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9475 Gerwig Lane, Ste. A
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Dr. Seung Oh
President
California State Board of Pharmacy
2720 Gateway Oaks Dr., Ste 100
Sacramento, CA 95833

March 13, 2025

President Oh and Members of the California State Board of Pharmacy,

As you wind down the discussion on modifications to your compounding regulations, I'm making one last plea for you to consider two minor, non-substantive tweaks to the language. Without these easy changes, I can guarantee you with 100% certainty the language you are considering will do nothing to bring medication flavoring back to California families. That would be a tremendous shame considering how far you've come on the exemptions.

The changes I'm suggesting are new. They are not simply a repeat of what you have already rejected. In my previous comments, I realize now the suggested edits would have opened a massive loophole for pharmacies to perform other forms of non-sterile compounding, like making magic mouthwash, without adhering to your modified rules. That was never our intention. I apologize if it came across that way.

As you'll see from the suggested edits to the text below, you can avoid all confusion by focusing solely on the act of flavoring, instead of the facility that performs it. The language I'm proposing allows flavoring to stand alone, independent of other activities performed in the pharmacy, making it highly likely you will achieve the goal of getting flavoring back in California's pharmacies.

Thank you for your continued support on this important issue. I look forward to the final discussion.

Regards,

Chad Baker
Senior Vice President, Government Relations
FLAVORx, Inc.
cbaker@flavorx.com

Institution/Contact Name	FLAVORx/Chad Baker	
Section, Subdivision	Proposed Language	Recommendation/Comment
1735.1, Introduction & Scope.	(i) A facility that limits its compounding to combining a flavoring agent with a prescribed FDA approved drug in an oral liquid dosage form at the request of a prescriber, patient, or patient's agent shall be exempt from the requirements established in subdivision (f) and Sections 1735.2 – 1735.13. A facility that performs any other form of nonsterile compounding at any time is not exempt as provided in this subdivision.	As you know from my previous comments, the language is a dealbreaker for pharmacies since it ties flavoring regs to other activities a pharmacy may need to perform. I realize that previous suggested fixes to the language created a potential loophole where pharmacies could argue they would be exempt from the new, modified non-sterile compounding requirements for practices unrelated to flavoring. That was not our intention, and I apologize if it came across as such. We are only concerned with flavoring. The issue is the mention of "facility" so let's focus on the "act" instead. Here's an easy fix that ensures the exemptions only apply to flavoring medications: **(i) the sole act of combining a flavoring agent with a prescribed FDA approved drug in an oral liquid dosage form at the request of a prescriber, patient, or patient's agent shall be exempt from the requirements established in subdivision (f) and Sections 1735.2 – 1735.13. The performance of any other form of nonsterile compounding is not exempt from the requirements established in subdivision (f) and Sections 1735.2-1735.13.**

Institution/Contact Name	FLAVORx/Chad Baker	
Section/Subdivision	Proposed Language	Recommendation/Comment
1735.15, Flavoring Agents	(a) In addition to the standards in USP Chapter 795 and section 503a (21 U.S.C. §353a) the of the Federal Food, Drug, and Cosmetic Act (FDCA) section 503a (21 U.S.C. §353a) a facility that limits its compounding as described in Section 1735.1(i) shall establish the following SOPs:	For the same reasons stated above, this language will prevent pharmacies from flavoring medications. The fix is the same. Focus on the "act' and not the "facility". Here is what we suggest: **(a) In addition to the standards in USP Chapter 795 and section 503a (21 U.S.C. §353a) the of the Federal Food, Drug, and Cosmetic Act (FDCA) section 503a (21 U.S.C. §353a) facilities shall establish the following SOPs for the sole act of combining a flavoring agent with a prescribed FDA approved drug in an oral liquid dosage form**:

March 20, 2025

Department of Consumer Affairs, Board of Pharmacy
First Floor Hearing Room
2720 Gateway Oaks Dr., Ste 100
Sacramento, CA 95833

Re: Novo Nordisk Inc. Comments to California Board of Pharmacy Notice of Proposed Regulatory Action Concerning Compounded Drug Products, Fourth Modified Text

To Whom It May Concern:

Novo Nordisk Inc. ("NNI") appreciates this opportunity to submit comments in response to the California Board of Pharmacy (the "Board") Notice of Proposed Regulatory Action Concerning Compounded Drug Products, Fourth Modified Text ("Proposed Rule" or "Fourth Modified Text").[1]

Novo Nordisk is a healthcare company with a 100-year history of innovation in developing medicines to treat serious chronic diseases, like diabetes and obesity. NNI is the only company in the United States with FDA-approved medicines containing semaglutide. Semaglutide is the foundational molecule that serves as the primary ingredient for Novo Nordisk's well-known, prescription only medicines: Rybelsus® (semaglutide) tablets to improve glycemic control in adults with type 2 diabetes; Ozempic® (semaglutide) injection to improve glycemic control in adults with type 2 diabetes, to reduce the risk of major adverse cardiovascular events ("MACE") in adults with type 2 diabetes and established cardiovascular disease, and to reduce the risk of sustained eGFR decline, end-stage kidney disease and cardiovascular death in adults with type 2 diabetes and chronic kidney disease; and Wegovy® (semaglutide) injection to reduce the risk of MACE in adults with established cardiovascular disease and either obesity or overweight or for chronic weight management in adult and pediatric patients with obesity or adults with overweight.

We write to alert the Board to a new critical patient safety issue raised by the most recent changes to the Proposed Rule, notably by allowing compounding of untested fixed-dose combinations of a Category 1 bulk drug substance with a component of an FDA-approved drug.

[1] Notice of Proposed Regulatory Action Concerning: Compounded Drug Products, https://www.pharmacy.ca.gov/laws_regs/1735_npa_24.pdf; Fourth Modified Text, https://www.pharmacy.ca.gov/laws_regs/1708_fmrt.pdf.

In addition, while we acknowledge the Staff Responses to NNI's comments to the Third Modified Text, we urge the Board to further consider the legal considerations raised in our prior comments and update the Proposed Rule to account for these important issues.

We provide our specific comments on the most recent Proposed Rule using the Board's requested format.

Section, Subdivision	Proposed Language in Fourth Modified Text	Comment / Recommended Language Revision
1736.9	~~(e)(1)Except as provided in (2), When when a bulk drug substance or API is used to compound a CSP, it shall comply with a USP drug monograph, be the active substance of an FDA approved drug, or be listed in 21 CFR section 216, or unless authorized by a public health official in an emergency use situation for a patient specific compounded sterile preparation.~~ ~~(2) A bulk drug substance nominated for inclusion in 21 CFR section 216.23(a) and for which the FDA determined that the nomination included adequate information for the FDA to evaluate the substance and that the substance does not appear to present significant safety risks, and accordingly included in the published 503A Category 1 bulk drug substances list, may be used in compounding in~~	**Comment:** The Proposed Rule's bulks provisions should be further revised to protect patients against harmful combinations of compounded drugs that have not been assessed for safety or effectiveness. The Board states that it intends to "provide a legal pathway in California to compounding using bulk drug substances included on the FDA Category 1 bulk drug substances list that meet the requirements of federal law, federal guidance and national standards." The Fourth Modified Text, however, goes far beyond the Board's stated intent by proposing to allow untested and unsafe compounding of Category 1 substances in combination with components of an FDA-approved drug. We strongly urge the Board to add our recommended text below to limit the scope of this allowance and protect patients from unknown harms associated with compounded combination products. As written, the Board's Fourth Modified Text would permit compounding of "semaglutide" with co-active ingredients. Combining ingredients that have not been studied with "semaglutide" heightens the complexity of compounded "semaglutide" formulations and introduces some known risks and, critically, a myriad of unknown risks.[2] Developing a fixed-dose combination product is an extremely complex process and requires a careful assessment of the individual drugs alone and when used in combination. This is particularly true when the co-active ingredient is a Category 1 bulk drug substance that has not been evaluated by FDA for its own safety and effectiveness. FDA itself states that a fixed-dose combination "may present greater risk compared to clinical development of an individual drug" and "should ordinarily be reserved" for circumstances where there is a (a) combination intended to treat a serious disease or condition, (b) strong biological

[2] *See* FDA, *FDA alerts health care providers, compounders and patients of dosing errors associated with compounded injectable semaglutide products* (Jul. 26, 2024), https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-providers-compounders-and-patients-dosing-errors-associated-compounded ("FDA is aware that some compounders incorporate additional ingredients, such as cyanocobalamin (Vitamin B-12), pyridoxine (Vitamin B-6), levocarnitine (L-Carnitine) and nicotinamide adenine dinucleotide (NAD), into their semaglutide products. The safety and effectiveness of combining semaglutide with other ingredients has not been established.").

Section, Subdivision	Proposed Language in Fourth Modified Text	Comment / Recommended Language Revision
	~~accordance with this article if all of the following conditions are satisfied.~~ ~~(A) Any facility using a bulk drug substance permitted by this subdivision shall:~~ ~~(i) Assign a beyond use date, supported by stability data obtained using stability-indicating analytical methods consistent with the provisions established in USP 797 Section 14.4.3, or stability information for a patient enrolled in a clinical trial that is approved by a U.S. Department of Health and Human Services (HHS) registered Institutional Review Board (IRB). The stability data or information is required regardless of the USP Category of CSP.~~ ~~(ii) Dispense pursuant to a patient-specific prescription that documents the clinical circumstances that require the use of a bulk drug substance currently on the 503A Category 1 bulk drug substance list.~~ ~~(iii 3) Failure to compound pursuant to this subdivision and the facility's SOPs~~	rationale for use of the combination, (c) full nonclinical characterization of the activity of both the combination and the individual drugs, or a short-term clinical study on an established biomarker that suggests the combination may provide a significant therapeutic advantage over an available therapy and is superior to the individual agents, and (d) compelling reason why the new drugs cannot be developed independently.[3] These circumstances do not exist for the compounded fixed-dose combination products purporting to contain "semaglutide." Because fixed-dose combination products are more complicated than individually formulated drugs, extensive testing, which compounders do not conduct, is essential to ensure that all ingredients in the drug product work together to provide the expected safety and efficacy profile. Co-active ingredients in compounded "semaglutide" drugs that are not present in FDA-approved semaglutide products include Body Protection Compound-157 (BPC-157), L-Carnitine (levocarnitine), vitamin B-12 (cyanocobalamin or methylcobalamin), glycine, pyridoxine, chromium PIC, tirzepatide, and nicotinamide adenine dinucleotide (NAD+). Testing conducted on some of these compounded samples with multiple APIs revealed impurities and degradants caused by the interactions between the semaglutide and the co-active ingredient, underscoring how complex it is to create such a formulation. For instance, testing revealed safety and efficacy concerns involving a compounded drug containing semaglutide and NAD+, an oxidized form of NAD. NAD and NAD+ "substantially degrade when exposed to light, moisture, alkaline pH, or standard room temperatures; therefore, [they] will not be stable under ordinary storage conditions."[4] Testing results for the sample showed extremely high levels of oxidations and di-oxidations, likely due to the NAD+ reacting with the semaglutide peptide. These testing results indicated that the stability of semaglutide was compromised, which may adversely impact its effectiveness. In addition, the oxidation may result in the formation of aggregates with the potential to induce or enhance immune responses. Novo Nordisk received a complaint from a patient who took compounded "semaglutide" and NAD, was hospitalized, and was diagnosed with liver cirrhosis. The FDA Adverse Event Reporting System (FAERS) also includes one report associated with "semaglutide" and NAD+ where a patient suffered a liver injury, was hospitalized, and ultimately

[3] FDA, Guidance for Industry, *Codevelopment of Two or More New Investigational Drugs for Use in Combination* 3 (June 2013), https://www.fda.gov/media/80100/download.
[4] FDA, Briefing Document: Pharmacy Compounding Advisory Committee 4 (June 17–18, 2015).

