#	Section	Commenter	Comment	Staff Response
1	General	Loh Francis	The commenter expressed frustration with the Board and the proposed compounding regulations. Although the commenter indicated that they understand the need for everyone to have an opportunity to comment, the commenter indicated that it is frustrating to that those opposing the regulation are interfering and delaying the regulations. Based on all the discussions the commenter has listened to and read, they indicate that it is clear that the vast majority of commenters are requesting access to specific compounded products from bulk drug substances that are outside the purview of the Board. The Board cannot approve these drugs and cannot authorize them to be compounded. The commenters stated that these individuals need to take their fight where it belongs: the FDA. The commenter stated that it is shocking that these commenters are threatening Board members and making crazy accusations without any evidence but then demanding the Board provide evidence. Protect Californians and pass these regulations now. This has gone on long enough! Stop accepting the false narrative being put forth by a few and amplified by their followers.	Board staff have reviewed the comment and do not recommend any change to the Board's proposed text. Board staff appreciate the commenter's focus on public protection and note that the Board is required to follow the legal requirements to promulgate regulations.
2	General	L. Linton	The commenter has Neuro Lyme Disease. The commenter references a letter from Stop The Bop stating why these compounds are critical to survival for so many Californians. The commenter adds that finding the right treatment for their Lyme Disease, doctors need to know that they have access to these compounds whenever they feel they're needed in my treatment plan as do the doctors of Long COVID patients, firefighters that just fought the Palisades and Eaton fires and thousands of other California patients for whom these drugs are their hope to better health or even a cure. Please do not cut off access to these compounds or the compounding pharmacies that provide access to these critical drugs. They are widely available across the rest of the United States so it seems if California wants to be seen as a shining example to the rest of the US of how to live a healthy lifestyle the state needs to make sure access to these compounds is available to some of its sickest patients. Without it there will be patients with diseases or illnesses similar to mine who	Board staff believe that the commenter is referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk drug substances. After further consideration of the issue, Board staff believe that an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.

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			will never be able to live a healthy life again. In 2025 it is totally unacceptable to ban safe and studied compounds that can heal people.	
3	General	J. Smith	The commenter has multiple rare chronic illnesses. Some of their only good days are because of compounded intravenous things like glutathione, b12 and other b vitamins. Please, do not take these things away. The commenter adds "If my health gets any worse I don't know what point there is for me to stay alive. These compounds give me the health and hope I need to continue."	Board staff believe that the commenter is referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk drug substances. After further consideration of the issue, Board staff believe that an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
4	General	J. Boren	The commenter is against the banning of any natural medicine, specifically glutathione. The commenter states that taking Glutathione will destroy lives, if not kill those who desperately need it like firefighters, but there are thousands of people who need glutathione for their health. Please, do not do this.	Board staff believe that the commenter is referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk drug substances. After further consideration of the issue, Board staff believe that an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
5	General	D. Nicholas	I'd like to ask that you please reconsider the proposed regulations that would severely limit access to critical sterile	Board staff believe that the commenter is referring to proposed regulation sections 1736.9 and 1736.17

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			compounded medications like injected and nebulized glutathione, methylcobalamin, NAD+, and others. These treatments are essential for many, including firefighters and chronic illness patients such as my wife, who counts on them to live an unencumbered life. During the February 5, 2025 meeting, board members briefly considered the possibility of pulling out the part of these regulations that was causing the most stir with people, and I'm begging you to consider that option, if you cannot outright reject these new regulations in full.	related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk drug substances. After further consideration of the issue, Board staff believe that an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
6	General	C. Weis	I was diagnosed with Chronic Lyme and Bartonella in 2017. Since that time I have received Glutathione in all its forms with potentially live saving results. After experiencing both cognitive and memory impairments I became disabled from my career as a Masters Prepared RN. I subsequently received IV antibiotics which significantly caused elevated liver enzymes to alarming levels. Glutathione allowed me to continue my antibiotic therapy by normalizing my liver function. Since completing my IV antibiotics, I now take oral antibiotics on an intermittent basis when my cognitive function begins to once again decline. During these periods; usually twice each year, I also take glutathione supplements orally or topically. Additionally I receive IV glutathione with positive results within just a few days. My mind clears and my memory rebuilds itself. I become "me" again. I rely on my infusions of glutathione to help me regain the part of me that has been lost to this horrible chronic and life altering disease. Please do not remove Glutathione. Like so many others, I value it. Glutathione has saved my life.	Board staff believe that the commenter is referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk drug substances. After further consideration of the issue, Board staff believe that an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
7	General	C. Orr	Please do not restrict patients' access to glutathione and other modes of detoxing! When I had Lyme disease, I infused some on a daily basis and it helped tremendously. People who are fighting toxins of any kind need access to these treatments in	Board staff believe that the commenter is referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances

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			order to support their bodies' fight to get rid of them and take the burden off their system.	discussed in the FDA's guidance related to bulk drug substances. After further consideration of the issue, Board staff believe that an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
8	General	C. Miller	The commenter is a patient and these**(?)** are their treatment and to be dented**(?)** this is not fair.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. Board staff are challenged to provide a more significant response as the comment submitted does not appear complete.
9	General	C. Auerbach	The commenter got Lyme Disease during a hike in S. California in 1996 and got the bull's eye rash, but the approved medical blood test came back negative. With continually worsening health, TWO tests in 2005 that confirmed Lyme Disease. Short-term antibiotics were obviously no longer applicable. The commenter started having Grand Mal seizures in 2007 and has had a long and expensive journey back to functionality, which involved many different alternative therapies. Do not cut off people from treatments that actually work.	Board staff believe that the commenter is referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk drug substances. After further consideration of the issue, Board staff believe that an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
10	General	B. Mockus	Please stop creating bureaucracy and roadblocks that will change patients ability to CHOOSE for their own health and access these medications at prices we can afford. As a Lyme	Board staff believe that the commenter is referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances

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			disease and co-infection patient, these medications help me keep functioning. Without them, my quality of life will dramatically fail. There are so many areas of healthcare where we need to increase access, not reduce it. Please don't add to this problem. Please do not further regulate or restrict our access to the point where manufacturers and pharmacies will cease to make these items available. They are life sustaining for us.	discussed in the FDA's guidance related to bulk drug substances. After further consideration of the issue, Board staff believe that an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
11	General	A. Johnston	The commenter has been a private family nurse practitioner since 2017 and has been in healthcare since 2003. The commenter quickly realized that many patients are not optimally treated with prescription pharmaceuticals. Typically, these are a bandaid for the root cause of the issue, and the patient ends up with more adverse effects and symptomology that needs additional medications. The commenter began using compounded medications, vitamins, and molecular repair options such as NAD+ and NMN and saw amazing benefits in their patient population, including patients with neurogenerative disorders, alcoholics, severe cardiovascular and neurovascular disease. Without these options, these patients typically require hospitalization, infusions of iron, antibiotics, experience severe infections sometimes leading to death. And even mild cases of patients that experience chronic fatigue, depression and anxiety, and obesity have greatly improved their health and wellness. This impacts not only their day to day, but their ability to show up to work, show up in their community, and be present for their families. Taking these options away for patients would be like shooting them in the foot and expecting them to continue to walk at their usual pace. It's just not possible. The commenter strongly advises the Board to allow these options to be produced, manufactured, and shipped into the state, to prevent increasing morbidity, mortality, and even the exodus of	Board staff believe that the commenter is referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk drug substances. After further consideration of the issue, Board staff believe that an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.

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			patients leaving the state permanently or going to other states or countries to obtain their healthcare.	
12	General	A. Griffin	Please do not eliminate access to safe and critical Category 1 substances like glutathione, NAD+ and methylcobalamin. These products have been critical to our family's health as we try to recover from multiple rounds of Lyme disease and co-infections and the immunological and neurological issues those diseases cause. Glutathione is one of the very few substances my damaged body has been able to tolerate and benefit from in my 20+-year Lyme journey. Genetic testing has shown that I cannot make enough on my own and will likely need access to treatment with it for the rest of my days. It's bad enough that we have had to pay out-of-pocket for these substances for over two decades because of America's broken healthcare systems.	Board staff believe that the commenter is referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk drug substances. After further consideration of the issue, Board staff believe that an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
13	General	L. Mendelovich	The commenter is writing, as someone who needs glutathione to treat chronic illness, to express strong opposition to the proposed regulations that would severely limit access to critical sterile compounded medications like injected and nebulized glutathione, methylcobalamin, NAD+, etc. and to urge the Board to carve out the section about Category 1 bulk compounds from the larger regulation package.	Board staff believe that the commenter is referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk drug substances. After further consideration of the issue, Board staff believe that an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
14	General	L. Vorhees	Please do not restrict lifesaving compounds such as glutathione and methyl b12 in California. I need these compounds regularly to address chronic Lyme disease and genetic issues. I need all	Board staff believe that the commenter is referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances

