General Language Comments	Commenter	Comment	Response
All	Marie Cottman Pacific Compounding	Commenter states that the regulations lack evidence and recommends that the Board not move forward with the regulation and rescind the existing regulations.	Board staff have reviewed the comment and do not recommend changes to the proposed text based on this comment. The comments provided are general and do not provide specific recommended changes to the text. Board staff note that the proposed regulation focus on requirements necessary for public protection as included in the Initial Statement of Reason. The Board relied upon USP as the foundation for the requirements.
All	Unknown Commenter at Reg Hearing	Imposing restrictions for access to care to citizens is "absurd" and the requirements should be tabled to allow access to compounded medication.	Board staff have reviewed the comment and do not recommend changes to the proposed text based on this comment. The comments provided are general and do not provide specific recommended changes to the text. Board staff note that the proposed regulation focus on requirements necessary for public protection as included in the Initial Statement of Reason. The Board relied upon USP as the foundation for the requirements. The regulation text is not intended to create barriers to effective treatments as practices evolve. Staff note that the FDA evaluates research studies to determine the safety and efficacy of drugs and establish the appropriate and approved use of medications including compounded preparations. The Board defers to the FDA judgment and note that the FDA releases information, guidance documents, evaluation of research, etc and note that such FDA information establishes a standard of practice for which Board licensees must remain mindful of when evaluating prescriptions and exercising clinical judgment. The Board also note that pursuant to the provisions of BPC 4127(c) the Board must consider changes made to USP within 90 days.
All	UCSD	The regulations create a double standard between pharmacy licensees and medical licensees. The regulations must be developed with evidence based guidelines.	Board staff have reviewed the comment and do not recommend changes to the proposed text based on this comment. Staff note its jurisdiction are individuals and businesses within its practice act. Board staff read the comment as suggesting that the Board's proposed regulations would apply to a physician. It may be appropriate for the commenter to confer with those licensing boards to determine compounding requirements.
All	Erik Clausen	Commenter states that he sold his compounding pharmacy because of the USP requirements. The Board needs to do more to consider the impact of the regulations.	Board staff have reviewed the comment and do not recommend changes based on this comment. Board staff note that the proposed regulation focus on requirements necessary for public protection as included in the Initial Statement of Reason. The Board relied upon USP as the foundation for the requirements consistent with the requirements in Business and Professions Code seciton 4126.8 and provisions of Section 503A. The regulation of compounding practices have evolved significantly over the past 20 years in federal and state law and USP standards. Many of the requirements put forth in the proposed regulations are existing requirements that have been renumbered to align with the new structure of the compounding regulation text.
All	Dieter Steinmetz Coast Compounding	I am writing to request the implementation of new regulations or the amendment of existing ones regarding the pharmacist to technician ratio in retail compounding pharmacies. The current regulations, while addressing several important aspects, do not fully account for the unique requirements of compounding areas, especially in the context of hazardous, non-hazardous, and sterile compounding. If the Board of Pharmacy would consider adding compounding areas to 4115 or enacting a new regulation to address these issues, it would enhance compounding services and public safety. By establishing specific ratios and guidelines for technicians working in distinct compounding areas, we can ensure that these areas are adequately staffed, thereby reducing the risk of contamination and enhancing the overall safety and efficiency of retail compounding pharmacy operations.	Board staff have reviewed the comment and do not recommend changes based on this comment. Staff note that the comment is outside of the scope of the regulation. Staff note that the Licensing Committee is evaluating the current pharmacist to pharmacy technician ratio. The commenter may wish to participate or follow those efforts.
All	Rheta Silvas Kaweah Health	Consider including the terms Nonsterile Compounding or Sterile Compounding where applicable in the CCR Headers (e.g. CCR 1735 would read “Nonsterile Compounding Definitions” instead of Compounding Definitions. This would make it easier to navigate the table of contents in the law book.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. Staff note that each article is titled to indicate the scope of each article, e.g., CNSP, CSP, etc.