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	~~constitutes unprofessional conduct and shall be deemed as posing an immediate threat to the public health as established subject to the provisions in Business and Professions Code section 4127.3.~~ **(e) All APIs and other components used must be evaluated for suitability for use in sterile drug preparations, as provided in USP 797, Section 9.3 Components, and follow the USP drug monograph if one exists. Components labeled with "not for pharmaceutical use", "not for injectable use", "not for human use" or other equivalent statement must not be used to compound for these purposes.** **(f) If a component included in the published 503A Category 1 bulk drug substances list is used, it must be found suitable for sterile drug preparations as provided in USP Chapter 797, Section 9.3 Components. The facility's SOPs must establish a process to**	died. These adverse event reports (although limited in number and information) suggest that combinations of "semaglutide" with Category 1 substances may be dangerous.[5] Compounders attempt to justify their compounding of "semaglutide" products based on supposed clinical needs of patients. No clinical justification supports the serious risks associated with compounding "semaglutide" with Category 1 co-actives. The FDA-approved semaglutide medicines come in a variety of strengths and dosage forms to meet the needs of many patients, and if an individual patient has a medical need for a compounded Category 1 substance, the physician can prescribe that drug for the patient. Instead of using this approach, some compounding pharmacies offer prescribers options like the ability to "add Vitamin B6 or Vitamin B12 to semaglutide to prevent nausea or . . . request a formulation of the drug that is delivered under the tongue, . . . which is different from the injectables marketed by [Novo Nordisk] . . . ."[6] However, in those cases where a prescriber determines that a patient needs another drug to complement their therapy, such as vitamin B-6 or B-12, the patient could easily be separately prescribed that vitamin B-6 or B-12 medication alongside an FDA-approved semaglutide medicine, rather than be prescribed an unapproved compounded "semaglutide" product in which the "semaglutide" is mixed with vitamin B-6 or B-12. There is no clinical evidence that using these products in a fixed-dose combination will improve patient outcomes; to the contrary, there are significant unknown risks to patient safety from patients taking such unapproved compounded fixed-dose combination products. FDA expressed some of these unknown risks at an Advisory Committee meeting on methylcobalamin. FDA recommended against adding methylcobalamin to the list of 503A Category 1 substances partly because the Agency had "a concern regarding lack of available safety data with methylcobalamin, particularly for intravenous injections and infusions."[7] An Advisory Committee member raised a specific concern that a published study "found cobalt levels following Vitamin B12 injections were significantly high"[8]

[5] Unlike sponsors of FDA-approved medicines, compounding pharmacies do not do surveillance, evaluation, or reporting of adverse events to FDA. FDA has warned that "adverse events from compounded versions of these drugs are underreported." FDA, *FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss* (Oct. 2, 2024), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss.

[6] David Wainer, *The War Over Cheaper Ozempic Won't End Well for Some Investors*, WALL ST. J. (June 26, 2024).

[7] Transcript: Pharmacy Compounding Advisory Committee (Morning Session) 70 (June 9, 2021).

[8] *Id.* at 120.

Section, Subdivision	Proposed Language in Fourth Modified Text	Comment / Recommended Language Revision
	determine the quality of the API.	and multiple Advisory Committee members voted against adding methylcobalamin to Category 1 due to its unknown safety and effectiveness profile. As we note above, these unknown risks are amplified when methylcobalamin and other co-actives are compounded with "semaglutide." For these reasons, we urge the Board to expressly state that a Category 1 substance should not be permitted to be used as a co-active in a fixed-dose combination product. **Recommended language revision:** "(f)(1) A component included in the published 503A Category 1 bulk drug substances list shall not be used as a co-active in a fixed-dose combination product." **Comment:** We also suggest that the Board reinsert the requirement that a compounded drug is dispensed pursuant to a patient-specific prescription that documents the clinical circumstances that require the use of a bulk drug substance currently on the 503A Category 1 bulk drug substance list. This requirement is consistent with the Federal Food, Drug, and Cosmetic Act section 503A.
1735.1(e)(1)	(e) In addition to prohibitions and requirements for compounding established in federal law, no CNSP shall be prepared that: (1) Is essentially a copy of one or more commercially available drug products, unless: (A) the drug product appears in an American Society of Health-System Pharmacists (ASHP) **Drug Shortages List** or FDA Drug Shortages Database **of drugs** that are in short supply at the time of compounding or **within 60 days of the end of the shortage ~~and at the time of dispensing~~**, or **in a health care facility licensed pursuant to Health and Safety Code Section 1250 where the**	**Comment:** We reiterate our request that the Board update Section 1735.1(e)(1) to state only the prohibition on compounding of "essentially a copy of one or more commercially available drug products," as defined at Section 1735(d), and to remove the exceptions to the copies restriction at (e)(1)(A) related to shortage lists and inability of a health care facility to obtain a drug. As explained in NNI's comments on the Second and Third Modified Texts, the provisions relating to the ASHP Drug Shortage List and compounding when a health care facility cannot obtain a drug from the manufacturer or wholesaler are inconsistent with federal law and policy. These broad permissions for compounding copies create risks for patient safety and the public health, and undermine a key check on compounding of unapproved drug products. **Recommended language revision:** "(e) In addition to prohibitions and requirements for compounding established in federal law, no CNSP shall be prepared that: (1) Is essentially a copy of one or more commercially available drug products, as defined at Section 1735(d) of this article. Documentation by the pharmacist that the compounded drug product produces a clinically significant difference for the medical need of an identified individual

Section, Subdivision	Proposed Language in Fourth Modified Text	Comment / Recommended Language Revision
	drug product cannot be obtained from the manufacturer or wholesaler and documentation is maintained, or (B) The pharmacist **~~determines~~ verifies** and documents that the compounding produces a clinically significant difference for the medical need of an identified individual patient~~, as determined by:~~ ~~(i) the prescribing practitioner,~~ ~~(ii) the compounding pharmacist, and~~ ~~(iii) the dispensing pharmacist(s). (C) Documentation describing the conditions in (1)(A) & (1)(B) is maintained in a readily retrievable format.~~ (C) Documentation describing the conditions in (1)(A) ~~&~~ **and** (1)(B) is maintained in a readily retrievable format.	patient, as provided for at Section 1735(d) of this Article, must be maintained in a readily retrievable format."
1736.1(e)(1)	(e) In addition to prohibitions and requirements for compounding established in federal law, no CSP shall be prepared that: (1) Is essentially a copy of one or more commercially available drug products, unless: (A) the drug product appears in an American Society of	**Comment:** We reiterate our request that the Board update Section 1736.1(e)(1) to state only the prohibition on compounding of "essentially a copy of one or more commercially available drug products," as defined at Section 1736(e), for the same reasons as described above in our comments regarding Section 1735.1(e)(1). Specifically, the provisions relating to the ASHP Drug Shortage List and compounding when a health care facility cannot obtain a drug from the manufacturer or wholesaler are inconsistent with federal law and policy, create risks for patient safety and health, and undermine a key check on compounding unapproved drugs.

Section, Subdivision	Proposed Language in Fourth Modified Text	Comment / Recommended Language Revision
	Health-System Pharmacists (ASHP) **Drug Shortages List** or FDA Drug Shortages Database **of drugs** that are in short supply at the time of compounding or at the time of dispensing, or in a health care facility licensed pursuant to Health and Safety Code Section 1250 where the drug product cannot be obtained from the manufacturer or wholesaler and documentation is maintained, or (B) The pharmacist **~~determines~~** **verifies** and documents that the compounding produces a clinically significant difference for the medical need of an identified individual patient~~, as determined by:~~ ~~(i) the prescribing practitioner,~~ ~~(ii) the compounding pharmacist, and~~ ~~(iii) the dispensing pharmacist(s). (C) Documentation describing the conditions in (1)(A) & (1)(B) is maintained in a readily retrievable format.~~ (C) Documentation describing the conditions in (1)(A) & (1)(B) is maintained in a readily retrievable format.	**Recommended language revision:** "(e) In addition to prohibitions and requirements for compounding established in federal law, no CSP shall be prepared that: (1) Is essentially a copy of one or more commercially available drug products, as defined at Section 1736(e) of this article. Documentation by the pharmacist that the compounded drug product produces a clinically significant difference for the medical need of an identified individual patient, as provided for at Section 1736(e) of this Article, must be maintained in a readily retrievable format."

Thank you for the opportunity to provide comments on this Proposed Rule. We would be pleased to provide further input or clarification of our comments if needed.

Sincerely,

Robert B Clark

Robert B. Clark
Vice President, Regulatory Affairs
Novo Nordisk Inc.

100 Daingerfield Road, Suite 100
Alexandria, VA 22314

www.a4pc.org

Alliance for Pharmacy Compounding

Compounding the Joy of Living®

March 21, 2025

Anne Sodegren, Executive Officer
Seung Oh, President
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

President Oh, Director Sodegren, and Members of the California State Board of Pharmacy:

The Alliance for Pharmacy Compounding again urges the California State Board of Pharmacy to reject the proposed compounding regulations in their current form. The feedback from a broad coalition of stakeholders—hospital pharmacists, compounding pharmacies, physicians, academic institutions, and healthcare organizations—has been clear: these regulations are unworkable, unnecessary, and detrimental to patient care. Yet, despite extensive opposition, the Board seems determined to move forward without making the meaningful revisions needed to align these regulations with patient needs and practical compounding practices.

We acknowledge the significant time invested in this rulemaking process. However, that sunken cost does not justify pushing forward regulations that impose unclear, duplicative, and excessively burdensome requirements without clear evidence of benefit. The goal must be to ensure patient access to safe and necessary medications, not to create barriers that disrupt care without justification. Unfortunately, these regulations prioritize procedural finality over patient well-being, and the Board has failed to demonstrate how the proposed rules enhance patient safety.

The public comment process has been inadequate. Restricting pharmacists and other experts to two-minute speaking slots—without opportunities for meaningful discussion—has stifled necessary debate and left significant misunderstandings unaddressed. Several Board members have demonstrated a fundamental lack of knowledge regarding USP standards and their existing safeguards for patient safety. Moreover, some have incorrectly suggested that stability studies exist for certain compounded medications, such as nebulized formulations, when in reality, such studies are extremely limited or nonexistent.

To ensure that any regulatory changes are based on expertise and real-world applicability, we strongly urge the Board to convene a task force of pharmacists from diverse practice settings—including hospitals, academic medical centers, rural facilities, and compounding pharmacies. This group should also include USP committee

members to provide authoritative insight. A collaborative approach is essential to crafting regulations that truly enhance patient safety without unnecessary disruption.

The Board must recognize that USP standards already set a rigorous, evidence-based national benchmark for compounding safety. Imposing additional, conflicting state-specific regulations serves only to create confusion and limit patient access to vital treatments. Rather than advancing these flawed regulations, the Board should commit to enforcing existing USP standards while taking the time necessary to engage in meaningful dialogue with healthcare professionals.

These regulations are not supported by the very professionals responsible for patient care. Instead, they appear to serve the interests of groups with financial incentives to limit compounding—a fact that has not gone unnoticed by the compounding and broader healthcare communities. The few public comments in

support of these regulations have been made by Big Pharma and groups backed by pharmaceutical companies. We urge the Board to step back, listen to the overwhelming opposition, and pursue a regulatory approach that prioritizes patients over politics.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer

The Alliance for Pharmacy Compounding is the voice for pharmacy compounding, representing more than 600 compounding small businesses – including compounding pharmacists and technicians in both 503A and 503B settings – as well as prescribers, educators, researchers, and suppliers.

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March 21, 2025

Lori Martinez
California State Board of Pharmacy
2720 Gateway Oaks Drive, Ste 100
Sacramento, CA 95834

Submitted via electronic mail to: Lori Martinez, California State Board of Pharmacy

RE: ***Compounded Drug Products Regulations***

Dear Ms. Martinez:

Kaiser Permanente appreciates the opportunity to respond to the California Board of Pharmacy's request for comments on the proposed regulations addressing nonsterile compounding, sterile compounding, and hazardous drugs. Kaiser Permanente comprises the non-profit Kaiser Foundation Health Plan, the non-profit Kaiser Foundation Hospitals; and the Permanente Medical Groups, self-governed physician group practices that exclusively contract with Kaiser Foundation Health Plan. These entities work together seamlessly to meet the health needs of Kaiser Permanente's nine million members in California. Kaiser Permanente's pharmacy enterprise in California is comprised of hundreds of licensed pharmacies that are staffed by thousands of individual pharmacy licentiates. The frontmatter of this letter comprises our general comments on the entirety of the proposed regulations; our comments on specific elements of the regulations are in the table that follows (in the table, Kaiser Permanente's proposed changes are denoted in red font with a strikethrough for deletions).

Kaiser Permanente wishes to acknowledge that the Board has made some rational modifications to the proposed regulations during the more recent comment periods. However, at times, we have also encountered what we perceive to be disinformation intended to advance the rulemaking process in the face of significant public concerns. We would like to use this, perhaps final, written comment opportunity to provide our perspective on several of the most pernicious myths that we have encountered during the rulemaking process.

Myth: Many of the provisions in the proposed regulations have been in California pharmacy regulations for years and removing those longstanding requirements would be "taking a step back."

Fact: It is true that some of the requirements in the proposed regulations have been in existing compounding regulations for many years. However, a great deal has changed since the last ***major*** update to the Board's compounding regulations in 2011. Most significantly, beginning in 2020, the Pharmacy Law has required pharmacies to comply with the United States Pharmacopeial Standard's (USP) compounding chapters. With the statutory requirement to meet the requirements of the USP compounding chapters, separate compounding regulations are no longer necessary.

Myth: It is appropriate for the regulation to become effective based on the date the final regulation is filed with the Secretary of State.