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			the help I can get, and there are many others like me. Please do not add more chaos into a medical system that already fails me.	discussed in the FDA's guidance related to bulk drug substances. After further consideration of the issue, Board staff believe that an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
15	General	M. Millon	I want you to know that my son would be dead by now if it were not for his IV glutathione. Please do not make it impossible to get. This would be a crime against humanity.	Board staff believe that the commenter is referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk drug substances. After further consideration of the issue, Board staff believe that an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
16	General	N. Serocki	Do NOT restrict this effective treatment. I used it personally under the supervision of Dr. C. Martinez years ago. After nothing else was working in my serious debilitating illness, this is what gave me my life back, and it was a turning point that showed me I could recover and not stay bedridden. It was effective and did its job. I no longer needed them and recovered. Without it, I don't know if I would be here today. PLEASE do not restrict what I and many other patients have known for over 12 years. It works, it did not	Board staff believe that the commenter is referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk drug substances. After further consideration of the issue, Board staff believe that an approach that relies on a pharmacist's

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			harm, and it gave my body the ability to recover from a devastating illness. I had gone to many a doctor in San Diego before I found Dr. Martinez, MD, and her decision to use the IV Glutathione therapy and a couple of other items gave me my life back. There is no reason after years of safety and efficacy to remove this from patients. It is wrong to take this away and why would you want to reverse what patients have found helped them get their lives back, like me.	knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
17	General	M. Morgenstern	The commenter asks for the Board to listen to and pay attention to the public's comments about Category 1 Sterile Compounds. It appears that only three board members are actually listening to public comments. The rest of the board appears to be married to their own old tired biased agenda. As a local elected official I find it extremely disappointing that public comments from Pharmacists, Medical Doctors, Veterinarian's, Firefighters, Lyme Disease and Chronic Fatigue Patients and any other patient that has found using Category. 1 Sterile Compounds helpful for treatment are not being listened to and respected. We do not need stricter regulations on Category 1 Sterile Compounds. The fact that so many of the board members are ignoring public comments is beyond disturbing and lacks integrity. I have contacted both of my Assemblymembers' offices to inform my Assemblymembers that the public's comments are being ignored. Please stop the farce and listen to the good people of California and then act accordingly. You are suppose to actually listen to public comment and to represent the residents of California. So far only three board members are actually listening. I personally have found compounded Glutathione and B12 extremely helpful for treating Lyme Disease. Do not make it harder for Lyme Patients who are already suffering enough to receive treatment. Many of us are living in poverty after spending thousands of dollars attempting to get well. We do not need any added hardships inflicted on us from a board with their own agenda.	Board staff believe that the commenter is referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk drug substances. After further consideration of the issue, Board staff believe that an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.

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			The proposed amendments to Title 16 of the California Code of Regulations, Sections 1735-1738, impose unnecessary restrictions on access to Category 1 sterile compounds, such as glutathione, methylcobalamin, and NAD+. These regulations, as currently written, will devastate patient access to life-saving treatments in California, despite no evidence of safety risks warranting such measures. In the wake of the Palisades and Eaton fires, Californians are grappling with the health consequences of prolonged toxic smoke inhalation, including toxin buildup in lung tissue. For many, the only effective treatment to address these toxins is nebulized and intravenous glutathione. These therapies are utilized by firefighters, Lyme Disease and Long COVID patients, and individuals with conditions like ME/CFS and methylation impairment. Denying access to these critical treatments endangers vulnerable populations and ignores the unique health challenges faced by our state. USP does not require full stability studies for Category 1 or 2 sterile compounding. These requirements only apply to Category 3 compounding. For the Board to mandate such studies—which can cost $10,000 to $30,000 per formulation—imposes an insurmountable financial burden on pharmacies. This will force them to limit offerings to the most generic formulations, eliminating the ability to create customized treatments based on individual prescriber orders.	
18	General	R. Horowitz	The commenter is a board-certified internist with 41 years of experience who regularly uses compounded medication by excellent licensed pharmacists. Glutathione is part and parcel of the 9-week oral antibiotic protocol using dapsone combination therapy (see the articles below) which helps to lower methemoglobin levels, support detoxification and lower Herxheimer reactions by blocking NFKappa B during Lyme treatment. It has also been essential in protecting patients from the effects of COVID-19. I published the first article in the world medical literature on the use of GSH in COVID-19 in April 2020 and not one of my patients died during the pandemic using higher dose GSH helped	Board staff believe that the commenter is referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk drug substances. After further consideration of the issue, Board staff believe that an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed

#	Section	Commenter	Comment	Staff Response
			decrease oxidative stress (and the virus needs to lower GSH to replicate). Horowitz, R.I., Freeman P, Bruzzese, J. Efficacy of glutathione therapy in relieving dyspnea associated with COVID-19 pneumonia: A report of 2 cases. Respiratory Medicine Case Reports, April 21, 2020. Article Number: 101063 https://doi.org/10.1016/j.rmcr.2020.101063 Along with compounded glutathione, some of my patients require compounded B12 and other medication because of chemical sensitivity and mast cell activation. They can not live without them. Please do not restrict these essential compounded medications which are life saving in my patient population. Dapsone documentary: https://players.brightcove.net/6314452011001/PAMDt93Yi_default/index.html?videoId=6353288590112 10 Dapsone Articles on The Effective Treatment of Chronic LD & Associated Co-infections Including Bartonella: As of May 11, 2024 Horowitz, R.I.; Fallon, J.; Freeman, P.R. Combining Double-Dose and High-Dose Pulsed Dapsone Combination Therapy for Chronic Lyme Disease/Post-Treatment Lyme Disease Syndrome and Co-Infections, Including Bartonella: A Report of 3 Cases and a Literature Review. Microorganisms 2024, 12, 909. https://doi.org/10.3390/microorganisms12050909 Horowitz, R.I.; Fallon, J.; Freeman, P.R. Comparison of the Efficacy of Longer versus Shorter Pulsed High Dose Dapsone Combination Therapy in the Treatment of Chronic Lyme Disease/Post Treatment Lyme Disease Syndrome with Bartonellosis and Associated Coinfections. Microorganisms 2023, 11, 2301. https://doi.org/10.3390/microorganisms11092301 Horowitz RI, Freeman PR. Efficacy of Short-Term High Dose Pulsed Dapsone Combination Therapy in the Treatment of Chronic Lyme Disease/Post-Treatment Lyme Disease Syndrome (PTLDS) and Associated Co-Infections: A Report of Three Cases and Literature Review. Antibiotics. 2022; 11(7):912. https://doi.org/10.3390/antibiotics11070912 https://www.mdpi.com/2079-6382/11/7/912/htm	Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.

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			Horowitz, R.I.; Freeman, P.R. Efficacy of Double-Dose Dapsone Combination Therapy in the Treatment of Chronic Lyme Disease/Post-Treatment Lyme Disease Syndrome (PTLDS) and Associated Co-infections: A Report of Three Cases and Retrospective Chart Review. Antibiotics 2020, 9, 725. https://doi.org/10.3390/antibiotics9110725 Horowitz, R.I., Murali, K., Gaur, G. et al. Effect of dapsone alone and in combination with intracellular antibiotics against the biofilm form of B. burgdorferi. BMC Res Notes 13, 455 (2020). https://doi.org/10.1186/s13104-020-05298-6 https://bmcresnotes.biomedcentral.com/articles/10.1186/s13104-020-05298-6?fbclid=IwAR0qt8lyjHfOYlC_Z5k_a4DGxa49sYned_6xC8mRz66m2Wirekb0MX0vBRA#citeas Horowitz, R.I.; Freeman, P.R. Precision Medicine: retrospective chart review and data analysis of 200 patients on dapsone combination therapy for chronic Lyme disease/post-treatment Lyme disease syndrome: part 1. International Journal of General Medicine 2019:12 101–119 https://www.dovepress.com/precision-medicine-retrospective-chart-review-and-data-analysis-of-200-peer-reviewed-article-IJGM https://www.ncbi.nlm.nih.gov/pubmed/30863136 https://www.ncbi.nlm.nih.gov/pubmed/30863136?fbclid=IwAR11hYFa6D-ufSwXztzUEdI9a36vh_90K4Lhu5HN6N-MPMHKzNWt1IdoDyI Horowitz, R.I.; Freeman, P.R. Precision Medicine: The Role of the MSIDS Model in Defining, Diagnosing, and Treating Chronic Lyme Disease/Post Treatment Lyme Disease Syndrome and Other Chronic Illness: Part 2. Healthcare 2018, 6, 129. https://www.ncbi.nlm.nih.gov/pubmed/30400667 Horowitz RI, Freeman PR (2016) Are Mycobacterium Drugs Effective for Treatment Resistant Lyme Disease, Tick-Borne Co-Infections, and Autoimmune Disease?. JSM Arthritis 1(2): 1008.	