All	Paul Lofholm	Its my understanding that approved labeling applies to manufactured products only and not compounded prescriptions. Board of Pharmacy spells out labeling requirements. Diluent applies to CSP and not CNSPs Essential Copies applies to a specific product or USP monograph and all its ingredients Quality essentially means what's on the label is what is in the preparation [plus or minus 10%]	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. The comments provided are general and do not provide specific recommended changes to the text. Staff note that elsewhere in this document, responses are applicable to the general comments made.
All	California Veterinary Medical Association	Vets are struggling to procure compounded medications because compounding pharmacies are afraid to compounded due to possible Board enforcement. CVMA would like a meeting with the Board to discuss in future detail.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. Staff note that the proposed regulation text includes language reflecting requests from the CVMA and that public comment provided during the regulation hearing acknowledged the Board's actions to address concerns raised by CVMA.
All	CA Pharmacists Association	While CPhA understands the intention behind increasing the number of steps and requirements involved in compounding, CPhA is concerned about the unintended consequences these changes may have, particularly in the context of current healthcare challenges. 1. High Census with Increased Acuity of Hospital Patients: Hospitals are experiencing high patient volumes and increased acuity levels, necessitating timely access to compounded medications. The proposed changes could lead to delays in compounding, adversely affecting patient care and outcomes. 2. Technician Staffing Shortages: The healthcare industry is currently grappling with a shortage of pharmacy technicians. Adding more steps and requirements to the compounding process will exacerbate this issue, potentially leading to further delays and increased workload on already overburdened staff. 3. Record Drug Shortages: Many essential medications are in short supply, and compounding is often a critical solution to address these shortages. Additional regulatory requirements could hinder the ability of pharmacies to quickly and efficiently compound needed medications, prolonging shortages and impacting patient care. 4. Significant Increase in Sterile Compounding Requirements to Comply with USP 797: Compliance with the updated USP 797 standards already imposes substantial demands on pharmacies. The proposed changes will add further complexity, increasing the risk of medication errors and harm due to the heightened procedural burden. Considering these concerns, CPhA urges the State Board to carefully consider the input from the CHART group. It is vital to balance the need for stringent regulations with the practical realities of healthcare delivery. Streamlined and efficient compounding processes are essential to ensure patient safety and access to necessary medications.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. Board staff note that some of the comment is general in nature and does not offer changes for the Board to considered. Many of the areas raised by the commenter are not related to the issue of compounding and may already be under review and consideration by the Board. Further, the Board is note familar with the CHART group. Board staff not that the proposed regulation focus on requirements necessary for public protection as included in the Initial Statement of Reasons. The Board relied upon USP as the foundation for the requirements.
All	Rita Shane Cedars-Sinai	Commenter encourages the Board to look at the regulations and reduce some of the requirements which add steps and impact patient care. Commenter indicates they do not trust 503B facilities and do not wish to use them for compounded products.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. Board staff note that the proposed regulation focus on requirements necessary for public protection as included in the Initial Statement of Reasons. The Board relied upon USP as the foundation for the requirements. The Board staff further note that as included in the Initial Statement of Reasons, many of the requirements included in the proposed regulation text, are requirements in the existing regulations.