Fact: The Board should establish a rational delayed effective date—at least nine months—for these regulations to provide the regulated public with ample time to come into compliance with these new requirements. If the proposed regulation is finalized as written, organizations will need to make extensive

changes to compounding workflows, which will need to be memorialized in organizations' policies and standard operating procedures. The policy-writing and approval process is not automatic and, in some settings such as General Acute Care Hospitals, the updated policies must be reviewed and approved by the organization's governing body, which is also time-consuming. Many organizations will also need additional time to upgrade their electronic pharmacy systems to meet the new requirement in the proposed regulations to maintain an audit trail of all prior versions of all compounding records.

Myth: The public does not understand the proposed regulations and would benefit from "more education."

Fact: The vast majority of the feedback offered by the public has been rational and credible and should not be dismissed as ill-informed. The oral and written comments from both the regulated public and the lay public demonstrate a sophisticated understanding of pharmacy compounding, the proposed regulations, and the effects that the regulations are likely to precipitate.

Myth: Pharmacies are resistant to the proposed regulations because they just don't want to be regulated.

Fact: Kaiser Permanente supports commonsense, evidence-based compounding standards that promote the preparation of safe and effective compounded drug products, which is the reason that we support the adoption of the USP compounding standards for non-sterile, sterile, and hazardous drug products. The Pharmacy Law already requires "the compounding of drug preparations by a pharmacy… be consistent with standards established in the pharmacy compounding chapters of… USP," which provides an immediate path the Board could take to simply conform to the USP standards.[1]

Myth: If this regulation is not finalized, the Board would have to start the rulemaking process over.

Fact: The Board could move forward with enforcing the USP compounding standards and not promulgating new regulations without starting the rulemaking process over. The rulemaking package comprises a proposal to repeal the Board's current compounding regulations and a proposal to adopt the new compounding regulations. To proceed with enforcing provisions of the USP compounding chapters as required by Business and Professions Code section 4126.8, the Board should move to:

1. Accept the proposal to repeal sections 1708.3. 1708.4, and 1708.5 of Title 16, Division 17, Article 2 of the California Code of Regulations and to repeal 1735 et seq of Title 16, Division 17, Article 4.5 of the California Code of Regulations and to repeal 1751 et seq of Title 16, Division 17, Article 7 of the California Code of Regulations.
2. Reject the proposal to add new sections 1735 et seq of Title 16, Division 17, Article 4.5 of the California Code of Regulations, and to add new sections/Article 1736 et seq of Title 16, Division 17, Article 4.6 of the California Code of Regulations, and to add new sections/Article 1737 et seq of Title 16, Division 17, Article 4.7 of the California Code of Regulations, and to add new sections/Article 1738 et seq of Title 16, Division 17, Article 4.8 of the California Code of Regulations.

Kaiser Permanente appreciates the opportunity to provide feedback in response to the proposed regulations addressing nonsterile compounding, sterile compounding, and hazardous drugs. If you have questions, please contact John Gray (562.417.6417; john.p.gray@kp.org) or Rebecca Cupp (562.302.3217; rebecca.l.cupp@kp.org).

[1] Cal. Bus. & Prof. Code § 4126.8.

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Respectfully,

John P. Gray, PharmD, MSL
Director, National Pharmacy Legislative and Regulatory Affairs
Kaiser Permanente

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Section, Subdivision	Proposed Language	Recommendation/Comment
Article 4.5 Nonsterile Compounding		
Article 4.6 Sterile Compounding		
1736.1(b)	~~(b) (1) Except as allowed in paragraph (2), CSPs for direct and immediate administration as provided in USP Chapter 797 shall only be compounded in those limited situations where the failure to administer such CSP could result in loss of life or intense suffering of an identifiable patient. Any such compounding shall be only in such quantity as is necessary to meet the immediate need of the patient. If not already documented in the patient's medical record, documentation for each such CSP shall also include the compounded date and time, the patient's name and patient's unique identifier and the circumstance causing the immediate need of the patient. Such documentation need not be redocumented by the compounding staff if already available.~~ ~~(2) If the sterile compounding equipment or environment fail(s) to meet any required specification, after attempts to remediate pursuant to the facility's SOPs are unsuccessful, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering of an identifiable patient. This provision may only be used for 48 hours after such failure(s). All such failures must be documented in accordance with facility's SOP and shall be reported to the Board within 72 hours.~~	At this juncture, we have nothing new to say about this regulation; however, we do not want to risk our silence on the matter being misconstrued as agreement. We continue to believe that this regulation is not necessary because the USP standard on immediate use compounding strikes the appropriate balance between patient safety and timely access to compounded medications. This regulation will have a chilling effect on pharmacy personnel performing immediate use compounding, including in critical situations like Code Blue events in hospitals, and is likely to promote immediate use compounding by non-pharmacy personnel.
Article 4.7 Hazardous Drugs		
1737.15(a)	Deactivating, decontaminating, cleaning, disinfecting, and sporicidal agents shall be used in accordance with manufacturers' specifications, or subsequent ~~manufacturer approved~~ studies published in a peer-reviewed journal**,** and shall be surface compatible.	We appreciate the Board's continued willingness to discuss this section of the regulation. In response to our comment letter dated February 20, 2025, Board staff responded, "the recommendation to add in a provision for the study to be 'peered reviewed' does not ensure an independent reviewer is involved."[2] We find the Board's feedback perplexing as peer review is the gold standard process for independently evaluating the methodological rigor of a study. The

[2] California Board of Pharmacy, *Staff Recommended Response to Comments – Section 1737 et seq*, https://www.pharmacy.ca.gov/meetings/agendas/2025/25_mar_bd_mat_1737_comments.pdf (last visited Mar. 21, 2025).

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Section, Subdivision	Proposed Language	Recommendation/Comment
		University of California Office of Scholarly Communication describes peer review as the process by which "reviewers who are experts in the topic at hand… review new scholarship for relevance, accuracy, and importance to the field."[3] Typically, during peer review, "the identities of the reviewers and authors are kept anonymous to mitigate the risk of bias."[4] Therefore, we continue to recommend amending the regulation text to indicate that the study must be published in a peer-reviewed journal.

[3] University of California Office of Scholarly Communication, *Peer Review*, https://osc.universityofcalifornia.edu/scholarly-publishing/peer-review/ (last visited Mar. 21, 2025).
[4] *Id*.

CALIFORNIA MEDICAL ASSOCIATION

March 21, 2025

Lori Martinez
Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
PharmacyRulemaking@dca.ca.gov

Sent via e-mail

RE: Compounded Drug Products Regulations, Fourth Modified Text Noticed March 06, 2025

Dear Ms. Martinez:

On behalf of our over 50,000 medical student and physician members, the California Medical Association (CMA) submits the following comments on the fourth modified text of the Board of Pharmacy's (Board) proposed Compounded Drug Products regulations. The Board proposes to amend, repeal, and replace existing regulations, and to adopt new regulations relating to drug compounding.

1. **Language of Proposed Text Conflicts with Board's Description of Its Effect (throughout all sections)**

CMA is disappointed by the Board's continued refusal to revise its proposed language to clarify that the regulations do not apply to physicians. In its response to public comment requesting clarification on whether the regulations apply to physicians and other licensed practitioners, the Board effectively stated the regulations do not apply to licensees of other healing arts boards, noting: "[…] [the] Board's regulations apply to licensees within the Board's jurisdiction. The Board's jurisdiction is limited to those businesses and individuals within its practice act."[1]

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,[2] because their scope is not expressly limited to pharmacists and pharmacies, unlike the current regulation[3]. Thus, the Board's proposed regulations continue to violate the clarity standard of the

[1] Board Jan. 8, 2025 Meeting Materials, Staff Recommended Responses: General Comments, p. 13, https://www.pharmacy.ca.gov/meetings/agendas/2025/25_jan_bd_mat_gen_comm.pdf.
[2] The proposed regulations are generally drafted to apply to the act of compounding, and are not expressly limited to licensees of the Board of Pharmacy. See, e.g., proposed regulation text at § 1735.1 ("[…] the compounding of a CNSP shall meet the following requirements of this article."); § 1735.2 ("[…] the compounding of CNSP shall meet the following requirements of this article."); §§ 1735.3-1735.12 & 1735.14 ("[…] the following requirements apply to nonsterile compounding."); §§ 1736.2-1736.9, 1736.11-1736.20 ("[…] the following requirements apply to sterile compounding."); § 1736.21 ("[…] the following requirements apply to allergenic extracts.").
[3] 16 CCR § 1735(a) (defining "compounding" to mean "activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription").

Administrative Procedure Act (APA) because the language of the regulations plainly conflicts with the Board's description of the effect of the regulations.[4]

CMA would also like to address comments made by Board staff at its most recent meeting held on March 6, 2025. Board counsel summarized section 4170(c) of the Business and Professions Code (BPC), stating "the Medical Board of California and other healing arts boards are specifically charged with the enforcement of Pharmacy Law with respect to their respective licensees."[5] CMA has never disputed this fact. In fact, our letter dated December 9, 2024, cited BPC 2220.5, acknowledging the Medical Board's authority.

Further, BPC 2220.5 specifies this authority empowers the Medical Board to investigate or take disciplinary actions against physicians for violations "…of the Medical Practice Act and **any other provision of this division**," referring to the Healing Arts division (division 2 of the BPC, commencing with section 500), which contains the Pharmacy Law (chapter 9 of the BPC, commending with section 4000), among other healing arts laws. (BPC 2220.5(b) (emphasis added).) Thus, BPC 2220.5 and BPC 4170(c) both authorize the Medical Board to enforce the Pharmacy Law on physicians.

While these two statutes limit the Board of Pharmacy's authority to take **enforcement** action against a physician's license, they do not limit the scope of licensees to whom the Board's regulations may apply. Rather, they suggest the opposite.

The Pharmacy Law may, at times, apply to physicians, and in those situations, the Medical Board is authorized to take enforcement action if a physician is acting in violation of the law. Through the regulatory process, the Board of Pharmacy is implementing, interpreting, and making specific the Pharmacy Law which, in this case, the Medical Board has confirmed "may influence the standard of care for physicians who are compounding."[6] Allowing pharmacist-centric regulations to influence the physician standard of care is inappropriate and would harm patient care in California.

CMA reiterates its request from our prior comment letter dated December 9, 2024, to revise the proposed regulations to clarify they do not apply to compounding performed by physicians outside of a pharmacy setting, so that the proposed language of the regulations aligns with the Board's description of the effect of the regulations, as required by the APA.[7]

2. Requirement to Verify a Preparation Produces a Clinically Significant Difference Interferes with Exercise of Professional Judgment and Exceeds Federal Law (§§ 1735(d), 1735.1(e)(1)(B), 1736(d), 1736.1(e)(1)(B))

CMA reiterates its concern regarding the Board's proposed requirement for pharmacists to "verify" that a compounded drug produces a clinically significant difference for a patient. This proposed requirement creates an undue burden and restricts the professional judgment the

[4] Gov. Code §§ 11340(b) & 11349.1(a)(3); 1 CCR § 16 (a)(2).
[5] Corinne Gartner, Board Meeting, Cal. State Bd. of Pharmacy (Mar. 6, 2025), https://youtu.be/zoyPp_pDz9Q?t=6823 (starting at 1:53:43, quoted comments at 1:54:06).
[6] Letter from Reji Varghese, Exec. Dir., Med. Bd. of Cal., to Anne Sodergren, Exec. Officer, Cal. State Bd. of Pharmacy (Nov. 18, 2024), https://www.pharmacy.ca.gov/meetings/agendas/2025/25_jan_bd_mat_mbc_letter.pdf.
[7] Gov. Code §§ 11340(b) & 11349.1(a)(3); 1 CCR § 16 (a)(2).

Board intended to preserve. Mandating verification for every instance of compounding a commercially available drug that is not on a shortage list establishes a rigid, prescriptive standard. This contradicts the Board's stated goal of maintaining flexibility, and, as such, the language violates the clarity standard because it conflicts with the Board's description of the effect of the regulations in its formal response to members of the public regarding this issue.[8] We refer you to our comment letters dated January 27 and February 21, 2025, for detailed discussions of this issue.

To enhance clarity and ensure patients maintain timely access to medications, CMA reiterates its request from our prior comment letter, dated January 27, 2025, to remove "verify and" from proposed sections 1735(d), 1735.1(e)(1)(B), 1736(d), and 1736.1(e)(1)(B) of the third modified text.

Thank you for your consideration. Please feel free to contact me with any questions at (916) 444-5532 or asanchez@cmadocs.org.

Sincerely,

S. Alecia Sanchez
Chief Strategy Officer
California Medical Association

[8] Gov. Code § 11349.1(a)(3); 1 CCR § 16 (a)(2).

