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

				robust participation from a number of stakeholders from a cross-section of the Board's regulated public. As the formal rulemaking process began, the Board has followed the Administrative Procedures Act (APA). The Board respectfully refers the commenter to legal requirements for the rulemaking process established in the APA, Government Code section 11340 et seq.
2	General	CA Medical Association	**Language of Proposed Text Conflicts with Board's Description of Its Effect (throughout all sections)** CMA is disappointed by the Board's continued refusal to revise its proposed language to clarify that the regulations do not apply to physicians. In its response to public comment requesting clarification on whether the regulations apply to physicians and other licensed practitioners, the Board effectively stated the regulations do not apply to licensees of other healing arts boards, noting: "[…] [the] Board's regulations apply to licensees within the Board's jurisdiction. The Board's jurisdiction is limited to those businesses and individuals within its practice act." The language of the proposed regulations, however, is written in a manner that could be construed to apply to compounding in any setting and by any individual, because their scope is not expressly limited to pharmacists and pharmacies, unlike the current regulation. Thus, the Board's proposed regulations continue to violate the clarity standard of the with the Board's description of the effect of the regulations. CMA would also like to address comments made by Board staff at its most recent meeting held on March 6, 2025. Board counsel summarized section 4170(c) of the Business and Professions Code (BPC), stating "the Medical Board of California and other healing arts boards are specifically charged with the enforcement of Pharmacy Law with respect to their respective licensees." CMA has never disputed this fact. In fact, our letter dated December 9, 2024, cited BPC 2220.5, acknowledging the Medical Board's authority. Further, BPC 2220.5 specifies this authority empowers the Medical Board to investigate or take disciplinary actions against physicians for violations "…of the Medical Practice Act and **any other provision of this division**," referring to the Healing Arts	Board staff have reviewed the comment and do not recommend a change in the proposed text. Board staff note that the comment is outside the scope of the proposed changes in the fourth modified text. The Board respectfully refers the commenter to the Board's prior responses to these comments that have been considered several times during this rulemaking process.

			division (division 2 of the BPC, commencing with section 500), which contains the Pharmacy Law (chapter 9 of the BPC, commending with section 4000), among other healing arts laws. (BPC 2220.5(b) (emphasis added).) Thus, BPC 2220.5 and BPC 4170(c) both authorize the Medical Board to enforce the Pharmacy Law on physicians. While these two statutes limit the Board of Pharmacy's authority to take **enforcement** action against a physician's license, they do not limit the scope of licensees to whom the Board's regulations may apply. Rather, they suggest the opposite. The Pharmacy Law may, at times, apply to physicians, and in those situations, the Medical Board is authorized to take enforcement action if a physician is acting in violation of the law. Through the regulatory process, the Board of Pharmacy is implementing, interpreting, and making specific the Pharmacy Law which, in this case, the Medical Board has confirmed "may influence the standard of care for physicians who are compounding." Allowing pharmacist-centric regulations to influence the physician standard of care is inappropriate and would harm patient care in California. CMA reiterates its request from our prior comment letter dated December 9, 2024, to revise the proposed regulations to clarify they do not apply to compounding performed by physicians outside of a pharmacy setting, so that the proposed language of the regulations aligns with the Board's description of the effect of the regulations, as required by the APA.	
3	General	Kaiser	**Myth**: Many of the provisions in the proposed regulations have been in California pharmacy regulations for years and removing those longstanding requirements would be "taking a step back." **Fact**: It is true that some of the requirements in the proposed regulations have been in existing compounding regulations for many years. However, a great deal has changed since the last ***major*** update to the Board's compounding regulations in 2011. Most significantly, beginning in 2020, the Pharmacy Law has required pharmacies to comply with the United States Pharmacopeial Standard's (USP) compounding chapters. With the statutory requirement to meet the requirements of the USP compounding chapters, separate compounding regulations are no longer necessary.	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments received. The Board has appropriately considered all comments received and has made significant changes to the proposed regulation text based on comments received during the rulemaking process. Board staff disagree with the request from the commenter to repeal existing regulations. This issue was previously considered by the Board. The Board respectfully refers the commenter to the Board's prior response. Further, staff note the rulemaking record