All	CA Hospital Association Also provided at Reg Hearing	Generally, these regulations will not meaningfully enhance protection of, or promote the health and safety of, Californians. Federal law already requires compounding of drug preparations to be consistent with standards in the current version of the United States Pharmacopeia (USP)-National Formulary. The USP is an independent, scientific nonprofit organization focused on helping ensure a supply of safe, quality medicines. When developing compliance standards, the USP follows a deliberative and evidence-based process to determine when regulations are necessary before becoming legally recognized as the standard of practice. Each step undergoes rigorous scientific review, including input from experts, stakeholders, the public, industry, academia, and regulatory agencies. Input from these diverse perspectives informs regulation development and details legal recognition, conformance, testing practices, and terminology. USP scientists and experts have developed countless effective and evidence based regulatory standards, including those governing nonsterile compounding (USP 795), sterile compounding (USP 797), and hazardous drugs (USP 800). USP standards are referenced in federal regulations enforced by the Food and Drug Administration (FDA), ensuring compliance with the Food, Drug, and Cosmetic Act. Violations of these federal rules could subject licensees to enforcement by the FDA or the U.S. Department of Justice. Hospitals and their pharmacies prioritize compliance with these rigorous requirements. In addition to conforming with USP standards, hospitals are required to comply with a variety of other federal and state laws and regulations and undergo regular enforcement reviews to maintain their federal certification and state license to operate as hospitals. Given the existing and extensive federal set of USP compliance standards — developed with scientific rigor, stakeholder input, legal recognition, and a commitment to public health and safety — the necessity and value of these proposed regulatory additions and amendments should be evaluated. **Comments Continues on Next Line**	Board staff have reviewed the comment and do not recommend changes based on this comment. Board staff note that the comments are general in nature and do not provide specific recommendations to modify sections of the proposed text for the Board's consideration. Board staff note that the proposed regulation focus on requirements necessary for public protection as included in the Initial Statement of Reasons. The Board relied upon USP as the foundation for the requirements. Board staff also note that as included in the Initial Statement of Reasons, many of the requirements included in the proposed regulation text, are requirements in the existing regulations. Legal provisions, both federal and state law, require compliance with USP, e.g., BPC Section 4342 provides the Board with the authority to institute any action or actions as may be provided by that that are necessary to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the USP. Section 503A of the FDC Act includes as one of the conditions to compound under the federal exemption that the licensed pharmacy comply with the standands including the United States Pharmacopoeia chapter on compounding. Staff further note the regulation of compounding practices have evolved significantly over the past 20 years in federal and state law and USP standards. Consistent with the requirement established in BPC 4127.1, the Board through this process has reviewed revisions to USP and determined amendments that are necessary. It is not appropriate nor relevant to associate costs to comply with the USP Chapters in this rulemaking. The Initial Statement of Reasons generally describes the costs identified that are associated with the regulations itself. As an example, USP Chapter 800 requires the use of a specific type of glove. The costs for the gloves are necessary to comply with USP 800, federal law, Pharmacy Law to name a few. However, as the Board's proposed regulations could require impacted individuals to change their HD gloves more frequently than the USP, the Board highlighted the anticipated cost that could be incurred by a facility.
All	CA Hospital Association	**Comments Continued from Previous Line** Additionally, the BoP has not provided substantial evidence that hospital pharmacies are failing to follow either the BoP's current regulations or the detailed federal USP standards. No evidence has been presented by the BoP suggesting systemic challenges or indicating patients have been placed in harm's way, or that hospital pharmacies are not meeting safety standards that might necessitate additional BoP regulations. Duplicative and Resource-Intensive A lack of high-quality empirical evidence supporting the need for additional regulations is likely to generate confusion and redundancy, and not accomplish, as stated in the Initial Statement of Reason, an "effective and less burdensome" process. These duplicative regulations will divert patient care dollars from hospitals' finite resources, increase compliance confusion and uncertainty, reduce efficiency, and increase the risk of legal penalties. Striking a balance between necessary oversight and minimizing confusing and inefficient compliance standards is critical to foster a sustainable health care system for the needs of patients today and in the future. Benefit and Cost Impact Is Unclear While regulations are necessary for quality and safety, finding a balance between regulations and cost effectiveness remains a critical challenge in health care. In the past decade hospitals have expended millions of dollars to comply with the evidence-based USP standards. These proposed regulations will unnecessarily increase the costs and slow down the compounding process without evidence of the need to do so — at a time when hospitals are at once trying to hold health care cost growth in check and when nearly 50% are losing money every day in caring for patients.	see above.

All	John Gray Kaiser Permanente Also Provided at Reg Hearing	The board has not provide any empirical evidence such as peer-review Journal articles, meta analyses to support the proposed compounding regulations in the initial statement of reasons. During the board's February 2023 enforcement committee meeting, the board presented photographs showing dirty and disorganized pharmacies as evidence that the USP plus approach to regulating compounding is necessary to protect the Health and Welfare of California residents and Kaiser disagrees. Kaiser requests an effective date of 1 year from the date of OAL approval.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. Board staff note that the USP Chapters have been in effect since November 1, 2023. The Board further note that as included in the Initial Statement of Reasons, many of the requirements included in the proposed regulation text, are requirements in the existing regulations. Where a new requirement is established, board staff believe a delayed implentation is not necessary unless the text otherwise establishes a delay. Staff further note that it anticipates the Board will suggest that following implementation of the adopted text, staff focus on education of new requirements (those that are not currently required under existing law) as a means to facilitate compliance unless the practice places patients at risk.
