbered 1000 to 1999, the authority in question would need to make this requirement expressly applicable under law, regulation, or another appropriate vehicle that prescribes enforceable requirements."
1736.12(c)	Alliance for PHY Compounding	For Category 2 CSPs that are not sterility tested, it is impractical and would hinder patient care to wait for endotoxin testing to release the CSP. In addition, CSPs that use nonsterile starting components and are not sterility tested only have a 4- day BUD. Typical endotoxin testing would not be available before the end of the BUD.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Staff note that current regulation CCR 1751.7(e)(1) contains these requirements for batch-testing and is essential for patient safety. Staff note that endotoxin testing can be performed in house and completed within four hours. Further,

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		Recommend aligning with USP standards for endotoxin testing.	the provisions of the proposed regulations are limited to injectable CSPs made from nonsterile components.
1736.13(a)	Cedars-Sinai Torrance Memorial	Most health-systems utilize electronic health record (EHR) system which accurately provides the patient specific order rate, duration of infusion. Requiring a range of rates on the label could cause confusion and result in medication errors if nurses misinterpret the ranges. Rates are updated on an ongoing basis in response to changes in the patient's condition and the EHR is the source of truth for the current rate. The duration may not be specified at the time the CSP is initiated since duration will be based on the patient's response to therapy, e.g. blood pressure changes, determination of infection source, blood glucose, etc. Therefore, instructions for administration may reference the EHR when rate changes are anticipated. Additionally, due to changes in the patient's condition, the rate documented on the label may change by the time the CSP is hung on the pt. Recommend updating the regulation to: *A CSP label shall include all of the following and these can also be readily retrievable from the EHR:* (1) *Route of intended administration;* (2) *The solution utilized, if applicable;* (3) *Instructions for administration will include the rate and/or reference the EHR which serves as the source of truth for the rate of drug to be infused based on the patient's condition.* ~~*(A) For an admixed CSP, the rate of infusion, or range of rates of infusion as prescribed, or the duration for the entire CSP to be administered*~~	Board staff have reviewed the comment and recommend a change to the proposed text based on the comment. 1736.13(a)(s)(A) (A) For an admixed CSPs administered by infusion, the rate of infusion, or range of rates of infusion as prescribed, or the duration for the entire CSP to be administered. **A health care facility licensed pursuant to Health and Safety Code Section 1250 may reference the patient's chart in lieu of rate of infusion when a patient's condition requires a variable rate.**
1736.13(a)(3)(A)	Keck/USC	Displaying "rate of infusion, or range of rates of infusion" is not feasible to accomplish in many contemporary electronic medical record (EMR) systems. Most of labels for titratable medications display the rate as "As Directed", and the order	Board staff have reviewed the comment and recommend a change to the proposed text based on the comment. 1736.13(a)(3)(A)

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		details are specified in the EMR. This new proposal is not aligned with CMS-approved accreditation agency standards for patient care and not feasible to achieve with some, of not all of the current EMR systems. It will likely result in higher risk of medication errors and adversely impact patient care. Recommend revising as follows: A) For an admixed CSP, the rate of infusion, or range of rates of infusion as directed (unless the infusion rate is specified in a shared electronic medical record system), or the duration for the entire CSP to be administered.	(A) For an admixed CSPs administered by infusion, the rate of infusion, or range of rates of infusion as prescribed, or the duration for the entire CSP to be administered. **A healthcare facility licensed pursuant to 1250 may reference the patient's chart in lieu of rate of infusion when a patient's condition requires a variable rate.**
1736.14(a)(1)	Alliance for PHY Compounding	Components such as pH adjusters should be excluded from impacting the BUD of the formulation. These are typically made fresh, used, and disposed of. If the pharmacy were to document a 1-day BUD for the pH adjuster, then this language as written would cause the final preparation to have a 1- day BUD. Recommend aligning with USP's approach to exclude pH adjusters from the determination of the BUD.	Board staff have reviewed the comment. Staff note that while the issue addressed in the comment appears to be covered in the proposed text 1736.14(a)(1)(A), it appears that given the comment additional clarification to the language is necessary, staff believe amendment to the text may be appropriate by moving the language in 1736.14(a)(1)(A) to 1736.14(a)(3) 1736.14 Establishing Beyond-Use Dates. In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding. (a) A CSP's beyond-use date (BUD) shall not exceed: (1) The chemical and physical stability data of the active pharmaceutical ingredient(s) and any added substances in the preparation; **~~(A) Nothing in this section shall prohibit the allowances in USP 797 section 14.3 for pHaltering solutions.~~** (2) The compatibility of the container–closure system with the finished preparation (e.g., possible leaching, interactions, and storage conditions); and (3) The shortest remaining expiration date or BUD of any of the starting components. **Nothing in this section shall prohibit the allowances in USP 797 section 14.3 for pH-altering solutions.**
1736.14(b)	Stanford Health Care	**Comment:** Electronic health record (EHR) systems use the 24- hour format for time entries.	Board staff have reviewed the comment. While staff believe the language is sufficient clear, submission of