Section, Subdivision	Proposed Language	Recommendation / Comment
Non-Sterile Compounding		
CCR 1735.d	(d) "Essentially a copy" of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (API(s)) as the commercially available drug product, except that it does not include any preparation in which there has been a change made for an identified individual patient that produces for that patient a clinically significant difference, as **verified and documented** by the **pharmacist**, between that compounded preparation and the comparable commercially available drug product.	**Rationale:** We once more emphasize that us and others who commented on this section remain concerned with the wording of this section. We appreciate the board's position that the intent is to rely on the professional judgement of the pharmacist. At the same time, we object to the wording of the regulation and wish to point out that this section has the potential to be misinterpreted as written, both currently and in the future. It is important to get this right so that the intent is clear and does not cause confusion. The wording of ""Essentially a copy" of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (API(s)) as the commercially available drug product," could be interpreted to mean that ANY compound being made is defined as essentially a copy of a commercially available drug product. The trouble here is that any compounded drug that has the same API as a commercially available drug product will violate this regulation. Using the example of a hospital pharmacy that compounds a batch of 20 doses of "GI Cocktail" for use in the Emergency Department. To make this compound, the pharmacy mixes together Donnatal®, Viscous Lidocaine and an antacid such as Maalox®. By the definition above copied from the proposed regulation, it will be a violation of this proposed regulation since these doses are compounded and will be seen as including the same API as the commercially available products from which they are compounded. To further explain, since the compounded product contains lidocaine, it violates the proposed regulation since it contains the same API (lidocaine as the commercially available viscous lidocaine. Additionally, since the compounded product contains Donnatal®, it violates the proposed regulation since it contains the same API as the commercially available Donnatal®. Additionally, since the compounded product contains Maalox®, it violates the proposed regulation since it contains the same API as the commercially available Maalox®. These products are being used routinely in the ER for abdominal conditions. This proposed regulation, if it is read simply for the way it is stated, will imply that the pharmacist verifying the order will need to go through a process of verifying with the prescriber and then documenting each and every order for GI Cocktail that the change

		from the 3 commercially available products to a compounded GI Cocktail produces a clinically significant difference for each individual patient. This unintended consequence of altering the work of pharmacists and physicians in the ER was not explained in the ISOR. We are deeply concerned that the language as written, will cause additional communication and documentation of the communications for both physicians and pharmacists. We are concerned that board staff's previous response to this concern did not demonstrate their understanding of our concern. In the ISOR, the board states that the FDA guidance document is being utilized to provide guidance regarding this definition (ISOR section copied herewith for reference): New subdivision (d) adds the definition of "Essentially a copy." A definition is in current section 1735.1(k) of the board's regulations. It is retained and moved into this definitions section of the new language as it is not included within USP <795> and is used elsewhere in the proposed regulations. The board, however, amended the existing language slightly to provide additional clarity and consistency by amending "comparable" to the "same" active pharmaceutical ingredients (APIs). This change is necessary to align the definition with the FDA guidance document, which says "the compounded drug product has the same active pharmaceutical ingredient(s) (API) as the commercially available drug product." (This FDA guidance document is available as underlying data of this rulemaking; see item number 9 in the Underlying Data section of this document.) Further, this definition ensures that the pharmacist can use their professional judgment when determining if a compound is essentially a copy. Pharmacists must remain knowledgeable of current practice standards and legal requirements for the profession when exercising their professional judgment. It is important to note that the definition taken from the FDA guidance document and used in this proposed regulation, is only one part of three of the definition in the guidance document. Herewith the guidance document section on "Essentially a Copy" for reference: FDA intends to consider a compounded drug product to be essentially a copy of a commercially available drug product if: • the compounded drug product has the same active pharmaceutical ingredient(s) (API) as the commercially available drug product; • the API(s) have the same, similar, or an easily substitutable dosage strength; and

		• the commercially available drug product can be used by the same route of administration as prescribed for the compounded drug, unless, as provided by section 503A(b)(2), a prescriber determines that there is a change, made for an identified individual patient, which produces, for that patient, a significant difference from the commercially available drug product. The proposed regulation definition crucially leaves out the requirements for a same or similar dosage strength and route. By leaving out these clarifying terms, the definition is now so broad that it is inclusive of every single non-sterile and sterile compound being compounded by a pharmacy in the state of California. From our example above, it is open to interpretation by both the regulated public and board staff of what "essentially a copy" is because it will be everything with the same API. By the proposed definition, since diazepam tablets are commercially available, a pharmacy may not compound a diazepam drip from IV vials since the tablets contains an API that is commercially available (even though it is available in a completely different non-sterile dosage form). According to the definition, a hospital making a batch of oral suspension from tablets on a regular basis for its neonatal of pediatric unit, will be making essentially copies of the API in the tablets and will have to call and verify with the prescriber and then document the self-evident information that the change was made for each and every identified individual patient that produces for that patient a clinically significant difference. We are sure that we can all agree that this is not the intent of the regulation. By adding the crucial elements of strength and route it narrows the definition and it is much clearer and is aligned with both the FDA and board's intent. This addition of language provides clarification while still allowing flexibility for the pharmacist to use professional judgement. By adding the components that aligns with FDA guidance, it becomes clear that it will the same as federal statute and guidance, and we recommend that this regulation be deleted. We are concerned that Board staff's previous response to this concern did not demonstrate their understanding of our concern. While all involved currently in the creation and comments for the definition of "essentially a copy" may have a grasp and understanding of the intent of this proposed regulation, we must take the multiple comments from all stakeholders as an indicator that there will be future misunderstanding and misinterpretations of this language. It is of the utmost importance to recognize that ten to fifteen years from now these interpretations and intent will be forgotten, and the only guidance left to enforce are the words as written. We are sure that the current board would not want future board

		members and staff to enforce this rule under the misunderstandings that we and others took great pains to point out at this moment in time. We are concerned that Board staff's previous response to this concern did not demonstrate their understanding of our concern. **Recommendation:** (d) "Essentially a copy" of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (API(s)) as the commercially available drug product, **the API(s) have the same, similar, or an easily substitutable dosage strength; and the commercially available drug product can be used by the same route of administration as prescribed for the compounded drug** except that it does not include any preparation in which there has been a change made for an identified individual patient that produces for that patient a clinically significant difference, as **verified and documented** by the **pharmacist**, between that compounded preparation and the comparable commercially available drug product.
1735.12(b)	(b) The Board shall be notified in writing within ~~72~~ 96 hours of the facility's receipt of a complaint of a potential quality problem ~~**or the occurrence of an adverse drug experience as defined in 21 CFR 310.305(b)** drug event~~ involving a CNSP.	**Rationale:** We are concerned that board staff's comments regarding our concern does not reflect the intent that board members verbalized during the full board meeting. We therefore request that board members review our concerns and indicate their agreement or disagreement with staff's response. We once more reiterate our previous concerns. The way that this regulation is worded could be misinterpreted. This proposed regulation was discussed by the board during the last board meeting, and it was mentioned that the intent is for complaints that indicate true quality problems be reported to the board. From the way that it is written, the understanding that one could derive from the language is that the board must be notified of all complaints that could potentially indicate a quality problem. For example, a patient given a compounded gel, could complain that from their recollection it appears to have a slightly different opacity from one dispensed previously. Since this could potentially indicate a quality problem, the pharmacist will then report the complaint of a potential quality problem to the board. The pharmacist then investigates and finds that the medication was compounded correctly but the master formula was changed to a different gel base due to a change in manufacturers.

		One of our members reported to CSHP that they started to report all complaints that could indicate a potential complaint to the board. They were instructed by board staff that they should only report it when there was an actual quality problem since they were inundating the board with reports. It shows that there has been confusion with the current regulations. It is important that we use this opportunity to make the language as clear as possible. We are concerned that Board staff's previous response to this concern did not demonstrate their understanding of our concern and did not explain why board staff instructed the health system to stop reporting all potential quality problems. While all involved currently in the creation and comments may have a grasp and understanding of the intent of this proposed regulation, we must take the multiple comments from all stakeholders as an indicator that there will be future misunderstanding and misinterpretations of this language. It is of the utmost importance to recognize that ten to fifteen years from now these interpretations and intent will be forgotten, and the only guidance left to enforce are the words as written. We are sure that the current board would not want future board members and staff to enforce this rule under the misunderstandings that we and others took great pains to point out at this moment in time. **Recommendation:** (b) The pharmacy shall report in writing a product quality issue for any compounded product to the board within 96 hours after the pharmacy receives notice of the product quality issue.
Sterile Compounding		
CCR 1736(e)	(d) "Essentially a copy" of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (API(s)) as the commercially available drug product, except that it does not include any	**Rationale:** We once more emphasize that us and others who commented on this section remain concerned with the wording of this section. We appreciate the board's position that the intent is to rely on the professional judgement of the pharmacist. At the same time, we object to the wording of the regulation and wish to point out that this section has the

	preparation in which there has been a change made for an identified individual patient that produces for that patient a clinically significant difference, as **verified and documented** by the **pharmacist**, between that compounded preparation and the comparable commercially available drug product.	potential to be misinterpreted as written, both currently and in the future. It is important to get this right so that the intent is clear and does not cause confusion. The wording of ""Essentially a copy" of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (API(s)) as the commercially available drug product," could be interpreted to mean that ANY compound being made is defined as essentially a copy of a commercially available drug product. The trouble here is that any compounded drug that has the same API as a commercially available drug product will violate this regulation. ~~This unintended consequence of altering the work of pharmacists and physicians in the ER was not explained in the ISOR.~~ We are deeply concerned that the language as written, will cause additional communication and documentation of the communications for both physicians and pharmacists. We are concerned that board staff's previous response to this concern did not demonstrate their understanding of our concern. In the ISOR, the board states that the FDA guidance document is being utilized to provide guidance regarding this definition (ISOR section copied herewith for reference): New subdivision (d) adds the definition of "Essentially a copy." A definition is in current section 1735.1(k) of the board's regulations. It is retained and moved into this definitions section of the new language as it is not included within USP <795> and is used elsewhere in the proposed regulations. The board, however, amended the existing language slightly to provide additional clarity and consistency by amending "comparable" to the "same" active pharmaceutical ingredients (APIs). This change is necessary to align the definition with the FDA guidance document, which says "the compounded drug product has the same active pharmaceutical ingredient(s) (API) as the commercially available drug product." (This FDA guidance document is available as underlying data of this rulemaking; see item number 9 in the Underlying Data section of this document.) Further, this definition ensures that the pharmacist can use their professional judgment when determining if a compound is essentially a copy. Pharmacists must remain knowledgeable of current practice standards and legal requirements for the profession when exercising their professional judgment. It is important to note that the definition taken from the FDA guidance document and used in this proposed regulation, is only one part of three of the definition in the guidance document.

		Herewith the guidance document section on "Essentially a Copy" for reference: FDA intends to consider a compounded drug product to be essentially a copy of a commercially available drug product if: • the compounded drug product has the same active pharmaceutical ingredient(s) (API) as the commercially available drug product; • the API(s) have the same, similar, or an easily substitutable dosage strength; and • the commercially available drug product can be used by the same route of administration as prescribed for the compounded drug, unless, as provided by section 503A(b)(2), a prescriber determines that there is a change, made for an identified individual patient, which produces, for that patient, a significant difference from the commercially available drug product. The proposed regulation definition crucially leaves out the requirements for a same or similar dosage strength and route. By leaving out these clarifying terms, the definition is now so broad that it is inclusive of every single non-sterile and sterile compound being compounded by a pharmacy in the state of California. From our example above, it is open to interpretation by both the regulated public and board staff of what "essentially a copy" is because it will be everything with the same API. By the proposed definition, since diazepam tablets are commercially available, a pharmacy may not compound a diazepam drip from IV vials since the tablets contains an API that is commercially available (even though it is available in a completely different non-sterile dosage form). According to the definition, a hospital making a batch of oral suspension from tablets on a regular basis for its neonatal of pediatric unit, will be making essentially copies of the API in the tablets and will have to call and verify with the prescriber and then document the self-evident information that the change was made for each and every identified individual patient that produces for that patient a clinically significant difference. We are sure that we can all agree that this is not the intent of the regulation. By adding the crucial elements of strength and route it narrows the definition and it is much clearer and is aligned with both the FDA and board's intent. This addition of language provides clarification while still allowing flexibility for the pharmacist to use professional judgement. By adding the components that aligns with FDA guidance, it becomes clear that it will the same as federal statute and guidance, and we recommend that this regulation be deleted. We are concerned that Board staff's previous response to this concern did not demonstrate their understanding of our concern.