All	Scripps Health	The regulations will increase the cost of caring for patients both directly and indirectly it will prevent access to Medical Services increase weight times for very sick patients and encourages an evidence based approach to the regulations. The commenter states that the regs adds standards, are duplicative. and are resource intensive.	Board staff have reviewed the comment and do not recommend changes based on this comment. Board staff note that the comments are general in nature and do not provide specific recommendations to modify sections of the proposed text for the Board's consideration. Board staff note that the proposed regulation focus on requirements necessary for public protection as included in the Initial Statement of Reasons. The Board relied upon USP as the foundation for the requirements. The Board further note that as included in the Initial Statement of Reasons, many of the requirements included in the proposed regulation text, are requirements in the existing regulations. Legal provisions, both federal and state law, require compliance with USP, e.g., BPC Section 4342 provides the Board with the authority to institute any action or actions as may be provided by that that are necessary to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the USP. Section 503A of the FDC Act includes as one of the conditions to compound under the federal exemption that the licensed pharmacy comply with the standands including the United States Pharmacopoeia chapter on compounding. Staff further note the regulation of compounding practices have evolved significantly over the past 20 years in federal and state law and USP standards. Consistent with the requirement established in BPC 4127.1, the Board through this process has reviewed revisions to USP and determined amendments that are necessary. It is not appropriate nor relevant to associate costs to comply with the USP Chapters in this rulemaking. The Initial Statement of Reasons generally describes the costs identified that are associated with the regulations itself. As an example, USP Chapter 800 requires the use of a specific type of glove. The costs for the gloves are necessary to comply with USP 800, federal law, Pharmacy Law to name a few. However, as the Board's proposed regulations could require impacted individuals to change their HD gloves more frequently than the USP, the Board highlighted the anticipated cost that could be incurred by a facility.

All	Walgreens	In general, Walgreens is concerned with any language that extends, expands, duplicates, or conflicts with the current recommended standards of USP General Chapters <795>, <797>, and <800>, as it is unnecessary and overreaching. The recommended standards listed in USP's compounding chapters have been extensively discussed, debated, and challenged to ensure safe compounding practices that can be practically applied. However, the proposed regulations now require pharmacists to understand and reference two sets of standards and regulations impacting compounding practices. This duplication and additional standards will cause confusion, even for pharmacies with extensive compounding experience. As suggested throughout the proposed language, the additional requirements above and beyond the General Chapters of USP, intend to hold California pharmacies to a higher standard than established by the national authorities without evidence of additional patient safety. We are especially concerned that the proposed language will further limit patient access to compounding services, especially to what was previously known as "simple compounds." Simple compounds are generally known as non-hazardous compounded products that do not require advanced techniques, equipment, or calculations, such as creams, lotions, gels, solutions, suspensions, ointments, or pastes. Most states are utilizing USP as the only standard to reference to ensure patient safety for compounding practices. However, some states are also taking action to carve out "simple compounding" due to the low risk to patient safety and concerns for readily available access to these products. We ask the board to review the language used for Mississippi's compounding regulations as an example of a regulatory agency seeking to balance patient safety with the practical application of compounding practices	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. The comments provided are general and do not provide specific recommended changes to the text. Rather, the comments appear to be more commentary. Because compounded drugs are not FDA-approved, FDA does not verify their safety, effectiveness, or quality before they are marketed. Poor compounding practices can result in serious drug quality problems, such as contamination or a drug that contains too much active ingredient. This can lead to serious patient injury and death. The Board has provided education through presentations during public meetings on the general requirements in federal law (Section 503A of the FDC Act) and the requirements of several USP Chapters to aid licensees in gaining an understanding of such requirements. These presentations are available on the Board's website. The commenter's use of the phrase "simple compounding" is not limited by the proposed regulation. Nonsterile compounding that is limited in nature does not require special licensure or equipment under the Board's proposed regulations.