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		Recommendation: Revise language to include 24-hour time format (e.g., 23:59).	the comment indicates clarification may be necessary. Board staff believe modification to the language can provided additional clarity to the regulated public. 1736.14. (b) Beyond-use dates (BUDs) assigned with only a date shall expire at 11:59 p.m. **or 23:59** on that date.
1736.14(c)	Alliance for PHY Compounding	Sterility testing can take more than 2 weeks for results to be reported, and patients may need access to the compounded preparations before testing results are available. Restricting formulations to release after testing creates a situation where patients could be denied a medication if testing cannot be performed fast enough to prevent suffering or patient harm. Recommend aligning with USP, allowing release before receipt of sterility and endotoxin results as long as the pharmacy has a program in place in the event they need to perform a recall.	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that the language of the proposed text is consistent with current provisions in CCR 1751.7(e). Board staff note that the proposed regulation text allows for alternative forms of testing that provide results within 72 hours. The suggestion from the commenter would be contrary to requirements of Chapter 797 which states, "sterility testing performed **and** passed" for Category 2 when establishing a longer BUD. Staff further note that consistent with the Chapter's provisions, a shorter BUD can be established without sterility testing.
1736.17(a)(1)	Wedgewood Pharmacy	This has been mentioned in previous comment sections, USP Chapters above 1000 are for reference only and not intended to be a regulatory requirement.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Board staff note that the Initial Statement of Reasons documents the basis for inclusion of USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. Business and Professions Code section 4126.8, establishes compliance with pharmacy compounding chapters. Staff further notes, USP states that, "Although it is possible for FDA or another government authority in the U.S. or elsewhere to require the use a USP General Chapter numbered 1000 to 1999, the authority in question would need to make this requirement expressly applicable under law, regulation, or another appropriate vehicle that prescribes enforceable requirements."
1736.17(a)(2)(C)	Cedars-Sinai Torrance Memorial	Many health-systems currently utilize IV room workflow system that utilizes barcode scanning to check for correct components before allowing	Board staff have reviewed this comment and recommend a change to the proposed text. The proposed regulation text requires a **method** to

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

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

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1736.17(a)(2)(F)	Donald Cottman	There is no definition of "potential quality problem" to determine if compliance has been achieved.	Board staff have reviewed the comment and believe the commenter is referring to 1736.17(f). Staff do not recommend a change to the proposed regulation text based on the comment. Staff note that USP Chapter 797 refers to CSP quality and quality problems throughout the Chapter. Staff also note that the proposed regulation text in CCR Section 1736(g) defines "quality." As a licensed health care professional, pharmacist must exercise professional judgment to make a determination based on the complaints received is indicative of a potential quality problem.
1736.17(d)	CSHP Cedars-Sinai Torrance Memorial	In many health-system pharmacies there are many items entering the sterile compounding spaces including into the SEC and PEC. The proposed language as it is written, could be interpreted to suggest that the SOP must state that how each item introduced from the unclassified space be cleaned and the contact time be timed and then this time be documented. Requiring monitoring and documentation of the monitoring of the dwell time for each individual item adds a significant burden to the workload of sterile compounding staff. It will take them away from performing the work of compounding medications for acutely ill patients and will further contribute to the potential for increased compounding while providing no demonstratable benefits. In practice, this requirement could be interpreted that the wiping and dwell time of medication and related sterile compounding items such as syringes, needles etc. sterile isopropyl alcohol be individually timed and documented when introduced to the PEC for sterile compounding. We suspect that the intent of this regulation is for SOPs to sufficiently address documentation and following manufacturer recommended dwell times as part of sterile compounding practice and wish to point out the potential for misinterpretation during enforcement inspections.	Board staff have reviewed the comment recommend a change to the proposed text to provide clarity. Board staff note that the proposed regulation text establishes the parameters for development and use of an SOP. The proposed regulation text does not establish the SOP requirements themselves. Development of the SOP must be developed by responsible individuals including the PIC and other designated staff. The SOPS themselves will determine how a facility will document compliance with its SOPs. As an example the "method to ensure" could be determined in the SOP as being done through random auditing. The proposed regulation text is intended to provide the facility flexibility in operationalizing the requirement through the development of the SOP. (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 contact **~~dwell~~** time required, and **~~how~~ the method to ensure** ~~dwell~~ contact time **is achieved ~~will be monitored and documented~~**.