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			Horowitz RI, Freeman PR (2016) The Use of Dapsone as a Novel "Persister" Drug in the Treatment of Chronic Lyme Disease/Post Treatment Lyme Disease Syndrome. J Clin Exp Dermatol Res 7: 345. doi:10.4172/2155-9554.1000345 Tardo AC, McDaniel CE and Embers ME (2023). Superior efficacy of combination antibiotic therapy versus monotherapy in a mouse model of Lyme disease. Front. Microbiol. 14:1293300. doi: 10.3389/fmicb.2023.1293300 https://www.frontiersin.org/articles/10.3389/fmicb.2023.1293300/full	
19	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 believe that the commenter is referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk drug substances. After further consideration of the issue, Board staff believe that an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
20	General	S. Gevorkian	The commenter is writing to express strong opposition to the proposed ban on the compounding of NAD, glutathione, B12, and other essential compounds. This proposal is an unnecessary and harmful restriction that will have serious consequences for patients, healthcare providers, and the advancement of medical treatment. Compounded therapies are a critical component of individualized patient care, offering solutions that cannot be met by standard pharmaceuticals. NAD, glutathione, and B12 are used in a variety of medical applications, including neurological support, immune function, metabolic health, and chronic disease management. Banning these compounds from	Board staff believe that the commenter is referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk drug substances. After further consideration of the issue, Board staff believe that an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate.

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			compounding pharmacies will deprive patients of access to safe, effective, and often life-changing treatments. The proposed ban undermines the medical autonomy of licensed healthcare professionals who rely on compounding to provide personalized treatment plans for their patients. Many individuals depend on compounded formulations because commercially available alternatives are inadequate, inaccessible, or do not meet their specific medical needs. Without these options, patients will be left with fewer choices, leading to worsened health outcomes, increased healthcare costs, and the potential need to seek care outside of California. There is no substantial evidence that compounding these substances poses a widespread public health risk when performed by licensed professionals following appropriate guidelines. Instead of imposing an outright ban, the Board should focus on maintaining high standards for compounding safety, ensuring that patients continue to have access to these vital compounds while upholding quality and regulatory oversight. This ban does not serve the best interests of the public or the medical community. It disregards the scientific basis for these treatments, the needs of thousands of patients, and the role of physicians, naturopathic doctors, and other licensed providers who prescribe these compounds responsibly. The Board should consider the real-world impact of such a decision and recognize that compounding is an essential practice that supports patient health in ways that standard pharmaceuticals cannot. I urge you to reject this proposal and work toward policies that protect patient access to necessary treatments without imposing blanket prohibitions that will do more harm than good. Patients and healthcare providers should not have to fight for access to well-established and beneficial therapies. I strongly encourage the Board to reconsider this approach and prioritize solutions that enhance safety without eliminating access to vital medical care.	Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
21	General	S. Shah	I am urging you to please keep Category 1 steriles such as gluatatione, B12, NAD+, etc., **allowable** in the state. Being able to use this detoxification compounds has been life saving to me	Board staff believe that the commenter is referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances

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			and my family and others that have genes that do not allow normal detoxification.	discussed in the FDA's guidance related to bulk drug substances. After further consideration of the issue, Board staff believe that an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
22	General	W. Freitag	The restrictions you are proposing on natural compound treatments like Vitamin B12 and Glutathione is a slap in the face to our heroic firefighters and first responders. They selflessly expose themselves not just to physical harm but to the toxic chemicals that leech from devastating wildfires like the ones experienced in LA last month. Firefighters and first responders rely on these simple, affordable and effective compounds to detoxify so they can keep doing the critical work to keep all Californians safe. Another group at risk from these proposed regulations are those suffering from Lyme Disease and other ailments like Cystic Fibrosis, where the simple, affordable treatments have shown true efficacy. My good friend is one such person, and she relies on glutathione to treat her Lyme illness. Another angle to consider here is that the banning of such compounds is a violation of the interstate commerce clause of the United States Constitution, and that any attempt to regulate the sale and distribution of these compounds can (and will) be challenged in federal court. Meanwhile, no other state is considering such a ban. All you are doing here is burdening the people of our great state with the requirement to cross state lines to seek these vital treatments. Save yourselves the humiliation. Back down now.	Board staff believe that the commenter is referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk drug substances. After further consideration of the issue, Board staff believe that an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
23	General	S. Johnson	I am submitting this comment in strong opposition to the proposed regulations on sterile compounding, particularly those that would severely limit access to critical compounded	Board staff believe that the commenter is referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances

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			medications, including nebulized glutathione, methylcobalamin, NAD+, and other necessary treatments. These treatments are essential for thousands of patients across the state—especially those suffering from chronic conditions such as ME/CFS, Long COVID, and for firefighters exposed to toxins in the line of duty. The key issue with the proposed regulations is the financial burden they place on pharmacies, making the continued availability of these life-saving medications effectively unsustainable. Stability studies, which are required by these new regulations, are costing between $10,000 and $30,000 per formulation, with some common combinations potentially costing upwards of $90,000 to comply. These costs are prohibitively expensive for many pharmacies, especially smaller ones that rely on compounding customized medications for their patients. To be clear, these stability studies are not required under current FDA or USP guidelines for many of the substances in question. As Maria Serpa correctly noted in her statement, the FDA's Category 1 list of approved bulk substances already ensures these treatments are safe and can be compounded without the need for additional studies. However, the proposed regulations introduce additional stability study requirements and documentation, making compliance financially unfeasible for many compounding pharmacies. Serpa's assertion that these regulations merely reflect federal and USP guidelines is misleading. She stated that "nothing in here says that each and every pharmacy needs to test all of these things for each and every compound," but this does not reflect the reality of the regulations as they are written. These rules will require many pharmacies to perform tests they are not currently required to under federal standards. This will raise the cost of these medications, making them inaccessible to patients who rely on them, despite the FDA and USP guidelines already providing a clear pathway for their safe use without such additional regulatory burdens. For example, Section 1736.9 of the proposed regulations introduces requirements for stability testing that exceed USP	discussed in the FDA's guidance related to bulk drug substances. After further consideration of the issue, Board staff believe that an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.

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			<797> standards. The FDA 503A guidelines permit the use of published, reputable stability data from manufacturers or other sources, and USP <797> similarly does not mandate in-house stability studies for substances like glutathione and NAD+. These proposed additional testing requirements create a financial barrier that will result in reduced availability of these medications, despite their long-established safety in compounded formulations. The Board has failed to provide compelling evidence to justify the proposed regulations. The November 2024 education session was biased and misleading, with none of the examples presented being relevant to the current circumstances. Despite clear objections from the public, including on the day of the presentation, the Board continues to reference this session as a necessary source of information for the public and fellow Board members to shape and justify these proposed regulations. This ongoing reliance on inaccurate and unsubstantiated information undermines the credibility of the regulatory process. I also want to address the impact this will have on public health, particularly during California's ongoing wildfire crisis. As we know, toxic smoke and particulate matter released by wildfires severely impact respiratory health, especially for vulnerable individuals. Research has shown that nebulized glutathione has a protective effect against harmful toxins like hydrogen cyanide, benzene, and polycyclic aromatic hydrocarbons released by wildfires. This is especially relevant as many individuals who are already battling the health impacts of long-term exposure to environmental toxins—such as first responders and people with compromised respiratory health—rely on treatments like nebulized glutathione to protect their lungs and reduce exposure to harmful substances. Denying access to treatments like this will undoubtedly harm those most at risk. Moreover, the recent decision by the National Institutes of Health (NIH) to limit indirect costs for research institutions—capping them at just 15%—has serious implications for the future of medical research. These cuts reduce the ability of universities and research	

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			organizations, including those in California, to conduct critical research that could lead to FDA-approved treatments for conditions like ME/CFS, Long COVID, and other chronic illnesses. NIH cuts threaten the infrastructure that supports studies on vital treatments, and without FDA-approved therapies for these conditions, compounded treatments remain one of the few viable options. The proposed regulatory burdens on pharmacies add further barriers to accessing these treatments, exacerbating the risk for patients who have no other options. Indirect costs are essential for covering the basic infrastructure of research—everything from lab space and equipment to the salaries of the support staff who make these studies possible. By limiting this funding, NIH is essentially cutting the financial foundation necessary to conduct any significant research, including the kind of research that could lead to FDA-approved treatments for conditions like ME/CFS, Long COVID, and others that are currently underserved by existing treatments. In the absence of FDA-approved treatments for these conditions, researchers in California and across the nation have been working tirelessly to explore alternatives, including compounded medications like nebulized glutathione, methylcobalamin, and NAD+. However, with these severe cuts to research funding and regulatory barriers created by the proposed California regulations, these treatments—often essential for patients with chronic illnesses—will become increasingly difficult to access. This is a direct threat to patient health, particularly as more people with conditions like ME/CFS and Long COVID struggle to find effective care. These cuts and proposed regulatory hurdles are a public health crisis in the making. Research into these critical treatments, especially as California faces the ongoing risk of wildfire smoke and the environmental toxins that accompany it, is essential for safeguarding vulnerable populations. The increasing financial burden on pharmacies due to unnecessary regulatory requirements only further exacerbates the issue, making it less likely that patients will have access to the compounded treatments they need.	