All	Marci Bencomo Pacifica Compounding	The proposed regulations do not appear to aid patient safety as they are redundant or overly restricted. Pharmacy and Pharmacy staff would suffer because they would need to spend time learning the requirements.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. The comments provided are general and do not provide specific recommended changes to the text. Rather, the comments appear to be more commentary. Because compounded drugs are not FDA-approved, FDA does not verify their safety, effectiveness, or quality before they are marketed. Poor compounding practices can result in serious drug quality problems, such as contamination or a drug that contains too much active ingredient. This can lead to serious patient injury and death. Board staff note that the proposed regulation focus on requirements necessary for public protection as included in the Initial Statement of Reasons. The Board relied upon USP as the foundation for the requirements. The Board staff further note that as included in the Initial Statement of Reasons, many of the requirements included in the proposed regulation text, are requirements in the existing regulations. Legal provisions, both federal and state law, require compliance with USP, e.g., BPC Section 4342 provides the Board with the authority to institute any action or actions as may be provided by that that are necessary to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the USP. Section 503A of the FDC Act includes as one of the conditions to compound under the federal exemption that the licensed pharmacy comply with the standards including the United States Pharmacopoeia chapter on compounding. Staff further note the regulation of compounding practices have evolved significantly over the past 20 years in federal and state law and USP standards. Consistent with the requirement established in BPC 4127.1, the Board through this process has reviewed revisions to USP and determined amendments that are necessary.
Article 4.5 Nonsterile Compounding	Mark Johnston CVS Health Also provided at Reg Hearing	Commenter applauds the Board for removing the requirement for routine resting and analysis and adding the requirement for compliance with USP <1163>, as it allows for the use of clinical discretion and professional judgment.	The Board agrees the comment.

Non-Sterile	Paul Lofholm	my observation is the CNSP proposed regulations have been written to follow the CSP regulations. It appears to be over restrictive given the benefit to risk of the patient. Furthermore, the proposed regulations will drive up costs: supplies increased, training increased, insurance increased, lack of trained personnel, and overall cost to achieve a new level of quality. The result will be decreased access to compounding services to the people of California.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. The comments provided are general and do not provide specific recommended changes to the text. Rather, the comments appear to be more commentary. Because compounded drugs are not FDA-approved, FDA does not verify their safety, effectiveness, or quality before they are marketed. Poor compounding practices can result in serious drug quality problems, such as contamination or a drug that contains too much active ingredient. This can lead to serious patient injury and death. The Board relied upon USP as the foundation for the requirements. The Board also note that as included in the Initial Statement of Reasons, many of the requirements included in the proposed regulation text, are requirements in the existing regulations.
Sterile Compounding	Ryan Cassata, Fire Fighters + 15	Forever toxins cause cancer in fire fighters. Commenter states that the Board's regulations are making sterile compounding illegal. Sterile Compounding of IV and Nebulized glutathione is needed medication to remove forever toxins from fire fighters and prevent cancer. Glutathione is necessary for treatment of autoimmune disease treatment.	Board staff note that the comment appears to be limited to specific provisions related to CSP bulk ingredients. Staff note that the proposed regulation text as initially noticed, if enacted, would allow for compounding using a bulk drug substance in an emergency use situation for a patient-specific compound if authorized by a public health official. (CCR 1736.9(e)). This language as drafted could specifically allow for compounding of glutathione especially in cases of wildfires and other declared disasters, with the authorization of a public health official. The proposed regulation text is not intended to create barriers to effective treatments, rather was intended to provide flexibility as practices evolve and research supports emerging treatments. However, in response to public comment, staff are recommending a proposed change to noticed text. The recommended text if approved would more directly allow for the compounding of a bulk drug substance that is included in the published 503A Category 1 bulk substance list under specified conditions. This additional provision is in recognition that treatment may be required beyond a declared disaster, e.g, a wild fire. Staff remind all commenters that the FDA evaluates research studies to determine the safety and efficacy of drugs and establish the appropriate and approved use of medications including bulk substances. The Board defers to the FDA judgment and note that the FDA releases information, guidance documents, evaluation of research, etc and that such FDA information establishes a standard of practice of which Board licensees must remain mindful when evaluating prescriptions and exercising clinical judgment including the proposed provisions related to bulk drug substances.