			Myth: It is appropriate for the regulation to become effective based on the date the final regulation is filed with the Secretary of State. **Fact**: The Board should establish a rational delayed effective date—at least nine months—for these regulations to provide the regulated public with ample time to come into compliance with these new requirements. If the proposed regulation is finalized as written, organizations will need to make extensive changes to compounding workflows, which will need to be memorialized in organizations' policies and standard operating procedures. The policy-writing and approval process is not automatic and, in some settings such as General Acute Care Hospitals, the updated policies must be reviewed and approved by the organization's governing body, which is also time-consuming. Many organizations will also need additional time to upgrade their electronic pharmacy systems to meet the new requirement in the proposed regulations to maintain an audit trail of all prior versions of all compounding records. **Myth**: The public does not understand the proposed regulations and would benefit from "more education." **Fact**: The vast majority of the feedback offered by the public has been rational and credible and should not be dismissed as ill-informed. The oral and written comments from both the regulated public and the lay public demonstrate a sophisticated understanding of pharmacy compounding, the proposed regulations, and the effects that the regulations are likely to precipitate. **Myth**: Pharmacies are resistant to the proposed regulations because they just don't want to be regulated. **Fact**: Kaiser Permanente supports commonsense, evidence-based compounding standards that promote the preparation of safe and effective compounded drug products, which is the reason that we support the adoption of the USP compounding standards for non-sterile, sterile, and hazardous drug products. The Pharmacy Law already requires "the compounding of drug preparations by a pharmacy… be consistent with standards	including the Modified Initial Statement of Reasons, Underlying Data, Documents Relied Upon and responses to comments articulates the basis for the proposed regulations and is consistent with the Board's consumer protection mandate. Board staff does believe it is appropriate to correct the comment regarding the applicability of USP national standards. Compliance with USP national standards was required before 2020. Board staff respectfully note that Section 503A has required compliance with USP national standards since at least 2013. Further several provisions of Pharmacy Law also referenced compliance with national standards prior to 2020. As an example, Business and Professions Code section 4342, passed in 1996, provided authority for the "Board to institute any action or actions… to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopeia or the National Formulary..." Board staff note that the Board previously considered an extended effective date and determined that it was not appropriate. The Board respectfully refers the commenter to the Board's prior response. Board staff further note that the revised USP compounding chapters became effective November 1, 2023. Consistent with the Board's policy statement, most pharmacies have already transitioned to the updated chapters. The Board recognizes that compounding is a complex area of practice. As part of the regulation development process and through the rulemaking, the Board has sought to provide education to interested stakeholders serving as adjunct educational materials beyond those included in Modified Initial Statement of Reasons. This education has included presentations,

			established in the pharmacy compounding chapters of… USP," which provides an immediate path the Board could take to simply conform to the USP standards.1 **Myth**: If this regulation is not finalized, the Board would have to start the rulemaking process over. **Fact**: The Board could move forward with enforcing the USP compounding standards and not promulgating new regulations without starting the rulemaking process over. The rulemaking package comprises a proposal to repeal the Board's current compounding regulations and a proposal to adopt the new compounding regulations. To proceed with enforcing provisions of the USP compounding chapters as required by Business and Professions Code section 4126.8, the Board should move to: 1. Accept the proposal to repeal sections 1708.3. 1708.4, and 1708.5 of Title 16, Division 17, Article 2 of the California Code of Regulations and to repeal 1735 et seq of Title 16, Division 17, Article 4.5 of the California Code of Regulations and to repeal 1751 et seq of Title 16, Division 17, Article 7 of the California Code of Regulations. 2. Reject the proposal to add new sections 1735 et seq of Title 16, Division 17, Article 4.5 of the California Code of Regulations, and to add new sections/Article 1736 et seq of Title 16, Division 17, Article 4.6 of the California Code of Regulations, and to add new sections/Article 1737 et seq of Title 16, Division 17, Article 4.7 of the California Code of Regulations, and to add new sections/Article 1738 et seq of Title 16, Division 17, Article 4.8 of the California Code of Regulations.	FAQs and summary documents along with responses to public comments.
4	General	Alliance for PHY Compounding	The Alliance for Pharmacy Compounding again urges the California State Board of Pharmacy to reject the proposed compounding regulations in their current form. The feedback from a broad coalition of stakeholders—hospital pharmacists, compounding pharmacies, physicians, academic institutions, and healthcare organizations—has been clear: these regulations are unworkable, unnecessary, and detrimental to patient care. Yet, despite extensive opposition, the Board seems determined to move forward without making the meaningful revisions	Board staff have reviewed the comment and do not recommend a change to the proposed text based on the comment received. Board staff note that the commenter is not recommending any changes to the proposed regulation text. The rulemaking record including the Modified Initial Statement of Reasons, Underlying Data, Documents Relied Upon and responses to comments articulates the basis for the proposed regulations and is consistent with