		While all involved currently in the creation and comments for the definition of "essentially a copy" may have a grasp and understanding of the intent of this proposed regulation, we must take the multiple comments from all stakeholders as an indicator that there will be future misunderstanding and misinterpretations of this language. It is of the utmost importance to recognize that ten to fifteen years from now these interpretations and intent will be forgotten, and the only guidance left to enforce are the words as written. We are sure that the current board would not want future board members and staff to enforce this rule under the misunderstandings that we and others took great pains to point out at this moment in time. We are concerned that Board staff's previous response to this concern did not demonstrate their understanding of our concern. **Recommendation:** (d) "Essentially a copy" of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (API(s)) as the commercially available drug product, **the API(s) have the same, similar, or an easily substitutable dosage strength; and the commercially available drug product can be used by the same route of administration as prescribed for the compounded drug** except that it does not include any preparation in which there has been a change made for an identified individual patient that produces for that patient a clinically significant difference, as **verified and documented** by the **pharmacist**, between that compounded preparation and the comparable commercially available drug product.
CCR 1736.1 Introduction and Scope. Subsection (b):	(b) (1) Except as allowed in paragraph (2),CSPs for direct and immediate administration as provided in the Chapter shall only be compounded in those limited situations where the failure to administer such CSP could result in loss of life or intense suffering of an identifiable patient. Any such compounding shall be only in such quantity as is necessary to meet the immediate need of the patient. If not already documented in the patient's	**Rationale:** We would like to continue our objections to this proposed regulation for the reasons that we and others have pointed out both in writing and written comments up to this point. As stated before, we object to the proposed regulation since it would severely limit pharmacies' ability to utilize the immediate-use provision to only those limited situations where the failure to administer such CSP could result in loss of life or intense suffering of an identifiable patient. This continues to narrow the scope of application of the immediate use provisions of USP to a point where it is practically unusable. We and others continue to point out the unintended consequences that this rule has been responsible for in the past, such as shifting compounding to disciplines that do not fall under the jurisdiction of the board. We are concerned that the board's response to

	medical record, documentation for each such CSP shall also include, the compounded date and time, the patient's name and patient's unique identifier and the circumstance causing the immediate need of the patient. Such documentation need not be redocumented by the compounding staff if already available. (2) If the sterile compounding equipment or environment fail(s) to meet any required specification, after attempts to remediate pursuant to the facility's SOPs are unsuccessful, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering of an identifiable patient. This provision may only be used for 48 hours after such failure(s). All such failures must be documented in accordance with facility's SOP and shall be reported to the Board within 72 hours. (3) If the sterile compounding equipment or environment fail(s) to meet any required specification in a critical access hospital, as defined in the Social Security Act 42 U.S.C. 1395i-4 section (c)(2)(B), after attempts to remediate pursuant to the facility's SOPs are unsuccessful, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering or an identifiable patient. This provision may be	stated concerns negates the complexity of health system operations by implying our practices are inefficient and potentially in accurate. . The Board's responses, at times, fails to provide evidence for the continued support of the proposed regulations that have been identified by the regulated entities as potentially harmful to the patients we serve. We thank the board for clarifying our questions regarding the expectations for reporting utilization of the proposed immediate use during instances when the appropriate compounding environment is not available at the time. A review of the ISOR does not address the increase in direct and indirect costs to licensees and the board of the proposed rules associated with the expected increase in reporting. The changed text makes clear the expectations that every single instance of initiation of immediate-use in this context be reported to the board, even in cases where routine maintenance of the engineering controls is scheduled and there is an emergent need for an immediate use compounded medication. We once more reiterate our concern that the board will not have adequate resources to manage the onslaught of additional reports that will be received from licensees. The subsequent increase in staffing will then be passed to licensees via increases in license fees. We are concerned that the board may underestimate the seriousness of challenges that many hospitals that are not designated critical access hospitals will experience in the state. Especially those that serve rural communities. We maintain our position that the board's proposal for immediate use in instances where there may be equipment and engineering control failures is egregiously inadequate. It does not account for both catastrophic failures of the equipment and environment or for catastrophes like natural disasters. We once more reiterate our stance that the additional allowance for critical access hospitals only addresses the problem partially. We object to this partial addressing of this problem and again recommend that the board recognize that there are many rural hospitals that are not designated as critical access hospitals. These hospitals can run into the exact same problems with equipment and engineering controls as critical access hospitals with equally devastating consequences. There are even standalone, single owner hospitals in metropolitan areas without the benefit of belonging to a health system that can be impacted. While we highly recommend that subsection (b) be changed to our recommendation below under the bolded heading of 'Recommendation", absent an acceptance of this recommendation, we recommend that the allowances of subsection (3) be changed to:

	used for 120 hours after such failure(s). All such failures shall be documented in accordance with facility's SOPs and shall be reported to the Board within 72 hours.	3) If the sterile compounding equipment or environment fail(s) to meet any required specification in a ~~critical access~~ hospital **that are not within 40 road miles of a hospital of the same corporate ownership** , ~~as defined in the Social Security Act 42 U.S.C. 1395i-4 section (c)(2)(B)~~, after attempts to remediate pursuant to the facility's SOPs are unsuccessful, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering or an identifiable patient. This provision may be used for 120 hours after such failure(s). All such failures shall be documented in accordance with facility's SOPs and shall be reported to the Board within 72 hours. To continue with the proposed requirement, in essence, means California pharmacists will be the only licensed professionals in the USA banned from utilizing the USP immediate-use allowance. It is concerning that other than stating that "this is existing language at section 1751.8(e)…" there are no reasons provided in the ISOR for the requirement that CSPs used for immediate administration be limited to situations where the failure to administer could result in loss of life or intense suffering. This requirement was created based on the old USP standards when there was limited understanding of the applicable microbiological principles and the wide clinical barriers it creates as it relates to immediate use. It is important that the board consider the negative impact on patient care that this antiquated rule creates. Since the ISOR does not address the objective and scientific reasons for the limitation on immediate use, we recommend that the regulation be deleted. We are concerned that the board has not demonstrated their understanding of our concern regarding this issue. The expectation of an emergency plan to provide compounding services when the hospital's sterile compounding operations are down are ideal and hospitals are required by federal regulations to have emergency plans. However, the proposed regulations are implying the hospital must have a backup cleanroom. This is a multi-million dollar investment which is not possible for most hospitals and especially for rural and stand alone hospitals. . The impact of the proposed regulations will have significant impact on hospitals financial solvency with unintended consequences to patient care. Elimination of low complexity immediate use provision creates additional hurdles to acquiring the medication that might be insurmountable and therefore jeopardize patient safety. We wish to provide the following realistic example: when a rural non-critical access hospital pharmacy has a sterile compounding airflow hood malfunction, and the replacement

		hood must be ordered and shipped, they can use immediate use compounding for two days. After this they must stop compounding. What is a pharmacy supposed to do then? Think about it, a licensee has the drugs in their hands, but they cannot go through the simple process of mixing it together in a few seconds to treat a patient. ~~.~~ In the absence of a workable solution, we recommend that the immediate use regulation be deleted. We are concerned that the board has not demonstrated their understanding of our concern regarding this issue that has the potential to shut down rural hospitals to the significant detriment of patients and communities. We continue to object to the boards business impact numbers. The immediate use regulation alone will cause a loss in income totaling millions of dollars if a hospital must close their doors and ship patients out to a hospital with a working cleanroom. The Board failed to capture the economic impact to health systems in their ISOR. The board's response to the question of "Business Impact" in ISOR states; "the board anticipates minimal ongoing costs ranging from approximately $5,700 to $15,000 per year related to administrative and maintenance workload." This statement applies to the multiple proposed regulations requiring the addition of new administrative procedures, reporting requirements, and enhanced testing. The amount stated is a gross underestimation of the true cost to health systems. Understandably the Board lacks the internal expertise to accurately reflect those anticipated costs associated with development of policies and procedures, monitoring implementation of those procedures, correctly reporting to the Board as proposed by this regulation and others, cost of monitoring visits by the Board, enhanced environmental and personnel testing requirements, purchase of additional inventory for PPE, implementation of technology to support the deployment of the policies and procedures and hiring of additional staff to support compliance with the proposed regulation. The Board further states in the ISOR under the header of "Business Impact" as it relates to the issue of cost the following: "This initial determination is based on the absence of testimony to that effect during the public discussion and development of the proposed regulation." The public meetings mandate testimony be limited to a few minutes and attendees tend to focus their input on the specific wording of the proposed regulation and not the cost. It is incumbent on the Board to actively pursue input from those that can accurately project the cost to health system of the proposed regulation. The Board should, during public meetings, or by other means seek input from experts who can inform the Board's ISOR development as it relates to both "Business Impact" and

		Economic Impact Assessment" to ensure the ISOR is an accurate reflection of the impact to health systems on cost and health care access. We continue to ~~wish to further~~ point out that the board has not responded to our comments regarding the economic impact of this proposed rule since they have not approached senior health system leaders who are best situated to assess and assist them with economic impact of this rule. Neither has the board shared their assessment of how this rule will increase their cost of enforcement of the proposed rule. USP 797 provides sufficient guidance in their improved and updated standards for immediate-use compounding, and we once more recommend that the board to require USP's standards and not engage in additional regulations that are not based on an articulated and proven evidence that such proposed regulations will enhance patient safety efforts beyond the national standards. We appreciate the complexities of regulating sterile compounding across the diversity of health system procedures and processes and we would like to invite board members and staff to consider doing site visits to gain a greater appreciation for how health systems promote patient safety and quality of compounded drug preparations. We would be happy to set up those site visits with our members. Specifically, we are inviting board members with limited background and experience in compounding. We once more are signaling our agreement that the routine utilization of immediate use in a hospital is an inappropriate practice. CSHP and our members have the same goals for patient safety as the board. It is unfortunate that some have engaged in this practice and now the majority of law-abiding facilities and pharmacy licensees must suffer the consequences. To account for the unfortunate choices of the few, whilst not punishing the majority we would recommend a more measured approach by limiting the time that an immediate use sterile compound can be used for up to 12 hours maximum from the time that compounding starts. This way the concerns for patient safety is addressed while it is also not so restrictive to the vast majority of ethical and law-abiding licensees. It also has the added benefit that it will not lock both licensees and board staff in a burden of reporting and administrative duties. Additionally, this problem does not have to be solved with multiple layers of regulation that attempts to solve for endless 'what-if' scenarios. As we have taken pains to point out in the aforementioned, these regulations will be creating insurmountable obstacles to patient care, which could in practice only be overcome by licensees making immediate use sterile compounds which

		would be a violation of the regulations if enacted. Please see our recommendation below. **Recommendation:** Remove the requirement limiting the use of immediate-use CSP's to situations where failure to administer could result in loss of life or intense suffering due to this being deleted from the new USP 797 standards and the profound negative impact on patients. This will subsequently remove the need for reporting to the board. **Recommended Text:** (b) CSPs for direct and immediate administration shall only be compounded in such quantity as is necessary to meet the immediate need of the patient. A compound made for immediate use shall have a maximum beyond use date of 4 hours and shall expire after 12 hours. Note: We note that the board did not show understanding of this recommendation in their response. We therefore wish to clarify that our recommendation is aligned with USP in that it copies the requirement of a beyond use date of 4 hours for immediate use. It must be noted that USP does not assign expiration dates to compounds. Contrary to board staff's assertion that we expand immediate use provisions, we actually limit the life span of an immediate use compound. Board staff's previous comment relayed their concern for patient safety where it is observed that some licensees engaged in preparing epidural and intrathecal compounds that stays on the patient for 24 hours or longer. We mimic the boards approach of adding additional rules to limit USP standards by addressing the stated concern of the board. With this recommendation, we place an expiration date on the compound, implying that a drip or infusion may be started within 4 hours of compounding and use on the patient must then be discontinued by the 12-hour expiration date.

03/21/2025

Lori Martinez
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
PharmacyRulemaking@dca.ca.gov
(916) 574-8618

Re: Notice of Proposed Action: Compounded Drug Products

Dear President Oh and Board Members,

Thank you once again for the opportunity to provide comments on the draft compounding regs. While we remain concerned about the implications of these regulations overall, we are providing comments on two remaining areas which we feel have not been adequately addressed. We also continue to advocate, along with many others that the compounding standards default to the standards set by the United States Pharmacopeia in USP 795, 797, and 800.

Wedgewood Pharmacy is the largest animal compounding pharmacy in the United States. We have been in business compounding for animal patients for almost 40 years and in that time, we have helped to treat millions of pets, horses, zoo animals, pocket pets, and many other animals. Our mission is to improve the lives of animals and those that love and care for them. In the last year our compounds have helped improve compliance for approximately 65,000 California based customers and many more nationally. We have a formulary of roughly 45,000 unique compounds in a variety of dosage forms, flavors, and concentrations specifically designed to improve compliance for our animal patients.