Article 4.6 Sterile Compounding	American Academy of Dermatology Association, American College of Mohs Surgery, American Society for Dermatologic Surgery Association, American Society for Mohs Surgery, California Society of Dermatology & Dermatologic Surgery, A. Haas, California Society of Plastic Surgeons Also Provided Oral Comments on Topic	Commenters are seeking language to allow a beyond use date of at least twelve-hours and repeal language in Article 4.6 requiring patient-specific prescriptions. This would enable buffered lidocaine to be prepared in advance of patient visits for that day, which ensures valuable time is not taken away from patient interaction. Commenters believe the regulation of physician in-office compounding should remain under the purview of the state medical board, however, indicate that it is essential that policymakers work collaboratively to ensure timely access to safe and effective medications for patients. Buffered lidocaine is routinely prepared in syringes in advance of patient visits with a beyond-use date (BUD) of at least 12 hours to facilitate patient access and patient comfort. USP is in the process of finalizing the monograph, which will include the required evidence of safe aseptic practices sufficient to exempt in-office preparation of buffered lidocaine from the onerous requirements that limit dermatologists from providing their patients with necessary treatment. Because the Board's proposal does not reflect the testing conducted as part of the monograph process, we urge you to refrain from adopting a regulation that would prohibit physician in-office preparation of compounding medications as adopting any regulations at this juncture will critically impact direct patient care.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. Staff note its jurisdiction are individuals and businesses within its practice act. Board staff read the comment as suggesting that the Board's proposed regulations would apply to a physician, in this instance an orthopaedic surgeon. It may be appropriate for the commenter to confer with their licensing board to determine in the practice described if the scenario described their comment is allowable.
Article 4.6 Sterile Compounding	Melanie Horn Sutter Health	Sutter Health generally supports the regulation of compounding; however, believes that the proposed regulations holds the practice of pharmacy to a higher standard than other licensed professions and therefore, pharmacists and pharmacy personnel are being asked to do more.	The Board appreciates the support of the board's regulation. Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. The Board relied upon USP as the foundation for the requirements. The Board also note that as included in the Initial Statement of Reasons, many of the requirements included in the proposed regulation text, are requirements in the existing regulations.

Article 4.6 Sterile Compounding	Jerome Potozkin, Daneil A. Di Cesare, Bill Resh, Tanya Kormeili, Jennifer Chen, Plus 21 Others Also Provided Oral Comments on Topic	Commenters urge the Board to allow a beyond use date of at least twelve-hours and repeal language in Article 4.6 requiring patient-specific prescriptions. This would enable buffered lidocaine to be prepared in advance of patient visits for that day, which ensures valuable time is not taken away from patient interaction. Commenters believe the regulation of physician in-office compounding should remain under the purview of the state medical board, however, indicate that it is essential that policymakers work collaboratively to ensure timely access to safe and effective medications for patients.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. Staff note its jurisdiction are individuals and businesses within its practice act. Board staff read the comment as suggesting that the Board's proposed regulations would apply to a physician, in this instance an orthopaedic surgeon. It may be appropriate for the commenter to confer with their licensing board to determine in the practice described if the scenario described their comment is allowable.