			needed to align these regulations with patient needs and practical compounding practices. We acknowledge the significant time invested in this rulemaking process. However, that sunken cost does not justify pushing forward regulations that impose unclear, duplicative, and excessively burdensome requirements without clear evidence of benefit. The goal must be to ensure patient access to safe and necessary medications, not to create barriers that disrupt care without justification. Unfortunately, these regulations prioritize procedural finality over patient well-being, and the Board has failed to demonstrate how the proposed rules enhance patient safety. The public comment process has been inadequate. Restricting pharmacists and other experts to two-minute speaking slots—without opportunities for meaningful discussion—has stifled necessary debate and left significant misunderstandings unaddressed. Several Board members have demonstrated a fundamental lack of knowledge regarding USP standards and their existing safeguards for patient safety. Moreover, some have incorrectly suggested that stability studies exist for certain compounded medications, such as nebulized formulations, when in reality, such studies are extremely limited or nonexistent. To ensure that any regulatory changes are based on expertise and real-world applicability, we strongly urge the Board to convene a task force of pharmacists from diverse practice settings—including hospitals, academic medical centers, rural facilities, and compounding pharmacies. This group should also include USP committee members to provide authoritative insight. A collaborative approach is essential to crafting regulations that truly enhance patient safety without unnecessary disruption. The Board must recognize that USP standards already set a rigorous, evidence-based national benchmark for compounding safety. Imposing additional, conflicting state-specific regulations serves only to create confusion and limit patient access to vital treatments. Rather than advancing these flawed regulations, the Board should commit to enforcing existing USP standards while	the Board's consumer protection mandate. These documents also demonstrate the significant opportunities for public engagement both during the regulation development process and through the formal rulemaking. Board staff respectfully refer the commenter to the Administrative Procedure Act (Government Code section 11340 et seq) to gain an understanding of the rulemaking process.

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

			as long as sterility and endotoxin testing are performed. • Removing enforcement of non-mandatory USP Chapters above 1000. • Ensuring regulations apply only to pharmacists, not medical practitioners. • Eliminating unnecessary documentation requirements not mandated by the FDA. I urge you to either withdraw the proposal entirely or revise it to protect patient access to life-saving medications.	fourth modified text in 1736.9 which highlights removal of the requirements. As the Board has previously noted, USP provides, "Although it is possible for FDA or another government authority in the U.S. or elsewhere to require the use a USP General Chapter numbered 1000 to 1999, the authority in question would need to make this requirement expressly applicable under law, regulation, or another appropriate vehicle that prescribes enforceable requirements. The Board's proposed regulation text is consistent with this approach and the Board, in some instances, is explicitly adopting a Chapter. As was previously shared, staff note the Board only has jurisdiction over individuals and businesses within its practice act. Board staff read the comment as suggesting that the Board's proposed regulations would apply to a physician. Business and Professions Code section 4170(c) makes clear that the Medical Board of California is specifically charged with the enforcement of Pharmacy Law (Chapter 9, Division 2 of the Business and Profession Code) with respect to its licensees. The Board believes it is appropriate to highlight information specifically related to compounding with bulk drug substances included on the 503A interim bulk drug substances. As the Board has previously stated in prior responses provisions of federal law established in Section 503A, relevant FDA guidance documents and relevant sections of the national standards, especially those sections related to components must all be considered when compounding with such substances. The FDA has not approved or authorized the compounding of these substances, nor has the FDA stated that compounding with these substances is safe in every instance. Rather, the FDA has released guidance that articulates an interim enforcement