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			On a personal note, my own experience underscores the urgency of this issue, the restriction of doctor-patient autonomy, and limiting interference in healthcare options. My primary care doctor, an osteopathic family medicine specialist at a large, multi-site practice, has been administering IVs with NAD+, glutathione, and Vitamin C with significant improvement in my symptoms. Given the severity of my medical condition, it is extremely difficult for me to leave the house to receive treatments in-office twice a week. The post-exertional malaise (PEM) I experience from such physical exertion makes it necessary for me to manage my energy very carefully and within a restricted "energy envelope." These trips, which require dressing, bathing, and traveling to the office, contribute to my symptom flare-ups and are simply unsustainable. My doctor has agreed that continuing this therapy at home with compounded medications would be the most practical solution, yet it is exceedingly difficult to find a pharmacy that will provide or ship these compounded treatments due to the burdensome and overly restrictive regulatory environment. It seems that pharmacies are already being forced to adhere to requirements that go beyond federal guidelines—requirements that appear to be both unnecessary and damaging. These limits patients like me from accessing treatments that provide tangible benefits, despite the widespread medical need for these therapies. In addition to the challenges facing patients like me, I want to highlight an issue that has been exacerbated by the current regulatory environment in California. AgelessRx, a well-known telemedicine provider, has been forced to stop shipping vials of NAD+ and glutathione to California patients due to these underground regulations. AgelessRx had previously provided these treatments to patients in California without issue, but as the harmful nature of these regulations and the punitive actions taken against compounding pharmacies have gained wider recognition, they ceased shipping these life-saving medications to the state. This is a clear example of how these regulations are not only overreach but are actively harming patient access to therapies that many of us rely on. Patients in California, including	

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			those with ME/CFS, Long COVID, and other chronic conditions, are now left without a viable option for obtaining these essential treatments. Furthermore, Simmaron Research, a prestigious ME/CFS research clinic, has partnered with AgelessRx to advance a groundbreaking clinical trial investigating the efficacy of Low-Dose Rapamycin in treating ME/CFS, Long COVID, and other infection-associated chronic conditions. This collaboration aims to leverage AgelessRx's expertise in decentralized clinical trials to enhance patient access and streamline the study process. Early trials suggest that Low-Dose Rapamycin has the potential to induce remission in ME/CFS patients, with significant improvement in symptoms such as post-exertional malaise (PEM) and fatigue. According to a study by Dr. Montoya and others published on Health Rising (2022), Rapamycin shows significant promise in improving chronic fatigue symptoms. Furthermore, PolyBio.org's ongoing Long COVID clinical trial on Low-Dose Rapamycin points to substantial potential for symptom relief in long-term COVID patients, showcasing the drug's capacity to modify immune response and treat chronic fatigue-related conditions. However, the restrictive and punitive regulations in California have created an environment where compounding pharmacies are unable to provide these essential treatments. The increasing recognition of the damaging nature of these regulations has led to limited access to life-saving therapies for Californians. This restriction creates a clear and dangerous gap in the availability of treatments for patients who are already struggling to find effective care. I applaud and highlight the statements made by Members Trevor Chandler, Jeff Hughes, and Dr. Nicole Thibeau, who have intelligently, thoughtfully, compassionately, and appropriately expressed support for expanding patient access to these critical treatments.	

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			Member Chandler demonstrated wisdom and applied his insight from years of grassroots advocacy, "Responses like this are not false; they are not to be disregarded. The voices we have heard deserve to be taken seriously, and they deserve to be given the respect of showing that the effort they did to have their voices heard at this meeting and advocate to us are taken as seriously as possible." Member Hughes demonstrated compassionate and forward-thinking advocacy on behalf of disabled individuals, firefighters, first responders, and those impacted by urban-wildland fires. Jeff Hughes' remarks, "There are hundreds, if not thousands, of people using these compounded medications across the state", reflect the reality of the wide-reaching need for these treatments. His comments underscore the urgent need for thoughtful, immediate action as this crisis intensifies in Los Angeles and across California. The world is watching how public health bodies will respond to this growing climate and environmental emergency. Additionally, Dr. Nicole Thibeau demonstrated vulnerability and the unmatched wisdom of lived experience. She highlighted the potential harm these regulations could cause. Her pointed question (whether these regulations could inadvertently create greater risks by limiting access to necessary treatments) reminds us that people will find ways to access critical medical care, whether it's for abortion or for treating conditions like Long COVID and ME/CFS, which currently lack FDA-approved treatments. And let's not forget that 5% of all ME/CFS patients complete suicide due to the unbearable suffering of the condition. Access to sterile compounds like GLP-1s, especially in times of shortage, saves lives and has been demonstrated to reduce risk and ideation of suicide. In July, Dr. Nicole Thibeau was moved by the outpouring of personal pleas from people with Long Covid and ME/CFS and urged, "People with chronic illnesses and disabilities are always an afterthought. And I'm encouraging us to reposition that as being one of our main focuses." She also very clearly said, "We're causing more harm if we take away treatments from people who have diseases that don't have any approved treatment." She reminded the entire board and the public that,	

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			"And if we take away tools that are helping them and protecting them, I can't feel like we're meeting our mission." These are the voices that must guide this decision-making process. Shockingly, today we're fighting to maintain our very existence. Seeing the severe, unconstitutional, and bigoted ongoing federal efforts to undermine existing hard-won protections under Section 504 of the Rehabilitation Act, California must once again lead the way. Section 504 of the Rehabilitation Act, established in 1973, was a direct result of activism in California, where disability rights activists in San Francisco led the historic 504 Sit-in, demanding equal access and protection for people with disabilities. This incredible movement was a turning point in the fight for disability justice, and California's leadership in this fight remains a point of pride. The recent federal complaint filed by Texas threatens to dismantle our precious healthcare and disability access protections. This is going to be the first of many deliberate efforts to erase basic human rights for people with disabilities, if not eliminate us completely. Given California's legacy of advocating for the disabled, the state must continue to take deliberate and incisive action to protect the chronically ill and disabled community, including those suffering from conditions like ME/CFS and Long COVID. The federal government's planned strategy to eliminate our rights makes it even more critical for the California Board of Pharmacy to ensure that residents have expanded access to lifesaving compounded treatments. These therapies are essential for individuals who have no FDA-approved alternatives. Without them, many will continue to suffer. California must preserve its role as a leader in disability rights by making access to these therapies not just a priority but a guarantee for its most vulnerable residents. The proposed sterile compounding regulations would place substantial financial burdens on pharmacies, effectively blocking access to essential treatments. At a time when federal	

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			protections are under attack, California cannot afford to restrict access to these life-saving therapies. Instead, the state must prioritize safeguarding healthcare access for its most vulnerable residents, ensuring that they receive the critical treatments they need to survive and thrive. In contrast, the Board's failure to engage meaningfully with stakeholders and their refusal to amend the proposed regulations in response to the overwhelming public opposition—which includes over 11,000 petition signatures and hundreds of written and in-person comments—raises serious concerns about the adequacy of the Board's regulatory process. By stating that the public "does not understand federal or state laws," the Board continues to dismiss well-informed, thoughtful concerns from patients, healthcare professionals, and advocates who rely on these treatments. No meaningful collaboration has been demonstrated between the Board and healthcare providers, including doctors, pharmacists, and naturopaths, to ensure that patient needs are met and that the regulations support, rather than hinder, effective medical care. I urge the Board to align these proposed regulations with the federal FDA and USP guidelines, which already provide a safe, well-established framework for compounding these essential medications. Further, I ask the Board to focus on creating a regulatory environment that makes these life-saving treatments more accessible and affordable, not less. (Refer to comment for supplied references)	
24	General	P. Pitts	My name is Peter Pitts. I am the President of the Center for Medicine in the Public Interest (www.cmpi.org) and a former Associate Commissioner at the FDA. I write to you to weigh in on the issue of drug compounding — and particularly the compounding of GLP-1 agonist products. I know you are likely to be inundated with comments on this issue, so I will be as consist possible. **A few key points**: * These products are illegal and unregulated. Caveat emptor is bad healthcare policy. * The advertising and marketing of these products are also illegal.	Board staff have reviewed the comment and do not recommend any changes to the proposed regulation text. Board staff agree with the public safety concerns raised by the commenter. The Board's proposed regulations generally seek to align with federal law and guidance and USP standard. The Board continues to monitor for information released from the FDA and evaluate for insanitary conditions during inspections.