Comments Regarding The Notice of Proposed Regulatory Action Concerning: Compounded Drug Products		
Section, Subdivision	Proposed Language	Recommendation/Comment
1735 (d)	(d) "Essentially a copy" of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (API(s)) as the commercially available drug product, except that it does not include any preparation in which there has been a change made for an identified individual patient that produces for that patient a clinically significant	Please clarify that this language applies to compounds intended for human patients. Guidance For Industry 256 provides a different definition of "Essentially a Copy" as it pertains to veterinary medicine that includes route of administration as a factor for consideration. Please consider the addition of language to align this definition with the federal standard as it relates to animal medicine.

	diference, as ~~determined~~ verified and documented by the pharmacist ~~prescribing practitioner~~, between that compounded preparation and the comparable commercially available drug product.	We do not recommend a direct reference to GFI 256 for the reasons outlined below.
1735.1 (e)(2) & 1736.1 (e)(2)	Is made with any component not suitable for use in a CNSP for the intended veterinary population, unless allowable under the Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA). When a veterinarian, acting within a valid veterinarian-client-patient relationship (VCPR), determines there is no medically appropriate human or animal drug that is FDA-approved, conditionally approved, or indexed to treat the animal, a pharmacy may use a bulk drug substance to compound an animal drug. This compound shall be in compliance with the Center for Veterinary Medicine Guidance for Industry #256 – Compounding Animal Drugs from Bulk Drug Substances issued August 2022.	We appreciate that the Board addressed our earlier concerns about the ambiguous reference to AMDUCA, but we continue to remain concerned about a direct reference to a Guidance Document that could be eliminated tomorrow by the current administration. What will compliance look like if the Agency rescinds or edits the guidance document making this reference irrelevant? We again make the following Recommendation: This compound shall be in compliance with current industry guidance. ~~the Center for Veterinary Medicine Guidance for Industry #256 – Compounding Animal Drugs from Bulk Drug Substances issued August 2022~~.

Thank you for your consideration.

From: Jennifer Shea <pshea4@comcast.net>
Sent: Saturday, March 8, 2025 9:25 AM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Pharmacy Rulemaking

Please DO NOT restrict access to IV glutathione and other alternative treatments.

Thank you,

Jennifer Shea

Sent from my iPad

From: Morey, Mark (CONTR) <MOREYMS@nv.doe.gov>
Sent: Monday, March 10, 2025 3:51 PM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Compounded Drug Preparations-public comment

Dear Mrs. Martinez,

The current for-profit model of health care in the US allows many people to fall through the cracks, leading to bankruptcies and early demise. Sicker people cost much more to treat than the cost of preventative treatments. For instance, insurance stops paying for treatment of Lyme disease after roughly a month because “long term Lyme doesn’t exist”. This false statement leads to a (shortened) life of suffering if the tick bite isn’t noticed or treated immediately, just to save money. Similarly, someone I love depends on compounded glutathione and b vitamins to stay healthy and so I am writing to protect the ability of compounding pharmacies to make these compounds. This is what she relies upon to maintain a bare minimal quality of life, paying out of pocket with money she doesn’t have. THAT’S how important it is she receives these compounded drug preparations, and the protection of pharmacies’ ability to make them.

Best regards,

Mark Morey, PhD.

Senior Principal Scientist

Special Technologies Laboratory

5520 Ekwill St., Suite B

Santa Barbara, CA 93111

(805)681-2206

JWICS: mark.morey@doe.ic.gov

From: Doctor Horowitz <Dr.Horowitz@hvhac.com>
Sent: Saturday, March 8, 2025 9:32 AM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Cc: Medical <Medical@hvhac.com>
Subject: Public Comment on Title 16 CCR Sections 1735-1738

Dear California Board of Pharmacy,

I am board-certified physician who published the first study on glutathione for COVID-19 in April 2020. Not one of my patients died during the pandemic. We also use glutathione regularly while doing dapsone combination therapy for chronic Lyme/PTLDS, as it helps reduce oxidative stress and methemoglobin, as well as Herxheimer reactions. This is an essential medication that patients must have! Please see below:

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

R.I. Horowitz, P.R. Freeman, Three Novel Prevention, Diagnostic and Treatment Options for COVID-19 Urgently Necessitat-ing Controlled Randomized Trials, Medical Hypotheses (2020)

https://www.sciencedirect.com/science/article/pii/S0306987720308276?via%3Dihub

10 Dapsone Articles on The Effective Treatment of Chronic LD & Associated Co-infections Including Bartonella: As of May 11, 2024. Most contain references on glutathione:

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

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-MPMHKzNWt1ldoDyI

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.

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

I am writing 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+, and others. These treatments are essential for many, including firefighters and chronic illness patients and the regulations would create unnecessary barriers that harm the healthcare system, businesses, and people of California.

During the February 5, 2025 meeting, certain board members misrepresented federal guidelines, claiming the FDA has recommended glutathione be restricted. However, glutathione remains on the FDA's Category 1 bulk compounds list, and is therefore legal under their current policy. USP guidelines also do not mandate stability testing for these compounds. Despite this, your proposal introduces extreme testing requirements that far exceed federal standards without any 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 costs of stability testing. These tests actually range from $10,000 to $30,000 per API. These prohibitively expensive tests would force pharmacies to discontinue offering most if not all formulations of these treatments, eliminating access to life-saving medications.

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 to reduce 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.

I appreciate comments made by Members Chandler, Hughes, and Thibeau, who expressed desire to protect patient access. Member Hughes emphasized the importance of these treatments, not just for firefighters but for people with ME/CFS, Long COVID, and other disabilities. He stated, "There are hundreds, if not thousands, of people using these compounded medications across the state," and called for California to lead the way in research that improves access.

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

As written, the proposal creates unnecessary barriers that will severely limit 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. I strongly urge The Board of Pharmacy to either (a) withdraw the proposal entirely from consideration, or (b) send these proposed regulations back to 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.

Thank you for your time and attention to this urgent matter. I trust you will act in the best interest of public health and patient access.

Sincerely,

Dr Richard Horowitz

Member HHS TBDWG 2017-2019

Co-chair HHS Co-infections and Other Tickborne Diseases Subcommittee 2017-2019

Member, HHS Babesia and Co-infections Subcommittee 2020

Member NYS Dept of Health TBDWG 2021-2024

Board certified Internal Medicine

Medical Director Hudson Valley Healing Arts Center

Medical@hvhac.com

From: R Smith <raylonspcb@gmail.com>
Sent: Monday, March 10, 2025 3:25 PM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Fwd: Rule changes impacting Category 1 sterile compounds

Contact Person: Lori Martinez

Agency Name: California State Board of Pharmacy

Address: 2720 Gateway Oaks Drive, Ste 100, Sacramento, CA 95834

Email: PharmacyRulemaking@dca.ca.gov

Fax: (916) 574-8618

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.

Regards,

Raylon Smith

Sunnyvale CA

From: Sara Johnson <sarajohnsonpm@gmail.com>
Sent: Friday, March 14, 2025 3:58 PM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Cc: Martinez, Lori@DCA <Lori.Martinez@dca.ca.gov>
Subject: Public Comment Regarding Notice of Fourth Modified Text - Compounded Drug Preparations

March 14, 2025

To the California Board of Pharmacy:

I am writing as a California resident and patient who relies on affordable, sterile compounded medications—including intravenous and injectable therapies compounded from Category 1 bulk drug substances—to maintain my quality of life. I strongly urge the Board to reconsider or revise the overly restrictive provisions outlined in Addendum 1 to the proposed regulations.

Specifically, I am deeply concerned that the Board's new requirements for stability testing, extensive documentation of clinical circumstances, and strict adherence to USP chapters beyond federal mandates will effectively eliminate or severely reduce access to essential sterile compounded medications, including but not limited to NAD+, glutathione, and methylcobalamin.

As currently proposed, these new testing requirements (with costs estimated between $10,000 to $30,000 per API) would drastically raise pharmacy overhead, which will inevitably be passed on to patients or cause pharmacies to discontinue compounding these vital medications altogether. Such outcomes would place compounded therapies financially out of reach for many, including myself, directly threatening my health and quality of life.

The Board’s proposed regulations conflict with the existing FDA Policy. I am particularly troubled by the misleading assertion in the Board's meetings and addendum documents implying that these extensive stability tests are required by FDA policy or USP guidelines. The FDA’s Interim Policy on Compounding Drugs Using Bulk Drug Substances explicitly states:

“FDA does not intend to take action against an outsourcing facility for compounding drugs using bulk drug substances identified in category 1 provided that the conditions described in the guidance document are met.” (FDA Interim Policy on Compounding)

Additionally, the FDA has already outlined specific conditions for compounding with Category 1 bulk drug substances, stating that a bulk substance not on the drug shortage list may still be compounded if:

- The bulk substance is included in Category 1 of FDA’s list;
- The manufacturers of the substance are all registered under Section 510 of the FDCA;
- The bulk substance is accompanied by a valid Certificate of Analysis (COA);
- If the bulk substance has a USP or NF monograph, it complies with that monograph; and
- The bulk substance is compounded in compliance with all other provisions of Section 503B of the FDCA. (FDA Interim Policy Source)

The Board’s proposed requirements exceed the scope of FDA guidance and create unnecessary regulatory burdens that are not aligned with federal policy. If the FDA has deemed these conditions

sufficient for safety and oversight, why is the California Board imposing additional, unnecessary restrictions that will make it impossible for patients to access affordable compounded medications?

This will cause unnecessary financial and public health consequences. The financial and administrative burdens imposed by this addendum will likely result in higher costs for compounded medications. For

patients like me, who depend on these treatments to maintain health and manage chronic conditions, any increase in cost or reduction in supply could have devastating consequences.

As a patient managing chronic illness, my consistent access to affordable NAD+ treatments has meaningfully improved symptoms where no other FDA approved drugs or treatments exist. Interruptions or prohibitive cost increases due to the Board's regulations would mean losing the stability these medications currently provide, potentially forcing me into greater disability, diminished independence, or worsening chronic symptoms. These aren't abstract risks—they're real, immediate threats to my health and well-being, and the Board must fully recognize the tangible consequences of its regulatory actions.

Serious legal and ethical concerns were raised during the Joint Hearing of the Senate Business, Professions and Economic Development Committee and the Assembly Business and Professions Committee – Joint Sunset Review Oversight Hearing on March 11, 2025. Testimony made it clear that the California Board of Pharmacy (CA BOP) is engaged in regulatory overreach, misinformation, and negligence, directly harming patients, healthcare providers, and even animals in need of critical care. The need for legal and administrative accountability has been made copiously evident.

If the Board insists on passing these excessively burdensome regulations, established checks and balances remain available, including legislative oversight and judicial review under the Administrative Procedure Act (APA).

Regulations that are arbitrary, capricious, or impose undue burdens without clear evidence of enhanced patient safety may be subject to legal challenge. Furthermore, if these financial burdens force pharmacies to discontinue these medications, patients—including myself—will inevitably suffer preventable declines in health, which directly contradicts the public health mission of this Board.

The request for revision is made yet again. I urge the California Board of Pharmacy to withdraw or substantially revise this proposal to align strictly with FDA and USP standards and eliminate excessive regulatory requirements that lack justification. The Board should prioritize maintaining patient access to these medically necessary, safely compounded treatments rather than imposing excessive barriers that will remove them from the market.

Thank you for your serious consideration of these critical concerns.

Sincerely,

Sara Johnson, Long Hauler with ME/CFS

Los Angeles, CA

From: Tim Delaney <timmyd73@gmail.com>
Sent: Friday, March 7, 2025 6:02 PM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Glutathione & b Vitamins

Someone that I love depends on compounded glutathione and b vitamins to stay healthy. It has become a critical part of her daily struggle to be as healthy as possible despite a multitude of debilitating heath problems that make one question the value of their own life. It is absolutely necessary to protect the ability of compounding pharmacies to make these compounds. The life giving medicine contained in glutathione and b vitamins are invaluable to my loved one and I urge you to do what's absolutely right and protect the ability by pharmacies to make these important compounds.

Thank you

Timothy Delaney

Please and thank you. 🤗

From: cheryl kitahata <ckitahata@gmail.com>
Sent: Wednesday, March 12, 2025 1:37 AM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Written Submission of Public Comment

2 Minute Speech to the Board of Pharmacy

Thomas Kitahata

3-1-25

To the California Board of Pharmacy, distinguished guests and my fellow cohorts in uniform, my name is Thomas Kitahata, 36-year veteran of the LAFD, Captain 2 and Task Force Commander, B Shift, at FS 69 in the Pacific Palisades. It is an honor to have this read by Kelly Nakamaru, an advocate for all things good, as I am out of the country.

It is my humble yet strong opinion that access to treatments that are beneficial to the health of Californians be protected.