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

				pharmaceutical grade equivalents (e.g., ingredients with potentially harmful impurities, ingredients labeled with "not for pharmaceutical use" or an equivalent statement). The Board's underlying data included in the Modified Initial Statement of Reasons contains additional information specifically related to this issue including as an example item 21, "FDA highlights concerns with using dietary ingredient glutathione to compound sterile injectables." The Board continues to monitor for information released from the FDA and evaluate for insanitary conditions during inspections and compliance with national standards.
7	General	T. Sanor	Why is the Board trying to get rid of a treatment that helps patients and has research supporting its efficacy. It appears as an affront to patient-centered healthcare advocates. I sent links to research last time. If you need those again, contact me. Sick patients have been ignored too long. Chronic illnesses from infections is now very much in the limelight w RFK Jr whommay or may not be right. At least he puts patients above profits unlike most of gov't for the past decades by ignoring pain and suffering especially of Lyme, a spirochete like syphilis yet much worse than syphilis as there are 30 plasmids, biofilms, persisters and there are no good early tests when it is treatable. Every known brain disordered pathway can be triggered by infections per IDSA researchers at "The Svience of Infections & Dementia" 2024 conference and 9.15.24 J of Inf Dis microbial issue. NeuroImmune.org confirms mental illnesses from infections such as Lyme, Bartonella, strep grp A and Covid too. AlzPi.org rconsortiym researchers include top univ and confirm Lyme, HSV, EBV, etc cause brain disorders and Michal Tal lab showed Lyme spirochetes in uterus recently, too. Dr Neil Spector's "Lyme in the Era of Precision Med" 2019 before he died of complications of a heart transplant after Lyme shows connection with cancer as does Eva Sapi. MeghanBradshaw.com for joint degeneration and chronic pain from Lyme. Lymedisease.org for research and the largest patient database will show how tragic it	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Board staff note that comments do not appear to be recommending any changes to the proposed text.

			is to ignore these patients, many thousands w children the most affected. PsychologyRedefined.com shows too that mental illnesses root causes can be infections including Lyme, Bartonella...having a cat w Bartonella causes 3x the chance of schizophrenia and it is a coinfection along w babesia that takes weeks to months to treat. A paradigm change to find root causes and not just treat symptoms will find cures. Now pharmacists just give lifelong meds for symptoms, not cures. BOP needs to be a leader in healing by listening yo patients who are dealing with preventable chronic pain, suffering. Physicians lije myself are not taught that the test is <50%sensitive and often no tick or rash is seen so when a patient has migrating, fluctuating pain, it is not believed and they are sent to psych. It is a scandal thousands of times worse than Tuskegee when syphilis was untreated as it has been decades of medical denialism of what is probable starting in 1995 iron key brain studies showing plaques, lesions consistent w severe symptoms.	
8	General	T. Kitahata	It is my humble yet strong opinion that access to treatments that are beneficial to the health of Californians be protected. In addition to daily exposure at work, I was also a first responder to the attacks of 9-11, Hurricanes Katrina, Ike, Gustav, Irma, Harvey, the Malibu fires of 1992, the Camp Fire in Paradise (and other large-scale wildfires), the Montecito mudslides, the LA Riots, the Northridge earthquake, exposed to harmful toxins from it all. I was also on duty 24/7 for 30 days during the Palisades fire, working the fire and then assigned to a command post to care for 2000 first responders from all over the nation, the National Guard, LAPD and law enforcement from multiple agencies, utility and essential workers, and the kind people who fed us. In short, my lungs and my entire body have recently, and over time, been compromised. I firmly believe my glutathione treatments have helped me get back to my baseline. I urge the Board of Pharmacy to allow access, to offer future protections to those who stand in harm's way and those who are sick and find relief from this natural compound.	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments received. Board staff note that the proposed modified text does not ban the compounding using bulk substances such as glutathione. Board staff note that the Board has confirmed the continued availability of compounded glutathione.