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			* There is a difference between drug compounders and companies running illegal pharmaceutical manufacturing operations. * Not stridently working to stop these illegal drug manufacturers is an open invitation to counterfeiters. * Playing Russian Roulette with the lives of Californians is unacceptable. Below are a few articles (by me) that support all of the above statements — and more. https://www.washingtontimes.com/news/2024/sep/5/compounders-of-drugs-that-fight-diabetes-obesity-s/ https://www.washingtontimes.com/news/2024/sep/19/weight-loss-confusion-lets-not-compound-problem/ https://www.washingtontimes.com/news/2024/feb/12/redlining-americas-girth-new-medicines-help-battle/	
25	General	Unknown Mailed Comment	A commenter states that if pharmacies can sell harmful tobacco and uppers, the Board can allow compounding pharmacy treatments. The commenter adds that Walgreens sells cigarettes, and CVS sells "uppers" caffeine pills that send college kids to the ER. Firefighters have given their lives to protect the state and are asking that the Board stop trying to block nebulized glutathione.	Board staff believe that the commenter is referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk drug substances. After further consideration of the issue, Board staff believe that an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.
26	General	B. Go	Issue #2: Given the BOP's previous claim in published administrative cases that the FDA requires the existence of a USP **DRUG** monograph in order to allow sterile compounding of any substance, not exempting 503a bulk drug category 1 substances, with the claim that the substance could not be determined to be pharmaceutical grade without such a monograph, I'd like you to	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. Board staff agree with the commenter that the Board's proposed regulation text allow for the compounding using an active pharmaceutical ingredient that does have a USP drug monograph under specified condition. Board staff further believe that its recommended

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			explicitly clarify, by responding to this comment, whether the proposed regulations, as currently worded, would allow for the STERILE compounding of bulk drugs under the 503a bulk category 1 list, **EVEN IF THERE DOES NOT EXIST A USP DRUG MONOGRAPH for the substance** (though there might exist a non-US drug monograph OR a US dietary supplement monograph), **and as long as stability study requirements, quality testing requirements and proper compounding procedures as delineated in the BOP's regulations are met.** Issue #3: Question: On day one of the February 5th meeting, one of the board members stated that a 503b Outsourcing facility is able to make patient-specific medications. This is not consistent with what I have been told by the outsourcing facilities themselves, as well as by my medical peers. Can you please confirm if that board member's statement was correct?	changes to language in sections 1736.9 and 1739.17 (please refer to Addendum 1 for the recommended text) continue to provide a legal pathway to compound with Category 1 bulk drugs substances. The Board also directs the commenter to Business and provisions code section 4129(e) that establishes the authority for an outsourcing facility licensed by the Board to dispense patient-specific compounded preparations under specified conditions.
27	General	Kaiser	The process of developing the new USP compounding chapters spanned more than 10 years with rigorous review of current scientific evidence and more than 10,000 public comments.[1] The end result was the updated USP compounding chapters, which were designed to provide comprehensive evidence-based best practices for the compounding of all compounded drug preparations in all compounding environments. Throughout the rulemaking process, the Board has assumed that adding what it views to be omissions from the USP compounding chapters to its own regulations will improve the safety of compounding and compounded products for California consumers. This is a faulty assumption; in fact, excessive regulations in healthcare, particularly those not supported by empirical evidence, can significantly increase complexity in the healthcare system and lead to an increased risk of errors. According to the American Hospital Association, regulatory overload not only raises costs to the healthcare system but also reduces the time healthcare professionals can dedicate to direct patient care, thereby increasing the likelihood of errors.[2] As such, we believe that the Board's decision to promulgate additional requirements on top of the USP standards, particularly regulations without supporting	Board staff have reviewed the comments and do not recommend changes to the proposed text based on the comments received. Staff note that the Board have previously considered the comments, most recently during its January 8, 2025. The Board does not believe a delay in effective date is appropriate except were identified in the proposed regulation text. It has been common practice for the Board to focus on education of new requirements to facilitate compliance when immediate public harm is not at stake and where the licensee is making a good faith effort to come into compliance with new requirements.

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			evidence, will increase the complexity that pharmacy licensees must navigate and is just as likely to introduce new sources of error as it is to protect California patients. Given these factors, Kaiser Permanente continues to support the following alternative approach: 1. The Board should 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. The Board should 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. 3. The Board should enforce the provisions of the USP compounding chapters as required by California Business and Professions Code section 4126.8. If the Board elects to finalize the proposed regulations, we continue to encourage the Board to establish a rational effective date for these regulations that will provide the regulated public with ample time to come into compliance with these new requirements. Given the nature of the changes that have been made during previous public comment periods, we believe that a period of nine months—rather than the one-year period we were previously requesting—from the date that the regulation is filed with the Secretary of State would be a reasonable effective date. If the proposed	

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			regulation is finalized as written, Kaiser Permanente will need to make extensive updates to our policies and standard operating procedures and enhancements to our pharmacy information systems. These tasks are time-consuming, costly, or both and, as such, the Board should establish a delayed effective date for organizations to do the work needed to meet these requirements.	
28	General	National Consumers League	Especially as our work relates to nutrition and health, NCL is deeply concerned about the growing epidemic of obesity, which now affects 41.9 percent of US adults – more than 100 million people – as well as 27.7 percent of Californians. Besides being a serious chronic disease that negatively impacts almost every aspect of health and well-being, obesity worsens the outcomes of over 230 obesity-related chronic diseases, is linked to approximately 400,000 premature deaths each year and costs the U.S. economy an estimated $1.72 trillion annually. While these facts should disturb all Americans, the reality is that obesity is still not viewed as a serious disease and health plans routinely exclude coverage for FDA-approved anti-obesity medications. Thus, too many Americans opt for unauthorized or counterfeit versions of weight loss drugs, and especially injectable glucagon-like peptide-1 receptor agonists (GLP-1s) used to treat diabetes and obesity. It is because of issues like this that NCL worked with the National Council on Aging and leading obesity experts to issue the first Obesity Bill of Rights for the nation so people with obesity will be screened, diagnosed, counseled, and treated according to medical guidelines. First among these rights is having accurate, clear, trusted and accessible information about obesity, which must include being warned about fake GPL-1s and the potential health consequences. The bill of rights also establishes the right to person-centered care, which necessitates that GLP-1s are produced safely and responsibly under the supervision of a qualified health provider and supplied by a licensed manufacturer or pharmacist. In furtherance of these rights, on February 5, NCL issued a national alert calling on consumers and health professionals to heed the warnings from the Food and Drug Administration6 that compounded versions of GLP-1 drugs	Board staff have reviewed the comment and do not recommend any changes to the proposed regulation text. Business and Professions Code section 4001.1 explicitly states that "Protection of the public shall be the highest priority for the Board when exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount." Board staff agrees with the public safety concerns raised by the commenter and notes that the Board's compounding regulations, along with federal and state legal requirements and national standards serve to protect consumers. The Board's proposed regulations generally seek to align with federal law and guidance and USP standard. The Board continues to monitor for information released from the FDA and evaluate for insanitary conditions during inspections.

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			now widely promoted on television and online are not FDA approved and may cause serious health problems. As the alert makes clear, an unregulated marketplace now exists where online telehealth companies and pharmacies are marketing untested compounded GLP-1 drugs or actual counterfeits that, according to the FDA, may contain incorrect dosages, the wrong ingredients, too much, too little or none of the active ingredients, and possibly bacteria. Even more worrying, a 2024 report from the National Association of Boards of Pharmacy7 warns that illegal online pharmacies are selling substandard or falsified GLP-1 agonists without holding the required pharmacy licensure and without requiring a valid prescription. Due to the serious health consequences associated with unapproved compounded weight loss drugs, a number of medical organizations and state Attorneys General have joined with NCL in issuing warnings that urge consumers to obtain prescriptions for GLP-1 medications from a trusted health provider and to fill the prescription an appropriately licensed pharmacy. At the same time, several state boards of pharmacy have issued public alerts and/or released policy statements directing compounders to comply with federal regulations. This is to ensure that compounding does not become a loophole for marketing knockoffs of available FDA-approved GLP-1 drugs. Recently, we learned that the California State Board of Pharmacy is considering modifications to its rules related to compounded drug preparations that we believe are inconsistent with federal law and may compromise patient safety. Thus, we encourage the Board to consider the existing fraud and patient harm from the lax controls over compounded GLP-1 drugs when finalizing its rulemaking. While the amended rules govern compounded drugs generally, the situation regarding untested, widely promoted and widely available compounded and counterfeit GLP-1s should be guidepost for determining the circumstances under which drugs should be compounded during a shortage and the requirements for reporting adverse reactions. Accordingly, NCL urges the Board to maintain federal requirements that spell out when	

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			compounding drug products is allowed as essentially copies of FDA-approved, commercially available drugs. Additionally, we believe that mandating compounding facilities to report adverse events associated with sterile and nonsterile compounded products is essential to identify potential quality issues and safety problems	
29	General	Obesity Action Coalition	Among the patient community, we fear the growth of compounded GLP-1 products will endanger patients and create a sub-standard of care. Compounded GLP-1 drugs were never intended to be widely marketed and distributed to treat chronic disease. It is difficult to name another disease state or therapeutic area with widespread compounding and outsourcing combined with predatory marketing strategies for treatments. For example, we don't see these practices with cancer patients, where someone can purchase chemotherapy at the local medi-spa or by filling out a form with an online telehealth vendor. It's also not acceptable for the treatment of obesity. People living with obesity have a right to FDA-approved medications and should not be subject to sub-standard healthcare. Policy reforms to address ongoing supply shortages and affordability barriers is critical to improve equitable access to safe, effective obesity care for all people living with obesity. The OAC appreciates the opportunity to comment on Division 17 of Title 16 of the California Code of Regulations - Board of Pharmacy to ensure limited availability of quality compounded GLP-1 products and strict standards for adverse event reporting. As a voice for people living with obesity, OAC looks forward to working with the state of California to ensure Californians have access to safe and FDA-approved treatments for this complex and chronic disease.	Board staff have reviewed the comment and do not recommend any changes to the proposed regulation text. Board staff agree with the public safety concerns raised by the commenter. The Board's proposed regulations generally seek to align with federal law and guidance and USP standard. The Board continues to monitor for information released from the FDA and evaluate for insanitary conditions during inspections.
30	General	Partnership For Safe Medicines	Compounded medications fill an important niche role in our drug supply chain. We have long appreciated the key role that compounding pharmacies play in servicing rare and unmet needs in our drug supply. Helping to fill in the gaps for temporary shortages and providing unique formulations for patients who cannot tolerate	Board staff have reviewed the comment and do not recommend any changes to the proposed regulation text. Board staff agree with the public safety concerns raised by the commenter.