In addition to daily exposure at work, I was also a first responder to the attacks of 9-11, Hurricanes Katrina, Ike, Gustav, Irma, Harvey, the Malibu fires of 1992, the Camp Fire in Paradise (and other large-scale wildfires), the Montecito mudslides, the LA Riots, the Northridge earthquake, exposed to harmful toxins from it all. I was also on duty 24/7 for 30 days during the Palisades fire, working the fire and then assigned to a command post to care for 2000 first responders from all over the nation, the National Guard, LAPD and law enforcement from multiple agencies, utility and essential workers, and the kind people who fed us.

In short, my lungs and my entire body have recently, and over time, been compromised. I firmly believe my glutathione treatments have helped me get back to my baseline. I urge the Board of Pharmacy to allow access, to offer future protections to those who stand in harm's way and those who are sick and find relief from this natural compound.

Thank you for my consideration on this important matter.

Thomas Kitahata

From: Teri Sanor <tlsanor@gmail.com>
Sent: Sunday, March 9, 2025 2:45 PM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Glutathione

Why is the Board trying to get rid of a treatment that helps patients and has research supporting its efficacy.

It appears as an affront to patient-centered healthcare advocates. I sent links to research last time. If you need those again, contact me. Sick patients have been ignored too long. Chronic illnesses from infections is now very much in the limelight w RFK Jr whommay or may not be right. At least he puts patients above profits unlike most of gov't for the past decades by ignoring pain and suffering especially of Lyme, a spirochete like syphilis yet much worse than syphilis

as there are 30 plasmids, biofilms, persisters and there are no good early tests when it is treatable. Every known brain disordered pathway can be triggered by infections per IDSA researchers at "The Svience of Infections & Dementia" 2024 conference and 9.15.24 J of Inf Dis microbial issue. NeuroImmune.org confirms mental illnesses from infections such as Lyme, Bartonella, strep grp A and Covid too. AlzPi.org rconsortiym researchers include top univ and confirm Lyme, HSV, EBV, etc cause brain disorders and Michal Tal lab showed Lyme spirochetes in uterus recently, too. Dr Neil Spector's "Lyme in the Era of Precision Med" 2019 before he died of complications of a heart transplant after Lyme shows connection with cancer as does Eva Sapi. MeghanBradshaw.com for joint degeneration and chronic pain from Lyme. Lymedisease.org for research and the largest patient database will show how tragic it is to ignore these patients, many thousands w children the most affected.

PsychologyRedefined.com shows too that mental illnesses root causes can be infections including Lyme, Bartonella…having a cat w Bartonella causes 3x the chance of schizophrenia and it is a coinfection along w babesia that takes weeks to months to treat.

A paradigm change to find root causes and not just treat symptoms will find cures. Now pharmacists just give lifelong meds for symptoms, not cures. BOP needs to be a leader in healing by listening yo patients who are dealing with preventable chronic pain, suffering. Physicians lije myself are not taught that the test is <50%sensitive and often no tick or rash is seen so when a patient has migrating, fluctuating pain, it is not believed and they are sent to psych. It is a scandal thousands of times worse than Tuskegee when syphilis was untreated as it has been decades of medical denialism of what is probable starting in 1995 iron key brain studies showing plaques, lesions consistent w severe symptoms.

Sincerely,

Teri Sanor, MD

Stop this action unless you can show past research is wrong.

Teri Sanor MD

From: Crystal Uribe <curibe.np@gmail.com>
Sent: Friday, March 21, 2025 6:30 AM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Public Comment on Title 16 CCR Sections 1735-1738

Dear California Board of Pharmacy,

I strongly oppose the proposed regulations that would severely limit access to essential compounded medications like injected and nebulized glutathione, methylcobalamin, and NAD+. These treatments are vital for patients with chronic illnesses, first responders, and many others who rely on them for their health and well-being.

The Board's proposal goes beyond federal guidelines, imposing excessive testing requirements with no clear safety justification. The financial burden of these unnecessary regulations would make these treatments inaccessible, harming both patients and pharmacies.

With over 11,000 signatures in opposition—including 1,000+ from firefighters—and strong concerns from medical experts, it's clear these restrictions are not in the public's best interest. The Board must reconsider and align regulations with federal and USP standards by:
• Allowing Category 2 compounding without full stability studies, as long as sterility and endotoxin testing are performed.
• Removing enforcement of non-mandatory USP Chapters above 1000.
• Ensuring regulations apply only to pharmacists, not medical practitioners.
• Eliminating unnecessary documentation requirements not mandated by the FDA.

I urge you to either withdraw the proposal entirely or revise it to protect patient access to life-saving medications.

Sincerely,
Crystal Uribe
Nurse practitioner

Healthy Regards,

Crystal Uribe, MSN, FNP-C, RN, CEN

Nurse Practitioner

From: Marjorie Morgenstern <mmorgenstern@ci.cloverdale.ca.us>
Sent: Friday, March 21, 2025 10:42 PM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Public Comment on Title 16 CCR Sections 1735-1738

Please listen to the numerous Pharmacists, Medical Doctors, Naturopaths, Firefighters and Lyme Patients asking you by public and written comment to go by the Federal rules for compounding instead of creating stricter regulations for California.

I am frustrated that this farce and abuse of power is allowed to drag on.

Sincerely,

City of Cloverdale Councilmember Marjorie Morgenstern

From: Amr Hussein <amrh1@yahoo.com>

Sent: Friday, March 7, 2025 8:17 PM

To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>

Subject: Public Comment on Title 16 OCR Sections 1735-1738

Dear California Board of Pharmacy,

I am writing 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+, and others. These treatments are essential for many, including firefighters and chronic illness patients and the regulations would create unnecessary barriers that harm the healthcare system, businesses, and people of California.

During the February 5, 2025 meeting, certain board members misrepresented federal guidelines, claiming the FDA has recommended glutathione be restricted. However, glutathione remains on the FDA's Category 1 bulk compounds list, and is therefore legal under their current policy. USP guidelines also do not mandate stability testing for these compounds. Despite this, your proposal introduces extreme testing requirements that far exceed federal standards without any 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 costs of stability testing. These tests actually range from $10,000 to $30,000 per API. These prohibitively expensive tests would force pharmacies to discontinue offering most if not all formulations of these treatments, eliminating access to life-saving medications.

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 to reduce 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.

I appreciate comments made by Members Chandler, Hughes, and Thibeau, who expressed desire to protect patient access. Member Hughes emphasized the importance of these treatments, not just for firefighters but for people with ME/CFS, Long COVID, and other disabilities. He stated, "There are hundreds, if not thousands, of people using these compounded medications across the state," and called for California to lead the way in research that improves access.

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

As written, the proposal creates unnecessary barriers that will severely limit 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. I strongly urge The Board of Pharmacy to either (a) withdraw the proposal entirely from consideration, or (b) send these proposed regulations back to 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.

Thank you for your time and attention to this urgent matter. I trust you will act in the best interest of public health and patient access.

Sincerely,

Amr Hussein

From: analisa madron <madronana@icloud.com>

Sent: Tuesday, March 11, 2025 8:06 AM

To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>

Subject: Public Comment on Title 16 CCR Sections 1735-1738

Dear California Board of Pharmacy,

I am writing 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+, and others. These treatments are essential for many, including firefighters and chronic illness patients and the regulations would create unnecessary barriers that harm the healthcare system, businesses, and people of California.

During the February 5, 2025 meeting, certain board members misrepresented federal guidelines, claiming the FDA has recommended glutathione be restricted. However, glutathione remains on the FDA's Category 1 bulk compounds list, and is therefore legal under their current policy. USP guidelines also do not mandate stability testing for these compounds. Despite this, your proposal introduces extreme testing requirements that far exceed federal standards without any adequate safety-based justification.

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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 to reduce 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.

I appreciate comments made by Members Chandler, Hughes, and Thibeau, who expressed desire to protect patient access. Member Hughes emphasized the importance of these treatments, not just for firefighters but for people with ME/CFS, Long COVID, and other disabilities. He stated, "There are hundreds, if not thousands, of people using these compounded medications across the state," and called for California to lead the way in research that improves access.

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

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* 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.

Thank you for your time and attention to this urgent matter. I trust you will act in the best interest of public health and patient access.

Sincerely,

Analisa Madron

Sent from my iPhone

From: Amy Rose <amylrose98@icloud.com>
Sent: Sunday, March 9, 2025 10:06 AM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Public Comment on Title 16 CCR Sections 1735-1738

Dear California Board of Pharmacy,

As a patient infected with lyme and Bartonella, it's very important for your board to know that NAD, glutathione and nutrients IVs have been VITAL to my healing journey. After years of being given antibiotics, which only destroyed my gut and did nothing to heal me from the bacterial infections, IVs supported my body and still do...ESPECIALLY NAD & GLUTATHIONE.

I am writing 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+, and others. These treatments are essential for many, including firefighters and chronic illness patients and the regulations would create unnecessary barriers that harm the healthcare system, businesses, and people of California.

During the February 5, 2025 meeting, certain board members misrepresented federal guidelines, claiming the FDA has recommended glutathione be restricted. However, glutathione remains on the FDA's Category 1 bulk compounds list, and is therefore legal under their current policy. USP guidelines also do not mandate stability testing for these compounds. Despite this, your proposal introduces extreme testing requirements that far exceed federal standards without any 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 costs of stability testing. These tests actually range from $10,000 to $30,000 per API. These prohibitively expensive tests would force pharmacies to discontinue offering most if not all formulations of these treatments, eliminating access to life-saving medications.

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 to reduce 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.

I appreciate comments made by Members Chandler, Hughes, and Thibeau, who expressed desire to protect patient access. Member Hughes emphasized the importance of these treatments, not just for firefighters but for people with ME/CFS, Long COVID, and other disabilities. He stated, "There are hundreds, if not thousands, of people using these compounded medications across the state," and called for California to lead the way in research that improves access.

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

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* 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.

Thank you for your time and attention to this urgent matter. I trust you will act in the best interest of public health and patient access.

Sincerely,

Amy Rose

P O Box 9363

Rancho Santa Fe, CA 92067

760 644-6150

From: Ashley Schmidt <ashschmidt01@gmail.com>

Sent: Sunday, March 16, 2025 5:53 AM

To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>

Subject: Public Comment on Title 16 CCR Sections 1735-1738

Dear California Board of Pharmacy,

I am writing 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+, and others. These treatments are essential for many, including firefighters and chronic illness patients and the regulations would create unnecessary barriers that harm the healthcare system, businesses, and people of California.

During the February 5, 2025 meeting, certain board members misrepresented federal guidelines, claiming the FDA has recommended glutathione be restricted. However, glutathione remains on the FDA's Category 1 bulk compounds list, and is therefore legal under their current policy. USP guidelines also do not mandate stability testing for these compounds. Despite this, your proposal introduces extreme testing requirements that far exceed federal standards without any 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 costs of stability testing. These tests actually range from $10,000 to $30,000 per API. These prohibitively expensive tests would force pharmacies to discontinue offering most if not all formulations of these treatments, eliminating access to life-saving medications.

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 to reduce 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.

I appreciate comments made by Members Chandler, Hughes, and Thibeau, who expressed desire to protect patient access. Member Hughes emphasized the importance of these treatments, not just for firefighters but for people with ME/CFS, Long COVID, and other disabilities. He stated, "There are hundreds, if not thousands, of people using these compounded medications across the state," and called for California to lead the way in research that improves access.

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

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* 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.

Thank you for your time and attention to this urgent matter. I trust you will act in the best interest of public health and patient access.

Sincerely,

Ashley Schmidt

719-740-7275

From: BBF <bethanie@bethaniebrady.com>
Sent: Sunday, March 9, 2025 8:08 AM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Public Comment on Title 16 CCR Sections 1735-1738

Dear California Board of Pharmacy,

I am writing 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+, and others. These treatments are essential for many, including firefighters and chronic illness patients and the regulations would create unnecessary barriers that harm the healthcare system, businesses, and people of California.

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* Remove the requirement of additional documentation of "clinical circumstances" which is not required by the FDA.

Thank you for your time and attention to this urgent matter. I trust you will act in the best interest of public health and patient access.

Sincerely,

Bethanie Farrell

T. 917. 327. 4945

From: Bob Manuc <bob.manuc@gmail.com>
Sent: Friday, March 7, 2025 8:22 PM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Public Comment on Tilte 16 CCR Sections 1735-1738

Dear California Board of Pharmacy,

I am writing 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+, and others. These treatments are essential for many, including firefighters and chronic illness patients and the regulations would create unnecessary barriers that harm the healthcare system, businesses, and people of California.

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* Remove the requirement of additional documentation of "clinical circumstances" which is not required by the FDA.

Thank you for your time and attention to this urgent matter. I trust you will act in the best interest of public health and patient access.

Sincerely,

Bob Manuc

(310) 845-0631

From: Dillon Cashman <dilloncashman@gmail.com>

Sent: Saturday, March 8, 2025 3:59 PM

To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>

Subject: Public Comment on Title 16 CCR Sections 1735-1738

Dear California Board of Pharmacy,

I am writing 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+, and others. These treatments are essential for many, including firefighters and chronic illness patients and the regulations would create unnecessary barriers that harm the healthcare system, businesses, and people of California.