	General	T. Delaney	Someone that I love depends on compounded glutathione and b vitamins to stay healthy. It has become a critical part of her daily struggle to be as healthy as possible despite a multitude of debilitating heath problems that make one question the value of their own life. It is absolutely necessary to protect the ability of compounding pharmacies to make these compounds. The life giving medicine contained in glutathione and b vitamins are invaluable to my loved one and I urge you to do what's absolutely right and protect the ability by pharmacies to make these important compounds.	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments received. Board staff note that the proposed modified text does not ban compounding using bulk substances such as glutathione. Board staff note that the Board has confirmed the continued availability of compounded glutathione.
10	General	R. Smith	Regarding potential new hurdles or restrictions to safe and effective compounds such as NAD+, Glutathione, and B-12 These compounds (using trusted compounding pharmacies like Infuserve) have proven a critical leg in the care of loved ones. Please do not restrict them further as many Californians/Americans will suffer even more than they are under a complex and frustrating system.	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments received. Board staff note that the proposed modified text does not ban compounding using bulk substances such as glutathione. Board staff note that the Board has confirmed the continued availability of compounded glutathione.
11	General	M. Morey	The current for-profit model of health care in the US allows many people to fall through the cracks, leading to bankruptcies and early demise. Sicker people cost much more to treat than the cost of preventative treatments. For instance, insurance stops paying for treatment of Lyme disease after roughly a month because "long term Lyme doesn't exist". This false statement leads to a (shortened) life of suffering if the tick bite isn't noticed or treated immediately, just to save money. Similarly, someone I love depends on compounded glutathione and b vitamins to stay healthy and so I am writing to protect the ability of compounding pharmacies to make these compounds. This is what she relies upon to maintain a bare minimal quality of life, paying out of pocket with money she doesn't have. THAT'S how important it is she receives these compounded drug preparations, and the protection of pharmacies' ability to make them.	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments received. Board staff note that the proposed modified text does not ban compounding using bulk substances such as glutathione. Board staff note that the Board has confirmed the continued availability of compounded glutathione and methylcobalamin.
12	General	J. Shea	Please DO NOT restrict access to IV glutathione and other alternative treatments.	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments received.

				Board staff note that the proposed modified text does not ban compounding using bulk substances such as glutathione. Board staff note that the Board has confirmed the continued availability of compounded glutathione and methylcobalamin.
13	General	S. Johnson	I am writing as a California resident and patient who relies on affordable, sterile compounded medications—including intravenous and injectable therapies compounded from Category 1 bulk drug substances—to maintain my quality of life. I strongly urge the Board to reconsider or revise the overly restrictive provisions outlined in Addendum 1 to the proposed regulations. Specifically, I am deeply concerned that the Board's new requirements for stability testing, extensive documentation of clinical circumstances, and strict adherence to USP chapters beyond federal mandates will effectively eliminate or severely reduce access to essential sterile compounded medications, including but not limited to NAD+, glutathione, and methylcobalamin. As currently proposed, these new testing requirements (with costs estimated between $10,000 to $30,000 per API) would drastically raise pharmacy overhead, which will inevitably be passed on to patients or cause pharmacies to discontinue compounding these vital medications altogether. Such outcomes would place compounded therapies financially out of reach for many, including myself, directly threatening my health and quality of life. The Board's proposed regulations conflict with the existing FDA Policy. I am particularly troubled by the misleading assertion in the Board's meetings and addendum documents implying that these extensive stability tests are required by FDA policy or USP guidelines. The FDA's Interim Policy on Compounding Drugs Using Bulk Drug Substances explicitly states: "FDA does not intend to take action against an outsourcing facility for compounding drugs using bulk drug substances identified in category 1 provided that the conditions described in the guidance document are met." (FDA Interim Policy on Compounding)	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments received. Board staff note that the proposed modified text does not ban compounding using bulk substances such as glutathione, methylcobalamin and NAD+. The Board's proposed regulations in this area do not go beyond federal law, federal guidance and national standards. The Board respectfully refers the commenter to 1736.9(e) which explicitly refers to the FDA guidance and relevant national standards. Board staff note that the commenter may, at least in part, be referring to a prior version of the proposed regulation text. Staff note that the fourth modified text does not include a requirement for stability studies, sterility and endotoxin testing on the bulk ingredient. Board staff respectfully refer to commenters to the fourth modified text in 1736.9 which highlights removal of the requirements. Board staff note that specifically related to veterinary compounding, the Board through various comment periods, has updated proposed text to incorporate recommended changes made by the California Veterinary Medical Association. Staff believe the commenter may be referring to statements made during a legislative hearing. Board staff have confirmed the availability of products for equine patients from sources including outsourcing facilities that are licensed in California.