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		Recommendation (BOLD): (d) The SOPs shall specify the process and products to be used on any equipment and other items entering from an unclassified area into the clean side of the anteroom, entering a PEC and entering the SCA. These SOPs must define at a minimum what product is to be used, the dwell time required~~, and how dwell time will be monitored, and documented~~.	
1736.18(a)	John Gray Kaiser	(a) The quality assurance program shall comply with section 1711 and the standards contained in USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. In addition, the facility's quality assurance program shall include the following: (1) A written procedure for scheduled action, such as a recall, in the event any compounded drug preparation is discovered to be outside the expected standards for integrity, quality, or labeled strength. We anticipate that hospitals and other health care facilities are the most likely entities to be impacted by the requirement for a facility's quality assurance program to include a written procedure for responding to out-of-range temperature variations within medication storage areas when a furnished drug may be returned for furnishing to another patient. In some cases, the procedure for managing this kind of temperature excursion might be jointly managed by several departments within the facility. We suggest amending the proposed regulation to clarify that a facility-wide procedure would meet this requirement.	Board staff have review the comment. While staff believe the current language is sufficiently clear, submission of the comment indicates otherwise. Board staff believe the additional language submitted by the commenter may provide additional clarity to the regulated public. 1736.18 Quality Assurance and Quality Control. In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding. 1738.18(a) The quality assurance program shall comply with section 1711 and the standards contained in USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. In addition, the **facility's quality assurance** program shall include the following:
1736.18(c)	CSHP Cedars-Sinai Torrance Memorial Alliance for PHY Compounding	The way the regulation is written, suggests that the review must be completed within 72 hours since it states that "such review shall be documented and dated as defined in the SOPs." The proposed language requirement for a documentation and dating of the review together with the preceding sentence's requirement for review within 72 hours from the receipt of the compliant could be seen as requiring the review to be completed within the	Board staff have reviewed the comment and do not recommend a change in the proposed text. Staff are concerned that the term "business day" could vary greatly based on the practice site and differing operating hours.

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

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		service. This severe economic impact was not stated in the initial statement of reasons. As an alternative to this required testing, an alternate strategy could be followed by compounding stock solutions from scratch for each patient visit. This will have equally impactful consequences as explained in the next bullet point. (c) ~~Any compounded stock allergy solution shall~~ comply with the requirements established in USP Chapter 51, Antimicrobial Effectiveness Testing ~~and the requirement established in USP Chapter 1207, Sterile Product Packaging – Integrity Evaluation related to container closure~~. A compounding record is required for any compounded stock solution.	and the smallest amount possible needs to be made all at once to avoid variations. Given this, Board staff believe it is appropriate to delete the provisions as suggested by the commenter. Staff note that significant education will be required as it believes that many pharmacies currently compound allergenic stock solutions. This is not allowed under the provisions of the USP Compounding Chapter. **~~(c) Any compounded stock allergy solution shall comply with the requirements established in USP~~ Chapter 51, Antimicrobial Effectiveness Testing and the requirement established in USP Chapter 1207, ~~Sterile Product Packaging – Integrity Evaluation~~ related to container closure. A compounding record ~~is required for any compounded stock solution.~~**