Article 4.6 Sterile Compounding	CA Orthopaedic Association Also Provided Oral Comments on Topic	As an orthopaedic surgeon, our commitment to patient care and safety is paramount. One crucial aspect of our practice involves the administration of medication such as corticosteroids, which would often be mixed into the same sterile syringe with local anesthetics, such as lidocaine and/or bupivacaine. It is unclear if this is considered "compounding", but we wanted to share how important this aforementioned practice is. The importance of mixing local anesthetics with other medications, such as corticosteroids for orthopaedic patients: 1. Patient Tolerance: -It can be painful for patients to receive musculoskeletal injections without local anesthesia. 2. Diagnostic Information: While there may be a longer-term goal of decreasing a patient's inflammation and pain in a joint, bursa or tendon sheath by means of administration of a corticosteroid, the coadministration of a local anesthetic can also give useful diagnostic information about the anatomic course of the patient's pain, by seeing if the paid decreases in the first few minutes, given the rapid onset of action of local anesthetics such as lidocaine. A rapid, significant reduction in pain would confirm the site that was injected is a significant source of the patient's pain. This allows for a refined diagnosis and for a more precise surgical plan to be developed, should the injection fail to solve the patient's problem in the long term. 3. Precise Patient Care: When a physician mixes local anesthetics with cortisone, they can tailor the ratio of the mix to that specific patient. These mixes are typically done individually for each patient. In conclusion, mixing local anesthetics with other medications, such as corticosteroids, for orthopaedic patients is a sterile, important and patient-specific process that is commonly performed multiple times each day in an orthopaedic office. As such, we respectfully request that no further regulatory requirements or barriers be erected around this process. We are unaware of any history of adverse events from the above-mentioned sterile mixing of local anesthetics with other medications such as corticosteroids. Thus, we oppose regulatory changes that would restrict or encumber an orthopaedic surgeon's ability to mix their medications in his or her office. Please consider proposed regulations which would hinder this ability	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. Staff note its jurisdiction are individuals and businesses within its practice act. Board staff read the comment as suggesting that the Board's proposed regulations would apply to a physician, in this instance an orthopaedic surgeon. It may be appropriate for the commenter to confer with their licensing board to determine in the practice described if the scenario described their comment is allowable.

Article 4.6 Sterile Compounding	CA Naturopathic Doctor Association (CNDA) Also provided at Reg Hearing	CNDA is requesting that the Board postpone any decisions made with regard to this issue and refer the matter to the Joint Sunset Review to allow for a full discussion of the legislature allowing for a better understanding of the impacts of this proposed rulemaking. The proposed products for regulation, methylcobalamin (vitamin B12) and glutathione are essential for patient care, specifically patients suffering from chronic health ailments. Naturopathic doctors (NDs) use compounding pharmacies routinely to provide safe and effective care for complex patients (e.g. patients with allergies to additives in pills). The California Board of Pharmacy has been taking action to limit access to some of these legal medications for Californians, in spite of the fact that they are able to be compounded in other states. Some examples are injectable methylcobalamin and glutathione for inhalation. Injectable methylcobalamin has been shown to be effective in helping people with ALS (Lou Gehrig's Disease), a terminal condition for which there are few helpful treatments. Inhaled glutathione has been shown to be helpful in patients with cystic fibrosis (a very serious genetic condition that affects the lungs). **We want to make sure that legislators are aware of these issues as the California State Board of Pharmacy heads into its next sunset review.** Proposed state restrictions that supersede the current requirements by federal law will remove products that serve to improve the daily quality of health, productivity, and longevity of patients relying on these specific compounded medications. Rather than improve safety, which has not been shown to be a known issue, it will be a deterrent to quality healthcare. Please consider this statement as an opportunity to voice our concerns and request postponement of this issue to the Board's sunset review.	Board staff note that the comments appear to be limited to specific provisions related to CSP bulk ingredients in proposed text CCR Section 1736.9. Board staff note that staff are recommending a proposed change to noticed text in part based on this comment that could address the specific products mentioned. The regulation text is not intended to create barriers to effective treatments as practices evolve. Staff note that the FDA evaluates research studies to determine the safety and efficacy of drugs and establish the appropriate and approved use of medications including compounded preparations. The Board defers to the FDA judgment and note that the FDA releases information, guidance documents, evaluation of research, etc and note that such FDA information establishes a standard of practice for which Board licensees must remain mindful of when evaluating prescriptions and exercising clinical judgment. The Board staff also note that pursuant to the provisions of BPC 4127(c) the Board must consider changes made to USP within 90 days.
Hazardous	Paul Lofholm	It appears to me that this section is institutionally-based and not typically of a NSCP. While the principles apply in general and anti-neo plastics are seldom compounded, hormones are. Usually these preparations are compounded in powder-containment hoods. Commenter also commented on the need for the Board to consider allowing irradition for sterilty methods and that USP Chapters above 1000 are guidelines and not requirements.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Referenced chapters include both required actions and recommended actions. Where a required action as established in the reference USP Chapter is applicable, compliance is necessary; however, where the provisions within a USP referenced Chapter is only recommended (e.g., "should") compliance is permissive unless otherwise specified in the Board's regulation text or other provisions of the law.