			Additionally, the FDA has already outlined specific conditions for compounding with Category 1 bulk drug substances, stating that a bulk substance not on the drug shortage list may still be compounded if: • The bulk substance is included in Category 1 of FDA's list; • The manufacturers of the substance are all registered under Section 510 of the FDCA; • The bulk substance is accompanied by a valid Certificate of Analysis (COA); • If the bulk substance has a USP or NF monograph, it complies with that monograph; and • The bulk substance is compounded in compliance with all other provisions of Section 503B of the FDCA. (FDA Interim Policy Source) The Board's proposed requirements exceed the scope of FDA guidance and create unnecessary regulatory burdens that are not aligned with federal policy. If the FDA has deemed these conditions sufficient for safety and oversight, why is the California Board imposing additional, unnecessary restrictions that will make it impossible for patients to access affordable compounded medications? This will cause unnecessary financial and public health consequences. The financial and administrative burdens imposed by this addendum will likely result in higher costs for compounded medications. For patients like me, who depend on these treatments to maintain health and manage chronic conditions, any increase in cost or reduction in supply could have devastating consequences. As a patient managing chronic illness, my consistent access to affordable NAD+ treatments has meaningfully improved symptoms where no other FDA approved drugs or treatments exist. Interruptions or prohibitive cost increases due to the Board's regulations would mean losing the stability these medications currently provide, potentially forcing me into greater disability, diminished independence, or worsening chronic symptoms. These aren't abstract risks—they're real, immediate threats to my health and well-being, and the Board must fully recognize the tangible consequences of its regulatory actions.	The rulemaking record including the Modified Initial Statement of Reasons, Underlying Data, Documents Relied Upon and responses to comments articulates the basis for the proposed regulations and is consistent with the Board's consumer protection mandate. These documents also demonstrate the significant opportunities to public engagement both during the regulation development process and through the formal rulemaking. The Board believes it is appropriate to highlight information specifically related to compounding with bulk drug substances included on the 503A interim bulk drug substances. As the Board has previously stated in prior responses provisions of federal law established in Section 503A, relevant FDA guidance documents and relevant sections of the national standards, especially those sections related to components must all be considered when compounding with such substances. The FDA has not approved or authorized the compounding of these substances, nor has the FDA stated that compounding with these substances is safe in every instance. Rather, the FDA has released guidance that articulates an interim enforcement discretion policy that applies if an authorized facility or individual compounds using certain unapproved bulk drug substances, such as glutathione and methylcobalamin, but only under very specific conditions. Such conditions include that the original manufacturer and all subsequent manufacturers of the bulk drug substance are establishments that are registered under section 510 of the FDCA; that the bulk drug substance is accompanied by a valid Certificate of Analysis; and that the drug product compounded using the bulk drug substance is compounded in compliance with all other conditions of section 503A (including, for example, that the compound has not been produced or held under insanitary conditions). As