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			the FDA-approved manufactured drug products help fill critical, albeit niche, gaps in America's pharmaceutical supply chain. Compounded medicines represent a tradeoff of safety versus patient need in our drug supply. As the FDA states, [These] unapproved versions do not undergo FDA's review for safety, effectiveness and quality before they are marketed. .. A compounded drug might be appropriate if a patient's medical need cannot be met by an FDA-approved drug, or the FDA-approved drug is not commercially available. However, compounded drugs are not FDA approved. This means the agency does not review compounded drugs for safety, effectiveness or quality before they are marketed. From FDA alert, "FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss" (12/18/2024) **Public misconceptions and patient safety risks in taking compounded medications…** While PSM endorses use of compounded medicine as a last resort to fill patient need, in recent years we have seen compounding facilities, medspas, and telehealth companies market compounded medicines to patients even when a commercially-available product was available. Many providers and patients misunderstand that having poor or no insurance is not a qualifying reason to access a compound medication. Concerned about the lack of knowledge in this area, in September 2024, PSM commissioned one of the only public opinion surveys about Americans' understanding of compounded medications. The findings are an excellent guide for policymakers: ● **90% of Americans are unfamiliar** with compounding pharmacies and the differences between compounded and FDA-approved drugs. ● **75% of Americans mistakenly believe** that compounded medications undergo rigorous FDA scrutiny for safety and effectiveness	The Board's proposed regulations generally seek to align with federal law and guidance and USP standard. The Board continues to monitor for information released from the FDA and evaluate for insanitary conditions during inspections.

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			• **93% of Americans express concern** upon learning that compounded weight-loss drugs are not FDA-reviewed. Consumers might not be getting the drug they expect. • **Support for FDA oversight and regulation** has strong bi-partisan backing amongst Democrats (94%), Independents (88%), and Republicans (88%) **…and some providers exploit that lack of knowledge.** We're seeing an unprecedented amount of compounded medication made right now, and much of it is being pitched to Americans without adequate disclosure of the risks. The most egregious example is the recent ad by hims&hers for their compounded GLP-1 medications that ran during the Super Bowl that was viewed by 127 million Americans. While compounded medications occupy an important niche in our drug supply, some compounders are attempting to expand it beyond this niche. However expanding the role occupied by compounded medications without acknowledging the lower safety profile is devolving the overall safety of our drug supply and endangering Americans. This standard would be inconsistent with federal law, and endanger patients by placing compounded medicines unapproved by the FDA and with lower safety standards, on the same level as medicines that have been through FDA scrutiny. **Lack of serialization of compounded medicines** All medicines, except compounded medications, must be part of the U.S.'s track and trace system. The expansion of the use of compounded medications will create a large untraceable supply of medicines in our drug supply, and create an opening for criminal behavior. The California Board Of Pharmacy should reject this rule. In 2013, after a series of major drug counterfeiting incidents that harmed American patients emanated from Florida's drug supply chain, Congress passed the Drug Supply Chain Security Act. The lesson of Florida's endangerment of the U.S. supply chain was that	

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			the supply chain required electronic traceability or criminals could easily infiltrate it, as they had shown repeatedly. At the time, compounded medications were excluded from track-and-trace requirements because the argument was that there was no supply chain and the quantity of compounded medicine in the drug supply was small and rare. That reality is no longer true. Compounding, particularly outsourcing facilities, have their own trade association, their own funded litigation initiatives to protect their interests, and their products are marketed to the public as a first line therapy. The revenue in this space is now enough to fund Super Bowl ads. Lack of traceability of compounded medicines is a growing danger to patients.	
31	General	E. Seibert	I am writing to you as just one person, disabled by Long COVID, fighting for continued survival in a city that has just faced a historic natural disaster. As you know, the wildfires in Los Angeles have been unprecedented for the State of California - upwards of 56,000 acres have burned, including homes, cars and industrial spaces. In addition to the direct damages caused by the fires, Angelenos continue to reckon with the health implications of poor air quality. While we are grateful that the fires have been contained, we are only just at the beginning. As we know from 9/11, continuing to live, work and play in close proximity to cleanup efforts has devastating long term effects on health with many survivors being diagnosed with short latency cancers due to poor air quality. It is a known fact that more people died from health complications relating to the air quality post-9/11 than on the day of the attacks. What is less known is that there are over 113,000 people registered on the World Trade Center Registry for longitudinal research into the long term health effects of exposure to 9/11 air. This cohort is not purely comprised of first responders - it includes ordinary people of all ages who just happened to live in proximity to the attacks taking place on 9/11. According to the Coalition for Clean Air webinars on General Safety Practices during this time, the clean up efforts will take 6-8 months at the very least. As efforts to move and safely store an	Board staff believe that the commenter is referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk drug substances. After further consideration of the issue, Board staff believe that an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.

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			unprecedented volume of ash takes place, hazardous air pollutants and carcinogens are being released into the air we breathe. Despite this, there is a tragic dearth of information on risk and mitigation being provided by the current administration - many Angelenos are not aware of the risks we take on by resuming "life as usual" just because the fires no longer burn. Unlike in 9/11, we have the tools - but the past actions of the Board have put those tools at risk. Thanks to the groundbreaking research taking place at Volunteer Fire Foundation, we know that nebulized glutathione reduces levels of high range environmental toxins, mycotoxins and PFAS ("forever chemicals") in first responders. Thanks to the work of 9/11 activists like Lila Nordstrom, we know that people of all ages -- including children -- living in close proximity to clean up sites are at risk of developing serious long term health complications due to worsening air quality related to the transportation and storage of ash from burn sites. I said it at last month's board meeting and I will say it again: Angelenos deserve access to nebulized glutathione too. We deserve to survive and thrive in the midst of natural disaster. We deserve to survive and thrive in the midst of a pandemic. We deserve to survive and thrive, period. But access to critical therapies like nebulized glutathione is at risk during a time when we need them the most. The vote taking place in March presents an opportunity, not only to learn from the events of 9/11, but to do better. So, do better. Listen to your stakeholders. Send these regulations back to committee. Align with USP standards. Re-build these regulations from the ground up in partnership with the people most affected. Center the needs of the most marginalized.	
32	General	Integrative Healers	I want to express my deep concerns regarding the proposed amendments to Title 16, Sections 1735-1738, and their real-world impact on access to essential compounded medications, specifically glutathione. While the Board has stated in hearings that these regulations do not limit access to necessary medications, our firsthand experience tells a different story. Previously, our medical providers were able to send firefighters home with their own nebulizers and prescriptions for compounded glutathione so they could nebulize daily or	Board staff believe that the commenter is referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk drug substances. After further consideration of the issue, Board staff believe that an approach that relies on a pharmacist's knowledge of compounding, including an

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			multiple times a week as part of their recovery from toxic smoke exposure. This is no longer possible due to restrictions resulting from Board actions. This change directly compromises our ability to provide life-saving care to the first responders who risk their lives to protect our communities. Furthermore, only one pharmacy is currently dispensing compounded glutathione due to the legal actions brought forth by the Board of Pharmacy. Over the last six weeks, we have treated more than 1,200 first responders in Los Angeles, and every single week, we struggle to secure enough glutathione for our clinics. All of our clinics are provided free of charge to firefighters—we do this not to generate revenue but to offer essential, life-saving care. In the last six weeks alone, we have treated firefighters who were first on the line for the Eaton and Palisades fires. Many of them are experiencing severe respiratory issues and are deeply concerned about their long-term health risks, particularly the potential for developing cancer. Firefighters have started calling this their "9/11," as they fear the long-term consequences of their exposure to toxic smoke and chemicals. After even a single treatment with nebulized glutathione, these first responders report noticeable improvements—they cough less, sleep better, and breathe more easily. These treatments are working, and we simply cannot afford to have our access restricted any further. The Board claims that these regulations will not limit access, but in practice, they already have. The cost of compliance with the proposed stability testing and documentation requirements will place an insurmountable burden on compounding pharmacies, effectively making these medications unavailable. These regulations are far stricter than those of any of the other 49 states. While the Board insists that these changes align with FDA standards, that is simply not true. We are working alongside cancer research foundations and medical professionals to ensure that firefighters have the best possible chance of preventing serious health conditions caused by toxic smoke exposure. Many of them have hope for the first time that they may not have to die in the line of duty—not from fire, but from the long-term consequences of their exposure. This is an urgent	understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text. Further, the Board has responded to comments related to item previously. As included in those prior responses, "As the Board has previously noted and the commenter suggests, USP provides, "Although it is possible for FDA or another government authority in the U.S. or elsewhere to require the use of 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." Specifically related to request four, Board staff note that the Board has previously considered this issue and respectfully refers the commenter to row 34 of this document for the Board's response.