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* 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.

Thank you for your time and attention to this urgent matter. I trust you will act in the best interest of public health and patient access.

I,ve had lyme for 18yrs. I couldn't walk at one point i did glutathione iv protocol and was back on my feet in three weeks. I,ve also used b12 shots on a daily basis for several years . I don't know why it works but b12 shots where critical in my ability to take care of myself unassisted.

Sincerely,

Dillon cashman

Dilloncashman@gmail.com

[Your Contact Information]

Sent from my iPhone

From: David R Thomas <milktrucmilkstone@yahoo.com>
Sent: Saturday, March 8, 2025 11:08 AM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Public Comment on Title 16 CCR Sections 1735-1738

Dear California Board of Pharmacy,

I am writing 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+, and others. These treatments are essential for many, including firefighters and chronic illness patients and the regulations would create unnecessary barriers that harm the healthcare system, businesses, and people of California.

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The unfeasible financial burden these regulations would place on pharmacies is a critical concern. Member Serpa's cost estimates—$16.10 per glutathione vial and $8.06 per methylcobalamin vial—dramatically understated the actual costs of stability testing. These tests actually range from $10,000 to $30,000 per API. These prohibitively expensive tests would force pharmacies to discontinue offering most if not all formulations of these treatments, eliminating access to life-saving medications.

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 to reduce 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.

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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,

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Thank you for your time and attention to this urgent matter. I trust you will act in the best interest of public health and patient access.

Sincerely,
David R Thomas
darith1lymee@gmail.com
5708671719

From: Erin-Kate Barton <erinkatebarton@gmail.com>
Sent: Saturday, March 8, 2025 2:38 PM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Public Comment on Title 16 CCR Sections 1735-1738

Dear California Board of Pharmacy,

I am writing 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+, and others. These treatments are essential for many, including firefighters and chronic illness patients and the regulations would create unnecessary barriers that harm the healthcare system, businesses, and people of California. During the February 5, 2025 meeting, certain board members misrepresented federal guidelines, claiming the FDA has recommended glutathione be restricted. However, glutathione remains on the FDA's Category 1 bulk compounds list, and is therefore legal under their current policy. USP guidelines also do not mandate stability testing for these compounds. Despite this, your proposal introduces extreme testing requirements that far exceed federal standards without any 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 costs of stability testing. These tests actually range from $10,000 to $30,000 per API. These prohibitively expensive tests would force pharmacies to discontinue offering most if not all formulations of these treatments, eliminating access to life-saving medications. 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 to reduce 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. I appreciate comments made by Members Chandler, Hughes, and Thibeau, who expressed desire to protect patient access. Member Hughes emphasized the importance of these treatments, not just for firefighters but for people with ME/CFS, Long COVID, and other disabilities. He stated, "There are hundreds, if not thousands, of people using these compounded medications across the state," and called for California to lead the way in research that improves access. 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 Board's engagement process and has raised serious concerns about regulatory overreach. As written, the proposal creates unnecessary barriers that will severely limit access to life-saving treatments. These barriers create an unjustifiable financial burden on patients and

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Sincerely,

Erin-Kate Barton

917-518-1863

From: i i <timaambrosini@gmail.com>
Sent: Saturday, March 8, 2025 8:52 PM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Public Comment on Title 16 CCR Sections 1735-1738

Dear California Board of Pharmacy,

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Thank you for your time and attention to this urgent matter. I trust you will act in the best interest of public health and patient access.

Sincerely,
[Your Name]
[Your Contact Information]

From: Joeyanna <gijoeyanna@gmail.com>
Sent: Monday, March 10, 2025 6:15 AM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Public Comment on Title 16 CCR Sections 1735-1738

Dear California Board of Pharmacy,

I am writing 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+, and others. These treatments are essential for many, including firefighters and chronic illness patients and the regulations would create unnecessary barriers that harm the healthcare system, businesses, and people of California.

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Thank you for your time and attention to this urgent matter. I trust you will act in the best interest of public health and patient access.

Sincerely,
[Joanna Dowlearn]
[gijoeyanna@gmail.com]

From: Julie Hoffer <juliehoffer@yahoo.com>
Sent: Saturday, March 8, 2025 11:46 AM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Public Comment on Title 16 CCR Sections 1735-1738

Dear California Board of Pharmacy,

I am writing 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+, and others. These treatments are essential for many, including firefighters and chronic illness patients and the regulations would create unnecessary barriers that harm the healthcare system, businesses, and people of California.

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Thank you for your time and attention to this urgent matter. I trust you will act in the best interest of public health and patient access.

Sincerely,

Julie Hoffer

Lyme Disease Patient

From: Jennifer Love <jenns226@gmail.com>
Sent: Monday, March 10, 2025 9:13 AM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Public Comment on Title 16 CCR Sections 1735-1738

Dear California Board of Pharmacy,

I am writing 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+, and others. These treatments are essential for many, including firefighters and chronic illness patients and the regulations would create unnecessary barriers that harm the healthcare system, businesses, and people of California.

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Sincerely,

Jennifer Love

From: Jamie Martinez <jamiemartinez660@gmail.com>
Sent: Saturday, March 8, 2025 9:58 AM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Public Comment on Title 16 CCR Sections 1735-1738

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Sincerely,

Jamie martinez

7613 n cr 100 east Chrisney Indiana 47611

8126601087

Sent from my iPhone

From: Pecos Ranger <rddj5@aol.com>
Sent: Saturday, March 8, 2025 5:30 PM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Public Comment on Title 16 CCR Sections 1735-1738

Dear California Board of Pharmacy,

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Sincerely
JOSEPH G. REDDAN

Chief forester
Flexilis Forestry LLC
American Canyon, CA
Durango, CO
(505) 426-4921
TSP#: 18-22364, Tree Farm Inspector # 168296 Registered Professional Forester # 3187

From: James Tse <a9602343@gmail.com>
Sent: Saturday, March 8, 2025 12:46 PM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Public Comment on Title 16 CCR Sections 1735-1738

Dear California Board of Pharmacy,

I am writing 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+, and others. These treatments are essential for many, including firefighters and chronic illness patients and the regulations would create unnecessary barriers that harm the healthcare system, businesses, and people of California.

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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 to reduce 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.

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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,

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Thank you for your time and attention to this urgent matter. I trust you will act in the best interest of public health and patient access.

Sincerely,
Wang-Kong Tse
A9602343@gmail.com

From: Liz Farzan <lizfarzan@gmail.com>
Sent: Saturday, March 8, 2025 1:15 PM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Public Comment on Title 16 CCR Sections 1735-1738

Dear California Board of Pharmacy,

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Sincerely,

Liz Farzan

From: Laurie Hytner <lhytner1@gmail.com>
Sent: Sunday, March 9, 2025 8:31 AM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Public Comment on Title 16 CCR Sections 1735-1738

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Thank you for your time and attention to this urgent matter. I trust you will act in the best interest of public health and patient access.

Sincerely,
[Your Name]
[Your Contact Information]

From: Laurel Taylor <laurelanntaylor@aol.com>
Sent: Saturday, March 8, 2025 6:50 PM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Public Comment on Title 16 CCR Sections 1735-1738

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Sincerely,

Laurel Taylor

Laurelanntaylor@aol.com

From: Melodie Dustin <melodiedu4@gmail.com>
Sent: Saturday, March 8, 2025 10:28 AM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Public Comment on Title 16 CCR Sections 1735-1738

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Sincerely,

Melodie Dustin

Sent from my iPad

From: Mark Reynolds <mtrey714@yahoo.com>
Sent: Sunday, March 9, 2025 6:12 AM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Public Comment on Title 16 CCR Sections 1735-1738

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Mark Reynolds

Mtrey714@yahoo.com

From: Ola <kungsholmiaab@gmail.com>
Sent: Saturday, March 8, 2025 10:33 AM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Public Comment on Title 16 CCR Sections 1735-1738

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Sincerely,

[Your Name]

[Your Contact Information]

Skickat från min iPhone

From: Rebecca Welsh <welshrebecca@yahoo.com>
Sent: Saturday, March 8, 2025 11:03 AM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Public Comment on Title 16 CCR Sections 1735-1738

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Sincerely,

Rebecca Welsh

1140 Groen Court

Ripon CA 95366

From: Sonali Shah <studiosonali@yahoo.com>
Sent: Monday, March 10, 2025 10:48 PM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Cc: Martinez, Lori@DCA <Lori.Martinez@dca.ca.gov>
Subject: Re: Notice of Fourth Modified Text - Compounded Drug Preparations

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state laws or their application, dismissing the well-informed concerns raised by patients, healthcare professionals, and advocates. The failure to engage meaningfully with stakeholders undermines the credibility of the Board's engagement process and has raised serious concerns about regulatory overreach.

As written, the proposal creates unnecessary barriers that will severely limit 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. I strongly urge The Board of Pharmacy to either (a) withdraw the proposal entirely from consideration, or (b) send these proposed regulations back to committee and re-write them to align them with and not exceed federal and Pharmacopeia standards by making the following changes:

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* 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.

Thank you for your time and attention to this urgent matter. I trust you will act in the best interest of public health and patient access.

Sincerely,
Sonali Shah

415-846-5973

From: Tracy Carter <tracy.carter66@icloud.com>
Sent: Monday, March 10, 2025 9:55 AM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Public Comment on Title 16 CCR Sections 1735-1738

Dear California Board of Pharmacy,

I am writing 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+, and others. These treatments are essential for many, including firefighters and chronic illness patients and the regulations would create unnecessary barriers that harm the healthcare system, businesses, and people of California.

During the February 5, 2025 meeting, certain board members misrepresented federal guidelines, claiming the FDA has recommended glutathione be restricted. However, glutathione remains on the FDA's Category 1 bulk compounds list, and is therefore legal under their current policy. USP guidelines also do not mandate stability testing for these compounds. Despite this, your proposal introduces extreme testing requirements that far exceed federal standards without any 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 costs of stability testing. These tests actually range from $10,000 to $30,000 per API. These prohibitively expensive tests would force pharmacies to discontinue offering most if not all formulations of these treatments, eliminating access to life-saving medications.

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* 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.

Thank you for your time and attention to this urgent matter. I trust you will act in the best interest of public health and patient access.

Sincerely,

Tracy Carter

P.O. Box 737

Port Orford, OR

Tracyannthearc@yahoo.com

From: Maya Lindemann <mayalindemann@gmail.com>
Sent: Thursday, March 20, 2025 5:22 PM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Public Comment on Title 16 CCR Sections 1735-1738

Dear California Board of Pharmacy,

I am writing 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+, and others. These treatments are essential for many, including firefighters and chronic illness patients and the regulations would create unnecessary barriers that harm the healthcare system, businesses, and people of California.

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The unfeasible financial burden these regulations would place on pharmacies is a critical concern. Member Serpa's cost estimates—$16.10 per glutathione vial and $8.06 per methylcobalamin vial—dramatically understated the actual costs of stability testing. These tests actually range from $10,000 to $30,000 per API. These prohibitively expensive tests would force pharmacies to discontinue offering most if not all formulations of these treatments, eliminating access to life-saving medications.

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 to reduce 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.

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* 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.

Thank you for your time and attention to this urgent matter. I trust you will act in the best interest of public health and patient access.

Sincerely,

[Your Name]

[Your Contact Information

From: Stephanie Hwang <stef.hwang@icloud.com>
Sent: Thursday, March 20, 2025 6:24 PM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Public Comment on Title 16 CCR Sections 1735-1738

Dear California Board of Pharmacy,

I am writing 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+, and others. These treatments are essential for many, including firefighters and chronic illness patients and the regulations would create unnecessary barriers that harm the healthcare system, businesses, and people of California.

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* Remove the requirement of additional documentation of "clinical circumstances" which is not required by the FDA.

Thank you for your time and attention to this urgent matter. I trust you will act in the best interest of public health and patient access.

Sincerely,

Stephanie Hwang

From: jennifer <jeng8029@gmail.com>
Sent: Thursday, March 20, 2025 11:12 PM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Public Comment on Title 16 CCR Sections 1735-1738

Dear California Board of Pharmacy,

I am writing 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+, and others. These treatments are essential for many, including firefighters and chronic illness patients and the regulations would create unnecessary barriers that harm the healthcare system, businesses, and people of California.

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Thank you for your time and attention to this urgent matter. I trust you will act in the best interest of public health and patient access.

Sincerely,
Jennifer
650-208-1011

From: stevie raya <stevie.raya@gmail.com>
Sent: Friday, March 21, 2025 9:18 PM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Public Comment on Title 16 CCR Sections 1735-1738

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Stevie Raya

San Francisco, CA