			Patients and animals are already suffering due to the board's overreach. The real-world consequences of these excessive regulations extend beyond human patients—they are already harming animals due to unnecessary restrictions on veterinary compounding. As Dr. Grant Miller, Director of Regulatory Affairs for the California Veterinary Medical Association, testified, "California is the only state in the country in which veterinarians are reporting that they do not have access to critical drugs to treat their patients. These drugs are not available in FDA-approved formulations, and thus we may only obtain them through compounding pharmacies. However, excessively stringent Board of Pharmacy regulations have shrunk the number of California veterinary compounding pharmacies to just a few." "As a result, critical eye medications for horses and important medications for exotic animals such as birds and reptiles are nowhere to be found. Without drugs like ophthalmic diclofenac ointment, ophthalmic antifungal medications, and certain ophthalmic antibiotics, veterinarians have to watch helplessly as innocent horses and other animals lose their eyesight." This is an avoidable tragedy caused directly by the Board's restrictive policies, yet the Board continues to push even more severe restrictions under the proposed regulations in Addendum 1. Furthermore, a licensed pharmacist from an animal compounding pharmacy testified, "Ten years ago, we had over 100 compounding pharmacies throughout California. Now, only a handful remain to service the 40 million residents, the 20 million pets, and the 500,000 horses that live here. This is a dire situation." The Board's actions are actively reducing the availability of critical, life-sustaining medications, harming both human and animal patients alike. Serious legal and ethical concerns were raised during the Joint Hearing of the Senate Business, Professions and Economic Development Committee and the Assembly Business and Professions Committee – Joint Sunset Review Oversight Hearing on March 11, 2025. Testimony made it clear that the California Board of Pharmacy (CA BOP) is engaged in regulatory overreach, misinformation, and negligence, directly harming patients, healthcare providers, and even animals in need of	the Board has noted previously, until the FDA formally makes a determination regarding bulk drugs substances nominated for inclusion in 21 CFR 216.23, the Board has determined that there is a need at the state level to provide a pathway to allow for such compounding. Board staff respectfully also refer the commenter to Chapter 797 Section 9.3 Components, which specifically provides that all APIs and components used must be evaluated for suitability for use in sterile drug preparations. "Components labeled with "not for pharmaceutical use", "not for injectable use", "not for human use" or equivalent statement must not be used to compound for these purposes. The Chapter continues that any component found to be of unacceptable quality must be promptly rejected, clearly labeled as rejected, and segregated…Any other lots of that component from that vendor must be examined to determine whether other lots have the same defect." Further, from the FDA Guidance Document, Insanitary Conditions are Compounding Facilities (dated November 2020) which provides examples of insanitary conditions including " Using active ingredients, inactive ingredients, or processing aides, that have or may have higher levels of impurities compared to compendial or pharmaceutical grade equivalents (e.g., ingredients with potentially harmful impurities, ingredients labeled with "not for pharmaceutical use" or an equivalent statement)". The Board's underlying data included in the Modified Initial Statement of Reasons contains additional information specifically related to this issue including as an example item 21, "FDA highlights concerns with using dietary ingredient glutathione to compound sterile injectables." The Board continues to monitor for information released from the FDA and evaluate for insanitary conditions during inspections and compliance with national standards.