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			public health issue, and we need you to listen to the communities most affected by your decisions. I have attended the hearings, and there has been no support from the public for these changes. None. The public overwhelmingly opposes these amendments. As public officials, it is your duty to listen to the voices of those you serve. This is a democracy, and we need our regulatory bodies to act in alignment with the needs and realities of the people. Our asks are simple: 1. Align California's regulations with federal standards to ensure patients have access to essential Category 1 sterile compounded medications. 2. 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. 3. Eliminate adherence to USP Chapters above 1000, which are not enforceable requirements and are meant for informational purposes only. 4. Amend the language to specify that Title 16 sterile comp. I urge you – please consider these proposed regulations. The lives of firefighters depend on it.	
33	General	C. Frost	On February 5, 2025, Member Maria Serpa asserted that the proposed updates to Title 16 are the only way to ensure Category 1 sterile compounds do not contain endotoxins. This is incorrect. Current USP standards already address and require measures to ensure sterile compounded medications meet endotoxin limits: ● USP <797> (Sterile Compounding): Requires endotoxin testing for certain high-risk compounded sterile products (CSPs). ● USP <85> (Bacterial Endotoxins Test): Establishes testing methods and specific endotoxin limits based on dosage form. ● USP <71> (Sterility Testing): Verifies that CSPs are free of microbial contamination which are the usual cause of endotoxins. The FDA Is Not to Blame for Glutathione's Inaccessibility in California If the FDA were truly preventing the use of glutathione, glutathione would not be readily available in 49 other states.*	Board staff believe that the commenter is referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk drug substances. After further consideration of the issue, Board staff believe that an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate. Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.

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			Member Serpa claimed the FDA is responsible for glutathione's inaccessibility in California, but this is false. In fact, the FDA's interim policy places glutathione on its Category 1 list—meaning it is among the bulk drug substances FDA has not objected to during the list's development. As the FDA states: "Patients' care should not be disrupted while the [503A bulks] list is under development… FDA seeks to avoid unnecessary disruption to patient treatment while the Agency considers the bulk drug substances that were nominated with sufficient support to permit FDA to evaluate them." Sterile compounded glutathione is not available in California for one reason only: the underground enforcement actions of this very Board. *StopTheBOP has contacted dozens of compounding pharmacies across the country and has not identified another state that prohibits Category 1 sterile compounds. Pharmacies offering Category 1 sterile products—such as methylcobalamin and glutathione—continue to provide them everywhere except California. At the January 8 board meeting, Member Maria Serpa claimed these regulations do not exceed USP and FDA requirements, but this is patently false. The proposed regulations exceed USP Standards in the following ways: ● USP does not require full stability studies for Category 1 or 2 sterile compounding. These requirements only apply to Category 3 compounding. For the Board to mandate such studies—which can cost $10,000 to $30,000 per formulation—imposes an insurmountable financial burden on pharmacies. This will force them to limit offerings to the most generic formulations, eliminating the ability to create customized treatments based on individual prescriber orders. ● The additional documentation of clinical circumstances for APIs on the FDA's interim Category 1 list far exceeds FDA requirements. These APIs are already treated like any other active ingredient under FDA guidelines, with no such documentation mandate. ● The requirement to perform multiple tests on APIs, including tests listed in USP Chapters above 1000 (informational-only	Further, the Board has previously responded to request three in responses to previously comments received. As included in those prior responses, "As the Board has previously noted and the commenter suggests, 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." Specifically related to request four, Board staff note that the Board has previously considered this issue and respectfully refers the commenter to row 34 of this document for the Board's response.

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			chapters), is both excessive and unprecedented. California would be the only state enforcing such standards on 503As, further restricting access without improving safety. I am deeply disturbed by the repeated false claims certain Board members and staff continue to make about federal standards. At best, these misrepresentations reflect negligence and incompetence, calling into question whether these proposed regulations are ready to be enacted. At worst, they suggest a deliberate effort to mislead both the public and fellow Board members—potentially serving hidden interests that seek to curtail patient access to safe, effective alternative medications. This troubling pattern raises serious concerns about the motivations behind these regulations and we hope other board members investigate these false statements as well and choose to act in the best interest of the public. These burdensome regulations will have devastating consequences, especially for patients needing compounded treatments tailored to their specific health needs which is the entire purpose of 503A compounding pharmacies. While pharmacies may justify the cost of stability studies for a generic glutathione multiple-dose vial, they will not be able to produce more individualized options such as essential preservative-free formulations or combinations. In essence, these regulations force 503A pharmacies to function as 503Bs which is effectively eliminating patient-specific sterile compounding. Doctors, organizations, patients, and firefighters have repeatedly told you that they do not want these regulations. The Alliance for Pharmacy Compounding and numerous individual pharmacists have also voiced strong opposition. And yet, you continue to move forward, closing your ears to the outcry from those directly affected by your decisions. As California faces an unprecedented public health crisis due to widespread toxic smoke exposure, including asbestos, lead, microplastics, and potentially thallium, this Board has a moral and ethical obligation to protect the public. Instead of actively making it harder for Californians to access critical treatments, preserve access by fixing this proposal. Our asks are simple:	

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			1. Align California's regulations with federal standards to ensure patients have access to essential Category 1 sterile compounded medications. 2. 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. 3. Eliminate adherence to USP Chapters above 1000, which are not enforceable requirements and are meant for informational purposes only. 4. Amend the language to specify that Title 16 sterile compounding regulations apply specifically to pharmacists and not to doctors.	
34	General	CMA	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 Administrative Procedure Act because the language of the regulations plainly conflicts with the Board's description of the effect of the regulations. CMA reiterates its request from CMA's 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.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. The Board has considered this issue on several occasions most recently during its January 8, 2025, Board meeting. The Board respectfully refers the commenter to the Board's prior response. 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. It may be appropriate for the commenter to confer with their licensing board to discuss their concerns. Board staff note that the Medical Board of California has previously provided a written response to individuals inquiring about the applicability of the Board of Pharmacy's regulations to individuals and practices that operate under the jurisdiction of the Medical Board of California. Below is the information provided from the Medical Board - -

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				Dear Ms. Sodergren: I understand that some concerns have been raised by stakeholders about the applicability of the Board of Pharmacy's pending compounding regulations to licensees of the Medical Board of California (MBC). Existing statute (see Business and Professions Code (BPC) section 2220.5) makes it clear that only the MBC can discipline its physician licensees. Whenever a physician is engaging in compounding (or any other action that their medical license authorizes them to perform) they must always do so consistent with the standard of care. For the purposes of MBC's enforcement program, the standard of care is established by expert testimony in the context of the facts and circumstances of a specific case. It is certainly possible that whatever regulations that are implemented by the Board of Pharmacy may influence the standard of care for physicians who are compounding, especially since some of the proposed regulations reflect what is already required for physician compounding under federal law, including, but not limited to, Section 503A of the Federal Food, Drug, and Cosmetic Act (BPC section 2225(b) allows MBC to investigate violations of federal law related to the practice of medicine). Feel free to share this message with others as you see fit who might also be concerned about the applicability of their pending regulations to the physician community. Please contact me if you have any further questions. Sincerely, Reji Varghese Reji Varghese is the Executive Director for the Medical Board of California. The Medical Board is charged with evaluating compounding practices and the standard of care relevant to its licensees.