Hazardous	Rick Rhoads University Compounding Also provided at Reg Hearing	Reference chapters are guidelines and difficult to enforce.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Referenced chapters include both required actions and recommended actions. Where a required action as established in the reference USP Chapter is applicable, compliance is necessary; however, where the provisions within a USP referenced Chapter is only recommended (e.g., "should") compliance is not mandated unless otherwise specified in the Board's regulation text or other provisions of the law.
Article 4.7 Hazardous Drugs	Mark Johnston CVS Health Also provided at Reg Hearing	Commenter states that USP 800 contains a broad carve-out for facilities that do not engage in hazardous drug compounding and thus only dispense hazardous drugs in manufactured dosage forms, however proposed Article 4.7 does not contain such a carve-out. Subjecting community pharmacies to 1737.6, 1737.7, 1737.9 and 1737.10 is impractical, costly, and overly burdensome, with no proven benefit to public safety. Commenter requests that the following edit be made to each section in Article 4.7: In addition to the standards in USP Chapter 800, Hazardous Drugs – ~~Handling~~ Compounding in Healthcare Setting shall meet the following requirements of this article.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. Further, staff note that USP 800 does not provide a carve-out as suggested by the commenter. USP 800 is relevant to the handling of all HDs as determined by CDC/NIOSH (National Institute of Occupational Safety and Health). As included in the Initial Statement of Reasons, additional legal requirements may be established by other regulators, e.g., CalOSHA, for which compliance is also required. The Board is not deviating from the titles used in USP.

Article 4.7 Hazardous Drugs	Occupational Safety and Health Standards Board (OSHSB)	As compounded drugs can pose a safety risk to works, individuals handling hazardous drug must be aware of the safety and health risks. OSHSB requests that a Note be added to article 4.7 to alert licensees of the Cal/OSHA regulations within Title 8. OSHSB provided the following language: Note: To ensure proper worker protections, additional safety and health requirements are included in title 8 of the California Code of Regulations.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. Board staff note that the Initial Statement Reasons reminds stakeholders about the obligation to comply with other legal requirements, including those established in California Code of Regulations, Title 8. Staff note that some changes to the proposed regulation text are being offered to remove provisions that strictly address employee protections., e.g. provisions related to wipe sampling.
Notice	Philip Smyth Medisca, Scott Brunner Alliance for Pharmacy Compounding Also provided at Reg Hearing	The majority of compounding pharmacies are small businesses and these changes will likely have a significant financial impact on their operations. We ask that a thorough financial impact report be completed to fully understand the cost of compliance.	Board staff have reviewed the comment and do not recommend changes based on this comment. Board staff note that the comments are general in nature and do not provide specific recommendations to modify sections of the proposed text for the Board's consideration. Board staff note that the proposed regulation focus on requirements necessary for public protection as included in the Initial Statement of Reasons. The Board relied upon USP as the foundation for the requirements. The Board staff further note that as included in the Initial Statement of Reasons, many of the requirements included in the proposed regulation text, are requirements in the existing regulations. Legal provisions, both federal and state law, require compliance with USP, e.g., BPC Section 4342 provides the Board with the authority to institute any action or actions as may be provided by that that are necessary to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the USP. Section 503A of the FDC Act includes as one of the conditions to compound under the federal exemption that the licensed pharmacy comply with the standards including the United States Pharmacopoeia chapter on compounding. Staff further note the regulation of compounding practices have evolved significantly over the past 20 years in federal and state law and USP standards. Consistent with the requirement established in BPC 4127.1, the Board through this process has reviewed revisions to USP and determined amendments that are necessary. It is not appropriate nor relevant to associate costs to comply with the USP Chapters in this rulemaking. The Initial Statement of Reasons generally describes the costs identified that are associated with the regulations itself. As an example, USP Chapter 800 requires the use of a specific type of glove. The costs for the gloves are necessary to comply with USP 800, federal law, Pharmacy Law to name a few. However, as the Board's proposed regulations could require impacted individuals to change their HD gloves more frequently than the USP, the Board highlighted the anticipated cost that could be incurred by a facility.