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

			medications are essential for many, including firefighters and chronic illness patients. Commenters state that the regulations would create unnecessary barriers that harm the healthcare system, businesses, and people of California. Commenters state that during the February 5, 2025 meeting, board members misrepresented federal guidelines, claiming the FDA has recommended restricting glutathione. However, glutathione remains on the FDA's Category 1 bulk compounds list and is legal under their current policy. USP guidelines also do not mandate stability testing for these compounds. Despite this, the proposal introduces extreme testing requirements far exceeding federal standards without adequate safety-based justification. Commenters state that the unfeasible financial burden these regulations would place on pharmacies is a critical concern. Member Serpa's cost estimates—$16.10 per glutathione vial and $8.06 per methylcobalamin vial—dramatically understated the actual costs of stability testing. These tests actually range from $10,000 to $30,000 per API. These prohibitively expensive tests would force pharmacies to discontinue offering most, if not all, formulations of these treatments, eliminating access to life-saving medications. Commenters add that the need for treatments like nebulized glutathione is more urgent than ever since southern California's severe Urban Wildfires released record levels of harmful toxins like lead and asbestos into the environment. Nebulized glutathione has demonstrated efficacy in reducing these harmful substances in the body. Restricting access to these treatments would escalate health risks, including fatal cancers, for first responders, vulnerable residents, and future generations. Commenters indicate that public opposition to these regulations is overwhelming, with over 11,000 signatures on a petition—with an estimated 1,000+ from California firefighters—and hundreds of pages of comments submitted in writing and in person over the past year. Yet, the Board has failed to meaningfully respond to	Board staff note that the proposed modified text does not ban compounding using bulk substances such as glutathione, methylcobalamin and NAD+. The Board's proposed regulations in this area do not go beyond federal law, federal guidance and national standards. The Board respectfully refers the commenter to 1736.9(e) which explicitly refers to the FDA guidance and relevant national standards. Board staff note that the commenter may, at least in part, be referring to a prior version of the proposed regulation text. Staff note that the fourth modified text does not include a requirement for stability studies, sterility and endotoxin testing on the bulk ingredient. Board staff respectfully refer to commenters to the fourth modified text in 1736.9 which highlights removal of the requirements. As the Board has previously noted, USP provides, "Although it is possible for FDA or another government authority in the U.S. or elsewhere to require the use a USP General Chapter numbered 1000 to 1999, the authority in question would need to make this requirement expressly applicable under law, regulation, or another appropriate vehicle that prescribes enforceable requirements. The Board's proposed regulation text is consistent with this approach and the Board, in some instances, is explicitly adopting a Chapter." As was previously shared, staff note the Board only has jurisdiction over individuals and businesses within its practice act. Board staff read the comment as suggesting that the Board's proposed regulations would apply to a physician. Business and Professions Code section 4170(c) makes clear that the Medical Board of California is specifically charged with the enforcement of Pharmacy Law (Chapter 9, Division 2 of the Business and Profession Code) with respect to its licensees.

			meaningful input from dozens of medical experts, consistently ignoring their expertise. The Board has repeatedly suggested that the public doesn't understand federal and state laws or their application, dismissing the well-informed concerns raised by patients, healthcare professionals, and advocates. The failure to engage meaningfully with stakeholders undermines the credibility of the Board's engagement process and has raised serious concerns about regulatory overreach. Commenters believe that the proposal creates unnecessary barriers severely limiting access to life-saving treatments. These barriers create an unjustifiable financial burden on patients and pharmacies and fail to reflect the true costs and needs of the community. Commenters strongly urge the Board to either (a) withdraw the proposal entirely from consideration or (b) send these proposed regulations back to the committee and re-write them to align them with and not exceed federal and Pharmacopeia standards by making the following changes: * Adhere to USP by allowing Category 2 compounding without requiring full stability studies, provided sterility and endotoxin testing is performed and a reasonable beyond-use-date (e.g., 45 days refrigerated) is applied. * Eliminate adherence to USP Chapters above 1000, which are not enforceable requirements and are meant for informational purposes only. * Amend the language to specify that Title 16 compounding regulations apply only to pharmacists. As written, this board appears to begin regulating medical practices which is regulatory overreach. * Remove the requirement of additional documentation of "clinical circumstances" which is not required by the FDA.	Board staff note that it has confirmed the continued availability and compounding of glutathione and methylcobalamin for California patients. The Board believes it is appropriate to highlight information specifically related to compounding with bulk drug substances included on the 503A interim bulk drug substances. As the Board has previously stated in prior responses provisions of federal law established in Section 503A, relevant FDA guidance documents and relevant sections of the national standards, especially those sections related to components must all be considered when compounding with such substances. The FDA has not approved or authorized the compounding of these substances, nor has the FDA stated that compounding with these substances is safe in every instance. Rather, the FDA has released guidance that articulates an interim enforcement discretion policy that applies if an authorized facility or individual compounds using certain unapproved bulk drug substances, such as glutathione and methylcobalamin, but only under very specific conditions. Such conditions include that the original manufacturer and all subsequent manufacturers of the bulk drug substance are establishments that are registered under section 510 of the FDCA; that the bulk drug substance is accompanied by a valid Certificate of Analysis; and that the drug product compounded using the bulk drug substance is compounded in compliance with all other conditions of section 503A (including, for example, that the compound has not been produced or held under insanitary conditions). As the Board has noted previously, until the FDA formally makes a determination regarding bulk drugs substances nominated for inclusion in 21 CFR 216.23, the Board has determined that there is a need at the state level to provide a pathway to allow for such compounding.

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