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35	General	Alliance of PHY Compounding	The Alliance for Pharmacy Compounding asks that the California State Board of Pharmacy not to pass the proposed compounding regulations as currently written. As stakeholder feedback has indicated, these regulations are just not ready for implementation and there is no buy-in from the healthcare community. A broad coalition of hospital pharmacists, compounding pharmacies, physicians, academic medical centers, and healthcare institutions have consistently raised concerns about the unintended consequences of these rules. Yet, the Board appears poised to move forward without addressing these concerns meaningfully. We do appreciate the many hours this Board has taken to review iterations of the proposed compounding regulations. Unfortunately, they are still filled with ambiguities and unnecessary obstacles to patient access. We understand the desire to finally pass these regulations and "move on." However, it is of the utmost importance to get these regulations right, as the lives of Californians will be affected. The Board must not – as it appears to be doing – put the expediency of the process ahead of patient access to necessary medications, particularly when the Board has not shown a justification for some of the new rules or indicated how the rules make patients safer. Additionally, we are troubled that it appears that no written responses to the final round of public comments will be provided before the vote, as has been customary in the past. Instead, the Board intends to include responses in the Final Statement of Reasons, which suggests that the third modified text is functionally the final version—leaving no room for substantive changes before adoption. If that is the case, the Board is prioritizing expediency over stakeholder input and may be violating state administrative procedures rules. This rulemaking process has not provided a true opportunity for public engagement. The two-minute time slots for public comment, without the ability for follow-up or meaningful discussion, have shut down dialogue and prevented pharmacists from responding to Board members' misunderstandings about the real-world impact of these regulations. A fundamental misunderstanding persists among some Board members regarding USP general chapters and the high standards those	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on the comments received; however, staff note that recommended changes will address some of the comments. The Board respectfully refers the commenter to Addendum 1 for the recommended changes related to Category 1 bulk drug substances. Board staff note that the Board is complying the with legal requirements established for promulgating regulations and consistent with those provisions, will be considering comments received during the most recent 15-day comment period at the March 6, 2025, Board Meeting, During the meeting members will consider the comments received and determine what action is appropriate. Board staff believe it is important to highlight the Board's public meetings that provided opportunity to participate in the development of the proposed regulation text. These efforts began in 2019, where suspended while appeals were underway related to USP revisions, and resumed following finalization of related USP Chapters. Staff respectfully refer the commenter the underlying data referenced in the public rulemaking document that include information from several public meetings that occurred during the regulation development process in 2023 and note that information about the Board's public meetings in 2019 are also available on the Board's website. Board staff also note that the Board has previously responded to comment regarding USP Chapters over 1,000. The Board's previous response included in part, "USP provides, "Although it is possible for FDA or another government authority in the U.S. or elsewhere to require the use of 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

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			chapters already set for patient safety. Members of the Board also have made statements falsely suggesting the availability of stability studies for the specialized formulations of nebulized medications that are needed by Californians. The consequences of passing these regulations as written will be harmful to public health. Patients will lose access to critical medications and the care of pharmacists due to overly restrictive and duplicative requirements that go beyond USP standards without improving safety. Critical concerns that remain unresolved include: • Restrictions on immediate-use compounding that exceed USP standards, unnecessarily limiting access to time-sensitive medications. • Additional bulk drug testing requirements for Category 1 drugs, which duplicate testing already performed under USP standards, adding unnecessary costs and delays. • Requiring adherence to guidelines set in USP Chapters above 1000, even though those chapters are not intended for enforcement by USP. Before finalizing any new rules, we strongly urge the Board to form a task force of pharmacists from community hospitals, academic medical centers, rural hospitals, community pharmacies, and compounding pharmacies to share their expertise. This task force should include USP committee members to provide accurate, real-world insight. This approach would ensure the Board is fully informed before implementing regulations that could disrupt patient care. The Board must also acknowledge that California's approach to compounding regulation is outdated. USP standards have now set the national benchmark for patient safety while balancing medication access. Rather than layering unnecessary and conflicting state regulations on top of USP standards, the Board should listen to the pharmacists in the profession—who have overwhelmingly opposed these proposed regulations precisely because they go too far and do not make patients safer. Given these concerns, we urge the Board to enforce existing USP standards in the interim while taking the necessary time to become better informed on the realities of compounding practice. Patients' ability to receive care is at stake, and it is	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"

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			simply too important to rush forward with misguided regulations. Please heed the hundreds of people who have spoken up at previous meetings who have overwhelmingly opposed these regulations.	
36	General	M. Cottman	I believe that this rule making has failed to meet the intent of the process as described in Chapter 3.5- Administrative Regulations and Rulemaking, ARTICLE 1 - General, Sections 11340 and 11340.1. If you are not familiar with it, you can find the full text here (https://law.justia.com/codes/california/code-gov/title-2/division-3/part-1/chapter-3-5/article-1/section-11340/). In addition to creating a more transparent process that included public participation, Section 11340 enumerates why our rule making process exists. In the 1994, the California Legislature recognized the following (paraphrased) facts: a) There had been an unprecedented growth of administrative regulations, b) Law language created unclear and unnecessarily complex regulations, c) Substantial time and public funds were spent to adopt regulations that may not be necessary, d) The imposition of prescriptive standards on entities through regulations that place an unnecessary burden and discourage innovation, research, and development and e) The complexity and lack of clarity of regulations put small businesses at a distinct disadvantage THUS the Legislature established the Office of Administrative Law (OAL) to 1. Review adopted regulations 2. Reduce the number of administrative regulations and 3. Improve the quality of those regulations. With the INTENT that Agencies shall actively seek to reduce the regulatory burden on private entities by substituting performance standards for prescriptive standards wherever performance standards can be reasonably expected to be as effective and less burdensome, and that this substitution shall be considered during the course of the agency rulemaking process. a) This rule making process is creating more rules than it is repealing. b) As evidenced by the volume of comments that you have received and the number of revisions you have had to publish,	Board staff have reviewed the comment and do not recommend any changes to the proposed regulation text based on the comments received. The Board has appropriately followed the rulemaking process. The Board has provided information throughout the rulemaking process and the rulemaking record to support the proposed regulation text, including information from the FDA and USP. The Board respectfully refers the commenter to the Modified Initial Statement of Reasons, underlying data and documents added to the rulemaking.

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			these rules remain unclear and unnecessarily complex. Page 1 of 9 c) This rule making process started 3 years ago on January 28, 2022. The number of hours spent on this rule making by Board Members, Board Staff, Attorneys, and all the stakeholders is clearly substantial… all in an effort to adopt regulations that may not be necessary (as USP is an adequate performance standard). NOTE: Throughout the rule making process, several commenters have asked for the Board to provide evidence or data to support that these proposed rules will improve patient safety and to my knowledge, no valid data or evidence has been provided. The comment responses continue to be "Board Staff have reviewed the comment and do not recommend any changes…" or similar to this. If facts or data are not presented to justify the staff's rationale, then it must just be an opinion. What credentials do the staff have to rank them as experts in the topic of pharmaceutical compounding? Certainly, they must be at least equally qualified as the members of the USP committee, no? d) I can guarantee that these rules and regulations will discourage innovation, research, and development of custom compounded medication solutions for patients in need. Additionally, these regulations will increase costs which will further impede access to necessary therapies for the California public. e) Most of your licensed compounders are small businesses, like mine. I have 10 employees. We provide unique services to 1,500 patients per month. Without a doubt, my business, and much more importantly, my patients, will be adversely affected by these proposed rules. Summatively, over the last three years, the Board Staff have neglected to answer the most important question: How do these "in addition to USP Chapters" requirements ACTUALLY improve patient safety beyond the full adoption of the USP Compounding Chapters? There has been no evidence presented in the comment replies or at the hearings that these proposed prescriptive standards will, in fact, improve patient	

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			safety. Rather, I would argue that the performance standards provided throughout the USP Chapters are sufficient guidance for your licensees to result in safe compounds. Additionally, the regulatory burden of these proposed prescriptive requirements can be reasonably expected to be MORE burdensome and MORE expensive, but NOT result in safer compounds. As evidence of this, I remind you that the Board Staff stated in the last Comment Responses "Board staff notes that a variety of nonpharmacy personnel have authority to compound including for example physicians and veterinarians." And compound they will, if these regulations go through! Their regulatory bodies will allow them to compound in compliance with the standards of USP which will be more cost effective for patients, who will elect NOT to have a pharmacist prepare their compound. I implore you to REJECT the Recommended Third Modified Text of Compounded Drug Products dated January 30, 2025. After three years of discussions and revisions, this text does not meet your mandate of Protecting the Public any better than if your licensees comply with the USP Chapters as written by the expert committees over a 12 year period from 2010-2022. As an alternative, I RECOMMEND that you move forward with a repeal of sections 1735-1735.8 of Article 4.5 and repeal sections 1751-1751.12 of Article 7 without any additional revision or adoption of rules. All of the USP compounding chapters are codified in BPC Section 4126.8 and can stand on their own until such time as rulemaking for requirements proven to improve patient safety can commence	
37	General	111 Commenters + L. Mendelovich	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 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	Board staff believe that the commenter is referring to proposed regulation sections 1736.9 and 1736.17 related to FDA Category I bulk drug substances discussed in the FDA's guidance related to bulk drug substances. After further consideration of the issue, Board staff believe that an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards is appropriate.

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			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. 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 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. 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. The 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 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	Please refer to Addendum 1 – Board Response to Comments Received Specifically Related to Proposed Regulation Text Sections 1736.9 and 1736.17 (FDA Category 1 Bulk Drug Substances) for the Board's full response and recommended text.

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			Board's engagement process and has raised serious concerns about regulatory overreach. As written, 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.	